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:

As health care stakeholders representing diverse organizations, we appreciate the efforts of the Centers for Medicare and Medicaid Services (CMS) to assess the effects of the current coding and payment policy for biosimilars within Medicare Part B 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).

Our vision for the biosimilar marketplace in the U.S. aligns closely with the one CMS outlines in the proposed rule, specifically, "fostering a robust, and competitive marketplace and encouraging the innovation that is necessary to bring… products to the marketplace." Only by encouraging a strong and sustainable market within Medicare Part B can the potential for savings tied to the development of biosimilars and, most importantly, the opportunity for expanded patient access to these innovative therapies, be fully realized.

Unfortunately, the current payment and coding policy creates a framework that significantly reduces incentives for the development of a robust biosimilars market, which in turn leads to increased barriers to access for patients. Under the current policy, all biosimilars for a single reference product are combined into a single Average Sales Price (ASP) calculation and Healthcare Common Procedure Coding System (HCPCS) code. This policy is a significant departure from how CMS treats other drugs in Part B, as no other blended codes exclude the original reference product from the blended code with its follow-on counterparts. Additionally, this proposal is not consistent with the scientific principles used by the Food and Drug Administration (FDA) in its approval of biosimilars. Non-interchangeable biosimilars are exclusively compared to the reference product, and not one another. Therefore, there is no scientific justification for grouping such products together, and each should receive its own unique payment calculation and code.

Additionally, there is compelling evidence within the European Union (EU) biosimilars arena that promoting a robust market leads to lower costs and improved access for patients. The introduction of biosimilars in the EU market has led to a substantial and immediate reduction in the average price for the biosimilar and originator products. At the same time, this has led to an even larger increase in patient volume and access to both biosimilars and their reference

originator products. A sustainable and robust biosimilars market, such as the EU market, is built upon creating incentives for manufacturers to continue to develop lower cost alternatives to costly originator biologics, like expanded patient volume and access. Separate codes for non-interchangeable biosimilars help stimulate future competitors to the market.

In conclusion, we the undersigned organizations believe that it is imperative **CMS revise their current payment and coding policy related to biosimilars, and instead of using a single payment calculation for non-interchangeable biosimilars, CMS should provide non-interchangeable biosimilars with their own unique HCPCS codes and ASP calculations.** Adopting this revised policy will have a positive impact on the future sustainability of the biosimilars market. We are dedicated to working with CMS on this issue in order to foster biosimilar development and ensure the greatest possible level of patient access. Thank you for your consideration.

Sincerely,

Citizens Against Government Waste
CVS Health
Express Scripts
FreedomWorks
National Association of Chain Drug Stores (NACDS)
National Taxpayers Union
Pharmaceutical Care Management Association (PCMA)
Prime Therapeutics