August 28, 2015

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

Re: CMS – 1631 – P, Proposed Reimbursement Rate for Medicare Part B Drugs/ Payment for Biosimilar Biological Products

Dear Acting Administrator Slavitt:

I am writing on behalf of the Alliance for Patient Access, a national network nearly 700 physicians advocating for patient access to approved therapies and appropriate clinical care. Since its founding nearly a decade ago, AfPA has made comment on numerous policy matters that impact patient access to approved therapies, including legislative proposals, regulations and health plan coverage policies.

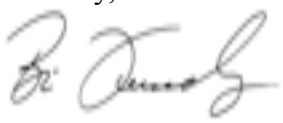
AfPA sponsors the National Physicians Biologics Working Group (NPBWG), through which more than sixty specialists who prescribe biologic therapies convene to consider policy matters related to the introduction of biosimilar therapies. These neurologists, oncologists, rheumatologists, dermatologists and gastroenterologists have joined together in making comment at the federal and state level on policy questions regarding the clinical research, naming, labeling, and substitution of biologic therapies. NPBWG has found one indisputable fact has proven central to each of these subject areas: biosimilar therapies are not generic versions of biologics and accordingly policy should not treat them as such. Congress, the Food and Drug Administration and the World Health Organization, have all repeatedly affirmed that biosimilars cannot be treated as identical to the reference biologic.

When establishing billing codes for biosimilar therapies under the Healthcare Common Procedure Code System (HCPCS), so called "J-Codes", the Centers for Medicare and Medicaid Services' (CMS) should adopt a rule that likewise is premised on the fact that biosimilars are not generic medications. Accordingly each non-interchangeable biosimilar must be assigned a separate reimbursement code from that of the referenced product and from each other.

AfPA and NPBWG welcome the introduction of biosimilars but with the common understanding that these new products must come to market and be administered in a fashion that respects the inherent risks of immunogenicity associated with any biologic therapy. In the case of an adverse event it is critical that the patient, physician, and healthcare system can immediately identify the exact product the patient received. By providing that each FDA approved biologic and biosimilar has its own unique J-Code, CMS will ensure the ability to completely track and trace each individual product thereby allowing the patient's physician to access the correct prescriber information and other data regarding the product the patient actually received. CMS adopting this policy will ensure appropriate pathways of pharmacovigilance for the benefit of all patients being treated with biologics.

For prescribers to have confidence in biosimilars and for patients to realize their benefits, it is necessary that federal and state policy to be transparent and science based. CMS policy defining unique J-Codes for each FDA approved biologic product furthers these patient centered objectives. Accordingly, AfPA urges CMS to amend the rule to provide for a unique payment code for each biosimilar medicine.

Sincerely,



Brian Kennedy
Executive Director