Biosimilars FORUM

Stakeholder Engagement on J-Code Issue

As part of its solicitation of public comments on its Medicare Physician Fee Schedule proposed rule, the Centers for Medicare and Medicaid Services (CMS) requested feedback and additional information on its reimbursement policy for biosimilars, which blends all biosimilars to a reference biologic into a single, blended billing code. Many organizations have expressed concern that such a policy would have adverse effects on the future of the biosimilars industry.

In response to CMS' call for additional information, **199 organizations** submitted comments calling for CMS to reverse its current reimbursement policy for biosimilars as soon as possible and institute a policy of assigning an individual billing and payment code to each biosimilar product. These organizations included local, state, and national organizations that ranged widely in size, and represented patients, providers, payers, and other interested parties, including the:

American Medical Association
American Pharmacists Association
AmerisourceBergen
Arthritis Foundation
Biotechnology Innovation Organization (BIO)
CVS Health
Digestive Disease National Coalition
Iowa Oncology Society
Lupus and Allied Diseases Association, Inc.
National Organization for Rare Disorders
National Consumers League
Oncology Managers of Florida
Pharmaceutical Care Management Association
RetireSafe
U.S. Pain Foundation
Vizient

As mentioned previously, organizations that responded to CMS' comment solicitation were diverse in terms of size and representation, with patient advocacy organizations submitting the most comments of any group:

- 96 Patient Advocacy
- 39 Industry
- 44 Provider
- 2 Pharmacy
- 6 Payer
- 11 Other
- 1 Legislative

In general, these organizations issued strong calls for CMS to reverse its policy as soon as possible. Examples include:

> ***"The AMA urges CMS to revise [its reimbursement] policy and…urge instead that each biosimilar should be assigned a unique HCPCS code for billing and payment effective January 1, 2018, in order to ensure continuity of a patient's course of treatment (clinical benefit) and to lower overall costs to the Medicare program (fiscal benefit)." – American Medical Association (AMA)***

> ***"In order for biosimilar development to advance, manufacturers must believe that their products are capable of evolving in the marketplace. Applying shared codes to these products will impede development and obstruct competition, in turn resulting in diminished patient choice and increased treatment costs." – Lupus and Allied Diseases Association, Inc.***

In addition, of the comments submitted several were stakeholder sign-on and coalition letters that lent the support of nearly 100 additional patient and provider organizations. This large and diverse response to the CMS' comment solicitation indicates an almost universal urgency by patient, provider, payer, and industry groups alike for CMS to reverse its current reimbursement policy for biosimilars to keep the biosimilars market strong and ensure the broadest possible patient and physician access to these important and lifesaving therapies.

If you have any questions regarding the information above, please contact Miranda Franco (miranda.franco@hklaw.com) or Ethan Jorgensen-Earp (ethan.jorgensen-earp@hklaw.com).