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Federal EIN: 20-4039120

September 3, 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

Dear Acting Administrator Slavitt:

The Global Healthy Living Foundation (GHLF) is a 501 (c)(3) patient group that works to improve the quality of life for people with chronic disease, often focusing on those least able to advocate for themselves. As a patient advocacy organization, GHLF represents more than 80,000 chronically ill patients across the country. Many of these individuals have rheumatoid arthritis, take biologics, and stand to benefit greatly from the addition of biosimilars to the market. I am writing to you today to express our collective opposition to a provision in the CMS proposed rule to the 2016 Medicare Physician Fee Schedule that seeks to assign one Healthcare Common Procedure Coding System (HCPCS) code to all biosimilars to a particular reference product.[1]

Our community is incredibly optimistic about the potential of biosimilars. More specifically, we are hopeful that with the addition of biosimilars, patients will experience an expansion in access via increased treatment options. Patients also stand to benefit greatly if predicted cost savings from biosimilars are in fact passed on to them. We have worked tirelessly at the state, federal, and international levels over the past five years communicating the patient perspective on policies that will impact the implementation and utilization of biosimilars. Ensuring the safety and efficacy of this new class of products along with protecting the patient-physician relationship has been our priority.

Our positions on issues such as interchangeability, substitution, extrapolation of data, naming, and labeling have been based on the inherent fact that biosimilars are not generics. Scientifically, they are not identical replicas of the innovator biologics they mimic. Further, biosimilars based on the same reference biological product are also inherently different from each other. They may be highly similar, but given their subtle differences; not exact copies.

This is why after reviewing the CMS proposed rule to the 2016 Medicare Physician Fee Schedule we are extremely concerned to see that rule does not align with the Biologics Price Competitions and Innovation Act or reflect the science of biosimilars. The recent proposed rule

[1] https://www.federalregister.gov/articles/2015/07/15/2015-16875/medicare-program-revisions-to-payment-policiesunder-the-physician-fee-schedule-and-other-revisions

suggests that biosimilar reimbursement should be calculated based on a multi-drug source model. Essentially grouping multiple biosimilar products together and calculating reimbursement based off aggregated data points. This policy is reflective of a belief that biosimilars of a common biologic reference products are, like generics, interchangeable and should be reimbursed as such.

Biosimilars should be given a separate HCPCS code to ensure that the product is treated as distinct and unique in terms of safety, effectiveness, and clinical utility.

We strongly believe that HCPCS codes assigned to biosimilars cannot follow a generics model, as currently proposed by CMS. GHLF strongly encourages CMS to reconsider the proposed rule and further examine the impact it will have on patient access and cost.

Thank you for your time and consideration; they are greatly appreciated.
Sincerely,

Seth Ginsberg
President, Global Health Living Foundation