



September 8, 2015

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: Comment on CMS-1631-P (“Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016”)

Dear Sir or Madam:

On behalf of the 30 million Americans with one of the approximately 7,000 known rare diseases, NORD would like to thank the Centers for Medicare and Medicaid Services (CMS) for the opportunity to provide comments on the proposed rule titled, “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016.”

As an organization representing millions of patients across the United States with rare diseases, we are dedicated to assuring that rare disease patients receive individualized care that is specific to their medical needs. Access to more therapeutic options, including biosimilars, is a primary means to achieve this goal.

In light of this, we are concerned that this proposed rule undermines the goal of a robust biosimilars market. We respectfully urge you to adopt separate Healthcare Common Procedure Coding Systems (HCPCS) (also known as J-codes), for each biosimilar.

Biosimilars are highly similar, but not identical, to the original biologic medicine. *Importantly, different biosimilars of an originator drug can be highly similar, but cannot be identical, to one another.* The CMS proposal for shared biosimilar J-codes ignores these fundamental facts and inappropriately replicates a model that has been used for generic drugs. The consequences of such an ill-advised policy will be to reduce innovation and deprive the marketplace of biosimilars that compete on the basis of benefit (efficacy, safety, quality, indication) rather than just price.

NORD is the leading voice of the rare disease community dedicated to helping people with rare “orphan” diseases and assisting the organizations that serve them. We believe strongly that every patient deserves the medical care that is best suited for their medical situation and that is most likely to give them the best results. The population we serve and represent is often dependent on biologics to treat conditions that are complex and involve complications from co-morbidity and polypharmacy.

A robust biosimilars market helps us address these many concerns and is unlikely to happen without changes in the proposed CMS policy.

We thank CMS for the opportunity to comment, and we look forward to working with CMS on ensuring that rare disease patients receive the innovative treatments they need. For questions regarding NORD or the above comments, please contact Paul Melmeyer, Associate Director of Public Policy, at pmelmeyer@rarediseases.org or (202) 588-5700, ext. 104.

Thank you in advance for your consideration.

Sincerely,

A handwritten signature in cursive script, appearing to read "Peter L. Saltonstall". The signature is written in dark ink on a light-colored background.

Peter L. Saltonstall
President and CEO