



December 9, 2015

The Honorable Orrin G. Hatch, Chairman
United States Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Chairman Hatch:

The National Organization for Rare Disorders (NORD) thanks you for opposing the Centers for Medicare & Medicaid Services' (CMS) recent proposal that places biosimilars of a single reference product under one Healthcare Common Procedure Coding System (HCPCS) code. We urge you and your colleagues to request CMS to adhere to current law that states that the calculation for reimbursing biosimilars shall be made separately, strongly implying that each biosimilar should have its own unique payment rate and HCPCS code.

CMS finalized their policy in the 2016 Medicare Physician Fee Schedule, but it appears to have been done without a regard towards the public's concern and opposition. As you know, Medicare Part B reimbursement of biosimilars is calculated by the weighted average of sales prices under each HCPCS code. This ill-advised policy will reduce innovation, and deprive the marketplace of biosimilars that compete on the basis of benefit (efficacy, safety, quality, indication) rather than just price. Additionally, the ability to track and trace each biosimilar medicine will be negatively impacted, which could have grave patient safety implications to rare disease patients who benefit from the innovation and greater treatment options of biosimilars.

As an organization that represents millions of individuals with rare diseases and the organizations that represent them, we have many concerns with the CMS decision. NORD strongly believes 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 will help us address these concerns, but it is less likely to happen without changes to the proposed CMS policy.

In sum, we are committed to principles of patient-centered care and a clinically-sound prescribing process for biologics, including biosimilars. A single HCPCS billing code and reimbursement rate for all biosimilars of a single reference product seriously jeopardizes these principles, undermining innovation, science and safety.

We thank you in your continued efforts to prioritize the safety of all patients, including our members and the rare disease community.

Respectfully,

Peter L. Saltonstall
President and CEO