United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

October 22, 2015

Andrew Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Mr. Slavitt:

I am writing to express my deep concern about the payment policy for biosimilars included in the Centers for Medicare and Medicaid Services (CMS) 2016 Medicare Physician Fee Schedule proposed rule. Specifically, the CMS proposal to assign all biosimilars of the same reference product to a single Healthcare Common Procedure Coding System (HCPCS) billing code and establish a blended payment amount is misguided and short-sighted. I strongly urge that the proposal not be finalized.

This CMS proposal will discourage innovation by dampening the incentive to develop biosimilars. This is especially troubling as the biosimilars market is still evolving. Congress established a regulatory pathway and Medicare payment parameters for biosimilars in 2010. To-date, the Food and Drug Administration (FDA) has approved only one biosimilar, which Medicare does not yet cover. The CMS proposal sends the wrong signal at a critical time, in an area that holds tremendous promise for patients across the country.

Beneath my overarching concern about the adverse impact on innovation, I have a number of specific concerns. The proposal treats biosimilars the same as generic drugs, despite the fact that biosimilars are more complex, costly, and time-consuming to manufacturer. Further, it would assign all biosimilars of the same reference product to the same HCPCS code even though the FDA may approve a biosimilar for a subset of the conditions for which the reference product is indicated. Assigning all biosimilars of a reference product to the same HCPCS code would also interfere with the ability to track usage of each biosimilar—complicating patient safety and research efforts. In addition, the proposal is contrary to the statutory language that specifies that each biosimilar should be paid on its own average sales price (ASP), which requires the assignment of a unique HCPCS code.

Biosimilars hold great promise for achieving positive health outcomes while reducing the cost to Medicare, other payers, and patients. It makes little sense to erect barriers to a market that has yet to materialize. I urge CMS to establish a policy in the 2016 PFS final rule that assigns a unique HCPCS code so that each biosimilar is paid on its own ASP. Such a policy is needed to ensure an innovative and robust biosimilars market.

Sincerely,

Orrin Hatch
Chairman
Senate Committee on Finance