

September 9, 2017

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1676-P

The forty-six (46) undersigned organizations are writing to express our concerns about the current Centers for Medicare and Medicaid Services (CMS) policy related to payment for biosimilar biological products. We urge that this policy be reversed in the context of CMS' calendar year (CY) 2018 Medicare Physician Fee Schedule (MPFS) final rule.

We are encouraged by the promise of biologics and the increased access that biosimilars will create to address some of the most debilitating and difficult to treat diseases for which there are currently only a limited number of therapies. The current CMS policy, which assigns a single billing code and payment rate to all biosimilars to a given reference product, betrays that promise. This policy will have the effect of limiting patient and provider access based solely upon economic considerations and without regard to clinical considerations, such as the number of indications covered by a given product. Additionally, excluded from reimbursement would be patient-centric considerations, including patient support programs and provider education necessary for such complex medicines.

Equally as important, the current policy brings with it additional risk and uncertainty, creating significant disincentives for manufacturers to enter or stay in the biosimilars market. Biosimilars not only cost less than biologicals but they also introduce pricing competition into the market that can lower prices for pharmaceuticals overall. If the CMS policy adopted two years ago does not change, this pricing competition may not come to fruition.

In its CY 2018 proposed rule, CMS is taking a step forward toward reversing this policy by soliciting "new or updated information on the effects of the current biosimilar payment policy." We believe that action must be taken during this rulemaking to ensure that this nascent biosimilars market is allowed to develop. By addressing this policy at a later date, any changes that would be possible would result in significant instability in the market, dissuading potential biosimilar manufacturers from entering the space and incentivizing companies with biosimilar products in their pipelines to leave, thus limiting patient access to these important therapies.

We strongly encourage CMS to reverse their position on biosimilar reimbursement as soon as possible in the context of the final rule, redrafting the relevant language to assign to each biosimilar a separate and distinct billing and reimbursement code. In doing so, physicians, as well as their patients with some of the most difficult diseases to treat in the United States,

September 9, 2017
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Attention: CMS-1676-P

including cancer, anemia, and autoimmune disorders such as rheumatoid arthritis and psoriasis, will have access to these lifesaving therapies.

Thank you for your attention to this important issue.

Sincerely,

ADAP Advocacy Association (aaa+)
Advocates for Responsible Care
Alliance for Patient Access
Association of Community Cancer Centers
Cancer Specialists of New York
Caregiver Action Network
Chicago Hispanic Health Coalition
Community Access National Network
Community Oncology Alliance
Empire State Hematology and Oncology Society
Georgia AIDS Coalition
Global Healthy Living Foundation
Hawaii Society of Clinical Oncology
Healing Hearts of Central Ohio
Healthcare Leadership Council
HealthyWomen
HeartBrothers Foundation
Indiana Oncology Society
International Oncology Network
Iowa Oncology Society
Kansas Society of Clinical Oncology
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
Malecare

Mended Hearts National and all Mended Hearts
284 Chapters
Minnesota Society of Clinical Oncology
Missouri Oncology Society
Montana State Oncology Society
National Minority Quality Forum
Nevada Oncology Society
North Carolina Oncology Association
Patients Rising
Rocky Mountain Oncology Society
Rx In Reach
Sisterlink Collaborative (NY)
South Carolina Oncology Association
Strategic Health Resources, LLC
Tennessee Oncology Practice Society
Texas Society of Clinical Oncology
The Arizona Clinical Oncology Society
The Veterans Health Council
US Pain Foundation
Vietnam Veterans of America
Virginia Association of Hematologists and
Oncologists
West Virginia Oncology Society
Wisconsin Association of Hematology and
Oncology