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

CMS-1676-P
ID: CMS-2017-0092-0012
RIN: 0938-AT02
Re: Medicare Physician Fee Schedule

Dear Administrator Verma:

As patient advocacy organizations, we are writing to comment on the above-captioned payment rule (CY 2018 MPFS Final Rule). We oppose the CMS policy on Payment for Biosimilar Biological Products that assigns shared codes to multiple distinct biological products. We believe this Rule to be inconsistent with efforts to ensure the safety of all biologic medicines, and likely to result in fewer treatment options and higher costs to patients. We urge CMS to reconsider this policy, and instead assign each and every biologic and biosimilar medicine its own distinct payment code.

Biosimilars offer new treatment options and lower costs to the patients we represent. But the CMS Rule as it stands undermines this shared goal:

First, it disproportionately prioritizes cost among the many factors that go into making a treatment decision. These include whether or not a biosimilar was approved for a particular indication; whether its comparability to the reference product was ever demonstrated by studies in that indication or whether its effects were merely extrapolated from studies in different indications; whether the FDA determined the biosimilar is "interchangeable" with its reference product (producing the same effects without additional risks); product features such as ease and frequency of administration; the quality of patient support programs; the degree of discomfort associated with injections; whether it can it be administered at home; and whether it will be consistently available (not subject to shortages). These are important patient considerations above and beyond the simple price paid.

Second, the use of a shared identifier for multiple different biologic products implies an identicality between them which does not exist and an interchangeability between them that may or may not have been demonstrated. For this reason, both the Food and Drug Administration (FDA) and World Health Organization (WHO) have recognized the need for clear product identification among biologics and biosimilars, and have proposed differentiating them with a four-letter suffix. The CMS Rule stands in stark contrast to the policies of these regulators. Its merging of distinct products into a single payment code could put patients at increased risk of adverse reactions and/or suboptimal treatment.

Finally, shared codes may also have the unintended consequence of disincentivizing biosimilar development itself. Regardless of whether a manufacturer develops a less expensive manufacturing process or a delivery system that makes compliance more likely or reduces waste but costs more, they will be paid at the same rate. Reduced biosimilar development means

reduced price competition, which could jeopardize any potential cost savings to patients and payers.

When this Rule was first proposed, patients, physicians, innovator and biosimilar manufacturers submitted comments on the policy. In its Final Rule, CMS acknowledged the above concerns were widely shared among commenters:

> "Most of these [more than 75] commenters stated that the CMS proposal will create access issues…Other concerns included a belief that as a result of the proposal, prescribers' choices will be limited, that tracking or pharmacovigilance activities will be impaired, and that innovation and product development will be harmed, leading to increased costs for biosimilar products."[1]

We note that since this Rule was finalized, CMS has begun to introduce unique modifiers for biosimilars which share a HCPCS code with their reference biologic. We commend CMS and the new Administration for recognizing the need for accurate tracking of these medicines and their effects in patients including adverse events. The use of modifiers represents an important step toward ensuring clear product identification. However, it remains our position that entirely unique HCPCS codes will address this need most efficiently while offering patients the additional benefits described above.

As patient advocacy organizations, we want to ensure that all patients facing the life-threatening diseases these medicines are designed to treat will have the full range of treatment options available to them and we are concerned that this rule may limit those options. Accordingly, we respectfully urge CMS to reverse the shared payment code rule for biologics and biosimilars.

Thank you for the opportunity to comment on this important issue.

Sincerely,

Alliance for Safe Biologic Medicines
Alliance for Patient Access
American Academy of Dermatology
American Autoimmune Related Diseases Association
American Association of People with Disabilities
American Council on Science and Health
Association of Black Cardiologists
Association of Clinical Research Organizations
Association of Gastrointestinal Motility Disorders
Colon Cancer Alliance
Global Colon Cancer Association
Global Healthy Living Foundation
Health HIV
Hepatitis Foundation International
Interamerican College of Physicians & Surgeons
International Cancer Advocacy Network

[1] 80 Fed. Reg. 71093 (November 16, 2015)

International Foundation for Autoimmune & Autoinflammatory Arthritis (IFAA)
Kidney Cancer Association
Lupus and Allied Diseases Association
MANA
National Alliance on Mental Illness
National Hispanic Medical Association
National Infusion Center Association (NICA)
National Organization For Rare Disorders (NORD)
National Psoriasis Foundation
RetireSafe
United Spinal Association
U.S. Pain Foundation
ZeroCancer