Global Healthy Living Foundation
515 North Midland Avenue
Upper Nyack, New York 10960 USA
+1 845 348 0400
+1 845 340 0210 fax
www.ghlf.org

January 5th, 2024

Chiquita Brooks-Lasure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-4205-P
Baltimore, MD 21244-1850

RE: GHLF Comments on Changes Regarding Biologic Substitution (CMS-4205-P)

Dear Administrator Brooks-Lasure,

Thank you for the opportunity to comment on the proposed changes to Medicare Advantage (Part C) and the Medicare Prescription Drug Benefit (Part D) regarding biologic substitutions. The Global Healthy Living Foundation supports the access and growth of the biosimilar market; however, we are concerned that the proposed changes will have unforeseen consequences and allow insurance companies to make unchecked changes to their formularies.

By way of background, the Global Healthy Living Foundation (GHLF) is a 501(c)(3) patient group that works to improve the quality of life for people with chronic disease, often focusing on those least able to advocate for themselves. Through our websites, social media channels, and conventional media, GHLF reaches more than 10 million chronically ill people monthly in the United States – in English and Spanish. Our patient community is often forced to try multiple different medications before finding the one that works best for them, and biosimilars provide exciting new options for our patients. However, we believe that the choice to take biosimilars should be made between a patient and their physician, not through the loosening of substitution and notification regulations.

When patients select their health plans, they spend countless hours ensuring that the medications that they rely on are covered. Patients go through a process that oftentimes takes longer than a year to find a medication and treatment plan that works for them. Any time that regulations are loosened to allow changes to a formulary without proper notification, it harms patients and perpetrates a “bait-and-switch” practice where patients no longer have access to the medication they selected the health plan for. This is made worse when physicians are unable to veto any possible changes due to a lack of notification. Biosimilars, while innovative and interchangeable, are not 100% copies of their reference biologic and substitution should not be treated akin to a generic substitution of a branded product. We would like to see changes to the proposed rule that ensure that insurance companies will not be able to claim that biosimilar substitutions are simple “maintenance changes” and instead reflect the reality that they are a separate medication option.

On behalf of those in our community, we hope that you ensure that the patient-physician relationship remains the deciding factor in treatment options regarding biosimilars and biologics. Should you need to hear from more patients directly, we are ready to help connect you with those who would like to share their story with you.

Sincerely,

Steven Newmark, JD
Director of Policy
Global Healthy Living Foundation