Your Generics & Biosimilars Industry

July 23, 2021

The Honorable Xavier Becerra
U.S. Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20210

Submitted via http://www.regulations.gov

RE: Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs (CMS-9905-NC)

Dear Secretary Becerra:

The Association for Accessible Medicines and the Biosimilars Council (collectively "AAM") appreciate the opportunity to provide input in response to the Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs (CMS-9905-NC). AAM is the nation's leading trade association for manufacturers and distributors of generic and biosimilar prescription medicines.

The US healthcare system has saved nearly $2.2 trillion in the last decade due to the availability of low cost generics. Generic medications represent 90% of all prescriptions filled but only 20% of prescription drug spending in the United States where the remainder can be attributed to the branded traditional and specialty market. In 2020 alone, generic, and biosimilar medicines generated $338 billion in savings. Beyond the healthcare system, patients have a firsthand experience of the benefits of generic medicines. 92% of generic prescriptions are filled $20 or less. AM's core mission is to improve patients' lives by advancing timely access to affordable, FDA-approved generic and biosimilar medicines. Further, AAM supports concrete solutions to reduce patient and taxpayer spending through greater adoption of generic and biosimilar medicines.

As the Department of Health and Human Services, the Department of Labor, the Department of the Treasury, and the Office of Personnel Management (collectively "the Departments") acknowledge in their request for information (RFI), several key concepts will require additional clarification during the regulatory process.

Measurements Specific to Brand Name Drugs Should Only Include Innovator Drugs and Reference Biologics

The RFI asks for input on the definition of "prescription drug." However, the RFI does not consider how the term "brand drug" should be defined. The Consolidated Appropriations Act of 2021 ("the Act") directs commercial and group health plans to report specified information on the "50 brand prescription drugs most frequently dispensed by pharmacies." The Departments should make clear in regulations that reporting requirements for those elements are limited to innovator prescription drugs approved by the U.S. Food and Drug Administration (FDA) under a new drug application (NDA) and reference biologics approved by the FDA under a biologics license application (BLA). Multiple-source drugs approved under an abbreviated new drug application (ANDA) or 505(b)(2) application, and biosimilar and interchangeable biologics should not be included in the reporting for these elements. Congress expands reporting to more broadly include "prescription drugs" for certain elements, recognizing that there is a difference between "brand prescription drugs" and "prescription drugs."

Measurements of "Greatest Increase in Plan Expenditures" Should be Based on Increases in Absolute Plan Spending, not Percentage Increases in Plan Spending

The Departments specifically request input on how plans should measure the prescription drugs with the "greatest increase in plan expenditures" from the previous year. This metric should focus on the absolute increase in expenditures in order to accurately identify the price modifications that have a consequential impact to overall spending. For example, a scenario where a drug increased in price from $0.02 a tablet to $0.04 a tablet would represent a 100% price increase, despite the absolute increase in price of $0.02. But that percentage increase may be less impactful than a 10% price increase in a drug costing $40,000 per year. This is why brand biologics and specialty drugs represent roughly 2% of overall prescription volume, but more than half of all spending. Therefore, it is essential that the Departments establish a metric that will capture a comprehensive assessment of drug pricing practices that Congress intended: those placing the greatest pressure on plan budgets. This is achieved by looking at absolute increases in price and aggregate spending rather than percentage increases.

Standardization Will be Necessary to Accurately Compare Data Between Plans

The Act definitively directs plans to report data based on the plan year, not the calendar year. However, because each carrier establishes plan years differently, it will be crucial that the Departments identify a method to standardize the data reported in order to accurately compare between plans. Because of the variability in plan years between carriers and contracts, it may be difficult to generate conclusions from data across plans, as it is likely this data does not capture the same 12 months of spending. While the Departments are limited by statute to collecting information on a plan year basis, this factor should be taken into consideration in establishing parameters for the collection, reporting, and analysis of data in the proposed rule.

Again, AAM appreciates the opportunity to provide feedback on the inquiries posed by the Departments through the RFI. We look forward to continuing to collaborate with the Administration on delivering lower-cost pharmaceutical options for Americans, reducing pressures on patients, employers, and taxpayers. If you have questions, or need anything else, feel free to contact me.

Sincerely,

Christine M. Simmon
Senior Vice President, Policy & Strategic Alliances, AAM
Executive Director, Biosimilars Council