



July 23, 2021

Amber Rivers
Director
Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
U.S. Department of Labor
200 Constitution Avenue, NW
Room N-5653
Washington, DC 20210

VIA ELECTRONIC DELIVERY

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

Dear Director Rivers:

The Biotechnology Innovation Organization (BIO) is pleased to provide feedback on the tri-Department's Request for Information (RFI) on Reporting Pharmacy Benefit and Prescription Drug Costs.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions. BIO membership includes biologics and vaccine manufacturers and developers who have worked closely with stakeholders across the spectrum, including the public health and advocacy communities, to support policies that help ensure access to innovative and life-saving medicines and vaccines for all individuals.

We appreciate the thoughtful approach the Departments are taking in implementing the transparency provisions of the Consolidated Appropriations Act of 2021. These reports will help shed light on the complexities and nuances of the prescription drug supply chain. We look forward to reviewing proposed requirements related to this reporting in future rulemaking. In response to three issues raised by the Departments in this RFI, we offer the comments below.

Copay Accumulator and Maximizer Programs

The Departments seek information on the definition of "rebates, fees, and any other remuneration," and specifically whether and how copay accumulator programs should be accounted for in this data collection. In incorporating data on payer use of accumulator and maximizer programs, **we urge the Departments to recognize that manufacturer assistance provided to patients is not "remuneration" and is separate and distinct from streams of "rebates, fees, and other remuneration" that may exist between payers and manufacturers.** By design, patients are the sole intended recipient of

manufacturer assistance programs, not health plans or their contracted pharmacy benefit managers (PBMs). The structure of this data collection and the biannual report should reflect that reality.

We believe this reporting requirement on plans and PBMs can be an important source of information on the proliferation of both copay accumulator and maximizer programs, and strongly encourage the Departments to require plans and issuers to report on their use, though as stated above, accumulator data should not be included in rebates, fees or other remuneration reported by plans and PBMs. While actionable information that current or potential enrollees could use to determine if their plan has adopted an accumulator can still be difficult to find, aggregate information on the scope of these programs would help policymakers better understand the population of impacted individuals.

As we have commented previously, we are deeply concerned about the growing use of copay accumulator and maximizer programs and the onerous cost sharing burden they place on patients. In stopping amounts from manufacturer assistance programs from accruing to patients cost sharing obligations, accumulator and maximizer programs increase patients' out-of-pocket medicine costs and can upend access to needed therapies. The link between excessive cost sharing and patients abandoning prescriptions is well established. Research has shown that more than two-thirds of commercially insured patients (69%) abandoned their prescription at the pharmacy when cost sharing exceeded \$250, while only 11% did so when cost sharing was \$30 or less.¹ By helping patients pay their cost sharing, manufacturer assistance programs can help to improve patient adherence and prevent unnecessary medical spending. A better understanding of how plans and PBMs are deploying programs that disrupt this dynamic would help inform critical policy discussions.

Greatest Increase in Plan Expenditures

This data collection requires plans and issuers to report on the 50 prescription drugs with the greatest increase in plan expenditures over the previous year, and the change in amounts expended by the plan or coverage in each plan year.

As a baseline measure, **plan expenditures on prescription medicines should be reported net of all rebates and price concessions.** This measure best reflects the actual cost borne by the plan for a particular medicine. We also recommend the Departments select multiple measures that reflect the complexity of the pharmaceutical supply chain. For example, only reporting on the absolute increase of dollars spent on a medicine (net of rebates and other price concessions) would mask whether spending increases were due to either pricing factors or changes in utilization.

There are many options for how this measure can be reported. However, we strongly support the selection a set of holistic measures that accurately reflect the dynamics of prescription drug reimbursement.

International Drug Comparisons

The RFI questions whether the public report resulting from this data collection should include a comparative analysis of prescription drug costs in other countries. **We strongly recommend against this approach.** These types of comparisons are often flawed and could yield results that are more confusing than they are informative. For example, most

¹ IQVIA "Patient Affordability Part Two: Implications for Patient Behavior & Therapy Consumption." May 2018. Available at: <https://www.iqvia.com/locations/united-states/patient-affordability-part-two>

international comparisons focus solely on list prices, and exclude from calculations the discounts and rebates negotiated by health plans and PBMs in the United States (as discussed above). Many times, the prices paid for medicines in other nations lack context and incorrectly imply that medicine price differentials are a major driver of increased health care spending in the United States. Thus, comparisons across commercial prices in this country and international markets would be far from “apples-to-apples.” The Departments should not include this type of comparison in the final report.

We appreciate your consideration of these comments and look forward to additional rulemaking on this data collection. Should you have any questions, please do not hesitate to contact us at (202) 962-9200.

Sincerely,

/s/

Crystal Kuntz
Vice President
Healthcare Policy and Research