June 28, 2024

Department of Consumer and Business Services
Insurance Regulation
350 Winter Street NE
Salem, OR 97301

Attn. Karen Winkel via email: Karen.J.WINKEL@dcbs.oregon.gov

RE: Prescription Drug Affordability Board, Drug Manufacturers Annual Fee Assessment

Dear Ms. Winkel,

The Association for Accessible Medicines (AAM) appreciates the opportunity to provide comments in response to proposed rules regarding the Drug Manufacturers Annual Fee Assessment. AAM is the leading trade association for the developers and manufacturers of generic and biosimilar medicines. Its core mission is to improve the lives of patients by advancing timely access to high quality, affordable, and FDA-approved generic and biosimilar medicines. The use of generic and biosimilar medicines saved nearly $4 billion across the United States in 2022 including $3.9 billion in Oregon alone.

AAM appreciates the opportunity to participate in the recent Rulemaking Advisory Committee meeting on March 7 as well as providing public comment during the June 25 rules hearing. These comments build upon those made during those meetings.

AAM remains opposed to funding allocations based on the utilization of the National Drug Code (NDC) database. The NDC database is not designed to be utilized for this purpose and doing so creates an unnecessarily complex process. As proposed, the rule distributes fees across all manufacturers based on its number of NDCs with no consideration whether that drug product is commercially available. This methodology unfairly imposes a disproportionate share of the total fee on low-cost generic manufacturers instead of brand manufacturers that are responsible for over 80% of prescription drug spending. More than 90% of prescriptions are filled with generic medications, but in 2022 they accounted for less than 18% of total prescription drug spending and less than 2% of total U.S. health care spending. patients:also deliver value to

patients; ninety-three percent of generic drugs have copays under $20 (as compared to 59% of brand-name drugs), and their average copay is $6.16 (as compared to $56.12 for brands)."[1]

AAM previously suggested a more equitable and transparent approach should be adopted than the methodology proposed in the current draft rule. Ideally, manufacturer fees should be based on revenue derived in the state as originally adopted by the legislature. However, recognizing the work that has been done, should the state determine that the use of the NDC database is its preferred method, the rule should be modified to tier assessments and insure lower-cost manufacturers are not underwriting the PDAB and transparency program reviews of higher cost drugs. This can be accomplished by adding a multiplier to each of the three classifications currently delineated in the rule.

Proposed Rule Results in Cost Saving Manufacturers Paying Disproportionate Amount of the Fee

AAM and the healthcare data and analytics firm Avalere partnered to examine the Food and Drug Administration (FDA) NDC directory to determine the proportion of funding that would be assigned to brand versus generic manufacturers as categorized by the proposed rule. After filtering out non-prescription drugs and consolidation by ownership, 1,133 corporate entities remained. Each entity can be assigned as "brand" or "generic" based on the greater number of NDC's held by the entity. This process reveals nearly equal distribution between brand (49%) and generic (51%) manufacturers. However, the classifications determined by the proposed rule would result in primarily generic manufacturers funding a disproportionate percentage of the total fee.

The large classification includes 220 corporate entities; 73% are primarily generic manufacturers and 27% are primarily brand manufacturers. Considering this classification would pay 70% of the total annual fee, generic manufacturers would be required to pay the most significant portion charged. The medium classification breaks down nearly equally between brand and generic manufacturers and requires these companies to pay 25% of the total fee. The small classification is comprised of 55% brand manufacturers and 45% generic manufacturers which would pay the remaining 5% of the total fee.

Based on the findings of Avalere, under the proposed rule, for each $1 million of total fees primarily generic manufacturers would be responsible for over 65% ($658,500) while brand companies would pay below 35% ($341,500). This is not an equitable methodology considering the scope of work being conducted by the PDAB and transparency program.

Applying a Tiered System with the Use of the NDC Database is a More Equitable Method for Setting Fees for All Manufacturers

AAM recognizes the effort to devise a comprehensive and transparent process to charge manufacturers to cover the state costs for its PDAB and drug price transparency program. Applying a tiered approach to the current framework will result in a more equitable

[1] AAM. The U.S. Generic & Biosimilar Medicines Savings Report. September 2023. https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf.

methodology. Based on national sales data, generic drugs represent less than 20% of total drug spending while brand drugs take over 80%. AAM suggests this revenue distribution be included in each classification prior to the fees being assigned.

Of the 70% paid by manufacturers in the large classification, 80% of that total should be borne by those manufacturers determined to be primarily brand and 20% by those determined to be primarily generic. Similarly, this should be applied in the medium and small classifications as well. This would result in primarily brand manufacturers paying 80% of the total fee and primarily generic manufacturers paying 20%--a result similar to the legislature's original intent in 2021. Further, it will focus fees on those drugs actually being considered for an unaffordability determination by the PDAB.

Should you have any questions regarding the findings from Avalere or AAM's comments or suggested solution, please feel free to contact me at brett.michelin@accessiblemeds.org.

Thank you,

Brett Michelin
Senior Director, State Government Affairs
Association for Accessible Medicines