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June 21, 2024

Karen Winkel, Rules Coordinator
350 Winter St. NE
Salem, OR 97301
karen.j.winkel@dcbs.oregon.gov

Re: Drug Manufacturers Annual Fee Assessment

Dear Ms. Winkel:

The Pharmaceutical Research and Manufacturers of America appreciates the opportunity to review and comment on the Department of Consumer and Business Services' (the "Department" or "DCBS") proposed rule regarding annual fees assessed to drug manufacturers (the "Proposed Rule"), which sets forth a fee structure intended to cover expenses related to the Department's Drug Price Transparency program and the Prescription Drug Affordability Board's ("PDAB's" or "Board's") operations. PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. We appreciated the opportunity to provide feedback on the draft version of this rule as a participant in the Rules Advisory Committee ("RAC"), and provide below our comments with respect to the Proposed Rule.[1]

I. Enhanced Transparency Related to Proposed Fee Assessments

PhRMA recognizes that the Department shared preliminary with the RAC about the estimated annual budget to support the two programs and the number of entities estimated to be subject the fee. To provide greater transparency with respect to how the proposed fee assessments will be determined in the future, PhRMA requests that DCBS commit to annually providing this information via its public website.

II. Clarifications Regarding Use of NDCs to Determine a Manufacturer's Size Category

PhRMA reiterates previous comments requesting additional details on the process and data sources for identifying NDCs and how the Department will identify which NDCs should be used to appropriately determine the size category of a manufacturer.[2] Greater transparency in this process will help DCBS avoid size determinations, and ultimately fee assessments, that may be based on erroneous information.

III. Enhanced Procedural Protections and Safeguards

[1] In filing this comment letter requesting changes to the Proposed Rule, PhRMA reserves all rights to legal arguments with respect to Oregon Senate Bill 844 (2021), as amended by Oregon Senate Bill 192 (2023) (collectively, the "PDAB statute"). PhRMA also incorporates by reference all prior comment letters to the extent applicable.

[2] *See* Proposed Rule § 836-200-0553(3). As previously discussed in our March 14, 2024 letter, the number of NDCs associated with a particular manufacturer may not correlate with the size of its commercial sales: certain products may be available in a wider range of dosages or packaging than others, which would correspond to a larger set of NDCs; further, a particular NDC may reflect a product or package size that is no longer sold in the commercial marketplace, including outdated or otherwise obsolete products that are no longer manufactured, and certain NDCs may not be used for commercial market transactions (e.g., NDCs for sample packs). *See* Letter from PhRMA to DCBS (Mar. 14, 2024).

PhRMA appreciates that the Department's Proposed Rule provides the opportunity for manufacturers to request a correction if their size category is incorrect. PhRMA continues to request these additional protections in the fee assessment process:

- **Deadline for Payment of Fees**. PhRMA requests that the Proposed Rule be revised to extend the 30-day post-assessment deadline to pay fees to 60 days.[3] While the current prescription drug transparency assessment under 836-200-0555 is due within 30 days of reporting, that assessment only applies a flat $400 fee to manufacturers who are subject to reporting requirements.[4] Providing manufacturers 60 days to make payment, rather than 30, would provide them additional time to evaluate and respond to their assessment before making payment.

- **Suspension of Interest on Assessments**. PhRMA asks that DCBS revise its Proposed Rule provision regarding accrual of interest to suspend the accrual of interest on assessments during the pendency of an appeal.[5] Manufacturers should not be penalized for exercising their appeal rights; nor should they be required to pre-pay assessments that are subject to appeal if the assessments appear erroneous or otherwise unlawful.

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We thank you again for this opportunity to provide comments and feedback, and for your consideration of our concerns. Although PhRMA has concerns with the Proposed Rule, we stand ready to be a constructive partner in this dialogue. Please contact dmcgrew@phrma.org with any questions.

Sincerely,

Dharia McGrew, PhD
Director, State Policy

Merlin Brittenham
Assistant General Counsel, Law

[3] *See* Proposed Rule § 836-200-0553(7).
[4] Or. Admin. R. § 836-200-0555.
[5] *See* Proposed Rule § 836-200-0553(7) (stating that "[a] manufacturer shall pay interest at nine percent per annum on any assessment that is not paid when due").