VIA Electronic Delivery

June 12, 2026

Oregon Division of Financial Regulation

Department of Consumer and Business Services

350 Winter St. NE

Salem, OR 97309

Re: Draft Rule from DCBS Drug Price Transparency Rules Advisory Committee (RAC) Governing the Oregon Prescription Drug Price Transparency (DPT) Program

Dear Oregon Division of Financial Regulation (DFR):

The Biotechnology Innovation Organization (BIO) and Oregon Life Science appreciate the opportunity to comment on the Draft Rule amending the Drug Price Transparency Program requirements for prescription drug manufacturers (Draft Rule).

The Biotechnology Innovation Organization (BIO) is the premier biotechnology advocacy organization representing biotech companies, industry leaders, and state biotech associations in the United States and more than 35 countries around the globe. BIO members range from biotech start-ups to some of the world's largest biopharmaceutical companies – all united by the same goal: to develop medical and scientific breakthroughs that prevent and fight disease, restore health, and improve patients' lives. BIO also organizes the BIO International Convention and a series of annual conferences that drive partnerships, investment, and progress within the sector.

Oregon Life Sciences is the state's trade association and champion for the life sciences industry. With members across biotech, medical devices, diagnostics, digital health, biomanufacturing, and supporting services, Oregon Life Sciences works to advance discoveries, foster collaboration, strengthen the workforce, and grow Oregon and Southwest Washington's innovation economy.

Our comments are as follows.

Prescription Drug Reporting- Annual Price Increase: 836-200-0533

836-200-0533(2): The Draft Rule refers to mandatory reporting at the beginning and the end of the reporting year. We request that OR DFR provide a definition of the term "reporting year," to reduce ambiguity. For instance, DFR could refer to the previous version of the rule which specified that reporting year would include the calendar year preceding the report.

836-200-0533(4): We are concerned that the Draft Rule's requirement to report the specific date of every price change during the reporting year would impose a significant administrative burden. Collecting, validating, and reporting each date of a price change would require system modifications and manual reconciliation efforts that go beyond the information needed for most price transparency and oversight purposes.

836-200-0533(8): Requiring manufacturers to report a drug's initial launch price does not meaningfully advance the objective of monitoring price increases during the reporting year. For products that were launched prior to the reporting period, the initial launch price is not relevant to assessing whether, and by how much, the drug's price changed over the last year.

836-200-0533(9): The proposal to require manufacturers to report "all factors" that contributed to a price increase during the reporting year creates uncertainty regarding the scope of the reporting obligation. While DFT staff has stated that the language "factors may include, but are not limited to" implies permissibility to report only the factors that are relevant to a manufacturer's situation, it remains that a manufacturer may reasonably conclude that certain considerations were not material contributors to a price increase, while the Department may disagree and assert that additional factors should have been disclosed, with no clear standard for the level of detail required.

Further, reporting "all factors" would be extraordinarily burdensome and inherently subjective in nature, resulting in inconsistent enforcement. Pricing decisions are often influenced by numerous interrelated business, economic, operational, regulatory, and market considerations, making it difficult to determine which factors "contributed" to a particular price increase and to what extent. The additional data required from reporting "all factors" creates significant operational burden while the tight 60-day deadline remains the same, leaving little time for manufacturers to collect this information.

If the intent is to maintain flexibility for manufacturers to explain the factors that influenced a pricing decision, the Draft Rule should instead require a good-faith description of the primary factors that the manufacturer reasonably believes contributed to the price increase. Otherwise, clarification is needed to demonstrate that manufacturers will still be able to retain flexibility in reporting the factors that are relevant to their situation.

836-200-0533(14): In addition to the previous requirement to report net profit to the prescription drug during the reporting year, the Draft Rule now requires manufacturers to also report net loss on the prescription drug during the reporting year. Requiring the reporting of net loss is not expressly tied to the statute's price transparency objectives and exceeds the scope of information that the legislature intended the DFR to collect.

836-200-0533(16): The Draft Rule requires manufacturers to report on the 10 highest prices paid for the prescription drug during the reporting year in any country other than the United States." While we recognize that this is not a material change from the previous version of the rule, as the rule had already required the disclosure of international prices, we would like to reiterate our strong opposition to the disclosure of international reference pricing and at "the prevailing exchange rate at the time of the report," which is too vague to provide clarity on how an exchange rate factor should be calculated.

Requiring manufacturers to report international reference prices can produce misleading comparisons because foreign governments use different methods and policy objectives when determining the value of new medicines. Many countries rely on centralized price controls, discriminatory metrics such as quality-adjusted life years (QALYs), and other cost-containment measures that stifle pharmaceutical innovation and access. For example, according to researchers at USC, the British National Health Service has long considered health improvements to be as low as one-third the value of even conservative American valuations.[1] Meanwhile, according to a 2024 report by RAND for the U.S. Department of

[1] Darius Lakdawalla and Dana Goldman "'Most-Favored Nation' Drug Pricing Has Three Significant Problems,"

Health and Human Services, most new medicines are launched first in the United States and other major high-income OECD countries typically have to wait about one year after they are launched in the United States.[2] The United States also has access to the largest share of new drugs overall. As a result, foreign prices do not provide an appropriate benchmark for assessing the value of medicines and is not a useful metric for Oregonians.

Further, for manufacturers that utilize out-licensing arrangements, pricing and distribution in foreign markets are often controlled by independent licensees or local partners. In these cases, the originating manufacturer does not control pricing outside of the U.S. and may not have access to such pricing information.

Prescription Drug Reporting – Patient Assistance Programs: 836-200-0532

The Draft Rule requires manufacturers to report granular information regarding their Patient Assistance Programs (PAP), including data on consumer counts, assistance value, refill limits, program duration, eligibility criteria, and verification processes. While we recognize that this is not a material change from the previous version of the rule, as the rule had already required the disclosure of detailed PAP information, we would like to reiterate our concerns regarding this level of detailed reporting. The information requested by Oregon appears significantly more expansive and operationally burdensome than reporting frameworks in most other states, which generally focus on higher-level reporting on PAP availability and design. This level of granularity may not be readily available in existing systems and could require manual reconciliation across vendors, hub data, copay programs, free-drug programs, and internal finance/reporting teams, which requires substantial administrative infrastructure.

Moreover, imposing such detailed reporting obligations could have unintended consequences impacting how manufacturers structure PAPs or reducing availability of PAP offerings altogether, potentially undermining patient access. The reporting of highly detailed operational and eligibility information also raises concerns about patient privacy protections, particularly where data could indirectly enable identification of vulnerable patient populations.

In the interest of promoting meaningful transparency efforts, we encourage Oregon to also require PBMs and insurers to report on copay accumulators and maximizers. Under the existing rules, manufacturers who meet the reporting thresholds must provide data on any applicable PAPs. However, copay accumulators and maximizers increase patient costs by not counting patient assistance programs toward a patient's cost-sharing requirements. This data is currently not reflected in the reporting requirements and omits a key piece of information in the overall affordability landscape.

BIO and OR Life Science appreciate the opportunity to provide feedback to the Oregon DFR through this Draft Rule. Should you have any questions, please do not hesitate to contact us at 202-962-9200.

April 14, 2025. https://schaeffer.usc.edu/research/most-favored-nation-drug-pricing-has-three-significant-problems/

[2] RAND for HHS ASPE, "Comparing New Prescription Drug Availability and Launch Timing in the United States and Other OECD Countries," February 2024. https://aspe.hhs.gov/sites/default/files/documents/430a3e61c234f06270b04414e797ad3a/new-drug-availability-launch-timing.pdf

Sincerely,

/s/

Melody Calkins
Director, Healthcare Policy and Reimbursement
Biotechnology Innovation Organization (BIO)