VIA Electronic Delivery September 9, 2024

Oregon Division of Financial Regulation
Department of Consumer and Business Services
350 Winter St. NE
Salem, OR 97309

Re: Draft Rule (OARs 836-200-0505- 836-200-0530) Governing the Oregon Prescription Drug Price Transparency (DPT) Program

Dear Oregon Division of Financial Regulation (DFR):

The Biotechnology Innovation Organization (BIO) and Oregon Bioscience Association (OR Bio) appreciate the opportunity to comment on the Draft Rule (OARs 836-200-0505- 836-200-0530) governing Oregon's Prescription Drug Price Transparency (DPT) Program.

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, delay their onset, or 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.

OR Bio, a state affiliate of BIO, represents biotech companies throughout Oregon developing critical lifesaving drugs, advanced health-care technologies, and cutting edge medical devices. Oregon Bio supports Oregon's bioscience community through networking, educational programs, enterprise support, advocacy, and the enhancement of research collaboration. We advocate for policies that foster innovation and work to ensure adequate access to health care products and services for all Oregonians, including those most vulnerable facing rare and orphan conditions searching for new treatments, therapies and cures.

Our comments are as follows.

New Prescription Drug Definition: 836-200-0505(6)

The Draft Rule includes new proposed language to clarify that drugs approved through supplemental approvals are considered "new prescription drugs." BIO opposes the additional language on supplemental approvals, as Supplemental Biologics License Applications (sBLAs)/ Supplemental New Drug Applications (sNDAs) fall outside the scope of new prescription drugs.

BIO recognizes that a change in NDC (National Drug Code) should trigger new drug reporting requirements for a drug that is launched under a newly approved NDA or BLA. However, the proposed definition incorrectly assumes that supplemental approvals coincide with new NDCs, which is not the case, for instance with a label expansion. A label expansion through a sBLA/sNDA is often redundant to the information given in the initial approval, and can be administratively complex if the manufacturer is required to focus on costs that are just relevant to the label expansion NDC. Oregon already receives information for new products through NDAs and BLAs, and the addition of supplemental approvals will only result in an unduly burdensome requirement for manufacturers and an influx of pricing information for the State to manage. Accordingly, BIO proposes to strike the language "or a supplemental approval" within the definition of "new prescription drug."

Threshold for Reporting New Prescription Drug: 836-200-0520

The Draft Rule proposes to update the reporting threshold from the 2018 to the 2024 threshold. BIO welcomes this change but requests additional clarifying language so that the threshold aligns with the Centers for Medicare & Medicaid Services (CMS)' stated threshold for each plan year. This alignment would be ideal to avoid static price points that are not updated with CMS' thresholds accordingly.

The Draft Rule also includes new language proposing that "the date of introduction is the FDA start marketing date or the date the product is first listed for sale in the United States, whichever is later." BIO recommends that this language could be clarified further by referencing a source for the FDA marketing start date, such as FDA's NDC SPL Data Elements File (NSDE).

Expectations of Reporting Manufacturers: 836-200-0525(4)

In the Draft Rule, DFR proposes to remove the allowance of a manufacturer's "good faith effort" when providing information required by ORS 646A.689 (2) to (7). BIO has serious concerns regarding the removal of "good faith effort." The drug pricing information requested from manufacturers is not readily available and typically contains highly confidential and trade secret information. Therefore, manufacturers frequently rely on reasonable assumptions to provide such information. Removing the "good faith effort" standard will significantly increase the level of risk and scrutiny for manufacturers, which may further result in industry reluctance and difficulty for manufacturers to provide future input into state-level policies, regulations, and statutes.

Form and Manner Requirements for Drug Pricing Reporting: 836-200-0530

BIO supports and appreciates the proposed new language stating that prescription reporting on price increases is voluntary rather than mandatory. In light of this change, BIO requests that Oregon clarify that no punitive action will be taken against any manufacturer that chooses not to report.

BIO and OR Bio appreciates 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.

Sincerely,

/s/

Melody Calkins
Director
Healthcare Policy and Reimbursement, BIO

/s/

Liisa Bozinovic
Executive Director
Oregon Bioscience Association