



August 17, 2018

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350 Winter St. NE, Salem, OR 9730

RE: HB 4005 Rulemaking Advisory Committee, July 31, 2018 Request for Information by close of business August 17, 2018

Dear Mr. O'Brien:

Thank you for holding the July 31, 2018 Rules Advisory Committee (RAC) meeting. The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to participate in the RAC meetings and looks forward to working with you throughout the regulatory development process. House Bill 4005 requires expansive reporting from biopharmaceutical manufacturers, and as such, it is crucial that the requirements of the bill are carried out in a manner that is fair, predictable, and as administratively simple to comply with as possible for both manufacturers and the state.

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. Since 2000, PhRMA member companies have invested more than \$600 billion in the search for new treatments and cures, including an estimated \$71.4 billion in 2017 alone.

This letter addresses the specific request for information (RFI) issuing from the July 31 RAC with a requested response date of close of business on August 17.

1) The Definition of "new prescription drug" –Section 2(1)(f).

The RFI asks for a proposed definition of "new prescription drug" for the purpose of complying with Section 2(1)(f) of the bill. In the context of HB 4005, we interpret this term to refer to approval of novel drug products. Therefore, PhRMA recommends the following definition of new prescription drug:

“New prescription drug” means the first drug product to be approved under an original new drug application, under an abbreviated new drug application, or under a biologics license application.”

This definition ensures that changes to existing approved drugs, such as packaging changes, will be excluded, and prevents such changes from triggering the definition and consequent reporting requirements.

2) Timeframes for DCBS requests for additional information and manufacturer responses—Section 2(7)(a).

HB 4005 requires the Department of Consumer and Business Services (DCBS) to prescribe by rule the period of time in which, after receiving the report of information included in subsections (2), (3), (5), or (6) of Section 2, DCBS may make a written request to the manufacturer for supporting documentation or additional information concerning the report, and the period of time allowed by the manufacturer to respond to the request. The request for information is divided into two parts, subsection 2(7)(a)(A) and 2(7)(a)(B).

Section 2(7)(a)(A) requires the department to prescribe by rule the time period “following the receipt of the report or information during which the department may request additional information.” The department should have a maximum of 30 days, following the receipt of the report, during which the department may request additional information.

Section 2(7)(a)(B) requires the department to prescribe by rule the time period “following a request by the department for additional information during which a manufacturer may respond to the request.” A manufacturer should have a minimum of 90 days to respond, and the DCBS rule should include explicitly or by reference the flexibility included in Section 2(7)(a)(B)(b), granting the department ability to extend the period of time, as necessary, on a case by case basis.

Additionally, there should be a process for manufacturers to indicate inability to comply with a departmental request due to the nonexistence, a deficiency, or unavailability of requested information. For example, a reporting entity may not have certain information for a product acquired after launch. This process should take the form of a written statement by the manufacturer to the department explaining their inability to comply with the supplemental request authorized in Section 2(7)(a)(B).

3) Establishing fees to be paid by manufacturers to pay DCBS costs –Section 2(12). Specifically, DCBS requests feedback on the merits of levying fees on all prescription drug manufacturers or only those that must file reports with the Department.

The fee allowed in Section 2(12), if levied, should be solely on manufacturers that are required to file a report, and should be collected in a manner that is fair, efficient, and minimizes the administrative burden to the manufacturer. The rule should reinforce the strict parameters

placed in subsection 12 that the fee is to be used *solely* to pay the costs of the department in carrying out the provisions of Section 2 of the bill.

4) Changes to health insurance rate review rules to implement Section 5 of HB 4005.

Section 5(1) of HB 4005 requires insurers that issue policies or certificates of health insurance for sale in Oregon that include a prescription drug benefit to include in their rate filings under ORS 743.018 information regarding drugs reimbursed by the insurer. Required information includes:

- The 25 most frequently prescribed drugs;
- The 25 most costly drugs as a portion of total annual spending;
- The 25 drugs that have caused the greatest increase in total plan spending from one year to the next; and
- The impact of the costs of prescription drugs on premium rates.

Biopharmaceutical manufacturers pay significant rebates and discounts, and an accurate accounting requires that they be included in the reporting related to drugs reimbursed by insurers contained in Section 5. The following information should be required reporting in subsection 1(b), (c), and (d).

Section 5(1)(b) requiring reporting of the 25 most costly drugs as a portion of total annual spending should be clarified in rule to be net of all rebates and discounts. Manufacturers pay billions of dollars in rebates each year, \$150 billion in 2017, and an accurate accounting of cost necessarily requires that “cost” is defined as net of all rebates and discounts. Additionally, insurers should include as part of their reporting an accounting of medical cost offsets attributable to those drugs.

Section 5(1)(c) requiring reporting of the 25 drugs that have caused the greatest increase in total plan spending from one year to the next, similar to Section 5(1)(b), should frame total plan spending in the context of net costs, accounting for rebates and discounts. Insurers should include as part of their reporting an accounting of the medical cost offsets attributable to those drugs and the results of their adherence programs or strategies if such programs or strategies have been implemented by the insurer.

Section 5(1)(d) requiring reporting of the impact of the costs of prescription drugs on premium rates should, as in the two previous subsections, frame the analysis in terms of net costs. Such reporting should include information on utilization and be in the form of an actuarial attestation. For the drugs reported in subsection 5(1)(b) and 5(1)(c) the insurer should report the impact of costs of prescription drugs on premiums in a per member/per month amount.

Thank you for the opportunity to submit these initial comments. PhRMA looks forward to continuing to work with the DCBS throughout the RAC processes.

Sincerely,

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