**FISCAL IMPACT OF PROPOSED LEGISLATION** **Measure: HB 4005 - A Combined**

79th Oregon Legislative Assembly – 2018 Regular Session
Legislative Fiscal Office

***Only Impacts on Original or Engrossed Versions are Considered Official***

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**Measure Description:**
Requires prescription drug manufacturer to report annually information to Department of Consumer and Business Services regarding prices of prescription drugs and costs associated with developing and marketing prescription drugs.

**Government Unit(s) Affected:**
Department of Consumer and Business Services (DCBS), Department of Justice (DOJ), Oregon Judicial Department (OJD), Oregon Health Authority (OHA), Legislative Assembly, Legislative Policy and Research Office (LPRO)

**Summary of Expenditure Impact - DCBS:**
Costs related to the measure may require budgetary action - See analysis.

| | 2017-19 Biennium | 2019-21 Biennium |
|---|---|---|
| Other Funds | | |
| Personal Services | 217,055 | 434,111 |
| Services & Supplies | 207,967 | 143,009 |
| **Total Other Funds** | **$425,022** | **$577,120** |
| Positions | 3 | 3 |
| FTE | 1.50 | 3.00 |

Funding for this new program will be derived from fees to be paid to DCBS by manufacturers. Such fees will be set via rulemaking and are yet to be determined.

**Analysis:**
HB 4005 with the combined -A11, -A13, -A15, and -A23 amendments establishes the Prescription Drug Price Transparency Act, requiring manufacturers of prescription drugs sold in Oregon to report specified information to the Department of Consumer and Business Services (DCBS), including:

1. Beginning July 1, 2019, and no later than March 15th of subsequent years, information regarding the costs and pricing of each prescription drug priced at $100 or more for a one-month supply or for a course of treatment lasting less than one month, with a net increase of 10% or more in the price of the prescription over the course of the previous calendar year.
2. Specified information about patient assistance programs offered to the general public in which a consumer may reduce the consumer's out-of-pocket costs for prescription drugs by using coupons or discount cards, receiving copayment assistance or by other means.
3. Beginning March 15, 2019, 30 days or less after the introduction of new prescription drug, specified research, development, marketing, cost, and pricing information regarding the new drug.

Manufacturers may be subject to a civil penalty for failure to comply with reporting requirements. The bill also requires insurers to include specified information regarding reimbursement of certain drugs along with current filing of health insurance rates. The bill authorizes DCBS to establish fees to be paid by manufacturers to pay the costs of carrying out the provisions of the bill.

In addition, the bill establishes the 18-member the Task Force on the Fair Pricing of Prescription Drugs charged with developing a strategy to transparency for drug prices across the supply chain. The task force is required to

submit a report to an interim legislative committee by November 1, 2018. The Legislative Policy and Research Director is directed to provide staff support to the task force. The task force sunsets December 31, 2020.

Department of Consumer and Business Services (DCBS)

The bill authorizes DCBS to prescribe by rule the form and manner by which manufacturers report the required information outlined above. The bill also allows DCBS to request additional information and supporting documentation. The bill requires DCBS to:

1. Verify that manufacturers have properly reported price increase information.
2. Provide an opportunity for state agencies, health care service contractors, health insurers, and other interested parties to receive notifications on planned increases of prescription drugs meeting the reporting requirements of the bill.
3. Post to its website specified information regarding the reported prescription drugs. The bill prohibits DCBS from posting trade secrets and information that does not require disclosure for public interest. DCBS must post to its website a report describing the nature of information and the department's rationale for withholding information.
4. Make available to consumers, online and by telephone, a process for consumers to notify the department about an increase in the price of a prescription drug.
5. No later than December 15 of each year, compile a report on the information collected under the provisions of this bill. The report must include recommendations for legislative changes to contain costs of prescription drugs.
6. Adopt a schedule of penalties, not to exceed $10,000 per day of violation, for failure to comply with reporting requirements.
7. Conduct a public hearing annually on prescription drug prices and insurers drug reimbursement.
8. Regularly update interim committees of the legislature on filings by insurers regarding specified information related to drug reimbursement.

The fiscal impact of this bill depends on the volume of reporting by manufacturers. The following fiscal impact for DCBS is based on: (1) the fact that at present, there are approximately 1,000 manufacturers licensed in Oregon; and (2) according to the AARP Public Policy Institute, between 2014-2015, retail prices for 268 widely used brand name prescription drugs increased by 15%, marking the fourth straight year of double-digit average annual price increases. DCBS based its workload calculations extrapolating from these numbers. However, the Legislative Office (LFO) notes that at this time, neither the number of manufacturers who will be reporting nor the volume of reporting from each manufacturer can be firmly ascertained.

Based on the number of manufacturers currently licensed by the Oregon Board of Pharmacy and national trends in prescription drug prices, DCBS projects the cost of complying with the provisions of this bill to be $425,022 Other Funds, 3 positions, 1.50 FTE for the 2017-19 biennium; and $577,120 Other Funds, 3 positions, 3 FTE for the 2019-21 biennium. Funding for this program will be derived from fees to be paid to DCBS by manufacturers. Such fees will be set via rulemaking and are yet to be determined.

Personal Services amounts reflect the cost of three new full-time permanent positions starting July 1, 2018:

- Operation and Policy Analyst (OPA3) - To oversee the ongoing management of the reporting system including: (1) working directly with manufacturers to respond to questions regarding the program; (2) serving as an overall resource on program requirements; (3) assisting with required rulemaking; (4) compiling required legislative reports; (5) working with the initial project team on data collection and the posting of information to the agency website for public viewing.
- Research Analyst (RA3) - To analyze, interpret, and tabulate reported information; to review the data for accuracy and completeness; to assist with the design of various reports; to provide technical consultation; and to assist with report preparation.
- Administrative Specialist (AS1) - To provide comprehensive administrative support to the program, including scheduling public hearings, serving as a contact for consumers when reporting prescription drug

price increases, maintaining the consumer notification process, and receiving and processing reports for the Operations Policy Analyst and Research Analyst.

DCBS will use existing policy staff and resources, with assistance from the newly established Operation and Policy Analyst position, to collaborate with all interested parties to convene both internal and external stakeholder advisory groups, and to conduct the required rulemaking. The department will also employ existing staff and resources to carry out enforcement related work.

Service and Supplies amounts include anticipated Department of Justice costs and IT resources to customize an existing IT system (iReg) to electronically receive the required data from drug manufacturers; and to modify an existing licensing and enforcement database (FIRE) to track consumer inquiries of drug price increases.

Department of Justice (DOJ), Oregon Judicial Department (OJD)

Passage of this bill is anticipated to have minimal impact on DOJ and OJD. With passage of this bill, DCBS would have the authority to impose civil penalties of up $10,000 a day for violations of the requirements. Manufacturers would have the right to challenge proposed penalties in contested case hearings. The bill also requires DCBS to post specified information from manufacturer reports on its website. DCBS must withhold certain exempt or confidential information. Decisions to withhold information could be challenged by public records petition to the Attorney General. At this time, the volume or complexity of the contested case proceedings that might result from this bill cannot be predicted or quantified. However, as a point of reference, three to six contested cases per calendar year, each requiring 25 to 35 hours of DOJ attorney time, plus a similar volume of public records petitions, each requiring 5 to 15 hours to process could require a total of 180 to 600 hours of attorney time at the current hourly bill rate.

Legislative Policy and Research Office (LPRO)

The bill requires LPRO to provide staff support to the task force. The 2017-19 Legislative Branch budget should contain funds allocated for LPRO support of interim committees and task forces.

Legislative Assembly

The bill specifies that non-legislative members of the task force serve as volunteers and are not entitled to compensation and reimbursement. However, four members of the task force will be legislative members who are entitled to per diem and travel reimbursement. Although the 2017-19 Legislative Assembly budget contains funds allocated for interim committee and task force, if the work required by this task force, or if the cumulative enactment of other legislation with interim committees and task forces exceeds expenditure levels beyond those assumed in the 2017-19 budget, additional General Fund resources may be required. The task force would not incur additional costs to the Legislative Assembly budget if the meetings are held at the Capitol building during Legislative Session, Task force or Legislative Days.

Oregon Health Authority (OHA),

This bill is anticipated to have a minimal impact on OHA. Representatives from the Oregon Health Policy Board and OHA are required to serve as members on the task force. The Oregon Health Policy Board and OHA will reprioritize duties to attend meetings, and use existing staff and resources to furnish the task force with existing available data, information, advice, and other support.