

August 27, 2018

Jesse Ellis O'Brien
Senior Policy Analyst
Oregon Department of Consumer and Business Services
Division of Financial Regulation

Dear Mr. O'Brien,

The coalition that supported HB 4005 appreciates the opportunity to participate in the RAC process and we look forward to working with you throughout this process.

The definition of “new prescription drug.” – Section 2(1)(f).

The coalition that passed HB 4005 would like to see a definition of “New Prescription Drug” that captures all new prescription drug products being introduced to the market, as well as all new prescription drug products that have new or adjusted chemical formulations and are being marketed as new prescription drug products.

California has posted draft regulations for Senate Bill 17, which HB 4005 mirrors in many ways. California's draft regulation should be broad enough to meet the above objective and serve as an initial guideline for Oregon.

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

Ultimately, the coalition would like timeframes implemented that provide for a practical and effective administration of the bill. In 2019, this section has a condensed timeline due to an initial July 1st submission deadline and a March 15th deadline in 2020 and beyond. However, if one set of timeframe regulations can be adopted that would provide greater consistency for all parties. With that in mind, we would make an initial recommendation of:

- 90 days for DCBS to make a request for information. We assume this would be an acceptable amount of time for DCBS to review submissions and ascertain where they need additional information.
- Somewhere in the range of 30 days for manufacturers to respond.
- Leaving 1.5 months for DCBS to complete their report by December 15.

We would look to DCBS on where you all think additional time in 2020 and beyond would be most helpful to the agency.

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.

While the coalition supports assessing a fee on manufactures that are required to report under the provisions of HB 4005, our foremost concern is effective and sustainable administration, and we encourage the adoption of whatever fee structure is needed to accomplish that objective.

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

Reporting requirements of health insurers under HB 4005 appear to be straightforward and should not require substantive changes to the rate review process, other than the inclusion of additional information regarding their costs associated with prescription drugs. If the agency holds a different view, we'd be interested to learn more and provide additional feedback.

Thank you for your time and consideration.

Respectfully,

A handwritten signature in blue ink that reads "Courtney Helstein". The signature is written in a cursive style with a large initial "C" and a vertical line separating the first and last names.

Courtney Helstein