

HB 4005 Rulemaking Advisory Committee

Request for Information on Initial Rulemaking Considerations

At the July 31 meeting of the Prescription Drug Price Transparency rulemaking advisory committee, the group agreed to respond to a request for additional information prior to the second meeting on August 28.

The Department of Consumer and Business Services (DCBS) requests feedback from the committee in response to the following questions. These questions can be divided into two categories.

1. Feedback to inform DCBS's efforts to draft proposed rule language for the following provisions of HB 4005. DCBS will provide draft language addressing these issues prior to the August 28 meeting. *Please provide responses to these questions by COB August 17 if possible.*
 - The definition of “new prescription drug.” – Section 2(1)(f).
 - Timeframes for DCBS requests for additional information and manufacturer responses – Section 2(7)(a).
 - 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.
 - Changes to health insurance rate review rules to implement Section 5 of HB 4005.
2. Feedback to inform the implementation of other key provisions of HB 4005. The committee will begin discussing these issues at the August 28 meeting, but DCBS will not provide draft language in advance of that meeting. *Please provide responses to these questions by 12pm August 27 to enable staff to distribute content in advance of the August 28 meeting.*
 - Clarifying required content of reports and expectations for reporting manufacturers. Please provide detailed feedback on any additional clarification that may be helpful to enable meaningful reporting on the data elements outlined in Section 2 (3)-(6). In addition to general feedback on the implementation of these requirements, DCBS specifically requests stakeholder feedback on data that should be required under the following provisions:
 - For drug price increase reports, “The factors that contributed to the price increase” – Section 2 (3)(c).
 - For new specialty drug reports, “The methodology used to establish the price of the new prescription drug” – Section 2 (6)(b).
 - Clarifying the meaning of “timely,” “timely manner,” “inaccurate or incomplete” – Section 2(8).
 - Regarding the schedule of civil penalties required by Section 3, DCBS requests feedback

on whether these penalties should be established by rule or through other guidance to drug manufacturers. We also request any feedback about how to vary the penalties “based on the severity of the violation.”

- Regarding the requirement for an annual public hearing – Section 5 (2) – DCBS requests feedback on whether this requirement necessitates rulemaking, as well as any feedback on the format or structure of this hearing.
- DCBS requests stakeholder feedback regarding any key rulemaking or operational considerations in the implementation of the trade secret disclosure exemption requirements in Section 2 (10).

Your feedback will be critical as DCBS moves forward with implementing this new law, and is deeply appreciated.

All written feedback will be shared with the full committee and posted to the committee’s web page: <https://dfr.oregon.gov/community/committees-workgroups/Pages/prescription-price-transparency-rac.aspx>

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