

August 24, 2018

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Sent via Email to: [INS.Rules@oregon.gov](mailto:INS.Rules@oregon.gov)

Dear Mr. O'Brien,

Thank you for holding the July 31, 2018 Rules Advisory Committee (RAC) meeting. Kaiser Foundation Health Plan of the Northwest (KFHPNW) appreciates the opportunity to participate in the RAC meetings and looks forward to working with you throughout the regulatory development process.

This letter provides feedback on the specific request for information issued following the July 31 RAC.

### **1) The Definition of “new prescription drug” –Section 2(1)(f).**

The State of California is in the process of implementing its own pharmaceutical price transparency statute, 2017 SB 17. This statute has many structural similarities to HB 4005. Under the California regulation, “new prescription drug” is defined as:

[A] drug receiving initial approval under an original new drug application under Section 355(b) of Title 21 of the United States Code, under an abbreviated new drug application under Section 355(j) of Title 21 of the United States Code, or under a biologics license application under Section 262 of Title 42 of the United States Code. Each product listed on the application shall be considered a new prescription drug.

The definition of a new prescription drug should include instances in which the drug is combined with another, the dosage is modified, the delivery mechanism is modified, etc. since these types of “evergreening” activities can lead to the marketing of a “new,” often expensive, drug.

### **2) Timeframes for 2018 HB 4005 Section 2(7)(a)**

HB 4005 Section 2(7)(a) empowers DCBS to make a written request to a manufacturer for supporting documentation or additional information concerning a required report under HB 4005. DCBS has requested feedback regarding both its own time frame for making such a request, as well as the time frame a manufacturer will have to respond to such a request.

The time frames for requesting additional information and reporting should be informed, to the extent possible, by the deadline for annual reporting by DCBS to the legislature to ensure DCBS has adequate time to request and digest any additional information.

In HB 4005, Section 2(2) requires manufacturers to report on certain price increases by July 1, 2019 (and then by March 15 in subsequent years (Section 7(2))). Beginning March 15, 2019 manufacturers are also required to report on new prescription drugs that meet or exceed the federal definition of specialty drug within 30 days of introducing the drug for sale in the U.S. market. Section 2(13) requires DCBS to report annually by December 15 to the legislature.

Given the reporting timelines above and the desire to ensure that DCBS has adequate time to request and review additional information, for 2019 KFHPNW recommends 60 days for DCBS to request additional information related to manufacturer reports required under Section 2(2) and Section 2(13) and 30 days for manufacturers to respond. Beginning in 2020, KFHPNW recommends 90 days for DCBS to request additional information and 60 days for manufacturers to respond. We recognize that, depending on the timing, additional information about a new specialty drug reported under Section 2(13) may not be requested or submitted in time for reporting by DCBS to the legislature by the Dec. 15 deadline. Because of the volume of reports that DCBS may receive in any given year, it is appropriate to give DCBS a relatively longer period to review the reports it receives and request additional information. KFHPNW believes this would give the agency adequate time to prepare its report to the legislature even if a manufacturer's response is not timely. In general, we recommend intervals structured as multiples of 30 days, in keeping with widespread usage in statute, regulation, and general legal practice.

### **3) Feedback on the merits of levying fees on all prescription drug manufacturers or only those that must file reports with the Department.**

KFHPNW's priority and primary concern is to ensure that DCBS has predictable and adequate resources to administer the program. We would support fees assessed on all manufacturers. Applying a flat fee to all manufacturers could ensure a more stable, and established revenue stream that would make the program sustainable over the long term.

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

The information required to be reported by insurers under Section 5 is straightforward and unambiguous. KFHPNW does not believe changes to the rate review rules are unnecessary.

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

Sincerely,

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