

**To: 2018 HB 4005 Rulemaking Advisory Committee (“RAC”)**

Jesse Ellis O’Brien  
2018 HB 4005 RAC Members  
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**From: Mark O. Griffith, Health Care Advocate, OSPIRG**

**Re: July 31 RFI - “New Drug,” Timeframes; Fee Structure; Insurance Rate Review**

Dear Colleagues,

Thank you to Jesse for organizing this committee and providing the opportunity to give feedback on the implementation of Oregon 2018 HB 4005 (“4005”). I’m writing today on behalf of OSPIRG to provide responses to the Department of Consumer and Business Services’s (“DCBS”) request for information regarding the definition of “new drug,” timeframes under the regulations, fee structuring, and changes to DCBS regulations related to insurance rate review.

### **The Definition of “New Prescription Drug” under Section 2(1)(f)**

The State of California is in the process of implementing its own pharmaceutical price transparency statute, 2017 SB 17, which shares many structural similarities to 4005. On August 5, 2018, California’s Office of Statewide Health Planning and Development (OSHPD) issued its draft regulations for public comment. We submit that OSHPD’s proposed definition for “new prescription drug” is a good model for DCBS to follow in formulating its definition under the new regulations for 4005.

The relevant section of California’s regulations will be implemented at CCR Title 22, Division 7, Chapter 9.5, Article 1, §96060, subsections (f) and (g), reading in relevant part:

*“(f) ‘New Prescription Drug’ means 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.*

*“(g) ‘Prescription Drug’ means a drug, as defined in Section 321(g) of Title 21 of the United States Code, or a biological product as defined in Section 262(i)(1) of Title 42 of the United States Code, that*

*(1) is intended for human use;*

*(2) is not a device within the meaning of Section(h) of Title 21 of the United States Code;*

*(3) by federal or state law, can be lawfully dispensed only on prescription by a licensed healthcare professional; and*

*(4) is purchased or reimbursed by an entity described in subdivision (a) of Health and Safety Code Section 127675.”*

Our principal concern with the “New Prescription Drug” language under HB 4005 is that the definition is broad enough to capture all new prescription drug products built around new chemical entities, as well as all new prescription drug products founded on a new indication or reformulation. California’s draft regulation is sufficiently broad that it should capture all relevant products, and should be regarded as a baseline standard for Oregon’s definition.

#### **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 appropriate time frame should be considered in light of the broader picture for annual reporting under HB 4005 for both manufacturers and DCBS. The required reports each year under Section 2(2) of HB 4005 are due on March 15th, while DCBS’s annual report under Section 2(13) is due on December 15th of each year. This gives a DCBS a turnaround time of 8 months.

We recommend a time period of 120 days for DCBS to respond to required reports under Section 2(2), and a time period of 30 days for manufacturers to respond to a request for supporting documentation or information. A longer period for DCBS action is justified with respect to Section 2(2) as all manufacturers are theoretically subject to the reporting requirement, and more time may be needed for DCBS staff to review all of the submissions and determine which require additional action. This gives DCBS 4 months to prepare its report. This should give the agency adequate time to prepare its report 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.

## Fee Structure

OSPIRG's main concern with respect to fee implementation under HB 4005 relates to the effective administration of the program. Applying a flat fee to all manufacturers will create a more stable, certain revenue stream that could help make the program sustainable over the long term. On the other hand, only applying fees to manufacturers who are required to report could make implementation easier by reducing the administrative burden of fee collection. Additionally, applying fees only to manufacturers who must file reports would add an additional retributive aspect to implementation of 4005, by only charging fees to apparent "bad actors."

## Changes to Health Insurance Rate Review Rules

Section 5 and Section 8 of 4005 will likely require some changes to DCBS's existing regulations related to insurance rate review. Our understanding of 4005 is that any resulting changes to the rate review process were not intended to be a comprehensive modification of insurance rate review in Oregon, but rather were a convenient way to implement a small portion of 4005's general push to increase transparency in prescription drug prices.

As such, we recommend that any changes to existing insurance regulations be limited to the bare minimum necessary to implement 4005's additional requirements. This rulemaking should not be viewed by any stakeholders as an opportunity to reform insurance rate review in a comprehensive fashion.

Thank you for your time and consideration.

Respectfully submitted,



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