

October 15, 2019

To: 2018 HB 4005 Rulemaking Advisory Committee
Jesse Ellis O'Brien
2018 HB 4005 RAC Members
Sent by Email to: Jesse.E.O'Brien@Oregon.gov

From: Robert Judge, Director of Pharmacy Services, Moda Health

Subject: Moda Health Comments on Preliminary Draft HB 4005 Rules

Dear Mr. O'Brien and members of HB 4005 RAC,

Thank you for providing Preliminary Draft HB 4005 Rules for review and feedback. I am providing feedback today on behalf of Moda Health as a participant in the Rulemaking Advisory Committee (RAC) for consideration by the Department of Consumer and Business Services' ("DCBS"). HB 4005 represents a major step forward in bringing consumers more information about drug costs by requiring greater transparency from manufacturers and insurers. In support of this objective, I am hopeful that my comments will help improve the clarity concerning the proposed Rules as DCBS continues its deliberation.

My comments concern the following sections of the proposed Rules:

- 836-200-0500 Definitions
- 836-200-0505 Form and Manner Requirements for Drug Pricing Reporting
- 836-200-0550 Assessments Against Prescription Drug Manufacturers
- 836-053-0473 Required Materials for Rate Filing for Individual or Small Employer Health Benefit Plans

836-200-0500 Definitions

A key consideration for DCBS is assessing how best to establish the information required to be provided under HB 4005 and to ensure that parties understand what is expected to be provided. To this end, I am recommending the RAC consider the following additional definitions or clarifications to proposed definitions:

1. Addition to the definition for Reporting Manufacturer. HB 4005 requires manufacturers to report certain data on drugs that they market. This definition should include specificity around the manufacturer's drug. I propose that "holds the National Drug Code (NDC) for a prescription drug" be added to the definition.

Additionally, it is important to consider that many medications are marketed under different trade names in different countries. For example, Pfizer markets a chemically identical version of Viagra in New Zealand named Avigra. There are no provisions in the proposed rule for this consideration. This is especially important in consideration of the requirement to have manufacturers report

their 10 highest prices paid for the prescription drug in countries other than the United States as required under Section 2(3)(j) of HB 4005. Failure to include this in Definitions may expose the state to under-reporting by a manufacturer. DCBS should evaluate including a requirement that manufacturers include the chemical entity or biologic product in addition to the trade name when they report data.

2. "One-month supply" and "Course of treatment". The proposed definitions may be open to different interpretations so that data for drugs in therapeutic classes are reported differently. As a consequence, I recommend amending the definition to include the daily dosage under which the product was approved by the FDA. DCBS may want to consider changing the definitions for the above referenced terms to the following:
 - a. "One-month supply: The recommended daily dosage units of a prescription drug pursuant to its prescribing label as approved by the federal Food and Drug Administration for 30 days."
 - b. "Course of Treatment: The recommended daily dosage units of a prescription drug pursuant to its prescribing label as approved by the federal Food and Drug Administration for a normal course of treatment that is less than 30 days."

836-200-0505 Form and Manner Requirements for Drug Pricing Reporting

1. Additional consideration should be given to how a manufacturer will report data to ensure that such data is standard and easily analyzed by DCBS, sorted by manufacturer. Under General Requirements, item (1), it is proposed that manufacturers be directed to supply information by National Drug Code (NDC) and Group Product Identifier (GPI).

Requiring drug information by NDC will enable DCBS to capture both the labeler (manufacturer) and drug/strength/form. Specifically, DCBS should require manufacturers to supply 9-digit NDCs, which include the first 4 letters that represent the manufacturer, repackager, or distributor followed by the next 5 characters which represent the product code, and identifies the specific strength, dosage form (i.e., capsule, tablet, liquid) and formulation of a drug for a specific company. Requesting NDC data will allow DCBS to track price changes by drug and manufacturer.

Requiring drug information by GPI will allow DCBS to assess information by equivalent drug products (e.g., generics) that have the same active ingredients, strength, route, form, and therapeutic use. This will enable DCBS to assess individual manufacturer price movements in comparison with other generic manufacturers.

2. Prescription Drug Reporting - Price Increase, item (2)(f), should be reconsidered to require additional clarifying information from the manufacturer. In addition to requesting GPI data, DCBS should require a manufacturer to indicate whether the drug is one of the following:
 - a. An innovator multiple source drug;
 - b. A non-innovator multiple source drug; or

- c. A single source drug.

Definitions for these can be found in subparagraph (A) of paragraph (7) of subdivision (k) of Section 1396r-8 of Title 42 of the United States Code. This information will provide DCBS with a fuller understanding of the pricing and positioning for the product being reported.

836-200-0550 Assessments Against Prescription Drug Manufacturers

1. In consideration of any fee that is assessed on manufacturers for this program, it is understood the importance of establishing a fee basis that enables DCBS to carry out the requirements of HB 4005. The approach that is proposed in the draft rule makes consideration for ensuring that any such fee is predictable and consistent year to year, and is not solely tied to the number of manufacturers or filings by manufacturers in any given year. We support this approach.

836-053-0473 Required Materials for Rate Filing for Individual or Small Employer Health Benefit Plans

1. We request that clarification or consideration be given to the following:
 - a. Items 2(l)(A), (B) and (C): Please clarify the data period for items A-C. Are insurers being asked to use the experience period that was used in the rate filing? We believe that this would make sense.
 - b. Item 2(l)(B), (C) and (D): The request that insurers include the “net impact of any rebate or other price concessions” on the Top 25 most costly drugs, the Top 25 drugs that have caused the greatest increase in total plan spending, and the impact of the costs of prescription drugs on premium rates should be removed as it is not required in the statute and is outside of the legislative authority given to the Department with HB 4005. Rebates are usually applied at rate setting to decrease premiums for all members.
 - c. Item 2(l)(D): Are insurers being asked for the portion of the proposed premium being attributed to prescription drugs? If so, this could be difficult to do accurately as it is dependent on the premium that will be required (e.g., the market average premium we are being requested to price to, or the projected premium we are expecting to receive). It would help to include a specific reference to the premium that is being referred to.

Additionally, because some plans receive rebates on a national level, rather than state-by-state from their PBMs, plans may not be able to report how rebates specifically impact the OR market. As a consequence, the impact of rebates on premiums will not be accurate as it will appear higher than it actually is given the denominator will be lower than it would be absent rebates. For this reason, rebates should be removed from this request.

Thank you for your consideration of these changes and clarifications.

Sincerely,



Robert Judge

Director of Pharmacy Services

Moda Health