

November 1, 2018

To: 2018 HB 4005 Rulemaking Advisory Committee
Mr. 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 Second Draft HB 4005 Rules

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

Thank you for providing a Second Draft HB 4005 Rules for review and feedback. I am providing feedback 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"). 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 Second Draft HB 4005 Rules:

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

836-200-500 Definitions

1. Item (5), Net yearly increase

The department proposes this term be defined as follows:

"...means the increase in the wholesale acquisition cost of a drug over the course of a calendar year. For a drug on the market for the entire year, the net yearly increase is calculated by subtracting the wholesale acquisition cost on January 1 of the year from the wholesale acquisition cost on December 31 of the same year. For a new prescription drug introduced after January 1 of any year, the net yearly increase is calculated by subtracting the wholesale acquisition cost on the drug's introduction date from the wholesale acquisition cost on December 31 of the same year."

Discussion and recommendation: This definition does not consider the impact of price changes on consumers over the course of the year since it only considers price at two discreet points in the calendar year. Instead, Moda recommends that the committee consider the average Wholesale Acquisition Cost (WAC) change over the prior twelve months in total by evaluating the monthly change throughout the year to account for increases or decreases at multiple points over a twelve month period.

Page 2

2. Item (9), Public Funds

The department proposes this term be defined as follows:

“...means any funds granted, loaned or otherwise provided by a national, state, local or foreign government entity.”

Discussion and recommendation: The U.S. public and private sectors are both involved in producing innovative drug products. Although private industry supplies significant funds that are devoted to research and development, the public sector—primarily the National Institutes of Health (NIH)—supports most of the nation’s basic research. In addition to the proposed definition for “public funds” as written, Moda recommends this definition also reference and include federally funded R&D through technology transfer, cooperative research and development, and intellectual property rights.

3. Item (10), Reporting manufacturer

The department proposes this term be defined as follows:

“means an entity
(a) Required to be registered with the Oregon Board of Pharmacy as a drug manufacturer;
(b) That engages in the manufacture of drugs as defined by 2018 Or Laws ch 7; and
(c) That sets or changes the wholesale acquisition cost of the drugs it manufactures.”

Discussion and recommendation: Moda proposes that the definition include additional specificity around the manufacturer’s drug. Consideration should be given to adding to the definition “holds the National Drug Code (NDC) for a prescription drug”.

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

1. Item (2), Prescription Drug Reporting - Price Increase.

The department proposes that this section require the following:

“For drugs meeting the conditions specified in 836-200-0502, the report furnished to the department must include at least the following information, along with any documentation necessary to support the information reported under this subsection:”

Discussion and recommendation: As mentioned in previous communication, 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), Moda proposes that DCBS consider requiring manufacturers 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. Item (2), Prescription Drug Reporting, sub-item (I)

The proposed rule requires that manufacturers report the following:

“The total sales revenue for the prescription drug during the previous calendar year;”

Discussion and recommendation: For clarity and completeness the rule should require that this data be reported for State of Oregon and for the U.S. markets.

3. Item (3), Prescription Drug Reporting – Patient Assistance Programs

During our October 22, 2018 RAC meeting, DCBS asked committee members to review language supporting reporting requirements for patient assistance programs and to provide feedback if needed.

Discussion and recommendation: The role that manufacturers play in financing Patient Advocacy Organizations is largely unknown today. Unlike payments to prescribers and lobbying expenses, manufacturers are not required to report payments to Patient Advocacy Organizations, in spite of the increasing number of these groups that now exist and the influence they wield in the public discourse. Beyond this, there is no information that is publicly available concerning the amount of financial support from manufacturers that is used to fund Patient Assistance Programs offered through Patient Advocacy Organizations. Gaining insight into this will help bring sunshine into the influence of money in the drug choices that are made and is wholly consistent with the statutory authority of HB 4005.

A March 2017 New England Journal of Medicine (NEJM) study reported that nationwide there were 104 large Patient Advocacy Organizations operating in the U.S. and that at least 83% of these received financial support from drug, device, and biotechnology companies (see “Conflicts of Interest for Patient-Advocacy Organizations”, NEJM, March 2, 2017, <https://www.nejm.org/doi/full/10.1056/NEJMs1610625>). In addition, an April 2018 study by Kaiser Health News (KHN) found that pharmaceutical companies gave at least \$116 million to Patient Advocacy Organizations in 2015 (see <https://khn.org/news/patient-advocacy-groups-take-in-millions-from-drugmakers-is-there-a-payback/>). These studies underscore the importance of gaining insight into the influence that manufacturer contributions may have on the activities of advocacy organizations they fund.

Current disclosure practices of Patient Advocacy Organizations are limited even though the NEJM study found that industry support for such organizations is common. To complete its study, KHN’s investigation relied on CitizenAudit and IRS form 990 filings by non-profit Patient Advocacy Organization filings to build its analysis.

While there are no requirements today for manufacturers to report their support for Patient Advocacy Organizations, yet alone Patient Assistance Programs, there is growing demand for this.

The proposed Second Draft HB 4005 Rule concerning Patient Assistance Programs is a good first step in this direction. The rule should require manufacturers to report this information in the spirit of greater transparency and sunshine. DCBS may wish to consider requiring manufacturers to report the size of the financial contribution made annually to Patient Advocacy Organizations as well as the amount targeted to Patient Assistance Programs. Moda recommends that contributions of \$100,000 or more annually to Patient Advocacy Organizations be reported.

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

1. Items 2(I)(B), (C) and (D)

We request consideration of requiring that insurers include rebates in the reporting of Top 25 drugs described in the above referenced item.

Discussion and recommendation: HB 4005 focuses on price increases of pharmaceuticals and the factors that drive these. As has been established in committee hearings when HB 4005 was considered and in the public meetings of the Joint Interim Task Force On Fair Pricing of Prescription Drugs, manufacturers alone establish the list price and list price increases for the pharmaceuticals they market. Insurers do not effect these decisions; rebates or discounts offered by manufacturers are controlled by manufacturers and do not effect list price or list price increases for drugs and are not applied uniformly across all carriers or PBMs operating in a market.

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 goes beyond the legislative authority given to the Department with HB 4005. Requiring insurers to include this information may dilute the legislative intent of HB 4005 and may also result in inaccurate or incomplete data being used for analyses of changes to list price from manufacturers. As has been stated previously, because rebates are tied to formulary decisions that are unique to each insurer or PBM, and some insurers receive rebates on a national level, rather than state-by-state from their PBMs – and may not receive the full value of a rebate from a manufacturer, DCBS may not be able to accurately ascertain how rebates specifically impact cost in the Oregon market. As a consequence, the impact of rebates on drug costs will be inaccurate and incomplete should this language be maintained.

Moda requests that the proposed rule remove “any rebates or other price concessions” in order to ensure uniform and accurate information, and to maintain consistency with the intent of HB 4005.

2. Items 2(I)(A), (B), (C) and (D), hospital and pharmacy drug utilization

Discussion and recommendation: At the October 22, 2018 RAC meeting there was a suggestion that insurers report drugs that are dispensed in both hospital and pharmacy settings. Moda recommends that consideration be given to drugs dispensed in outpatient settings only since a major objective of HB 4005 is to understand the factors contributing to pharmaceutical cost increases for consumers. Drugs dispensed in outpatient settings

Page 5

are more likely to process against a member's pharmacy benefit where copay or coinsurance and out of pocket limitations apply.

3. Item 836-053-0473 (2)(I)

Discussion and recommendation: At the October 22, 2018 RAC meeting a suggestion was made for the committee to consider adopting "direct and indirect remuneration" (DIR) as defined by the Centers for Medicare & Medicaid Services (CMS) instead of the current proposed language in the rule, "rebate or other concessions". Moda opposes this proposal. DIR applies to CMS reporting for Medicare only and is factored into CMS' calculation of final Medicare payments to Part D plans. It is currently being reviewed by CMS and the changes may have industry-wide implications which could go beyond the scope of the reporting requirement in HB 4005. Using a standard that is specific to Part D, and which may change is not something we should support for insurer reporting requirements for the Top 25 drugs required in 836-053-0473 (2)(I).

Thank you for your consideration of these changes and clarifications.

Sincerely,



Robert Judge
Director of Pharmacy Services
Moda Health