



August 27, 2018

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RE: HB 4005 Rulemaking Advisory Committee, July 31, 2019 Request for Information by Noon August 27, 2018

Dear Mr. O'Brien:

Thank you again for holding the July 31, 2018 Rules Advisory Committee (RAC) meeting. The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to participate in the RAC meetings and looks forward to working with you throughout the regulatory development process. House Bill 4005 requires expansive reporting from biopharmaceutical manufacturers, and as such, it is crucial that the requirements of the bill are carried out in a manner that is fair, predictable, and as administratively simple to comply with as possible for both manufacturers and the state.

PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than \$600 billion in the search for new treatments and cures, including an estimated \$71.4 billion in 2017 alone.

This letter addresses the request for information (RFI) from the July 31st RAC meeting with a requested response date of noon on August 27th, 2018.

- 1) Clarifying required content of reports and expectations for reporting manufacturers. Please provide detailed feedback on any additional clarifications that may be helpful to enable meaningful reporting on the data elements outlined in section 2 (3)-(6).**

HB 4005 seeks very detailed information pertaining to existing prescription drug price increase reporting, new drug notification, and patient assistance programs. PhRMA suggests simplifying the disclosure requirements as much as possible, limiting disclosure to information available in the public domain, and establishing a procedure that allows

manufacturers to designate and protect from public disclosure confidential trade secret information as required by law.

The following are some of the areas in HB 4005 that require additional clarification:

a. Section 2(3)—Existing prescription drug price increase reporting

Section 2(3)(d)

PhRMA believes clarification should be provided in rule or regulation regarding the reporting requirement in subsection 2(3)(d), which provides that manufacturers must report “the name of any generic version of the prescription drug available on the market.” Specifically, any regulation or rule promulgated in relation to this requirement should specify that reporting is limited to only generic versions of the prescription drug that are known at the time of reporting.

Section 2(3)(f)

PhRMA believes clarification should be provided in rule or regulation regarding the reporting requirements in subsection 2(3)(f), which provides that manufacturers must report “direct costs incurred by the manufacturer” to manufacture, market, and distribute the prescription drug, and those incurred “for ongoing safety and effectiveness research associated with the prescription drug.” Specifically, any rule or regulation promulgated in relation to this requirement should provide a clear definition of “cost,” “market,” “distribute,” and “safety and effectiveness research.”

Section 2(3)(j)

PhRMA believes clarification should be provided in rule or regulation regarding the reporting requirements in subsection 2(3)(j), which provides that manufacturers must report the “ten highest prices paid for the prescription drug during the previous calendar year in any country other than the United States.” Specifically, any rule or regulation promulgated in relation to this requirement should specify that the prices reported pursuant to subsection 2(3)(j) are list prices and not prices representative of any available or provided rebate or discount.

b. Section 2(4)—Additional verification of manufacturer reporting under subsection (2) and (3)

Section 2(4) specifically calls for verification of “price increases reported.” Since “price” is narrowly defined in Section 2(1)(i), PhRMA believes additional verification should only pertain to WAC price guides or other publications.

c. Section 2(5)—Patient assistance program reporting

PhRMA believes clarification should be provided in rule or regulation that the reporting requirements of Section 2(5), which pertain to patient assistance program

reporting, are applicable only to programs run by pharmaceutical manufacturers themselves and are not applicable to programs offered by independent charitable organizations to which a manufacturer may contribute.

d. Section 2(6)—New prescription drug reporting

Section 2(6)(a) and (b)

PhRMA requests clarification in rule or regulation that the information to be provided by pharmaceutical manufacturers pursuant to Sections 2(6)(a) and 2(6)(b) must be reported in a narrative manner, due to the wide range of factors and considerations taken into account by individual companies.

Section 2(6)(d)

PhRMA requests the phrase “not developed by the manufacturer” as used in Section 2(6)(d) to be defined to mean “did not fund in whole or in part Phase I, II, or III trials as defined in 21 CFR 312.21.”

2) 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:

a. For drug price increase reports, “factors that contribute to the price increase” – Section 2(3)(c)

Section 2(3)(c) requires reporting of the factors that contributed to the price increase for a prescription drug described in Section 2(2). PhRMA believes this should be a narrative description due to the wide range of factors and considerations taken into account by individual companies.

b. For new specialty drug reports, “The methodology used to establish the price of the new prescription drug”—Section 2(6)(b)

Section 2(6)(b) requires reporting of the methodology used to establish the price of a new prescription drug described in the first paragraph of subsection 6. PhRMA believes the rule should define “methodology” as the factors considered in establishing the price, and subsection (6)(b) should be interpreted to require a narrative description of these factors.

3) Clarifying the meaning of “timely,” “timely manner,” “inaccurate or incomplete” for the purpose of determining civil penalties –Section 2(8).

a. Clarifying Timely—Section 2(8)(a)

“Timely,” with respect to the reporting requirements listed in Sections 2(2) and 7(2), should be read to mean 11:59 PM on July 1, 2019, and 11:59 PM on March 15 respectively.

“Timely,” with respect to the notification requirements listed in Sections 2(6) and 6(6), should be read to mean 11:59 PM of the 30th day after introduction of a new prescription drug described in subsection (6).

“Timely,” with respect to the reporting requirements listed in Section 5(1) should be consistent with the rate filing timelines under ORS 743.018.

b. Clarifying Timely Manner—Section 2(8)(c)

“Timely manner” should be consistent with the department prescribed periods in Section 2(7)(a)(B) and incorporate departmental extensions listed in Section 7(b).

c. Clarifying Inaccurate or Incomplete—Section 2(8)(d)

“Inaccurate or Incomplete” information should be defined to be consistent with any rules addressing section 2(3)-(6) and (7), and should not include those instances where a manufacturer cannot produce the requested information¹.

4) 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.”

HB 4005 authorizes significant penalties on manufacturers in Section 3. PhRMA believes the civil penalties should be clearly outlined in rule for late submissions in Section 2(8)(a), and lack of timely response in Section 2(8)(c). “Failing to provide information” in Section 2(8)(b) should not apply to instances where a manufacturer cannot produce the requested information² or instances issuing from the extension authority granted the department in Section 2(7)(b) for requesting supporting documentation and additional information.

Concerning inaccurate and incomplete information under Section 2(8)(d), we suggest limiting the penalty provisions to untimely submissions in line with other states with similar laws.

Penalties should be reasonable and fair. There should be an exemption from penalty, or a low maximum, attached to an initial infraction.

¹ See comments in RFI response #1 on section 2(7)(a)—The department should establish by rule a protocol for manufacturers to indicate an inability to provide specific information required/requested.)

² Ibid. RFI response #1 on section 2(7)(a)

- 5) Regarding the requirements for an annual public hearing—Section 5(2)—DCBS requests feedback on whether these requirements necessitate rulemaking, as well as any feedback on the format or structure of this hearing.**

PhRMA believes the public hearing should be limited by administrative rule to the activities undertaken and reports received and filed by DCBS under Sections 2 and 5(1) during the preceding year. The scope of the hearing should be narrowly and specifically focused on these topics. The hearing must not include the presentation or discussion of information designated as proprietary and confidential trade secret information.

- 6) 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).**

PhRMA believes DCBS should take steps to ensure that information designated as proprietary and confidential trade secret information is protected from public disclosure. DCBS should thus define “public interest” in a manner that does not permit the disclosure of any information that qualifies as a trade secret under federal laws, such as the Trade Secrets Act, the Freedom of Information Act, and the Defend Trade Secrets Act. The “public interest” exception should not be interpreted so broadly that it nullifies the requirement that trade secrets be exempt from public disclosure by the State or otherwise conflicts with federal trade secret protections.

DCBS should develop a process that includes reasonable, confidential notice to manufacturers of potential disclosure by the state of trade secrets for manufacturers to defend their rights under applicable federal laws.

Thank you for the opportunity to submit comments. PhRMA looks forward to continuing to work with the DCBS throughout the RAC processes.

Sincerely,

Sheri Nelson

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