Drug Price Transparency Rule Advisory Committee meeting

Nov. 22, 2024

DFR | Division of Financial Regulation

Department of Consumer and Business Services

Welcome!

Agenda:

- Review meeting No. 3 comments and response
  - Questions
  - Discussion
- Discussion of draft rules (836-200-0505 to -0560)
- Input on Statement of Need and Fiscal Impact (SNFI)
- Public comment
- Next steps

Overview: Meeting No. 3 themes and next steps

Member topics and recommendations

- Clarity of certain provisions
  - Use of ‘NDC’ referring to NDC-9 or NDC-11
  - ‘good faith effort’ vs. ‘act in good faith’
  - Inclusion of virtual manufacturers
  - Trade secret requirements

DFR response

- NDC-11, DPT reporting is per package NDC
- Not a compliance shift, simply clearer and more consistent with current statute
- Intent to continue including virtual manufacturers – draft edits made
- Draft revisions made

836-200-0505: Reporting manufacturer definition

(11) "Reporting manufacturer" means an entity meeting all the following characteristics:

(a) Required to be registered with the Oregon Board of Pharmacy as a drug manufacturer;

(b) ~~That e~~Engages in the manufacture, directly or indirectly including through contracts with other entities, of prescription drugs available for sale in this state, as defined by ~~2018 Or Laws ch 7~~ ORS 646A.689(1)(d), that are approved by the United States Food and Drug Administration under:~~; and~~

(A) A new drug application;

(B) An abbreviated new drug application; or

(C) A biologics license application.

(c) ~~That s~~Sets or changes the wholesale acquisition cost of the drugs it manufacture~~r~~s ~~directly or indirectly, including through contracts with other entities~~.

(d) Does not only manufacture prescription drugs as a registered 503B facility (section 503B of the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. 353b).

836-200-0540 (1)(b): Information claimed to be trade secret

(b) Each filing that contains information claimed as trade secret by the manufacturer must include: ~~in accordance with standards set forth on the department's website and~~ for each individual piece of information claimed as trade secret: ~~, the name of the data element and a succinct detailedwritten explanation, and factual information demonstrating of why the information is exempt from disclosure that demonstrates under all of the followingrequirements~~:

(A) The name of the data element~~The information is not patented~~;

(B) A detailed written explanation, including factual information, demonstrating the information is exempt from disclosure in accordance with the following requirements: ~~The information is known only to certain individuals within the manufacturer's organization and used in a business the organization conducts;~~

(i) The information is not patented;

(ii) The information is known only to certain individuals within the manufacturer's organization and used in any business the organization conducts;

(iii) The information has actual or potential commercial value;

(iv) The information gives the manufacturer an opportunity to obtain a business advantage over competitors who do not know or use it; and

(v) The public interest does not require disclosure of the information.

Overview: Meeting No. 3 themes and next steps

Member topics and recommendations

- Alignment with statutory requirements
  - Manufacturer certification of accurate information
  - Draft language regarding marketing costs and pricing methodology
  - Independent Patient Assistance Programs

DFR response

- Some draft language changes
- More internal discussion planned
- More RAC discussion needed

836-200-0540 (1)(d): Information claimed to be trade secret

(d) On behalf of the reporting manufacturer, an authorized employee or officer of the manufacturer shall certify, to the best of their knowledge and belief, ~~and subject to the civil penalties in OAR 836-200-0560,~~ that:

836-200-0531 (1)(d):

(d) The methodology used to establish the price of the new prescription drug, including ~~a narrative description and explanation of~~ all ~~major financial and nonfinancial~~ factors, with any associated impact or explanation, that influenced the decision to set the price of the drug at the level it was first set by the reporting manufacturer following its approval for marketing by the United States Food and Drug Administration. Factors may include, but are not limited to:~~;~~

(A) Other prescription drugs including the drug name, labeler name, and price~~, regardless of generic or brand status, including the availability, price, drug name, and labeler name~~;

(B) Estimated manufacturing costs for the prescription drug;

(C) Estimated marketing costs for the prescription drug;

(D) Estimated distribution costs for the prescription drug;

(E) Estimated costs of ongoing safety and effectiveness research associated with the prescription drug;

(F) Other costs for the prescription drug; and,

(G) Other costs not specifically associated with the prescription drug.

Patient assistance programs: ORS 646A.689(1)(g) and OAR 836-200-0532 (2)

(g) "Patient assistance program" means a program that a manufacturer offers to the general public in which a consumer may reduce the consumer's out-of-pocket costs for prescription drugs by using coupons or discount cards, receiving copayment assistance or by other means.

(2) If a reporting manufacturer provides funding for an independent patient assistance program that reduces consumer out-of-pocket costs for a drug meeting the conditions specified in OAR 836-200-0515, the report furnished to the department under OAR 836-200-0530 (2) must have an appendix that provides the name of the independent program and includes all of the information specified in section (1) that is available to the manufacturer at the time of the report. If the independent program provides services in addition to reducing consumer out-of-pocket costs for the drug that is the subject of the report, the manufacturer may limit the information provided to the information applicable to the drug that is the subject of the report. Reporting manufacturers that provide funding for independent patient assistance programs must act in good faith ~~make a good faith effort~~ to secure this information.

Discuss draft rules 836-200-0505 to 0560

Discussion of State of Need and Fiscal Impact

- How will adoption of the rules affect equity in Oregon?
  - Who is this going to impact?
  - How might it impact one group different than others?

- Fiscal and economic impact?
  - For small businesses (<50) in Oregon?

- Other comments or questions?

Public comment

Next steps

- Final RAC comments due: Dec. 11, 2024
- Feb. 1, 2025 – Notice of proposed rulemaking published
- Feb. 24, 2025 – Rulemaking hearing
- March 3, 2025 – Public comments due
- March 25, 2025 – Permanent rulemaking filed

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