Drug Price Transparency Rule Advisory Committee meeting

Oct. 17, 2024

DFR | Division of Financial Regulation

Department of Consumer and Business Services

Welcome!

Agenda:

- Review meeting No. 2 comments and response
  - Questions
  - Discussion
- Review draft rules (836-200-0540 to -0560)
  - Questions
  - Discussion
- Public comment
- Next steps

Overview: Meeting No. 2 themes and next steps

Member topics and recommendations

- Concerns about breadth of reporting requirements
  - Preference for ‘narrative description’ option for marketing costs and pricing methodology
  - Want to retain flexibility if a particular item does not apply to a manufacturer
- Clarification of ‘other costs’
- Details of public funds

DFR response

- ‘Narrative description’ and ‘n/a’ options will remain in iReg
  - Discussion of potential options
- Brief discussion of ‘other costs’
- Remove additional language

Overview: Meeting No. 2 themes and next steps

Member topics and recommendations

- Confidentiality concerns, clarification re: advanced review and appeal
- Clarifying ‘Additional Information Request’ section
  - The number of requests
  - Clarification that extensions automatically granted

DFR response

- More discussion needed

- More discussion needed
- Language drafted to clarify automatic extensions

Overview: Meeting No. 2 themes and next steps

Member topics and recommendations		DFR response
• New drug definition ○ ‘Supplemental approval’ terminology not relevant	→	• Discuss draft revised language
• Reporting manufacturer definition ○ How are virtual manufacturers treated?	→	• Intent to continue including virtual manufacturers—more discussion needed
• Retain ‘good faith effort’ • Other?	→	• Change to ‘act in good faith’

836-200-0535: Additional information requests

(4) If additional time is needed, w~~W~~ithin 15 calendar days of receiving the department's request for supporting documentation or additional information following a report provided in accordance with ~~2018 Or Laws ch 7~~ORS 646A.689 and OAR 836-200-0515 to 836-200-053~~0~~, a prescription drug manufacturer ~~may~~ must submit a notice to the department for ~~request~~ up to 30 additional days to prepare and submit a response. A drug manufacturer's request for additional time must be in writing, and must explain the grounds for the request and the need for additional time to prepare a response. The department will automatically grant requests submitted in accordance with this subsection.

836-200-0505 (6): Clarifying ‘new prescription drug’ definition

Member comments

- ‘Supplemental approval’ language is not relevant here
- ‘Continuously’ marketed lacks clarity

DFR response

- The intent is to clarify if a new NDC is added at any point, it is considered a new prescription drug for DPT reporting purposes.
  - E.g., inclusion of new line or patent extenders
- Review revised language

836-200-0505 (6): Clarifying ‘new prescription drug’ definition

(6) "New prescription drug" means a prescription drug that has received initial approval under an original new drug application under 21 U.S.C. 355(b), under an abbreviated new drug application under 21 U.S.C. 355(j), or under a biologics license application under 42 U.S.C. 262. In cases where multiple products are included on an application or approved later ~~based on the prior approval or a supplemental approval~~, each product with a unique National Drug Code will be considered a new prescription drug. A new prescription drug’s introduction date is the date of the product’s initial~~its~~ market entry. A new prescription drug does not include:

(a) A product that is only for use under an emergency use authorization (EUA).

(b) A product with a change in the national drug code or labeler name that has been previously ~~continuously~~ marketed by the same or a different manufacturer.

(c) A vaccine that has been reformulated and replaces a vaccine using the same name, application number, manufacturer, and labeler.

836-200-0505 (11): Clarifying ‘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 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).

Review draft rules 836-200-0540 to 0560

836-200-0540: Information claimed to be trade secret

- Background and context from DFR
  - We receive a lot of questions about trade secrets and want to minimize administrative burdens on both sides
  - Often only one small piece of a larger narrative description is a trade secret
  - Changes aim to more efficiently identify trade secrets
- Questions from RAC?

836-200-0545: Public disclosure of prescription drug manufacturer filings

- Background and context from DFR
  - Process is automated, no need for review timeline at this stage
  - Believe this process was written before iReg system was in place
- Questions from RAC?

836-200-0560: Civil penalties

- Context from DFR
  - Adding ‘timely’ aligns more closely with statutory language
- Questions from RAC?

Public comment

Next steps

- Written comments due: Close of business on Nov. 4
- Next meeting: Nov. 22 from 10-11:30 a.m. (tentative)
- Division contacts:

Lily Sobolik
Senior policy advisor
DCBS | Division of Financial Regulation
Lily.Sobolik@dcbs.oregon.gov
971-446-8813
Pronouns: she/her/hers

Karen Winkel
Rules coordinator
DCBS | Division of Financial Regulation
Karen.J.Winkel@dcbs.oregon.gov
503-947-7694
Pronouns: she/her/hers