Drug Price Transparency Rule Advisory Committee meeting

Sept. 19, 2024

DFR | Division of Financial Regulation

Department of Consumer and Business Services

Welcome!

Agenda:

- Review meeting No. 1 comments and response
  - Questions
  - Discussion
- Review draft rules (836-200-0531 to -0535)
  - Questions
  - Discussion
- Public comment
- Next steps

Overview: Meeting No. 1 themes and next steps

Member topics and recommendations

- Clarifying definitions
  - New prescription drug
  - Start marketing date
  - Reporting manufacturer
  - Dosage

DFR response

- More discussion needed
  - Review suggestions from RAC members

Overview: Meeting No. 1 themes and next steps

Member topics and recommendations

- Good-faith effort’
  - Retain
- Voluntary annual drug price increase data reporting
  - Add ‘no penalty’ language
  - Do not add ‘voluntary’
- Other?

DFR response

- More discussion needed
  - Alternatives to removal
- No change proposed
  - Aligns with DFR bulletin 2024-3
  - New ‘voluntary’ language sufficient

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

- “New prescription drug” … In cases where multiple products are included on an application or approved later based on the prior approval or a supplemental approval, each product will be considered a new prescription drug. A new prescription drug’s introduction date is the date of the product’s initial 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 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 (6)
Clarifying ‘new prescription drug’ definition

Member comments

- DPT inconsistencies re: approach on new NDC considered a new drug
- Supplemental approvals do not coincide with new NDCs (e.g., label expansion)
  - Strike ‘supplemental approval’
- Continuously marketed definition unclear
- Authorized generics excluded?

DFR response

- Intent of changes is to clarify current practice
  - A new NDC that replaces an existing NDC (with a continuously active WAC) does not meet reporting criteria
- Clarify as a group the terminology for ‘supplemental approval’ (i.e., different FDA application number)
- More discussion needed

836-200-0520 (4)
Clarifying ‘start marketing date’ language

(4) The date of introduction is the FDA start marketing date or the date the product is first listed for sale in the U.S., whichever is later.

836-200-0520 (4)
Clarifying ‘start marketing date’

Member comments

- Reference a source for FDA start marketing date (e.g., NSDE)

DFR response

- Is there a preferred publicly available FDA source for ‘start marketing date’?
  - Both FDA directory (DPT’s current source) and NSDE are labeler reported

- ‘First available for purchase in Oregon’

- Replaced “listed for sale in the United States” with “first available for purchase in the United States”

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) Engages in the manufacture of prescription drugs available for sale in this state, as defined by ORS 646A.689(1)(d), that are approved by the United States Food and Drug Administration under:

(A) A new drug application;

(B) An abbreviated new drug application; or

(C) A biologics license application.

(c) Sets or changes the wholesale acquisition cost of the drugs it directly manufacturers or indirectly manufacturers through, including but not limited to, 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).

836-200-0505 (11)
Clarifying ‘reporting manufacturer’ definition

Member Comments

- ‘including but not limited to …’ overly broad and lacks clarity
  - Remove this language

- Need clarity on application to virtual manufacturers

DFR Response

- Discuss proposed revision

- Additional discussion on virtual manufacturers

836-200-0505 (11)
Clarifying ‘reporting manufacturer’ definition

- Current revision:

  (c) Sets or changes the wholesale acquisition cost of the drugs it directly manufacturers or indirectly manufacturers through, including but not limited to, contracts with other entities.

- Proposed change:

  (c) Sets or changes the wholesale acquisition cost of the drugs it manufactures directly or indirectly, including through contracts with other entities.

836-200-0505 (3)
Clarifying ‘dosage’ definition

(3) “Dosage” is the highest amount, strength, and frequency that a patient would take the drug as recommended by its prescribing label as approved by the United States Food and Drug Administration (such as one 10mg pill per day or one 5mL injection per week).

836-200-0505 (3)
Clarifying ‘dosage’ definition

Member Comments

- Using the ‘highest’ language could overestimate cost for some drugs

DFR Response

- The aim is a consistent standard for determining *reporting* threshold
  - Similar language in existing definition of ‘course of treatment’
  - Does not include off label uses

Discuss ‘good-faith effort’ options

Member comments

- Retain ‘good-faith effort’
  - Used in statute without definition
- Removal causes problems
  - Adds to reluctance and difficulty for compliance
  - Gives DCBS virtually unlimited discretion to assess penalties

DFR response

- Continued RAC discussion and internal DFR review

Review draft rules 836-200-0531 to -0535

836-200-0531
Prescription drug reporting – new prescription drug

- Questions for RAC
  - Is the additional language in 1(a) sufficiently clarifying?
  - What is the appropriate timing for capturing marketing cost prior to and post launch of a new prescription drug (1(c))?
  - Additional clarity needed on revised definition of ‘dosage,’ now seeing its usage?

836-200-0535
Additional information requests

- Questions for RAC
  - Clear that additional time now only requires submitting a notice, approval of a request is no longer needed?

Public comment

Next steps

- Written comments due: Close of business on Oct. 3
- Next meeting: Oct. 17, 10-11:30 a.m. (tentative)
- Division contacts:

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