

DPT RAC meeting

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Department of Consumer
and Business Services

Agenda

- Review and discuss draft rules
- Public comment
- Next steps

Revisions overview

- Added definition of “drug” (836-200-0505(3))
 - No inaccuracies existed in the rule but added definition is clarifying
- Updated CMS threshold for reporting on new prescription drugs (836-200-0520(2))
 - Left the previous thresholds for historical reference
- Changed the term “price” to “wholesale acquisition cost” for clarity (836-200-0531(4)(a) and 836-200-0533(9)(a))
 - “Price” is defined as “WAC” in the rules already but hope this will ease confusion

Revisions overview cont.

- Removed the term “reporting year” and reverted to the original language “the calendar year preceding the report” for clarity
 - For new data collection points added “calendar year prior to the year described in section (xx) of this rule”
 - Also updated subsequent language in 836-200-0533 to align
- Removed “or loss” from 836-200-0533(14)

Other Comments

- Concerns about Patient Assistance Reporting and reporting on international pricing
 - These requirements are in statute and rules must reflect statute; no changes were made in response to these comments
- Reporting on every price change is burdensome
 - These data points are necessary for the program to verify the net price increase to ensure proper reporting as required by statute
- Reporting “all factors...” in 836-200-0533(9) is burdensome
 - ORS 646A.689(3)(c) requires reporting on ‘*the* factors...’ and rule is clarifying that this means ‘*all* factors’ [emphasis added]

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 differently than others?
- Fiscal and economic impact?
 - For small businesses (<50) in Oregon?
- Other comments or questions?

Public comment

Next steps

- Written comments due – Close of business on July 8th
- Official Public Hearing: August 25th
- Division contacts:

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