

Final Action

COMAR 14.01.01.01-.05
COMAR 14.01.04.01-.05

November 27, 2023

Prescription Drug Affordability Board Staff



MARYLAND
Prescription Drug Affordability Board

COMAR 14.01.01

General Provisions

14.01.01.01 — Definitions

14.01.01.02 — Rules of Construction

14.01.01.03 — Open Meetings

14.01.01.04 — Confidential, Trade-Secret and
Proprietary Information

14.01.01.05 — Public Comment Procedures



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COMAR 14.01.04

Cost Review Study Process

- 14.01.04.01 — Public Reporting of Drug Affordability Issues
- 14.01.04.02 — Identifying Drugs Eligible for Cost Review
- 14.01.04.03 — Selecting Drugs for Cost Review
- 14.01.04.04 — Request for Information for Cost Review
- 14.01.04.05 — Cost Review Study



Summary of Pre-Proposal Public Feedback/Comment Process

- Two Rounds of Written Public Feedback/Comments Before Publishing Proposed Regulations in Md Register
 - 1st Draft Feedback Received by May 2, 2023 and May 5, 2023 (12 letters)
 - 2nd Draft Feedback Received by June 30, 2023 (8 letters)
 - 3rd Draft Posted on July 17, 2023
 - All written comments/feedback posted on Board website



APA Comment Procedure

- Proposed Regulations Published in Md Register Sept. 22, 2023
- 30-day public comment ended October 23, 2023
 - 2 comments submitted:
 - PhRMA (and resubmitted previous comment letters from earlier drafts)
 - National Organization for Rare Disorders (NORD)
 - Comments available on Board website



Staff Recommendation

- Staff recommends the Board adopt as proposed COMAR 14.01.01 General Provisions
- Staff recommends the Board adopt with nonsubstantive changes COMAR 14.01.04 Cost Review Study Process
 - Nonsubstantive correction of scrivener's error (word inversion) in 14.01.04.02.(2)(a)
 - FROM: (a) The 100 prescription drug products with the highest **patient total** out-of-pocket costs in the most recent available calendar year;
 - TO: (a) The 100 prescription drug products with the highest **total patient** out-of-pocket costs in the most recent available calendar year;





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