Cost Review Process and Regulations Presentation

PDASC Meeting

June 26, 2023

Andrew York

Draft Regulations

Public comment sought on the following draft regulations:

COMMENT PERIOD CLOSED MAY 5, 2023 (Posted on April 24, 2023)

- COMAR 14.01.01.02-.03 – Rules of Construction (Open Meetings)
- COMAR 14.01.01.04 – Confidential, Trade-Secret, and Proprietary Information
- COMAR 14.01.04.01- Public Information Act

COMMENT PERIOD CLOSED MAY 2, 2023 (Posted on April 11, 2023)

- COMAR 14.01.01.01 – General Provisions (Definitions- NEW)
- COMAR 14.01.02.02 – Prescription Drug Affordability Fund
- COMAR 14.01.03.01-05 – Cost Review Process

Comments Received (Cost Review and Fee Assessment)

12 comment letters on the cost review and fee assessment regulations received by May 2, 2023:

- Three letters from manufacturers and the pharmaceutical industry (PhRMA, BIO, and Boehringer Ingelheim)
- Three letters from payers (Carefirst, Kaiser Permanente, and ACLI/LLHIM)
- One letter from wholesalers (HDA)
- Two letters from health policy experts (Jane Horvath and Jim Gutman)
- Two letters from advocates and the public (Maryland Health Care for All and Partnership to Improve Patient Care)
- One letter from the technology sector (Maryland Tech Council).

Comments are posted on the PDAB website.

Comments Received (Rules of Construction, PIA, and Confidential, Trade- Secret and Proprietary Information)

- We received comments from two entities on the Rules of Construction (PhRMA), Public Information Act (PhRMA and HDA), and Confidential, Trade-Secret, and Proprietary Information (PhRMA) that had a comment period open until May 5, 2023.

- These comments came from one wholesaler and one from the pharmaceutical industry (4 letters total).

Comments are posted on the PDAB website.

Key Themes

- Concerns that the current regulations and processes were too vague and arbitrary, including inadequate guidance on how different factors would be considered and weighted
- Requests for extensive opportunities for public feedback and input, both on the industry side and public side.
- General confusion on the process, especially around the process and implications of eligibility and selection
- Substantial feedback on data sources and the quality of the data

Revisions to Draft Cost Review Study Process Regulations- COMAR 14.01.04.01-05

- Removal of Insulins as an eligibility criteria
- Selecting Drugs for Referral to Stakeholder Council has been updated for more detail
- Added information regarding identifying Therapeutic Alternatives
- Substantial changes to the definitions were also made in COMAR 14.01.01.01 – General Provisions (Definitions)

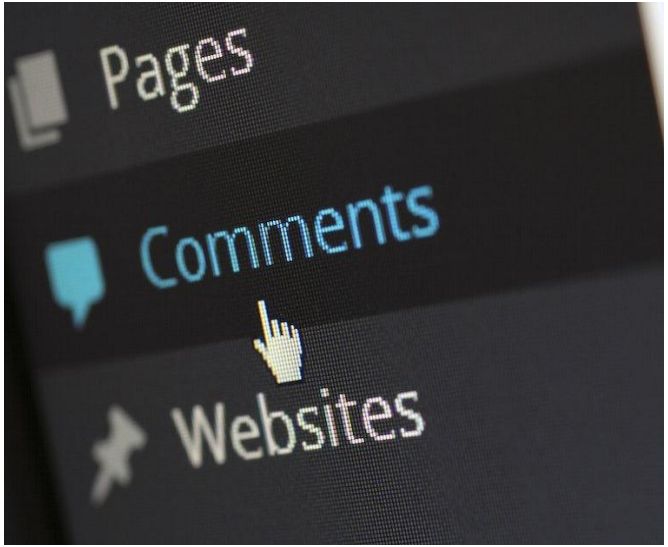
Regulations Currently Open for Comment

The following revised draft regulations are open for public comment until June 30, 2023:

- COMAR 14.01.01.01 – General Provisions (Definitions) (Second Draft)
- COMAR 14.01.01.02- General Provisions (Rules of Construction, Open Meetings) (Second Draft)
- COMAR 14.01.01.04 – General Provisions (Confidential, Trade-Secret, and Proprietary Information) (Second Draft)
- COMAR 14.01.03.01-05 – Cost Review Study Process (Second Draft)

Regulations Posted for Comment

- Additional Comments are Due: June 30, 2023
- Please submit all comments to comments.pdab@maryland.gov
- Updated regulations are posted on the website: https://pdab.maryland.gov/regulations.html



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