Title 14
INDEPENDENT AGENCIES

Subtitle 01 – Prescription Drug Affordability Board

Chapter 05 – Policy Review, Final Action, Upper Payment Limits

Authority: Health-General Article, §§ 21-2C-03 and 21-2C-15, Annotated Code of Maryland

.01 - .09
(text unchanged)

.10 Appeals of Upper Payment Limit Determinations.

A. Scope and Grounds for Appeal.
(1) An appeal to the Board under Health-General Article, § 21-2C-15, Annotated Code of Maryland is strictly limited to demonstrating that the Board's final Upper Payment Limit (UPL) determination failed to comply with the statutory requirements of Health-General Article, § 21-2C, Annotated Code of Maryland, or the regulatory criteria and methodologies established in COMAR Title 14, Subtitle 01.
(2) The Board will not consider:
(a) Constitutional challenges or claims exceeding the Board's statutory authority;
(b) Generalized policy, economic, or market objections; or
(c) New clinical, financial, or economic data, studies, expert declarations, or factual evidence that were not submitted to the Board during the cost review and public comment period.

B. Form and Length of Petition.
(1) An appeal shall be submitted as a single written document titled "Petition for Appeal of Upper Payment Limit Determination."
(2) Length.
(a) Except as provided in § B(2)(b) of this regulation, the petition shall not exceed 20 pages in length, or 5,200 words, inclusive of statement of facts, argument, and conclusion, but exclusive of the title page, table of contents, table of authorities, and certificate of service.
(b) The Board may, for good cause shown, grant leave to exceed the page limitation upon timely written motion filed by the appellant at least 10 calendar days before the filing deadline.
(3) Formatting. The petition shall be double-spaced with 1-inch margins on all sides and formatted in 12-point standard font. Footnotes may be single-spaced but shall not be smaller than 10-point font.
(4) Exhibits. Appellants may not circumvent the page limit through voluminous addenda. Attachments and exhibits are strictly limited to excerpts of materials already contained within the administrative record compiled prior to the entry of the Upper Payment Limit determination, such as previously submitted documents, public comment excerpts, or specific pages from the published Cost Review Study Report. Non-record exhibits shall be stricken.

C. Filing and Service.
(1) A petition for appeal shall be filed electronically, based on instructions posted on the Board website, with the Board within 30 days after the Board makes the decision to set the upper payment limit.
(2) For purposes of this subtitle, the date of the Board's decision to establish an upper payment limit shall be the 10th day following the date of publication of the notice of final action in the Maryland Register.
(3) Effect on Upper Payment Limit. The filing of a petition for appeal does not stay, suspend, or delay the effective date or enforcement of an Upper Payment Limit determination unless affirmatively granted by the Board upon written motion.

D. Procedures for Reviewing Appeals.
(1) Notice. Upon receipt of a petition for appeal, the Board shall notify the appellant and publish notice of the appeal on the Board's public website.
(2) Nature of Proceeding. The Board shall hear and decide the appeal on the written petition and the administrative record compiled prior to the entry of the determination. The Board will not conduct an evidentiary trial, accept live witness testimony, or permit discovery. The Board in its sole discretion may schedule oral argument.
(3) Board Staff Response. The Board or Board Counsel may request that Board staff or technical consultants submit a written technical evaluation report responding to the claims raised in the petition.
(4) Determination. Within 60 calendar days of the date an appeal is requested, the Board shall convene in public session to consider the appeal and issue a final written decision regarding the appeal.

E. Treatment of Confidential Information. If a petition references proprietary, commercial, or financial information previously submitted to the Board under Health-General Article, § 21-2C-10, Annotated Code of Maryland, the appellant shall file simultaneously:

(1) A confidential version under seal clearly marked "CONFIDENTIAL – FILED UNDER SEAL PURSUANT TO HEALTH-GEN. § 21-2C-10"; and
(2) A redacted public version suitable for public inspection under the Maryland Public Information Act.