abbvie

November 11, 2026

VIA ELECTRONIC MAIL

Christina Shaklee
Health Policy Analyst Advanced
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715
comments.pdab@maryland.gov

Re: November 2026 Board Comments—Proposed Emergency COMAR 14.01.05.10, Appeals of Upper Payment Limit Determinations

Dear Members of the Maryland Prescription Drug Affordability Board:

AbbVie Inc. ("AbbVie") respectfully submits these comments concerning the Maryland Prescription Drug Affordability Board's ("Board" or "PDAB") proposed emergency regulation governing appeals from upper payment limit ("UPL") determinations, COMAR 14.01.05.10 (the "Proposed Appeals Regulation").[1] AbbVie is a research-based biopharmaceutical company whose medicines, including SKYRIZI® (risankizumab-rzaa), Maryland patients rely upon every day.

Without notice, on Friday, November 6, 2026, the Board revised its previously posted November meeting agenda and posted an entirely new Proposed Appeals Regulation, requiring comments by Wednesday, November 11, 2026, allowing just five calendar days to evaluate and comment on regulations governing the exercise of the statutory right to appeal a UPL. That compressed timetable reflects urgency created by the Board's own schedule, rather than circumstances demonstrating that emergency adoption is necessary or that compliance with ordinary rulemaking procedures would be contrary to the public interest.

For the reasons set forth below, AbbVie requests that the Board withdraw the Proposed Appeals Regulation from emergency consideration and publish a revised regulation through the ordinary Maryland Administrative Procedure Act process that permits review of the entire basis for a UPL, provides evenhanded evidentiary procedures and effective relief, and preserves a separate route for reconsideration based on changed circumstances:[2]

[1] Maryland Prescription Drug Affordability Board, Proposed COMAR 14.01.05.10, Appeals of Upper Payment Limit Determinations, at https://pdab.maryland.gov/media/1448 (last visited Nov. 9, 2026).

[2] Nothing in this submission waives any objection to the Board's actions, including any constitutional challenge or claim that the Board has exceeded its statutory authority, merely because the Proposed Appeals Regulation purports to exclude that objection from consideration in the Board's internal appeal. Nor does this submission waive AbbVie's right to present any such objection in an appropriate forum. AbbVie incorporates by reference and preserves the objections raised in its prior comments concerning the Board's statutory authority, drug selection and cost review processes, affordability determinations, therapeutic alternative methodology, UPL framework, and related constitutional and administrative law issues. AbbVie preserves all objections to the Board's actions, including constitutional challenges and claims that the Board has exceeded its statutory authority, notwithstanding any provision of the Proposed Appeals Regulation purporting to exclude those objections from the Board's consideration. Nothing in this submission waives any such objection or any right to raise such an objection in an appropriate forum.

- The materials accompanying the proposal do not identify a circumstance requiring immediate adoption—the disclosed timetable instead suggests that the proposal is being accelerated to align with planned UPL actions. Accordingly, the Board should proceed through ordinary notice-and-comment rulemaking.

- The Proposed Appeals Regulation must preserve challenges to the complete legal, factual, economic, clinical, and methodological basis for the challenged UPL. Proposed § A(1) and § A(2), read together, create substantial uncertainty about the scope of that review. Although § A(1) permits an appellant to demonstrate that the UPL failed to comply with statutory requirements or the Board's regulatory criteria and methodologies, § A(2)(a) simultaneously excludes claims that the Board exceeded its statutory authority. To the extent these provisions are intended to foreclose challenges to statutory, factual, economic, clinical, or methodological defects in the predicates supporting the challenged UPL, they impermissibly narrow the appeal provided by Health-General Article § 21-2C-15.The Board should expressly confirm that review encompasses the substantive basis for the UPL, not merely procedural compliance.

- The Proposed Appeals Regulation would close the evidentiary record against the appellant while permitting Board staff or consultants to prepare a post-petition "technical evaluation report," without guaranteeing that the appellant will receive the complete report or have an opportunity to answer its factual, technical, or methodological assertions. Further, the Proposed Appeals Regulation also would allow a UPL to take effect during the appeal without a stated stay standard. These restrictions threaten the appeal's ability to identify error, prevent avoidable harm, and produce a reasoned decision capable of meaningful judicial review.

I. The Board Has Not Identified an Emergency That Justifies Bypassing Ordinary Rulemaking Procedures

Maryland's Administrative Procedure Act generally bars adoption of a proposed regulation until at least 45 days after publication in the *Maryland Register* and requires at least 30 days for public comment. Maryland law permits immediate adoption only if the agency declares that emergency adoptions is necessary, submits the proposed regulation and required fiscal impact statement to the Joint Committee on Administrative, Executive, and Legislative Review ("AELR Committee") and the Department of Legislative Services ("DLS"), and obtains AELR Committee approval for emergency adoption.[3] The publicly available materials do not identify an emergency declaration, submission of a fiscal impact statement with the Proposed Appeals Regulation, or AELR Committee approval authorizing emergency adoption. If the Board has taken or initiated those steps, it should make the relevant materials part of the public record before adopting the regulation. AELR Committee approval, moreover, does not itself establish the circumstances necessitating emergency adoption; it is a statutory prerequisite to immediate adoption after the agency determines that emergency adoption is necessary. An emergency regulations may remain effective for no more than 180 days. Although the statute does not separately define "exigency,"

[3] Md. Code Ann., State Gov't § 10-111(b)(1)(i)–(iii).

the Maryland Department of Health describes emergency actions as measures used in "exigent circumstances" that bypass the ordinary public notice-and-comment period.

The Board has not identified any circumstance requiring immediate action, rather than proceeding through ordinary notice-and-comment rulemaking. The statutory appeal right made the need for implementing procedures foreseeable. The Board's progression toward final UPL decisions does not, without more, explain why those procedures could not have been developed through ordinary rulemaking. Otherwise, an agency could create the predicate for emergency adoption by advancing its substantive program faster than the rulemaking needed to support it. The Board should disclose its justification for the emergency treatment, any emergency submission and accompanying fiscal-impact materials provided to AELR and DLS, and the status of the AELR review.

The disclosed timetable reinforces that concern. On November 2, the Board placed the Proposed Appeals Regulation on its November 16, 2026 agenda for a presentation, motion to adopt, and vote.[4] The agenda also schedules final action on cost review, implementation and monitoring, and product-specific UPL regulations. On November 6, the Board posted the Proposed Appeals Regulation with a November 11, 2026 comment deadline. Stakeholders therefore received only five calendar days for comment, compared with the minimum 30-day public comment period applicable in ordinary Maryland rulemaking. This compressed timeline underscores the need to explain why ordinary rulemaking is inadequate, particularly where the appeals proposal is being considered alongside final UPL actions.

The abbreviated comment period also falls short of the Board's own proposed minimum. In its proposed amendments to COMAR 14.01.01.05(B)(4), the Board would require "a period of at least 15 days for the submission of comments" when the Board requests public comment by posting notice on its website[5] Yet the Board afforded less than that period for comments on the Proposed Appeals Regulation, with submissions due November 11 before the planned November 16 vote. The Board should not establish procedures governing review of its UPL decisions through a process less protective than the public participation minimum it has itself provided.

Even if an appeal mechanism were needed immediately, and the Board has made no case that it is, that need would not justify every substantive restriction in this proposal. Indeed, Board staff characterize the Proposed Appeals Regulation as "simply establish[ing] the procedural framework necessary for the statutory appeals process" required by Health-General Article § 21-2C-15.[6] At the same time, the Board describes the proposal as establishing a"[s]trictly limited scope" of appeal, under which appeals are "only for demonstrating that the Board's final Upper Payment Limit (UPL) determination failed to comply with the statutory and regulatory

[4] Maryland Prescription Drug Affordability Board, November 16 Board Meeting Agenda (Revised 11/6/2026), at https://pdab.maryland.gov/media/1447 (last visited Nov. 9, 2026).
[5] Proposed COMAR 14.01.01.05(B)(4)(b), Maryland Prescription Drug Affordability Board, Draft Public Comment Procedures (July 22, 2026), at https://pdab.maryland.gov/media/1414 (last visited Nov. 9, 2026); see also Maryland Prescription Drug Affordability Board, Meeting Minutes, Agenda Item 5 (July 27, 2026), at https://pdab.maryland.gov/media/1441 (last visited Nov. 9, 2026).
[6] Maryland Prescription Drug Affordability Board, Presentation on Emergency Regulations, COMAR 14.01.05.10 Appeals of Upper Payment Limit Determinations (November 16, 2026 Meeting), at slide 2, at https://pdab.maryland.gov/media/1455 (last visited Nov. 9, 2026).

requirements."[7] The Proposed Appeals Regulation thus does considerably more than supply a filing address, deadline, or other interim machinery necessary to receive an appeal. The Board could, for example, adopt a narrowly tailored interim measure that identifies the filing address, preserves the statutory 30-day period, stays implementation while the appeal is pending, and otherwise protects the appellant's rights while a comprehensive appeals regulation proceeds through ordinary rulemaking. Even a need for basic filing machinery would not explain why the Board must now close the evidentiary record, restrict the grounds and arguments available on appeal, reserve oral argument to its sole discretion, permit post-petition technical supplementation by Board staff or consultants while prohibiting comparable supplementation by the appellant, and omit any clear standard governing stays or relief. [8]

Moreover, the Board's prior use of emergency rulemaking does not establish a need for it here. In December 2024, the Board characterized cost review amendments as "technical corrections" and expressed a desire to "work expeditiously." AbbVie's related comments objected that the Board's desire to work expeditiously did not establish an emergency and that the amendments affected the information and procedures governing preliminary affordability determinations. AbbVie's December 2024 comments thus identified the same fundamental distinction implicated here: an agency's desire to move expeditiously is not itself an emergency, particularly where the asserted urgency results from the agency's own regulatory timetable. Nor does characterizing consequential procedural restrictions as technical or administrative alter their effect on regulated parties' rights. Here, the Proposed Appeals Regulation determines what an aggrieved person may challenge, what evidence the Board may consider, and what process and relief will accompany an express statutory appeal. A desire to implement the Board's planned UPL actions expeditiously does not, without more, explain why the appeals regulation must take effect through emergency procedures.

The need for ordinary rulemaking is particularly acute where, as here, the regulations define the procedures governing an express statutory right of appeal. The Supreme Court of Maryland has explained that notice and comment is intended "to afford fair notice and a meaningful opportunity to comment to all persons who may be affected by the proposed regulation" and to provide the agency with "free-flowing information from a broad range of interests."[9] Maryland law likewise requires an agency to operate "within the confines of traditional standards of procedural and substantive fair play."[10] And the Maryland Attorney General has described public notice and comment as the "heart" of APA rulemaking because it serves the "twin functions of safeguarding public rights and educating the administrative lawmakers."[11]

Notice and comment is especially important where, as here, an agency proposes to leave consequential questions to undefined or unbounded discretion. The appeals rule would determine what may be challenged, what evidence may be considered, when the Board may supplement the record, whether an appellant may be heard orally, whether the challenged UPL will remain in

[7] *Id*. at slide 4 ("Strictly limited scope - appeals are only for demonstrating that the Board's final Upper Payment Limit (UPL) determination failed to comply with the statutory and regulatory requirements").
[8] Proposed COMAR 14.01.05.10(A)(1)-(2), (C)(3), (D)(2)-(3).
[9] *Adventist Healthcare Midatlantic, Inc. v. Suburban Hosp., Inc.*, 350 Md. 104, 123, 711 A.2d 158, 167-68 (1998).
[10] *Fogle v. H & G Rest., Inc.*, 337 Md. 441, 456, 654 A.2d 449, 456 (1995).
[11] 75 Op. Att'y Gen. Md. 36, 43 (1990).

effect, and what relief may be granted. Public participation can expose practical and legal consequences of those choices that may not be apparent from the text alone, including but not limited to the time required to assemble a product-specific record, the effect of implementation during an appeal, and the need to protect confidential information while maintaining a record suitable for judicial review.

The District of Maryland's decision in *Association of Community Cancer Centers v. Azar* further illustrates the importance of distinguishing an actual need for immediate action from an agency's desire to implement its chosen policy promptly.[12] In that case, CMS dispensed with advance notice and comment when adopting a nationwide Medicare Part B reimbursement model, invoking as its justification rising drug prices and the economic effects of the COVID-19 pandemic. In granting a temporary restraining order, the court concluded that the plaintiffs were likely to succeed in showing that the agency lacked good cause to dispense with notice and comment. Although the federal APA's good cause standard is not identical to Maryland's emergency regulation provision, the decision addresses the same fundamental danger: allowing the agency's implementation objectives to displace the procedures designed to inform consequential rulemaking.

The court explained that notice and comment is "essential to ensuring civic participation in the rulemaking process as well as informed agency decisionmaking." It cautioned that "an agency may not dispense with notice and comment procedures merely because it wishes to implement what it sees as a beneficial regulation immediately," because accepting that rationale would allow the exception to "swallow the rule and render notice and comment a dead letter."

The need for ordinary rulemaking is also reinforced by Maryland's statutory commitment to public participation in the Board's own work. The state's PDAB statute directs the Board to "provide the public with the opportunity to provide written comments on pending decisions of the Board." [13] That statutory policy makes it particularly difficult to justify adopting through emergency procedures a set of regulations defining the process for obtaining review of the Board's most consequential decisions without first affording the ordinary opportunity for informed public comment.

If the Board nevertheless believes immediate action is necessary, it should identify in the public record the specific event requiring immediate effectiveness; when that event became known; why ordinary rulemaking could not have been initiated in time; why a stay or narrower interim filing procedure would not address the asserted need; and why each restrictive provision of the Proposed Appeals Regulation must take immediate effect. Without those findings, the public and AELR cannot meaningfully assess whether the asserted emergency is genuine or simply the product of the Board's preferred implementation schedule.

Absent that showing, the Board should withdraw the emergency request and proceed through ordinary notice and comment. That course would preserve public participation without foreclosing lawful appeals regulations.

[12] *Ass'n of Cmty. Cancer Ctrs. v. Azar*, 509 F. Supp. 3d 482, 496–98 (D. Md. 2020).
[13] Md. Code Ann., Health Gen. § 21-2C-03(e)(5).

II. Proposed § A(1) and (A)(2) Cannot be Construed to Narrow the Statutory Basis for Appeal

Health-General Article § 21-2C-15 provides an appeal to a person aggrieved by the Board's decision to set a UPL.[14] Proposed § A(1) states that such an appeal may demonstrate that the final UPL determination "failed to comply with the statutory requirements" of Chapter 21-2C or the Board's regulatory criteria and methodologies. Proposed § A(2)(a), however, provides that the Board will not consider "claims exceeding the Board's statutory authority." As drafted, those provisions create a potentially consequential ambiguity..[15] The Board should affirm that this review encompasses substantive as well as procedural compliance, including whether the findings supporting the particular UPL satisfy applicable requirements and are adequately supported by the record. Proposed § A(2) should not exclude those challenges merely because they involve factual, economic, clinical, or methodological issues.[16]

A contention that the Board acted outside the authority conferred by Chapter 21-2C may also establish that the resulting UPL failed to comply with Chapter 21-2C. For example, a claim that the Board imposed a UPL without satisfying a statutory prerequisite, relied on a consideration the statute does not permit, or applied the UPL beyond the scope authorized by statute could be characterized both as statutory noncompliance cognizable under § A(1) and as a claim that the Board exceeded its statutory authority under § A(2)(a). Section A(2)(a) should not be construed to exclude such a claim merely because the same statutory defect also demonstrates that the Board exceeded its authority, and the regulation should say so.

At minimum, the regulation therefore should clarify that § A(2)(a) does not exclude a claim otherwise cognizable under § A(1) merely because the alleged statutory violation also demonstrates that the Board exceeded the authority conferred by Chapter 21-2C. An agency may not narrow by regulation the remedy the General Assembly provided.

Maryland law does not permit an agency to narrow a statutory remedy by regulation. A regulation is invalid if it exceeds the agency's statutory authority.[17] As Maryland's highest court has explained, an agency may not adopt a rule that "alters, adds to, extends or enlarges, subverts, impairs, limits, or restricts the act being administered."[18] The General Assembly granted an appeal to a person "aggrieved by an upper payment limit set by the Board."[19] The Board may prescribe reasonable procedures governing that appeal, but it may not use those procedures to exclude an otherwise cognizable statutory challenge to the legal, factual, or methodological basis for the UPL. The regulation should expressly confirm that an appellant may challenge both the basis for

[14] Md. Code Ann., Health-Gen. § 21-2C-15(a)–(c).
[15] Maryland Prescription Drug Affordability Board, Proposed COMAR 14.01.05.10, Appeals of Upper Payment Limit Determinations, § A(1)–(2), https://pdab.maryland.gov/media/1448 (last visited Nov. 9, 2026).
[16] Proposed § A(1) and § A(2)(a) also create uncertainty about challenges to the Board's statutory authority. Proposed § A(1) permits challenges based on noncompliance with statutory requirements, yet proposed § A(2)(a) excludes "claims exceeding the Board's statutory authority." If that exclusion reaches claims that the Board exceeded its authority in setting the UPL, it would withdraw a central category of the challenges proposed § A(1) expressly permits.
[17] Md. Code Ann., State Gov't § 10-125(d)(2).
[18] *Ins. Comm'r v. Bankers Independent Insurance Co.*, 326 Md. 617, 623, 606 A.2d 1072, 1075 (1992).
[19] Md. Code Ann., Health-Gen. § 21-2C-15(a).

imposing the particular UPL and the calculation of its amount, including the predicates on which those decisions rely.

A meaningful appeal must reach the predicates that support the final UPL. Those include drug eligibility and selection, the affordability determination, cost review findings, the reliability and completeness of data, the choice and comparability of therapeutic alternatives, the methodology used to derive the UPL, and the reasoned connection between the evidence and the Board's final action. Many such defects may themselves demonstrate that the UPL fails to comply with Chapter 21-2C or the governing regulatory criteria. The problem is that §§ A(1) and A(2), read together, do not make clear whether such challenges remain cognizable when they concern a predicate determination previously made during eligibility, selection, affordability review, or cost review. The Board should confirm that an appellant may challenge an unsuitable comparator, an erroneous net-cost calculation, or a failure to address relevant acquisition-cost or patient-access evidence where the alleged error bears on compliance with applicable statutory and regulatory requirements. Application of an announced methodology should not, by itself, dispose of a challenge to the validity of its inputs, assumptions, or application to the particular UPL.

Nor should a predicate necessary to the final UPL become insulated from the statutory appeal merely because the Board first made or announced that determination at an earlier stage of the decisional process. Stakeholders may have opportunities to comment on or object to those predicate determinations during earlier stages of the Board's process. But participation in an earlier comment process is not a substitute for the administrative appeal that § 21-2C-15 expressly provides from the Board's decision to set the UPL. Where an antecedent determination supplies a necessary legal, factual, or methodological basis for that final decision, the regulation should clarify that the appellant may challenge a material defect in that determination insofar as it affected the UPL under appeal. Otherwise, an error that materially affected the UPL could become effectively insulated from review merely because it originated at an earlier stage of the Board's process.

The regulation also must identify the relief available when an appeal succeeds. Recalculation may be appropriate where the error concerns only a numerical input or computational step. But where the appellant establishes that the drug was ineligible, that the affordability determination lacked a lawful or adequately supported basis, that the Board relied on an unsuitable comparator, or that the record does not justify imposing a UPL at all, recalculation would not remedy the defect. In those circumstances, the Board must be able to vacate or rescind the UPL, remove the product from the UPL, or remand the matter for legally sufficient proceedings. Otherwise, the regulation would preserve the central consequence of an action that the appeal has demonstrated to be invalid.

The Board need not resolve in this rulemaking every question concerning the formal classification of a UPL appeal to recognize that the procedures must be adequate to perform the function the statute assigns. Section 21-2C-15 directs the Board to "hear" the appeal, issue a final decision within 60 days, and produce a decision subject to judicial review under the Maryland Administrative Procedure Act.[20] Those commands at least require notice of the complete material before the decisionmaker, a meaningful opportunity to address that material, an impartial

[20] Md. Code Ann., Health-Gen. § 21-2C-15(a)–(c).

decisional process, and findings that disclose the factual and legal basis for the result. A procedure that forecloses the appellant's responsive evidence while permitting Board staff or consultants to supply additional reasoning after the petition is filed risks converting the statutory appeal from review of the original decision into an opportunity to reinforce that decision after the fact.

III. Proposed § A(2)(b) Must Preserve Product-Specific Economic and Market Challenges

Proposed § A(2)(b) would exclude "generalized policy, economic, or market objections."[21] The regulation should expressly confirm that an appellant may raise product-specific challenges based on, for example, the particular UPL's net-cost assumptions, treatment of provider or pharmacy acquisition costs, or analysis of supply and patient-access effects. Those challenges should not be excluded merely because they involve economic or market evidence.

For example, evidence may show that a physician practice, hospital, specialty pharmacy, or community pharmacy acquires the product at a cost above the amount that will be reimbursed under the UPL; that manufacturer rebates or discounts are retained elsewhere in the distribution chain rather than received by the provider purchasing or dispensing the product; that inventory, handling, distribution, or site of care requirements make the product unavailable at the imposed limit; or that the UPL will shift utilization toward a clinically different or more costly therapy. Those are product-specific objections to the factual basis and operation of the particular UPL, not generalized disagreement with the Board's policy.

The final regulation should expressly permit appellants to raise product-specific challenges concerning actual net prices and rebates; clinical value and indication-specific outcomes; the appropriateness of therapeutic alternatives; provider, pharmacy, and site of care acquisition costs; distribution and inventory requirements; supply continuity; patient access; switching and utilization effects; benefit design; cost shifting; and the interaction of the UPL with federal pricing and reimbursement rules. An appellant also must be permitted to show that these product-specific considerations demonstrate that the resulting UPL fails to satisfy applicable statutory or regulatory requirements or rests on materially incorrect factual, clinical, or economic predicates.

AbbVie has previously explained that any therapeutic alternative should be clinically appropriate for the same relevant patient population and supported by current clinical guidelines, safety and efficacy, clinical outcomes, and patient specific factors such as comorbidities and contraindications.[22] Because the selection and use of therapeutic alternatives may materially affect the Board's affordability analysis and resulting UPL, the final regulation should remove any ambiguity as to whether an appellant may challenge a comparator that materially contributed to the challenged UPL. The Board should confirm that an appellant may challenge the Board's selection and use of purported therapeutic alternatives supporting the particular UPL, including

[21] Maryland Prescription Drug Affordability Board, Proposed COMAR 14.01.05.10, Appeals of Upper Payment Limit Determinations, § A(2)(b), at https://pdab.maryland.gov/media/1448 (last visited Nov. 9, 2026).

[22] *See e.g.,* AbbVie Inc., Comments on Maryland Prescription Drug Affordability Board List of "Therapeutic Alternatives" (May 13, 2024), at 2–3, at (explaining that the Board's approach fails to account for "significant variance in factors such as safety, efficacy, [and] clinical outcomes," "alignment with clinical guidelines," and "patient specific factors," and explaining that purported alternatives may not be appropriate for the patient population treated with SKYRIZI® where those therapies have already failed).

but not limited to material differences in indications, mechanisms of action, routes of administration, sites of care, clinical outcomes, safety profiles, or patient populations.

IV. The Categorical Record Closure Is Overbroad and Structurally Asymmetric

Proposed §§ A(2)(c), B(4), and D(2) categorically exclude clinical, financial, economic, expert, or factual evidence not submitted during the cost review and public comment period.[23] A good cause exception would preserve a predominantly record-based appeal without excluding material evidence that could not reasonably have been presented earlier.

The problem is not hypothetical. The Board's final UPL analysis may rely on reasoning, calculations, comparisons, or implementation assumptions that were not disclosed during the earlier cost review comment period. New clinical results, FDA actions, supply constraints, contracting changes, acquisition cost information, or federal reimbursement developments also may arise after the record nominally closes. An appeal that cannot address newly available evidence or respond to the rationale first announced in the final action cannot reliably correct error.

The Proposed Appeals Regulation is also one-sided. Section D(3) bars appellants from submitting new expert or factual material but, by contrast, permits the Board or Board counsel to request a post-petition "technical evaluation report" from Board staff or consultants. The regulation does not require service of that complete technical evaluation on the appellant, that the report will be included in the administrative record subject to appropriate confidentiality protections, or that the appellant will have a meaningful opportunity to answer any new factual, technical, methodological, or expert material on which the Board may rely. That asymmetry invites post-decisional supplementation of the Board's rationale and deprives the appellant of a meaningful opportunity to test the information used to decide the appeal. The concern is particularly acute if the technical evaluation introduces new evidence, calculations, expertise, or methodological reasoning supporting the challenged UPL after the appellant has filed its petition. In that circumstance, the regulation would permit supplementation of the record with material supporting the challenged UPL while denying the appellant a comparable opportunity to submit evidence necessary to respond.

A post-petition report also may introduce calculations, factual premises, literature, or methodological explanations absent from the original final action. It should not serve as a post hoc substitute for the reasoning supporting that action. The final appeal decision should distinguish conclusions drawn from the original UPL record against those drawn from post-petition material.

Maryland's judicial review statute likewise recognizes that additional evidence may be appropriate where the evidence is material and there was good reason for the failure to present it in the original agency proceeding. Although that provision governs judicial review rather than the Board's internal appeal, it confirms that Maryland administrative law does not treat record closure as an inflexible end in itself in those circumstances.

[23] Maryland Prescription Drug Affordability Board, Proposed COMAR 14.01.05.10, Appeals of Upper Payment Limit Determinations, § A(2)(c), B(4), D(2), https://pdab.maryland.gov/media/1448 (last visited Nov. 9, 2026).

The regulation should distinguish among four circumstances: (1) newly discovered evidence that did not exist or could not reasonably have been obtained before the record closed; (2) evidence responding to reasoning, calculations, comparators, data, literature, or implementation assumptions first disclosed in the final UPL action or a post-petition submission; (3) material correcting an objectively verifiable record error; and (4) material changed clinical, financial, acquisition cost, supply, access, regulatory, or reimbursement circumstances. Evidence in the first three categories should be admissible upon a showing of materiality and good cause. Changed circumstances should also be cognizable through a separate manufacturer-initiated reconsideration procedure, without prejudice to their use in an appeal where relevant to the UPL's continuing operation. Any staff or consultant response should be provided promptly and in complete form to the appellant, subject only to legally required protections for confidential third-party information; included in the administrative record; and followed by a defined and adequate period in which the appellant may respond with legal argument and, where necessary to answer new factual or technical material, responsive evidence.

V. The Procedures Do Not Provide Adequate Protection Against Irreversible Harm

The regulation provides that filing an appeal does not stay the UPL unless the Board affirmatively grants a written motion, but it supplies no standard for deciding that motion.[24] A UPL can alter provider and pharmacy acquisition economics, reimbursement, contracting, stocking, distribution, and patient access before the Board completes review. Even if the appeal is later sustained, lost access, foregone dispensing, channel disruption, and distorted contracting may not be fully remediable.

The regulation should create a rebuttable presumption in favor of a stay when a timely appeal presents a substantial legal, factual, or methodological question and implementation before final disposition could impair supply continuity, provider or pharmacy acquisition, continuity of treatment, or patient access. The Board should be required to decide a stay motion on an expedited basis and issue written findings addressing likelihood of success, irreparable harm, harm to affected parties, patient access, supply continuity, and the public interest. If the Board denies a stay, it should explain how any harm caused during the appeal can practicably be remedied if the appellant ultimately prevails.

The Board also reserves oral argument to its "sole discretion" and categorically bars discovery and live testimony.[25] Although a record-based written appeal can be appropriate, oral argument should be available when the petition presents disputed technical methodology, material factual complexity, or significant access and supply consequences. The appellant should also receive the complete administrative record and an index identifying the evidence on which the Board relied.

Because the statute provides only 30 days to request an appeal, the Board should make the certified administrative record and a descriptive record index available no later than the date on

[24] Maryland Prescription Drug Affordability Board, Proposed COMAR 14.01.05.10, Appeals of Upper Payment Limit Determinations, § C(3), https://pdab.maryland.gov/media/1448 (last visited Nov. 9, 2026).
[25] Maryland Prescription Drug Affordability Board, Proposed COMAR 14.01.05.10, Appeals of Upper Payment Limit Determinations, § D(2), https://pdab.maryland.gov/media/1448 (last visited Nov. 9, 2026).

which it publishes notice of the final UPL action.[26] To preserve the full 30-day period the General Assembly provided for an aggrieved person to prepare and request an appeal, the complete record should be made available no later than the date on which the Board makes the decision that triggers the statutory appeal period. If the Board later corrects, supplements, or completes the record, the appellant should receive a corresponding extension sufficient to evaluate and address that material, including through supplemental claims, arguments, or evidence where necessary, without prejudice to any claims or rights previously asserted.

Several related procedural omissions should be corrected. The regulation should define "person aggrieved," specify the contents of the complete administrative record, establish standards governing oral argument and other discretionary decisions, and prescribe the remedies available on appeal. It also should identify the respective roles of Board counsel, Board staff, and technical consultants in preparing any response to the petition and advising the Board on the appeal and establish safeguards sufficient to ensure that personnel responsible for preparing a response to an appellant's claims do not simultaneously provide undisclosed decisional advice concerning that appeal. It should also require disclosure of material ex parte communications, and protections for confidential and third-party information in the petition, any technical evaluation report, oral argument, deliberative materials, and the public version of the final decision. The Board also should delete or substantially revise the deemed-decision provision in § C(2). The statute measures the appeal period from when the Board "makes the decision to set the limit."[27] The Proposed Appeals Regulation would instead deem that decision to occur on the tenth day after publication of notice of final action in the Maryland Register, without explaining why that date constitutes the date on which the Board made its decision.[28] An agency may prescribe procedures for exercising a statutory appeal, but it may not alter by regulation the event the General Assembly selected to trigger the appeal period. The Board therefore should not replace the statutory event with a deemed date untethered to when the Board actually "makes the decision to set the limit. At minimum, the regulation should identify the statutory authority for the selected trigger, ensure that the deemed date cannot shorten the period provided by the General Assembly, and require each notice of final action to state the exact date and time by which an appeal must be filed.

Finally, the regulation should prescribe the minimum contents of the Board's final written decision. It should identify each material claim presented; state the governing legal, evidentiary, and methodological standards; identify the evidence on which the Board relied; address material contrary evidence; resolve any request for relief; and explain the reasoned connection between the record and the result. A conclusory statement that the Board complied with applicable requirements would not permit the appellant, the public, or a reviewing court to determine whether the Board actually considered and resolved the issues presented.

The procedure for seeking additional pages is also impracticable. Proposed § B(2)(b) requires an appellant to move for leave to exceed the page limit at least ten calendar days before a

[26] Md. Code Ann., Health-Gen. § 21-2C-15(a)–(c).
[27] Md. Code Ann., Health-Gen. § 21-2C-15(a).
[28] Maryland Prescription Drug Affordability Board, Proposed COMAR 14.01.05.10, Appeals of Upper Payment Limit Determinations, § C(2), at https://pdab.maryland.gov/media/1448 (last visited Nov. 9, 2026).

petition that is itself due within 30 days.[29] That requirement consumes one third of the statutory appeal period and may require the appellant to determine the necessary scope of its petition before the Board has provided a complete record or the appellant has completed its review. The regulation should permit a page limit request to accompany the petition or, at most, require it five business days before the filing deadline. Any such motion should be decided promptly under a stated good cause standard.

VI. The Proposed Appeals Regulation Conflicts with the Board's Own Evidentiary and Reconsideration Framework

The Proposed Appeals Regulation is difficult to reconcile with the flexibility the Board has reserved for itself elsewhere. The Board's 2026 cost review framework permits staff recommendation memoranda and addenda containing recently available information that updates the dossier or dashboard. AbbVie has already explained that stakeholders must receive timely disclosure and an opportunity to respond to materially new information in such addenda. Yet the appeals rule would foreclose a manufacturer from submitting new evidence even when necessary to answer late-breaking information the Board itself added to the record.

The same inconsistency appears in COMAR 14.01.05.09 for "Reconsideration." Appeal and reconsideration serve different purposes and should not be conflated. An appeal tests whether the original UPL decision was lawful, adequately supported, and reasoned on the record before the Board. Reconsideration addresses material developments arising after that decision, such as new clinical evidence, FDA action, a supply disruption, a material change in acquisition cost, a change in federal reimbursement, or an unforeseen effect on patient access. A reconsideration mechanism therefore cannot cure an appeals rule that prevents review of the original decision. Conversely, an appeal should not be the only means by which a manufacturer may present material post-decision developments. The final regulatory architecture should preserve both mechanisms, specify the showing required for each, and ensure that seeking reconsideration does not waive or impair appeal or judicial review rights.

VII. Requested Revisions

If the Board nevertheless proceeds with emergency adoption of the Proposed Appeals Regulation, AbbVie requests that the Board at minimum make the following revisions to ensure that the statutory appeal provides meaningful, evenhanded, and judicially reviewable consideration of the challenged UPL:

- Clarify that § A(2)(a) does not exclude a statutory challenge otherwise cognizable under § A(1) merely because the alleged statutory violation also may be characterized as action exceeding the Board's authority, and permit an appellant to challenge any predicate eligibility, selection, affordability, cost review, comparator, data, or methodological determination to the extent it materially affected the UPL under appeal;

[29] Maryland Prescription Drug Affordability Board, Proposed COMAR 14.01.05.10, Appeals of Upper Payment Limit Determinations, § B(2)(b), C(1), https://pdab.maryland.gov/media/1448 (last visited Nov. 9, 2026).

- Clarify that product-specific economic and market objections are permissible, including evidence concerning actual net price, rebates and discounts, clinical value, indication-specific outcomes, therapeutic alternatives, provider and pharmacy acquisition costs, distribution and inventory requirements, supply continuity, patient access, benefit design, cost shifting, and interactions with federal pricing and reimbursement requirements;

- Permit the Board to vacate, rescind, remove, remand, or recalculate the UPL as appropriate to the defect established, rather than presuming that every successful appeal can be remedied through numerical recalculation;

- Permit material supplemental evidence upon good cause, including evidence that was previously unavailable despite reasonable diligence, responds to reasoning or material first disclosed in the Board's final action, corrects a demonstrable record error, or answers a staff or consultant submission;

- Require prompt provision to the appellant of the complete staff or consultant technical report, subject only to legally required confidentiality protections, inclusion of that report in the administrative record, and a defined and meaningful opportunity to respond to new factual, technical, methodological, or expert material, including with responsive evidence where necessary;

- Require the Board to provide the certified administrative record and a descriptive index no later than publication of the final UPL action, and extend the appeal period if the record is later corrected or supplemented;

- Establish an expedited stay procedure and a rebuttable presumption in favor of a stay when the appeal presents a substantial question and implementation could impair supply continuity, provider or pharmacy acquisition, continuity of treatment, or patient access;

- Provide oral argument when it would materially assist resolution of a significant legal, technical, factual, access, or supply issue, under a stated standard rather than unbounded discretion;

- Define "person aggrieved," the contents of the administrative record, the forms of relief available, the standards governing discretionary decisions, and the precise event that triggers the appeal period;

- Identify the respective roles of Board counsel, Board staff, technical consultants, and final decisionmakers in the appeal and establish safeguards to ensure that personnel responsible for preparing a response to an appellant's claims do not simultaneously provide undisclosed decisional advice concerning that appeal, together with appropriate disclosure of material ex parte communications;

- Require the final written decision to resolve each material claim, identify the governing standards and evidence, address material contrary evidence, and explain the basis for the result;

- Revise the page limit procedure so that a request for additional pages may accompany the petition or be filed no more than five business days before the petition deadline;

- Establish comprehensive confidentiality procedures governing third-party information, redaction disputes, technical reports, oral argument, deliberative materials, and public versions of the final decision; and

- Preserve a separate manufacturer-initiated reconsideration procedure for material post-decision changes without impairing appeal or judicial review rights.

* * * * *

Thank you for the opportunity to comment. The unusually compressed period provided for review of a regulation governing the exercise of an express statutory appeal underscores the need for ordinary notice-and-comment rulemaking. AbbVie respectfully urges the Board to withdraw COMAR 14.01.05.10 from emergency consideration and publish a revised proposed rule that provides a meaningful, evenhanded, and judicially reviewable process for challenging a UPL.

Sincerely,

Helen Fitzpatrick

Helen Kim Fitzpatrick
Vice President, State Government Affairs
On behalf of AbbVie Inc.

November 11, 2026

Via Electronic Correspondence

Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

RE: Comments on Proposed COMAR 14.01.05.10, Appeals of Upper Payment Limit Determinations

Dear Maryland Prescription Drug Affordability Board:

Aimed Alliance is a not-for-profit health policy organization that seeks to protect and enhance the rights of healthcare consumers and providers. We appreciate the Maryland Prescription Drug Affordability Board's ("PDAB" or "Board") commitment to addressing the rising cost of prescription drugs for Maryland patients. As the Board evaluates the *Emergency Regulations for COMAR 14.01.05.10: Appeals of Upper Payment Limit Determinations*, Aimed Alliance is concerned that the proposed scope and grounds for appeal restrict the statutory right to appeal an upper payment limit ("UPL") and could prevent patients aggrieved by a UPL from exercising that right.

Section 21-2C-15 of the Maryland Health-General Article governs appeals of UPL determinations and provides that "[a] person aggrieved by an upper payment limit set by the Board may request an appeal within 30 days after the Board makes the decision to set the limit." The General Assembly expressly provided a right of appeal to a "person aggrieved by an upper payment limit." It did not limit that right to claims that the Board failed to comply with a statutory requirement, regulatory criterion, or methodology. The proposed regulations, however, would substantially narrow the circumstances in which an aggrieved person could pursue an appeal.

Under the proposed *Scope and Grounds for Appeal,* an appellant aggrieved by a UPL could only request an appeal by demonstrating that the Board's final determination failed to comply with statutory requirements or regulatory criteria and methodologies. The Board would not consider constitutional challenges; claims exceeding the Board's statutory authority; generalized policy, economic, or market objections; or new clinical, financial, or economic evidence that was not submitted during the cost review and public comment period. The proposed rule on the grounds for appeal also places a higher burden on patients and providers to understand Maryland statutes, regulations, and procedures before being able to raise concerns with the Board based on lived experience and clinical evidence.

Thus, the proposed appeals framework limits the ability of patients to raise concerns about the impact of a UPL on access to treatment, in a manner inconsistent with the statute. UPLs may have downstream consequences on patient access, including through changes in formulary coverage, utilization management, or other responses to reimbursement changes. Yet, under the proposed regulations, concerns regarding impacts on patient access would not themselves provide a permissible basis for appeal unless the appellant can also demonstrate that the Board

failed to comply with a specific statutory or regulatory requirement. As a result, the proposed framework may prevent patients from meaningfully raising access concerns within the appeals process, even though the statute broadly affords a right of appeal to a person "aggrieved by" a UPL.

Although COMAR 14.01.05.09 provides the Board with authority to reconsider a UPL and expressly includes consideration of patient and stakeholder feedback, reconsideration is not a substitute for the statutory right of appeal. The reconsideration process is generally initiated at the Board's discretion, and the regulation does not expressly provide patients or other stakeholders with a right to initiate or request reconsideration of a UPL. Rather, patient and stakeholder feedback *may* be solicited only as part of the Board's reconsideration process once reconsideration is underway. By contrast, Health-General Article § 21-2C-15 expressly provides that a person aggrieved by a UPL may request an appeal and requires the Board to hear and decide on that appeal. Under the proposed appellate framework, a patient aggrieved by a UPL would be required to rely on the possibility that the Board will independently initiate reconsideration and solicit patient and stakeholder feedback, despite the General Assembly expressly providing persons aggrieved by a UPL with a right to appeal.

Accordingly, Aimed Alliance urges the Board to revise the *Scope and Grounds for Appeal* so that it reflects the language of Health-General Article § 21-2C-15 and preserves a meaningful opportunity for patients and other aggrieved persons to challenge a UPL that adversely affects them. Specifically, the Board should permit an appellant to raise concerns regarding the consequences of a UPL, including its impact on patient access, and should allow consideration of new evidence when the appellant demonstrates that such evidence was not reasonably available during the cost review and public comment period. At minimum, the Board should not adopt regulations that narrow the rights and protections expressly afforded by statute.

In conclusion, we respectfully urge the Board to revise the proposed *Scope and Grounds for Appeal* to better align with the statutory language and ensure that the appeals process remains an effective safeguard for Maryland patients. If you have any questions or wish to discuss these matters further, please contact us at obackhaus@aimedalliance.org.

Sincerely,

Olivia Backhaus
Staff Attorney

November 11, 2026

Mr. Andrew York
Executive Director
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

RE: Concerns Regarding Proposed Emergency Regulations Governing Appeals of Upper Payment Limit Determinations

Dear Mr. York:

I am writing on behalf of Color of Gastrointestinal Illnesses (COGI) to express our concerns regarding the Maryland Prescription Drug Affordability Board's (PDAB) proposed emergency regulations establishing an appeals process for Upper Payment Limit (UPL) determinations. COGI represents Black, Indigenous, and other people of color (BIPOC) affected by inflammatory bowel disease (IBD), digestive disorders, gastrointestinal cancer, and associated chronic illnesses. Our mission is to break down the barriers preventing people of color from achieving optimal health outcomes, including ensuring timely and affordable access to the treatments they need.

As we have emphasized in previous correspondence, COGI supports efforts to make prescription drugs more affordable for patients. However, we remain deeply concerned that the Board's activities could have unintended consequences for patient access to care, particularly for individuals already experiencing significant health disparities. We have repeatedly urged the Board to establish meaningful safeguards against these consequences, including a clear and enforceable process for addressing barriers to care that may arise from UPL determinations. Unfortunately, the proposed appeals regulations appear to further limit opportunities to address these concerns without establishing the protections patients need.

Under the proposed regulations, appeals of UPL determinations would be limited to demonstrating that the Board failed to comply with applicable statutory requirements or its established regulatory criteria and methodologies. The regulations would expressly exclude any new clinical, financial, or economic evidence that was not submitted during the original cost review and public comment period. While we recognize the importance of establishing a clear and orderly appeals process, we are concerned that these restrictions would leave patients without a meaningful opportunity to seek relief from its real-world consequences for access to care.
For patients living with chronic and progressive conditions, the consequences of a UPL

determination may not become apparent until after it has been implemented. Changes in formulary placement, increased prior authorization requirements, step therapy, or other utilization management restrictions could create new barriers to accessing prescribed treatments. These are not simply theoretical concerns. They reflect the challenges patients in our community already face when navigating insurance coverage and obtaining the medications that work for them.

As I shared with you during our conversation last week, I remain concerned that this plan lacks clarity and patient protections. I appreciated the opportunity to talk about these concerns with you. However, you mentioned during that call that, as the board, you work for me and the patients of MD and it doesn't feel that way. You also mentioned not having enough patient voices and asked for ways to engage, a clear indication that there has not been enough patient involvement in this process. While you also suggested that the Board's actions may not result in significant savings for patients or directly affect my care, I strongly disagree with the latter point. As I have emphasized since my testimony in 2025, these decisions have real implications for patients like me who depend on consistent access to effective treatment. Patients should not have to wait until their care is disrupted for their concerns to be taken seriously.

As an organization COGI is particularly troubled by the proposed exclusion of new clinical, financial, or economic evidence from the appeals process. If patients begin experiencing treatment disruptions, increased out-of-pocket costs, or other access barriers following implementation of a UPL, that evidence would not have been available during the original cost review. Yet, the proposed regulations provide no clear avenue for such information to inform potential corrective action, and the Board has not established a separate, enforceable process to address these unintended consequences.

We therefore urge the Board to establish a clear, accessible, and enforceable process for patients to raise concerns and seek recourse when UPL determinations adversely affect their access to care. At a minimum, the Board should clarify how patients and patient advocacy organizations can raise concerns about access barriers that emerge after implementation, how new evidence of unintended consequences will be evaluated, and what authority and procedures would allow the Board to reconsider, modify, or suspend a UPL when necessary to protect patient access.

COGI remains committed to working with the Board to advance policies that improve prescription drug affordability without compromising access to effective, individualized treatment. However, a process that prioritizes procedural compliance without providing a meaningful mechanism to address adverse patient outcomes cannot provide the

accountability and protections our community needs. We urge the Board to address these concerns before moving forward with the proposed regulations.

Thank you for your consideration.
Sincerely,

Dominique Daniels

EACH PIC COALITION

November 11, 2026

Maryland Prescription Drug Affordability
16900 Science Drive, Suite 112-114
Bowie, MD 20715

RE: Comments on COMAR 14.01.05.10 Appeals of Upper Payment Limit Determinations

Dear Members and Staff of the Maryland Prescription Drug Affordability Board:

The Ensuring Access through Collaborative Health (EACH) and Patient Inclusion Council (PIC) is a two-part coalition that unites patient organizations and allied groups (EACH), as well as patients and caregivers (PIC), to advocate for drug affordability policies that benefit patients.

We write to express serious concerns regarding the board's proposed emergency regulation establishing an appeals process for Upper Payment Limit (UPL) determinations. We strongly urge the board to defer adoption of the regulation and provide stakeholders with a meaningful opportunity for public review and comment.

Emergency Rulemaking Undermines Public Participation and Regulatory Accountability

The board's decision to advance a consequential regulation through an emergency process circumvents state-mandated public review and comment periods under Maryland's Administrative Procedure Act (see Maryland State Government Code § 10-111). In order for an independent state agency like the PDAB to use emergency rulemaking, it must first take the following steps:

(1) Formally declare the nature of the emergency that prevents it from following the APA's standard notice and comment periods,
(2) Submit the regulation to the Joint Committee on Administrative, Executive, and Legislative Review (AELR) and the Department of Legislative Services (DLS), along with a fiscal impact statement.
(3) Await AELR approval of the emergency rulemaking.

Therefore, EACH/PIC is asking if the board has already taken these actions and requesting copies of any and all the required documentation submitted to AELR and DLS.

Maryland's rulemaking requirements exist to ensure transparency, accountability, and meaningful public participation. Advancing such consequential procedures without adequate public scrutiny is a disservice to Maryland patients and undermines the principles of transparency and accountability that should guide the board's work. We urge the board to defer adoption until stakeholders have been afforded a meaningful opportunity to review and comment on the proposed procedures.

The Proposed Appeals Process Requires Additional Safeguards

Beyond our concerns with the emergency rulemaking, the proposed regulation establishes an overly restrictive appeals framework that limits the consideration of potential patient harm,

provides insufficient time to challenge UPL determinations, and lacks independent review of the board's decisions.

The proposal limits the basis of an appeal to statutory or regulatory compliance and excludes broader policy and economic considerations. These restrictions may prevent stakeholders from raising legitimate concerns about potential patient harm, including treatment disruptions, increased coverage restrictions, or other consequences that could undermine access to necessary medications.

The proposed 30-day filing deadline may not provide adequate time to identify and substantiate concerns regarding a UPL determination. Moreover, some patient impacts may not become apparent until after implementation.

Finally, the regulation assigns responsibility for deciding appeals to the same board that made the original UPL determination, with limited opportunities for additional evidence or oral argument. This raises concerns about whether stakeholders will receive a sufficiently independent and meaningful review of contested decisions.

EACH/PIC remains committed to working constructively with the board to advance policies that meaningfully improve prescription drug affordability while protecting patient access. However, the significance of this regulation demands a more deliberate and transparent process.

We strongly urge the board to postpone adoption of the emergency regulation, establish a meaningful public comment period, and reconsider the proposed appeals procedures to ensure they provide appropriate protections for patients and a fair opportunity to challenge UPL determinations.

Sincerely,



Tiffany Westrich-Robertson
tiffany@aiarthritis.org
Ensuring Access through Collaborative Health (EACH) Coalition Lead



Vanessa Lathan
vanessa@aiarthritis.org
Patient Inclusion Council (PIC) Coalition Lead

November 11, 2026

Maryland Prescription Drug Affordability Board 16900
Science Drive, Suite 112-114
Bowie, MD 20715

TO: Members of the Maryland Prescription Drug Affordability Board

I submit these written comments on behalf of the Let My Doctors Decide Action Network due to our deep concern over the potential implementation of the latest proposed Upper Payment Limits (UPLs) by Maryland's Prescription Drug Affordability Board. As a board-certified pediatrician and a pediatric rheumatologist with decades of experience caring for patients with chronic and disabling conditions, I have a personal understanding of what is at stake when access to specialized and effective therapies is disrupted. My primary focus is always ensuring the well-being of my patients, but as a result of your legislative charges, I fear that the Board's analyses and decisions cannot reflect this same mandate

The Board's increasing pathways for public engagement and addressing the challenge of prescription drug affordability is laudable. Every clinician, patient and citizen shares it. However, Upper Payment Limits (UPLs) as currently structured or when benchmarked to the Medicare's Maximum Fair Price under the Inflation Reduction Act create critical problems for all Maryland drug purchasers, not just to its governmental purchasers.

Maryland has already approved UPLs for two diabetes and weight-loss medications, Ozempic and Jardiance, and benchmarked them to the Medicare Maximum Fair Price, with implementation by state and local government purchasers starting January 2027. As we and others have commented in the past, the Board has not fully addressed how to measure and monitor the potentially predictable downstream effects of the non-medical switching that will occur when Marylanders are removed from a successful therapy. We remain hopeful this deficit will be corrected so everyone can learn from this experiment.

Dupixent and Skyrizi are now on a similar pathway. But these are fundamentally different medications used by fundamentally different patient populations with significantly different therapeutics. Dupixent and Skyrizi are biologics indicated for chronic inflammatory and immune conditions where therapeutic stability is not a convenience, it is a clinical necessity. Importantly, neither medication has an approved therapeutic equivalent, the standard for clinical care. Evaluations of the so-called "therapeutic alternatives" have shown that none of these other choices is as effective or has equivalent indications as these two. In fact, Dupixent is the **only** medication that blocks IL-4Rα, so there is no equivalent. While there may be decreased direct drug payments for these two critical medications, there is significant risk that total medical costs will increase due to the lack of therapeutic control of the underlying chronic inflammatory conditions should stable patients be taken off their medications.

The Medicare Maximum Fair Price was designed around a Medicare population; applying it as a universal ceiling across the entire population covered by Maryland's governmental entities is without precedence and lacks predictive data. Altering treatments by changing complex biologic medications used heavily in

pediatric and non-elderly populations raises serious concerns regarding the generalizability of that the benchmark model. Changing successful therapies for economic reasons in these patient populations carries tangible clinical risks. The loss of disease control, resultant disease flares, tissue injury/damage and in pediatric patients, irreversible developmental consequences are predictable. A single operation due a flare of Crohn's Disease as a result of a non-medical switch can cost more than a year's cost of Skyrizi. Any and all affordability determinations must grapple with these predictable sequelae.

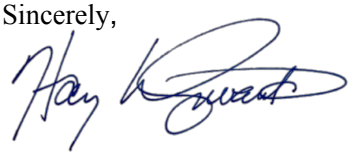
The reports of potential 2027 legislation that would automatically adopt Medicare's Maximum Fair Price as the UPL for medications in Maryland is deeply troubling. My understanding is that under this proposal, UPLs would be automatically applied universally, without any deliberative review or opportunity for clinical and patient input. While "efficient", this would also entirely bypass Maryland's unique cost review process, thereby depriving patients and clinicians the opportunity to meaningfully provide input. This approach has been considered and rejected elsewhere: governors in both Virginia and Nevada vetoed similar proposals, recognizing the significant risks that automatic, across-the-board price mechanisms create for a limited number of medications. A recent Milliman[1] evaluation shows that so far the MFP process has only generated 1% savings. While rubber-stamping Medicare price benchmarks for complex and unique medications like Dupixent and Skyrizi may lower governmental drug spending, its ability to significantly lower Maryland's health care costs is low. More likely, it will restrict access for the Marylanders who need these therapies most. We strongly urge the Board to oppose any effort to circumvent its own review public review and assessment process and make clear to the legislature that any meaningful and successful affordability reform must include, not exclude, the voices of patients and clinicians.

While we all wish to reduce our health care costs, addressing a limited number of expensive medications by itself cannot accomplish this overarching goal. Affordability is very much in the eye of the beholder. For Maryland's governmental entities, it is how to lower a specific line item in the budget. A Maryland patient focuses on whether their medication is on the formulary and can they afford the copay or coinsurance. Maryland's clinicians care whether they are able to prescribe the optimal medication for that patient's unique clinical circumstances. Addressing a single component of the available therapeutic interventions may sound great, but given the innate complexity of health care and the individuality of patient responses, it cannot achieve the true and yet unstated goal of the entire enterprise.

As an organization comprised of patient and clinician organizations, we look forward to working with you to achieve a more cost-effective health care system that also addresses the clinical needs of its "customers' - AKA patients. Since each of us is also a patient, we must work together if we wish to successfully reach that goal.

Thank you for your attention to this critical issue.

Sincerely,



Harry L. Gewanter, MD, FAAP, MACR
Board Member, Let My Doctors Decide Action Network

---

[1] https://media.milliman.com/v1/media/edge/images/millimaninc5660-milliman6442-prod27d5-0001/media/Milliman/PDFs/2026-Articles/10-20-26_Milliman-Medicare-Market-Intelligence-Part-D-trend-insights-H1-2026.pdf

November 11, 2026

Chair Cullison and Members of the Board
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715
Submitted via comments.pdab@maryland.gov

Re: November 2026 Board Comments: Emergency Regulation COMAR 14.01.05.10, Appeals of Upper Payment Limit Determinations

Dear Chair Cullison and Members of the Board:

Patients Rising is a national nonprofit that represents patients living with chronic and life-threatening conditions, including many Marylanders. We write to comment on the emergency regulation at COMAR 14.01.05.10, which sets the scope, form, and procedure for appeals of upper payment limit determinations under Health-General Article § 21-2C-15.

We begin from a shared interest. Maryland's upper payment limits are designed to lower what the State and local governments pay for prescription drugs, and we expect the State shares our view that those savings should not come at the cost of patients' access to their treatments. We do not object to an orderly appeals process with clear filing rules and a defined timeline. Our concern is narrower and more practical: as written, the regulation leaves no route for the one kind of evidence patients are most likely to have, which is evidence that a limit is affecting their ability to get and stay on treatment.

The regulation limits an appeal to showing that a determination failed to follow the statute or the Board's own criteria and methodologies. Section A(2) then excludes generalized policy, economic, or market objections, along with any new clinical, financial, or economic data that was not submitted during the cost review and public comment period. Filing an appeal does not delay a limit unless the Board grants a stay, and appeals are decided on the written record with no live testimony.

Taken together, these provisions create a timing gap. The harms patients worry about most can only appear after a limit takes effect: a pharmacy or infusion site that stops stocking a treatment, a plan that changes how a medicine is covered, or a delay while a patient is moved to a different therapy. That evidence cannot exist during the cost review, so under Section A(2)(c)

it can never support an appeal. The Board's statute allows it to reconsider a limit when a drug becomes a current shortage, but many access problems fall well short of a formal shortage and would go unaddressed.

The statute allows any person aggrieved by an upper payment limit to request an appeal, and the Board's own definitions in COMAR 14.01.01.01 describe an aggrieved person broadly, as anyone who has suffered or is exposed to potential loss or injury to a legitimate interest. Because Maryland's upper payment limits apply to drugs purchased or paid for by state and local governments, including through county, municipal, and other public employee health plans, the patients most directly affected are the Marylanders those plans and facilities serve. They plainly have a legitimate interest in whether their treatment remains available.

The emergency regulation does not say whether patients may file, and its requirements, including a formal titled petition of up to 20 pages, strict formatting rules, and exhibits limited to the administrative record, are written for parties with legal counsel. A patient whose pharmacy stops filling a prescription is unlikely to clear those hurdles within 30 days.

We respectfully ask the Board to make four changes before this regulation is finalized.

1. **Create a post-implementation patient access review.** The monitoring regulation also on the November 16 agenda, COMAR 14.01.06.04, asks governmental entities to report spending, net cost, formulary placement, and units once a year. It collects nothing from patients and is not tied to any path for reconsidering a limit. We ask the Board to add a public channel for patients, caregivers, clinicians, and pharmacies to report access problems after a limit takes effect, and to review those reports alongside the annual data with a clear path to reconsider or adjust the limit. Evidence of access harm that arises after the effective date should be expressly excepted from the bar in Section A(2)(c).
2. **Confirm that patients may appeal, and give them a usable path.** State in the final regulation that patients, caregivers, and organizations acting on their behalf may file as aggrieved persons, and provide plain-language instructions and a simplified form for patient filers.
3. **Adopt the permanent rule through standard notice-and-comment rulemaking.** A rule that defines the only check on upper payment limit decisions deserves a full comment period, and the comments received now should be addressed in the permanent version.
4. **Strengthen patient input during the cost review.** Because this regulation makes the cost review record decisive, patients need a real chance to contribute to it. We thank the Board

for publishing the dossier for one of the two biologics selected for cost review this summer, and we ask that the Board make this standard practice, with a defined comment period on each dossier before any preliminary affordability determination.

These steps would not weaken the Board's authority or slow its work. They would give the Board better information and show Marylanders that a limit set in their name will be watched for its effect on the patients who depend on these treatments. We would be glad to help connect the Board with Maryland patients and clinicians.

Yours in Advocacy,

Terry Wilcox

Terry Wilcox
Chief Patient Advocate
Patients Rising

November 11, 2026

Members of the Board
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715
By email: comments.pdab@maryland.gov

Re: Agenda Item VI, Final Action on Amendments to COMAR 14.01.04 and 14.01.01.05
(Board meeting of November 16, 2026)

Dear Members of the Board:

On October 5, 2026, I commented on the proposed amendments to COMAR 14.01.04 and 14.01.01.05. [1] My main point was that Maryland law directs the Board, to the extent practicable, to consider "the relative financial impacts to health, medical, or social services costs as can be quantified and compared to baseline effects of existing therapeutic alternatives." [2] The proposal did not say how that evidence informs a finding that a drug does not provide sufficient value.

As I read the draft of COMAR 14.01.04 posted for this meeting, it corrects the cross-reference in Regulation .05C(1)(e)(i) that I flagged. Regulation .01B(2) would still say nothing about how evidence on other health care costs informs the value finding. Regulation .05G(3)(a) would no longer require the preliminary determination report to summarize the information considered, although the final report would still have to do so. [3] The text of COMAR 14.01.01.05 posted for this meeting is a July 22 draft, so I cannot tell whether that regulation has changed. [4]

I am a health economist and the founder, President, and CEO of RxEconomics LLC. My work spans pharmacy benefit design, medication adherence, and medical cost offsets from prescription drug use.

My research clients include pharmaceutical and life-sciences companies. I prepared this submission independently; no client funded, requested, commissioned, or reviewed it.

I ask the Board to do four things:

1. **Before the vote, explain which of my October 5 recommendations the Board accepts and why it declines the others.** Commenters and future reviews would then know how the statutory factor on other health care costs relates to the value finding.

2. **In each cost review report, state what is known about the drug's effect on other health care spending.** The draft keeps that factor in Regulation .05C(1)(e)(ii), which supports beginning this reporting practice now.

3. **Keep the summary of the information considered in the preliminary determination report.** The public comments on that report, so it is where an account of the evidence is most useful.

4. **Publish guidance on how staff will review this evidence, and allow at least 30 days for technical requests.** A documented analysis takes longer to prepare than a routine comment, and no longer period required by law should be shortened.

For the second request, each report would name the therapeutic alternatives, the population, the time horizon, and who pays for each estimate. Drug costs would be compared as system net cost, which counts payor and patient

payments together, per equivalent course or period of therapy. Each dollar would be counted once, and social services costs, which the statute names, would be reported separately. The report would then describe four features of the evidence on other spending:

- its direction (favorable to the drug, meaning lower costs; adverse to the drug, meaning higher costs; negligible with sufficiently precise support; or indeterminate);
- whether the amount is large enough to matter for the affected budget;
- how certain it is; and
- whether it applies to Marylanders.

The same standards would apply whatever the evidence shows and whoever submits it. Where evidence is unavailable or inconclusive, the report would say so rather than treat the gap as evidence of no effect. The Board would weigh the evidence qualitatively, without a presumption, formula, fixed weight, or dollar-for-dollar adjustment, and explain whether and how it informed the determination.

My October 5 comment sets out this two-stage review, suggested regulatory text, and a proposal for a short methods form for technical submissions. I would be glad to discuss them with Board staff.

Respectfully submitted,

M. Christopher Roebuck, PhD, MBA
President & CEO
RxEconomics LLC
Miami, Florida
www.rxeconomics.com
mcr@rxeconomics.com

1. RxEconomics LLC. Comment on Proposed Action on Regulations, COMAR 14.01.04 Cost Review Study Process [26-133-P] and COMAR 14.01.01.05 Public Comment Procedures [26-132-P], 53:18 Md. R. 905 (September 4, 2026). Submitted October 5, 2026.

2. Health-General Article, §21-2C-09(b)(2)(ix), Annotated Code of Maryland.

3. Maryland Prescription Drug Affordability Board. Amendments to COMAR 14.01.04 Cost Review Study Process, clean and redlined, DRAFT 2026.11.06.v.1.2, posted for the November 16, 2026 meeting. https://pdab.maryland.gov/media/1449 and https://pdab.maryland.gov/media/1450

4. Maryland Prescription Drug Affordability Board. Amendments to COMAR 14.01.01.05, General Provisions, Public Comment Procedures, DRAFT 2026.07.22.1400.v1.1, posted for the November 16, 2026 meeting. https://pdab.maryland.gov/media/1414