MedChi
The Maryland State Medical Society

Your Advocate.
Your Resource.
Your Profession.

June 23, 2024

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

Re: Letter of Information - Process improvements

Dear Director York:

On behalf of MedChi, The Maryland State Medical Society, I am providing input on the first six drugs that will undergo the cost review process by the Maryland Prescription Drug Affordability Board (the "PDAB" or the "Board"))MedChi does not have an official position on upper payment limits or other actions under consideration by the PDAB regarding the affordability of prescription drugs. However, we offer the following suggestions to ensure a thorough and inclusive evaluation process.

Recommendations for Process Development

1. Inclusion of Physician and Patient Input

The evaluation process for any drug under consideration must include input from both physicians and patients. MedChi is ready to assist the Board in identifying the appropriate specialty physicians relevant to the specific drugs being considered. This will ensure that clinical perspectives are adequately represented, and that patient experiences and needs are thoroughly understood.

2. Stakeholder Engagement

Engage a diverse group of stakeholders throughout the evaluation process. This includes, but is not limited to:

- Patients who are directly affected by the drug in question.
- Physicians with expertise in the relevant medical specialties.
- Pharmacists, insurers, and pharmaceutical manufacturers.

Regular public meetings, forums, and surveys can facilitate meaningful stakeholder engagement and ensure transparency.

3. Utilize Data-Driven Analysis

Implement a robust data-driven approach to assess the cost-effectiveness of the drugs under consideration. Key elements of this approach should include:

- Comparative effectiveness research to understand how the drug performs relative to alternative treatments.
- Health economics studies to evaluate the broader financial impact on the healthcare system.
- Real-world evidence to provide insights into the practical implications of drug pricing on patient health outcomes and overall healthcare costs.

4. Consider Patient Impact

A critical aspect of the evaluation process should be the consideration of patient impact. Affordability measures should not compromise access to essential medications. The Board should evaluate the potential consequences of pricing decisions on:

- Patient adherence to prescribed treatments.
- Potential impact on the availability of or access to a prescribed treatment.
- Health outcomes, including both short-term and long-term effects.
- Quality of life for patients who rely on these medications.

Conclusion

MedChi is committed to supporting the Board in its mission to make prescription drugs more affordable while ensuring access to necessary treatments. We respectfully request that the process for evaluating the first six drugs, as well as any future drugs under consideration, includes comprehensive input from physicians and patients. MedChi is willing and prepared to assist the Board in identifying the appropriate medical specialists for consultation.

Thank you for considering our recommendations. We look forward to working collaboratively to develop a fair and effective process for evaluating prescription drug prices in Maryland.

Sincerely,

Gene Ransom, III
CEO, Maryland State Medical Society (MedChi)
1211 Cathedral St.
Baltimore, MD 21201

Maryland

Comments PDAB -PDAB- <comments.pdab@maryland.gov>

Board Selected Drugs (Dupixent-dupilumab)

1 message

Manav Singla [redacted] > Sat, Jul 6, 2024 at 5:58 PM
To: "comments.pdab@maryland.gov" <comments.pdab@maryland.gov>

TO: Maryland Prescription Drug Affordability Board

REGARDING:
Dupixent (dupilumab)
Drug Brand Name: Dupixent
Active Moiety or Active Ingredient: dupilumab
Application Number: BLA761055

Dear Members of the Maryland Prescription Drug Affordability Board,

I am writing to provide my input regarding the cost review study process for Dupixent. As a clinician, I understand the financial burden this medication imposes on the healthcare system. However, it is important to consider the overall value Dupixent offers compared to other proposed alternatives.

In my clinical practice, I have utilized Dupixent for its approved indications, including asthma, nasal polyps, atopic dermatitis, and eosinophilic esophagitis. For many of my patients, Dupixent has been life-transforming. Specifically, I have seen patients with eosinophilic esophagitis who were afraid to eat and had profoundly limited diets now thriving, eating normally, and living normalized lives.

From an asthma management perspective, I have experience with all available biologics and continue to use them as appropriate. However, many patients achieve better outcomes with Dupixent compared to their previous therapies. Its efficacy in treating multiple conditions simultaneously, such as atopic dermatitis alongside asthma and nasal polyps, sets it apart from other alternatives. I have treated both children and adults with asthma who have life-threatening and limiting disease, unable to participate in sports and exert themselves as any normal person, transformed into sport-playing people living normal lives, instead of being short of breath constantly with frequent emergency room and urgent care of visits, in addition to miss school and work days.

I am acutely aware of the high costs associated with these medications, which is a source of frustration for me and many others. I strongly advocate for government intervention to impose limits on the costs of these drugs at the federal level, as the current prices are unconscionably expensive.

In summary, Dupixent has transformed the lives of many of my patients with various conditions. These patients, often suffering from multiple conditions, find immense relief with Dupixent after experiencing limited benefits from alternative agents. Moreover, for eosinophilic esophagitis, there are no other equally effective biologics available on the market.

Thank you for considering my perspective. I urge the board to recognize the unique and comprehensive benefits of Dupixent in their cost review process.

[redacted]

Sincerely,

Manav Singla, M.D., F.A.A.P., F.A.A.A.A.I., F.A.C.A.A.I.
Allergy Asthma Specialists of Maryland
[redacted]

*Diplomate, American Board of Allergy & Immunology
*Adjunct Assistant Professor, Department of Pediatrics,
University of Maryland School of Medicine
*Assistant Professor of Clinical Pediatrics, Clinician Educator Track,
Georgetown University School of Medicine

[redacted]

PhRMA
RESEARCH • PROGRESS • HOPE

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By Electronic Submission

July 16, 2024
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715
comments.pdab@maryland.gov

RE: Board Selected Drugs

Dear Members of the Maryland Prescription Drug Affordability Board ("Board" or "PDAB"):

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the opportunity to comment on the list of selected drugs from the May 20, 2024, PDAB meeting and cost review study process (collectively, the "Selected Drug List").[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives.

PhRMA recognizes the Board's ongoing work to implement and carry out its responsibilities under the Maryland PDAB Statute ("PDAB Statute").[2] PhRMA continues to have concerns, however, about the Board's implementation of the PDAB Statute, including with respect to the Board's process in selecting the six therapies on the Selected Drug List. As detailed in our prior comment letters, these concerns include a lack of adequate transparency and sufficiently clear and meaningful standards, including with respect to the Board's selection process, determination of therapeutic alternatives, and the Sample Dashboard data relied upon by the Board in its drug selection and cost review processes.[3]

[1] *See* Board, Board Selected Drugs and any applicable information, https://pdab.maryland.gov/Pages/board-selected-da-info.aspx (last visited June 24, 2024).
[2] See Md. Code Ann., Health-Gen. § 21-2C-01-16 et seq.
[3] *See* Letter from PhRMA to Board Regarding Maryland Prescription Drug Affordability Board: Cost Review Study Process (May 10, 2024); Letter from PhRMA to Board Regarding Maryland Prescription Drug Affordability Board: Cost Review Study Process (Apr. 24, 2024); Letter from PhRMA to Board Regarding Rules of Construction and Open Meetings Proposed Rule; Confidential, Trade-Secret, and Proprietary Information; Public Comment Procedures; and Cost Study Review Process (Oct. 23, 2023); Letter from PhRMA to Board Regarding Definitions; Rules of Construction and Open Meetings; Confidential, Trade- Secret, and Proprietary Information; and Cost Review Study Process (June 30, 2023); Letter from PhRMA to Board Regarding Confidential, Trade-Secret, and Proprietary Information Proposed Rule (May 4, 2023); Letter from PhRMA to Board Regarding Rules of Construction and Open Meetings Proposed Rule (May 4, 2023); Letter from PhRMA to Board Regarding General Provisions; Fee Assessment, Exemption, Waiver, and Collection Amendments; and Cost Review Process (May 1, 2023). PhRMA incorporates by reference all comments, concerns, and objections that it has previously raised regarding the Board's implementation of the PDAB Statute.

I. Transparency

A. Comment Process

PhRMA is concerned that the process leading to the creation of the Selected Drug List has not provided manufacturers and other stakeholders with adequate transparency regarding the data and other considerations that informed the Board's decision-making. This lack of transparency has inhibited the ability of stakeholders to fully and meaningfully comment on the Board's proposals and decisions, and runs contrary to the Maryland Administrative Procedure Act's ("APA's") "purpose[,] ... [which is] to provide transparency and procedural regularity."[4] A comment process is only meaningful to the extent proposals include adequate details and technical information to allow stakeholders to provide substantive feedback on the agency's proposals. Administrative law recognizes both the centrality of the comment process to an agency's activities and the necessity of providing members of the public with the information they need to meaningfully comment.[5]

With respect to the current solicitation for comment on the Selected Drug List, PhRMA is also concerned that the Board has solicited comments on its Selected Drug List, but the only information it has provided to inform the comment process is the name, active moiety or ingredient, application number, and list of National Drug Codes (NDCs) for the six drugs that the Board has selected for cost reviews. This is not sufficient information for members of the public to provide full and meaningful comments. Among other things, the Board has provided no information about the specific decision-making that led to the Board's selections.[6] Accordingly, we respectfully ask that the Board re-issue its comment solicitation with more information regarding the decision-making leading to the Board's selection decisions.[7]

Compounding the issues regarding lack of transparency, the Board has not publicly posted recordings of its meetings and is the only Prescription Drug Affordability Board in the United States that has not done so.[8] This means that stakeholders who were unable to attend the Board's meetings were deprived of critical information regarding the Board's decision-making. We recognize that the Board has posted a recording of its May 20th meeting, and our understanding is that the Board intends to also record and

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[4] *Physicians for Soc. Resp. v. Hogan*, No. 2552, Sept. term, 2015, 2019 WL 6002122, at *11 (Md. Ct. Spec. App. Nov. 13, 2019); *see also* Tomlinson, *The Maryland Administrative Procedure Act: Forty Years Old in 1997*, 56 Md. L.Rev. at 198 ("Maryland's 1957 APA, like its federal and state counterparts, embodied the values of transparency, procedural regularity, and judicial review.").

[5] See 75 Op. Atty Gen. Md. at 43 (Jan. 23, 1990) ("[T]he heart of an APA's rulemaking requirements is its public notice and comment procedures. Designed to assure fairness and mature consideration of rules of general application, these significant provisions serve the important twin functions of safeguarding public rights and educating the administrative lawmakers."), *available at* https://www.marylandattorneygeneral.gov/Opinions%20Documents/Volume75_1990.pdf.

[6] The Board has previously published a slide deck summarizing input from the Stakeholder Council – but this does not reflect the *Board*'s ultimate decision-making. *See* Cost Review Study Process: Input from the Stakeholder Council (May 20, 2024), *available at* https://pdab.maryland.gov/Documents/comments/5.20.2024%20Cost%20Review%20Presentation%20PDASC%20feedback%20%2811%29.pdf.

[7] We note, however, that information held by the Board is subject to confidentiality and trade secret protections required by federal and state law, and ask that the information disclosed in the Board's solicitations be limited accordingly. *See* Md. Code Ann., Health-Gen. § 21-2C-10; *see also, e.g.*, See Letter from PhRMA to Board 4 (June 30, 2023) (describing confidentiality requirements).

[8] As PhRMA has previously explained, the Board's meeting summaries that the Board releases do not provide sufficient detail to give members of the public enough information to fully understand the Board's proceedings or the basis of the decisions made at meetings. *See* Letter from PhRMA to Board Regarding Maryland Prescription Drug Affordability Board: Cost Review Study Process (Apr. 24, 2024).

post its July 22 hearing on YouTube.[9] We respectfully ask that the Board clarify that it will post *all* of its past and future public meetings, and that such recordings be promptly posted (or linked) on the Board's website shortly after each meeting.

PhRMA acknowledges that the Board also intends to post separate Requests for Information ("RFIs") on its selected drugs.[10] PhRMA notes that, under the Board's regulations, the timeline for responding to the RFIs should begin on the date that the RFIs are publicly posted.[11] As such, there should be separate RFI deadlines that are distinct from the comment period on the Selected Drug List. PhRMA also asks that the Board grant good faith requests for an extension of the reporting deadline, and that the Board respond to all extension requests promptly to give stakeholders greater certainty about their RFI deadlines.[12]

B. Other Concerns

PhRMA continues to have other concerns about the Board's approach to implementing the PDAB Statute, including with respect to the lack of transparency on the data and considerations that informed the Board's decision-making in establishing its Selected Drug List. As explained in more detail in our May 2024 comment letter and other prior comments, examples of lack of transparency with respect to the Board's decision-making include as follows:[13]

- **Sample Dashboard**. PhRMA has ongoing concerns about the lack of transparency with respect to data elements and sources used to compile the Board's Sample Dashboard. The data in the dashboard continues to have multiple apparent limitations, such as not stating where cost information for each drug product was drawn from, including different years' pricing data from a mix of payers. Because of these limitations, stakeholders are unable to comprehensively review and determine whether the Board relied upon erroneous information when making decisions based on information contained in the dashboard. Further, PhRMA reiterates its request that the Board clarify if there is a comprehensive dashboard for all drugs determined to be eligible for cost reviews, and—to the extent such dashboard exists—that the Board make the full dashboard available to the public, subject to confidentiality and trade secret protections required by federal and state law.[14] To the extent no such comprehensive dashboard exists, PhRMA asks that the Board clarify exactly how it reached its selection decisions.

  Before the Board proceeds any further in its cost review process, we ask that it clarify the basis for how it selected the therapies included on its Selected Drug List, including how the Board used the information in its dashboard, and provide stakeholders with an additional opportunity to comment following that clarification. This would provide manufacturers an opportunity to provide meaningful input on any errors or other issues with the information in the dashboard related to their medicines.

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[9] *See* PDA Committee Session (May 20, 2024), *available at* https://www.youtube.com/watch?v=GaAz6mlOQds.
[10] PhRMA will provide separate comment on the Board's request for public input on the RFI forms. *See* "Board Selected Drugs and any applicable information," https://pdab.maryland.gov/Pages/board-selected-da-info.aspx.
[11] *See* Md. Code Regs. § 14.01.04.04(A)(6).
[12] *See id.* § 14.01.04.04(A)(7).
[13] *See generally* Letter from PhRMA to Board Regarding Maryland Prescription Drug Affordability Board: Cost Review Study Process 1–4 (May 10, 2024).
[14] *See* Md. Code Ann., Health-Gen. § 21-2C-10; *see also, e.g.*, See Letter from PhRMA to Board 4 (June 30, 2023) (describing confidentiality requirements).

- **Data Review Process**. PhRMA also continues to have concerns about the data review process that informed the Board's selection of eligible drugs and that will inform the Board's cost reviews. Given that the Board's selection and cost review processes require the compilation of voluminous data from diverse sources, there is an inherent risk that some data may be inaccurate, incomplete, or misleading. PhRMA therefore requests that the Board provide manufacturers an opportunity to review, evaluate, confirm and meet with the Board about the data it is relying on before the Board renders any final decisions on the basis of such data.[15] We ask that the Board provide this opportunity to manufacturers before conducting any cost reviews for any drug on the Selected Drug List.[16]

- **Cost Review Timeline**. The Board has indicated that it expects to post RFIs for the selected drugs "at a later date," but it has not provided an anticipated timeline for this process. PhRMA asks that the Board provide such timeline, as well as a detailed timeline regarding other anticipated components of the cost review process.[17]

- **Use of Active Moiety or Active Ingredient Information in Selecting Drugs.** PhRMA continues to have concerns with the lack of clarity regarding how the Board intends to group drugs together by active moiety for the purpose of cost reviews.[18] PhRMA requests that the Board clarify whether the term "unapproved generic" refers to drugs that meet the definition under Health-General Article, §21-2C-01(f)(3)..

- **Process for Identifying Therapeutic Alternatives**. PhRMA continues to have concerns with the Board's consideration of therapeutic alternatives in its drug selection and cost review processes, including how the Board determines which drugs are a "therapeutic alternative" for drugs under consideration. Further, the Board's broad regulatory definition for "therapeutic alternative" could lead to certain therapies being identified as therapeutic alternatives that are not appropriate for all patients using the therapy.[19] PhRMA reiterates its recommendation that, in order to guide the Board's consideration of therapeutic alternatives in a manner that is consistent with clinical evidence, the Board should adopt a standard of "clinical appropriateness" for its identification of therapeutic alternatives for a selected drug.[20] Specifically, when identifying the therapeutic alternatives for a drug subject to cost review, we ask that the Board do the following:

    - Engage meaningfully with the manufacturer on potential therapeutic alternative(s);

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[15] Consistent with its prior comment letters, PhRMA also asks that such mechanism protect confidential, proprietary, and trade secret information as required by federal and state law. *See* Letter from PhRMA to Board Regarding Maryland Prescription Drug Affordability Board: Cost Review Study Process 3 (May 10, 2024).

[16] We note that the Oregon PDAB recently decided to pause any further action on its ongoing affordability review process until 2025, while it reevaluates its data and methodologies for affordability reviews. *See* Oregon PDAB, June 26 meeting video recording, https://youtu.be/9z2VkDiR_XA?si=TPaatzjDdOAXgUEJ&t=3845 (time code 1:04:05).

[17] *See* Board, "Board Selected Drugs and any applicable information," https://pdab.maryland.gov/Pages/board-selected-da-info.aspx (last visited June 24, 2024).

[18] *See, e.g.*, Letter from PhRMA to Board Regarding General Provisions; Fee Assessment, Exemption, Waiver, and Collection Amendments; and Cost Review Process 9–10 (May 1, 2023).

[19] *See* Md. Code Regs. 14.01.01.01(B)(61) (defining "[t]herapeutic alternative" as "a drug product that has the same or similar indications for use as a particular drug but is not a therapeutic equivalent to that drug").

[20] *See generally* Letter from PhRMA to Board Regarding Maryland Prescription Drug Affordability Board: Cost Review Study Process 1 (May 10, 2024).

- Look to clinician guidance, including physician-driven evidence-based clinical guidelines, as a resource; and

- Reference other widely recognized, scientifically rigorous, evidence-driven resources to identify therapeutic alternative(s).

Further, we note that the Board has provided very little information to date regarding its process for determining or considering therapeutic alternatives. The Board has provided no specific details about how information about therapeutic alternatives will be considered in the drug selection and cost review processes, or how the Board will compare selected drugs to their listed therapeutic alternatives, including non-equivalent therapies. The Board also has not provided manufacturers an opportunity to comment on the Board's most recently added therapeutic alternatives from its May meeting, nor has it publicly posted its updated listing of therapeutic alternatives to its website following that meeting. The continued lack of clarity in this area impedes the ability of stakeholders to understand and meaningfully comment on the Board's therapeutic alternative decisions. In addition to providing an updated list of the therapeutic alternatives it has determined for each drug on the Selected Drug List, we ask that the Board provide manufacturers an opportunity to review, provide feedback, and meet with the Board about the data it is relying on to select therapeutic alternatives and the therapeutic alternatives it has identified, prior to considering any information on therapeutic alternatives within a cost review.

II. Clear, Specific, and Meaningful Standards

PhRMA reiterates its concerns about the lack of sufficiently clear, specific, and meaningful standards provided by the Board to govern its drug selection and cost review processes, as are necessary to avoid arbitrary and inconsistent decision-making.[21] The procedures provided by the Board lack detailed and concrete standards to guide the Board to reliably and consistently apply its criteria when analyzing drugs under consideration for either selection or cost reviews. PhRMA highlights the following as examples of its concerns regarding the lack of clear standards, with an emphasis on standards bearing on the Selected Drug List:

- **Selection Standards**. The Board has not provided clarity into the specific data and standards that it is applying as part of its selection process. Instead, the Board has only provided a summary of the metrics involved in its decision-making, without meaningful detail into how various factors have been weighted or balanced or adequate information about each of the statutory and regulatory factors considered for each specific drug. As a consequence, stakeholders have not been given clarity into how the Board makes its selection decisions, and the Board has not created a sufficient record of the reasoning supporting its decision-making. This approach raises concerns under the Maryland APA, which requires agencies to provide a "reasoned analysis" that shows the "basis of the agency's action" and adequate "factual findings ... to support the agency's conclusions."[22] Accordingly, PhRMA asks the Board to revise its drug selection processes and standards to require a consistent and transparent examination of each criteria enumerated in the

[21] *See, e.g.*, Letter from PhRMA to Board 4 (April 24, 2024); Letter from PhRMA to Board 2 (June 30, 2023); Letter from PhRMA to Board 2–3 (May 1, 2023).
[22] *Elbert v. Charles Cnty. Plan. Comm'n*, 259 Md. App. 499, 509 (2023); *see also, e.g.*, *Mortimer v. Howard Research and Development Corp.*, 83 Md. App. 432, 442 (1990).

PDAB Statute and the Board's regulations, as well a breakdown of which criteria the Board relied on in its decision-making regarding a specific drug.

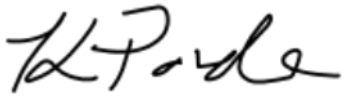
- **Use of Public Input**. PhRMA reiterates its request that the Board adopt additional procedures and standards regarding how it will consider public comment in each step throughout the drug selection and cost review processes, including in the Board's deliberations on therapeutic alternatives.[23] The PDAB statute and the Board's regulations require public notice and opportunity to comment on each meeting and pending decision of the Board.[24] In order to effectively implement these requirements, we ask that the Board provide additional transparency regarding how public comments are actually being considered and how they impact the Board's decisions – while protecting the confidentiality of any confidential, proprietary, or trade secret information received by the Board.

  Greater transparency will give the public and stakeholders an understanding of how their concerns are being considered by the Board and how they are weighed in the Board's decision-making. PhRMA also encourages the Board to create more opportunities for input from clinical experts and patients. These stakeholders are critical voices that should be duly considered in the selection and cost review processes, and PhRMA is concerned that patient communities and relevant clinical experts have not been adequately engaged thus far through the Board's current processes and solicitations for public input.

* * *

We thank you again for this opportunity to provide comments and feedback on the Board's drug selection and cost review processes and for your consideration of our concerns and requests for clarifications. Although PhRMA has concerns with these processes, we are ready to be a constructive partner in this dialogue. If there is additional information or technical assistance that we can provide as the cost review process is further developed, please contact Kristin Parde at Kparde@phrma.org.

Sincerely,



Kristin Parde
Deputy Vice President, State Policy

Merlin Brittenham
Assistant General Counsel, Law

[23] Letter from PhRMA to Board 4 (April 24, 2024); Letter from PhRMA to Board 2 (June 30, 2023); Letter from PhRMA to Board 2–3 (May 10, 2024).
[24] See Md. Code Ann., Health-Gen. § 21-2C-03 (e)(2), (4)–(5); Md. Code Regs. 14.01.01.03(B), 14.01.01.05; 14.01.04.03(D)(4).

Public Comments
Maryland Prescription Drug Affordability Board
Re: July 2024 Board Meeting Comments

Sent Via Email comments.pdab@maryland.gov

Dear Prescription Drug Affordability Board and Staff,

Boehringer Ingelheim wants to take the opportunity to provide our perspective in advance of the July PDAB Board Meeting, as we feel strongly that there are key areas of concern that could negatively impact patients. The two key areas we would like to focus on are Patient Focus and Value-Based Care.

Founded in 1885 and independently owned ever since, Boehringer Ingelheim is a research-driven company with 53,500 employees around the world dedicated to the discovery and development of breakthrough therapies that transform lives, today and for generations to come. As a leading research-driven biopharmaceutical company, we create value through innovation in areas of high unmet medical need focused on breakthrough therapies and first-in-class innovations for the patients we serve.

Once again, we appreciate this opportunity to share feedback.

Patient Focus

As we outlined in our comment letter to the board on April 19, 2024, imposing an upper price limit (UPL) may have serious unintended consequences on patients. This topic needs to be fully assessed to ensure patients receive appropriate access to care. We want to emphasize that other stakeholders share this concern, underscoring the widespread apprehension about the potential negative impact of an UPL.

The Alliance for Patient Access (AFPA) Fast Fact Sheet (February 2024) summarizes the problem:

> *"Prescription Drug Affordability boards are not designed to save patients money or improve access to health care. In fact, they could actually: Increase patients' costs… prevent patients from reaching their deductible … [and] reduce patient choices.*[1]

Specifically, implementing an UPL is unlikely to help patients at the pharmacy counter because manufacturers do not set the price the patients pay at the pharmacy counter. The insurer's plan design sets the price a patient pays at the pharmacy counter. The plan design uses tiering, co-pay,

[1] AFPA-PDABFastFacts-Feb2024.pdf (allianceforpatientaccess.org)

and/or co-insurance to set the price. The bottom line is that manufacturers are not involved in that process, and they are not in control of the price paid at the pharmacy counter.

Since we are not in control of the price at the pharmacy counter, Boehringer offers patients co-pay cards in an effort to make the pharmacy counter price more affordable. Co-pay cards are basically coupons that patients can present at the pharmacy counter to lower the cost of their prescriptions at the point of sale. While some may claim we should eliminate co-pay cards and simply lower prices, that argument misses the point. The price set by manufacturers has little to do with the price set by insurers under their plan design. (This reality ties into the issue with rebates that we referred to in our April 19, 2024, comment letter.) Manufacturer's co-pay cards are one of the few tools we have to help patients directly.

Furthermore, our concern about patient impact was confirmed in a recent Avalere study analyzing payer perceptions of UPL implementation and impact. The Avalere article summarized interviews with payers and explains how a UPL may cause health insurers to put more restrictions on patient access. This is the central point because health plans ultimately control how much a patient pays at the pharmacy counter.

> Avelere said, *"... all interviewees agreed that UPL – affected drugs or their competitors in the therapeutic class could see greater utilization management (e.g., step therapy, prior authorization), depending on how manufacturers respond to supply chain changes, rebating and UPL implementation. In addition, five of the six interviewees indicated that they expect formulary adjustments, such as moving selected drugs and therapeutic alternatives to different tiers. Such changes can affect beneficiary cost sharing."*[2]

Setting a UPL creates a maximum rate at which a prescription drug can be purchased and does not control how much a patient pays for a drug.

Value Based Care

Value is a vital component in drug cost analysis. Health Affairs' recent article Unanswered *Questions of State Prescription Drug Affordability Boards, June 2024,* summarized the issue:

> *"... the singular focus on drug prices in statutorily defined affordability review process minimizes clinical and societal benefits and the dynamics of a complex pricing and supply chain ecosystem. Value-related factors – including unmet needs and comparative effectiveness – are rarely included in PDAB legislation. Improved patient access to innovative treatments – a common goal across all stakeholders – is diminished by a singular focus on 'affordability' without consideration of value."*[3]

AFPA also points out the importance of value, saying of PDABS, in general, "given their focus on government spending, prescription drug affordability boards often take an overly narrow view of

[2] Research Explores Health Plan Perceptions of PDABs and UPLs | Avalere
[3] Unanswered Questions and Unintended Consequences Of State Prescription Drug Affordability Boards | Health Affairs

health care value. Board members drive discussion focused on cost to the state rather than cost to the patient, meaning patient and provider priorities and input get left out."[4]

Boehringer respectfully urges the Board and Staff to recognize the importance of their role in evaluating the cost of prescription drugs to patients. The issue is severely complex and requires a thorough understanding of the system. As we have said before, Boehringer wants to be part of the solution and we are happy to discuss other policy solutions to address the price a patient pays at the pharmacy counter. Your understanding and decisions can significantly impact the health system.

Finally, we also want to highlight the potential that the State Employee Plan may see cost increases due to reduced rebates. The high rebates that PBMs and other middlemen extract from manufacturers are distributed among many parties – among them the payors. Payors, such as the state employee plan, can use the rebated money to offset premiums or other uses. If a UPL is enacted, it is likely rebates will drop, and that may have the effect of increased premiums or other costs for the State Employee Plan.

Thank you for the opportunity to provide feedback. We are happy to discuss these comments further at your convenience.

Regards,

Bridget Walsh
VP, Government Affairs and Public Policy
Boehringer Ingelheim Pharmaceuticals, Inc.

[4] AFPA-PDABFastFacts-Feb2024.pdf (allianceforpatientaccess.org)

Johnson & Johnson

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T +1-800-526-7736
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Via Electronic Submission

July 17, 2024

Van T. Michell
Board Chair
Maryland Prescription Drug Affordability Board
comments.pdab@maryland.gov

Dear Board Chair Mitchell:

We write to provide the Maryland Prescription Drug Affordability Board (the Board) with information on Johnson & Johnson's recent white paper, "Influence of Prescription Drug Affordability Boards and Upper Payment Limits on the State Drug Pricing Ecosystem" (the UPL White Paper) in advance of the July 22, 2024 meeting.

At Johnson & Johnson, for more than 130 years, cutting-edge technologies and expert insight have helped us understand and address the serious health problems of today and unlock the potential medicines of tomorrow. We apply rigorous science and compassion to confidently address the most complex diseases of our time. We also recognize these medicines can only have an impact if patients can access them. We work tirelessly to improve access for patients across Maryland.

During the May 20, 2024 meeting, the Board asked how an upper payment limit (UPL) could negatively impact patient affordability and access. In response, we have attached a copy of the UPL White Paper. We would like to highlight the following points:

- **An upper payment limit (UPL) will not lower patients' out-of-pocket costs.**[1] In a recent Avalere survey commissioned by the Partnership to Fight Chronic Disease, health plans stated "[p]ayers will not pass their savings (if any) onto individuals. It's not realistic and somebody will need to make up the differences."[2]

- **A UPL will negatively impact patient access.**[1] In the same Avalere survey, health plans stated "[u]tilization management will undoubtedly go up with UPLs, whether for the drugs subjected to them or for competition."[2]

- **A UPL does not consider the drug supply chain in its entirety.**[1] A UPL does not consider the role that health plans and pharmacy benefit managers play in the supply chain, nor

[1] Janssen. "Influence of Prescription Drug Affordability Board and Upper Payment Limits on the State Drug Pricing Ecosystem." Access July 3, 2024.
[2] Partnership to Fight Chronic Disease. "Health Plans Predict: Implementing Upper Payment Limits May Alter Formularies and Benefit Design But Won't Reduce Patient Costs." Accessed July 3, 2024.

does it consider the negative impact on provider and pharmacy reimbursement, which may result in providers and pharmacies operating at a loss.[3]

Instead of a UPL, we recommend the following policy solutions to reduce patients' out-of-pocket costs without negatively impacting their access to the most appropriate, effective treatment options and sites of care:

- **Require that PBM rebates and discounts be directly shared with patients at the pharmacy counter.[4]**

- **Examine the use of utilization management tools (e.g., formulary exclusion lists, prior authorization, step therapy, and nonmedical switching) and evaluate how best to regulate them in the interest of patient access and out-of-pocket costs.[4]**

- **Prohibit diversion of cost-sharing assistance (i.e., copay accumulator programs, maximizer programs, and alternative funding programs) to ensure payment made by or on behalf of patients counts towards their cost-sharing burden.[5]**

We ask the Board to take these points and others made in the UPL White Paper into consideration as you move forward with your recommendations on the UPL process.

As one of the nation's leading healthcare companies, Johnson & Johnson has a responsibility to engage with stakeholders in constructive dialogue to address these gaps in affordability, access and health equity as well as protect our nation's leading role in the global innovation ecosystem.

We know that patients are counting on us to develop medicines and work to make them accessible to all patients. We live this mission every day and are humbled by the patients who trust us to help them fight their diseases and live healthier lives.

Sincerely,

Judy Jenkins, RN, BSN, MS
Director, U.S. State Government Affairs

[3] Health Affairs. "Unanswered Questions and Unintended Consequences of State Prescription Drug Affordability Boards." Accessed June 5, 2024.
[4] Janssen. "The 2021 Janssen U.S. Pricing Transparency Brief." Accessed July 3, 2024.
[5] Janssen. "The 2022 Janssen U.S. Pricing Transparency Brief." Accessed July 3, 2024.

Influence of Prescription Drug Affordability Boards and Upper Payment Limits on the State Drug Pricing Ecosystem

Image Info: Microscopic Biology.

janssen | PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Abstract & Executive Summary

Abstract

State policymakers are turning to prescription drug affordability boards (PDABs) and upper payment limits (UPLs) on branded medications to lower state drug expenditures and improve affordability for patients. However, UPLs on branded medications remain new and untested, with minimal understanding of their short- and long-term impacts on the drug pricing ecosystem and patient access. As presented, UPLs may offer states a short-term option for reducing overall drug spending for the state.

However, because UPLs focus solely on the price of a drug instead of the entire drug supply chain ecosystem, they may have long-term negative impacts across benefit design, patient access, pricing, contracting and future innovation.

These impacts may prohibit states from achieving their intended effects across state-regulated commercial markets and, in fact, create new negative consequences, including reduced patient access to needed medications and little to no reduction of out-of-pocket costs for patients. States seeking to implement UPLs on branded medications should consider the downstream consequences of focusing on drug price setting, specifically for patients and providers.

Executive Summary

Over the past 10 years, stakeholders have increased their focus on the rising cost of healthcare, in particular drug pricing, patient access and affordability. Manufacturers, insurers and pharmacy benefit managers (PBMs) have been the primary focus of scrutiny. In response, **legislators have passed laws designed to curb government prescription drug spending, improve patient accessibility and affordability and increase transparency in the pricing process at both federal and state levels.**

The passage of the Inflation Reduction Act (IRA) in August 2022 has further prompted states to act against perceived rises in drug prices and spending. States have turned to prescription drug affordability boards (PDABs) and new price-setting measures such as upper payment limits (UPLs) for branded medications in hopes of reducing overall state drug spending and patient drug costs. Upper payment limits are not new in policymaking: for example, the Federal Upper Limit sets a reimbursement limit for some generic drugs. However, UPLs have not been used on branded medications where the manufacturer and the plans currently negotiate value and access. These new UPLs purportedly allow states to set limits on the amount that will be reimbursed for specified branded drugs across state-regulated commercial markets. More than 10 state legislatures have debated price-setting thresholds such as UPLs in the last legislative session. As of November 2023, no state has fully implemented a UPL; however, Colorado is finalizing UPL rulemaking and may choose to implement UPLs in 2024.

UPLs on branded medications may have unintended consequences for stakeholders, pricing and value via altered benefit designs, manufacturer contracting, provider incentives, patient access and future innovation. Further, as additional state legislatures debate the merits of PDABs and these new applications of UPLs on branded medications, there is limited research to understand the long-term consequences of such policies.

This paper aims to address potential intended and unintended consequences of PDAB and UPL implementation on branded medications for states and the broader healthcare ecosystem.

The Initial Development of PDABs and UPLs

Early Attempts to Address Drug Pricing in the States

National healthcare expenditures have grown substantially, increasing from **$74.1 billion** in 1970 to **$4.3 trillion** in 2021.[1]

While much of this increase is due to hospital expenditures, a growing percentage is due to higher prescription drug expenditures, attributable to increases in both volume and costs. While the absolute cost of drug spending has grown, it has maintained a stable percentage of **overall healthcare spending at 14 percent** for several years.[2]

As such, lowering drug costs and improving patient affordability have been priorities for state lawmakers for many years. However, since the passage of the Patient Protection and Affordable Care Act (ACA) and the expansion of the individual market through state marketplaces, legislation targeting drug expenditures has multiplied.[3]

Prior to the development of PDABs and UPLs, states debated several other legislative and regulatory efforts, including increasing manufacturer price transparency within the commercial prescription drug supply chain. Drug price transparency legislation, which included manufacturer reporting requirements and advance notification of price changes (e.g., drugs with a wholesale acquisition cost [WAC] increase greater than 10 percent over the previous 12 months), rose to the forefront of state legislative initiatives around 2016. At least 24 states have enacted such laws.

However, state drug price transparency laws have not reduced prescription drug costs and improved transparency in the way states intended.[4] Research indicates that price transparency alone has minimal impact on overall costs for consumers because the information reported under transparency laws does not typically lead to actionable reductions in drug prices and reduced prices do not necessarily result in cost savings for patients.[5]

In addition to early drug price transparency legislation, some states also sought price-capping initiatives in the commercial market and in Medicaid. For example, New York's Medicaid Drug Spending Cap was enacted in 2017, allowing the state Medicaid program to negotiate with manufacturers for supplemental rebates if spending was set to exceed the cap or if a new drug was launched with a "high cost."[6] Maryland enacted an anti-price gouging law in 2017 that intended to penalize manufacturers for unreasonably increasing the cost of drugs.[7,8] However, a Court of Appeals struck down the Maryland law the following year stating it violated the commerce clause by regulating transactions taking place outside the state.[9] After the court decision, states began considering PDABs and price setting as a way to reduce prescription drug prices without negotiations with manufacturers.

PDAB and UPL Development

1

Background

PDABs are established through state legislation to independently review state drug spend and recommend ways to lower spending.[10] In 2017, the National Academy for State Health Policy (NASHP) developed model PDAB legislative language including a definition of prescription drug price setting through UPLs. This language was designed to give PDABs the ability to determine, using a UPL framework, if a drug is "unaffordable" for state purchasers and consumers.[6] The intent of the original model bill was to bring different stakeholders of the prescription drug pricing process together to increase transparency and set price thresholds to limit how much the state would pay for identified drugs.[11]

The original framework encouraged Boards to consider factors such as:

- Cost of administering and delivering the drug,
- Food and Drug Administration (FDA) shortage list status,
- Price of the drug in other countries and
- Other relevant administrative costs.

The framework does not require, however, that the value of the drug or the patient benefits be considered when determining a UPL.[12]

Even more notably, the NASHP model bill does not explicitly address patient cost sharing or affordability as a factor, although states are able to include it if they deem it necessary. NASHP updated the model legislation in 2022 to tie UPLs to reference-based pricing such as Medicare "negotiated rates" as developed by the IRA.[13] To date, UPLs have been designed as a cost-saving measure for the state and the plans that work within the state and have not been assessed as a mechanism to directly reduce out-of-pocket costs for patients.

2

PDAB Development

Maryland enacted the first PDAB in 2019 followed by Maine, New Hampshire, Oregon, Ohio, Colorado and Washington.[14] The scope of these PDABs varies from state to state. The majority of PDABs include advisory boards to analyze and recommend ways to lower state spending on certain products; others are required to release reports on their analyses or findings. In March 2022, Maine's PDAB released its first annual report containing administrative and legislative recommendations on how to reduce prescription drug prices in the state.[15]

While the composition of PDABs varies by state, most boards are composed of state-appointed experts in various fields of healthcare and economics. Many states' PDABs also include other stakeholders such as healthcare providers, advocates, manufacturers and insurance professionals.[10] The varied backgrounds of PDAB members can lead to differentiation in selection criteria for affordability review execution. Based on their individual areas of expertise, certain members may value utilization while others may value health equity.

PDABs often focus on branded drugs with list prices and use across state-regulated plans, using standard thresholds such as price and volume, to identify which drugs will be evaluated. For example, PDABs in Colorado and Maryland seek to evaluate drugs with a WAC greater than $30,000 per year. Ohio and Maine developed PDABs solely as ways to report to state legislatures on future drug pricing initiatives and ways states could engage with the supply chain to lower costs.[16, 17] However, some PDABs have the purported authority to set UPLs for select drugs.[14, 18]

States also need to provide funding for Boards to maintain their functionality. Some states have appropriated funds from the state budget for their PDAB, such as Washington's $1,460,000 allocation for the 2023 fiscal year.[19] Other states, like New Hampshire, fund their Boards through fees collected from manufacturers, insurers and PBMs.[14] Most states are still working to operationalize their Boards, with only Colorado, Maine and Maryland having active Boards as of July 2023.

3

UPL Development

Of the eight enacted PDAB laws, the following contain UPL price limit threshold provisions: Washington, Colorado, Minnesota and Maryland.[14] The goal of establishing UPLs is to set rates that state purchasers will pay for a certain number of products across plans regulated by the state (e.g., individual market, small-group market). States may include Medicaid plans as part of their state purchasers; however, Medicaid rates are likely already more steeply discounted than a UPL rate due to rebates through the Medicaid Drug Rebate Program (MDRP). So far, Minnesota is the only state to directly tie UPLs to Medicare "maximum fair price" (MFP) decisions developed through the IRA, although rulemaking to formalize this process has not been established.[20]

Other states with the authority to set UPLs have initiated their own criteria and processes for affordability review. Some states have thresholds on the number of drugs for which a UPL can be established. Currently enacted UPLs require states to determine the UPL-setting process through rulemaking considered by the PDAB.[14] PDAB laws with UPLs do not impact Employee Retirement Income Security Act of 1974 (ERISA) self-funded and Medicare plans.[10] However, these plans may opt into UPLs if enacted language allows. While price caps do exist in other markets, this has largely been untested in the state-regulated plans; as such, the impact of PDABs and UPLs on branded products is unclear.

PDAB and UPL Development Timeline

- Maryland enacted the first PDAB in 2019, followed by Maine, New Hampshire, Oregon, Ohio, Colorado and Washington.
- Many states' PDABs also include other stakeholders such as healthcare providers, advocates, manufacturers and insurance professionals.
- PDABs in Colorado and Maryland seek to evaluate drugs with a WAC greater than $30,000 per year.
- Ohio and Maine developed PDABs solely as ways to report to state legislatures on future drug pricing initiatives and ways states could engage with the supply chain to lower costs.
- States also need to provide funding for Boards to maintain their functionality.
- Some states have appropriated funds from the state budget for their PDAB, such as Washington's $1,460,000 allocation for the 2023 fiscal year.
- New Hampshire funds their Boards through fees collected from manufacturers, insurers and PBMs.
- Most states are still working to operationalize their Boards, with only Colorado, Maine and Maryland having active Boards as of July 2023.
- Of the eight enacted PDAB laws, the following contain UPL price limit threshold provisions: Washington, Colorado, Minnesota and Maryland.
- So far, Minnesota is the only state to directly tie UPLs to Medicare maximum fair price (MFP) decisions developed through the IRA, although rulemaking to formalize this process has not been established.

Current State of Play and UPL Implementation

PDAB/UPL Development in Three Key States

Three states with established PDABs are working toward developing a UPL setting process, with Colorado being the furthest along and in the process of finalizing rulemaking for its UPL.[10] The Colorado PDAB has released a list of five prioritized drugs for affordability review, following the release of a dashboard that includes 604 eligible drugs for selection.[21]

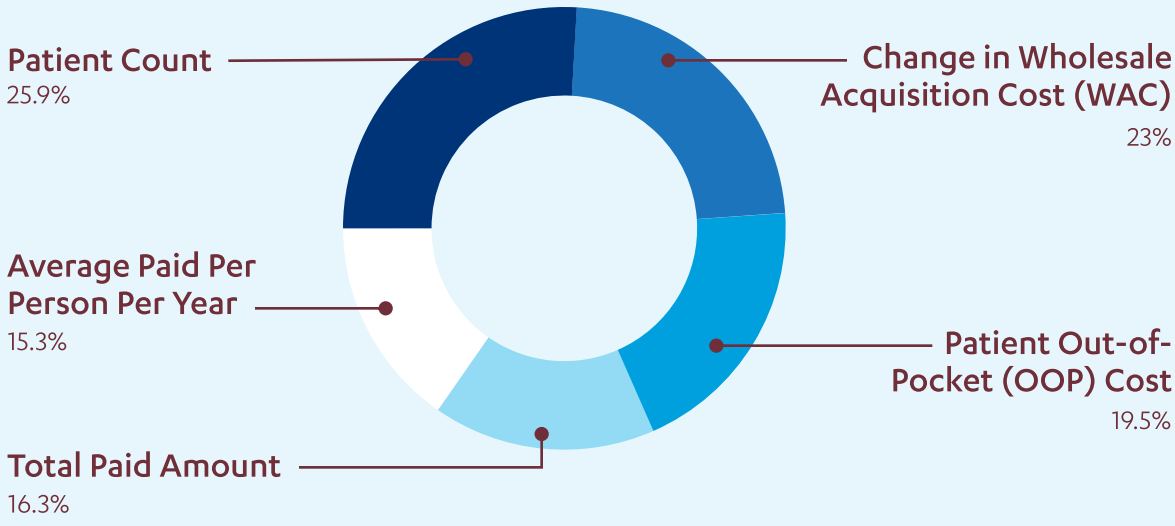
The 5 drugs selected for affordability review were:

1. Enbrel
2. Genvoya
3. Cosentyx
4. Stelara
5. Trikafta[22]

The Colorado PDAB plans to move forward with affordability reviews for the five selected drugs and may set UPLs for some, none or all of them, although the Board has the authority to set UPLs for up to 18 drugs (the CO PDAB has already announced it will not set an UPL for Trikafta).[23] The first UPLs in Colorado could take effect as early as 2024.

Each state's PDAB and UPL setting process and authorization can vary across items such as covered markets and targeted drugs. Maryland and Washington are two other states that have enacted PDABs. As a part of its 2021 legislative session, Maryland initiated the ability to include UPLs as part of its PDAB. Legislation that reestablishes this requirement and develops a plan of action to implement UPLs was enacted in the state's 2023 legislative session.[24, 25] Washington is one of the most recent states to enact a PDAB law that allows UPL setting. The Washington PDAB may set UPLs for up to 12 drugs beginning in 2027 and will begin identifying drugs to conduct affordability reviews by June 2023.[26] Though other states have enacted PDABs with abilities to set UPLs (i.e., Minnesota), Colorado, Maryland and Washington are the states that have begun taking steps to develop plans.

Factors Used to Determine the Priorities List of Eligible Drugs in Colorado Included:



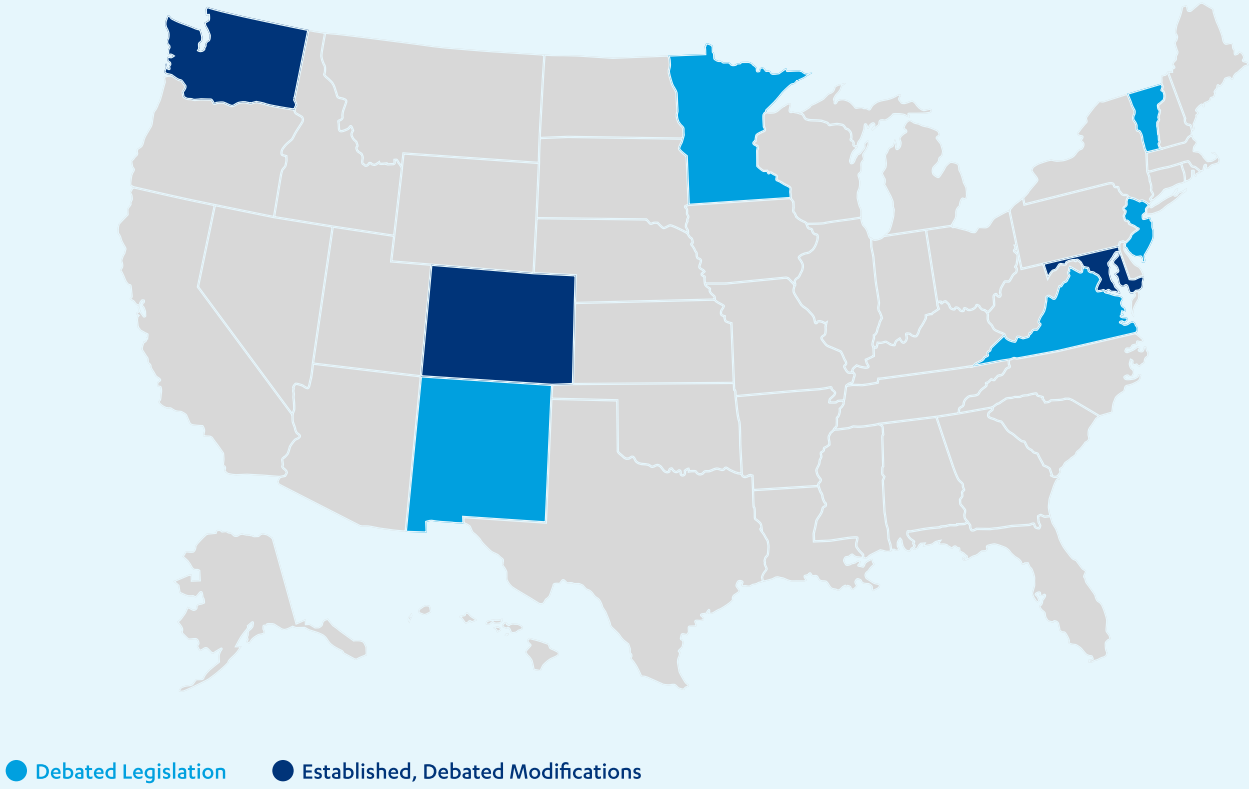
Key Characteristics of PDABs Across Three Enacted State Laws

	Colorado	Maryland	Washington
Bill Number	Colorado SB 175	Maryland HB 768	Washington SB 5532
Date Enacted	June 16, 2021	May 25, 2019	March 22, 2022
UPL Authorization	**Authorized.** The Colorado PDAB can set UPLs for up to 12 drugs within the first three years of implementation.[27]	**Progress toward authorization.** As a part of its 2021 legislative session, Maryland initiated the ability to include UPLs as part of its PDAB. However, no UPLs were set. HB 279 in Maryland's 2023 state legislative session gave the PDAB authority to set UPLs. If a UPL is established, the Maryland PDAB must report on UPL setting and the expansion of the UPL to other payers by December 1, 2026.[24]	**Authorized.** The Washington PDAB may set UPLs for up to 12 drugs, starting in 2027. A current bill seeks to move the Washington UPL ability forward by a year to 2026 as well as lower the thresholds for affordability review (e.g., WAC changes).[26]
Markets Covered	All state-regulated markets. This excludes self-funded plans that choose not to participate.	All public plans in the state.	All state-regulated markets. This excludes self-funded plans that choose not to participate
PDAB Drug Evaluation Criteria	• Brand-name drugs and biologics with a WAC ≥ $30,000 per year or course of treatment • Brand-name drugs or biologics with a WAC increase ≥ 10% during the previous 12 months • Biosimilars with a launch WAC that is not ≤ 15% lower than the referenced biologic • Generic drugs with a WAC ≥ $100 for a 30-day supply • Generic drugs with a WAC increase ≥ 200% in the previous 12 months[28]	• Brand-name drugs and biologics with a WAC ≥ $30,000 per year or course of treatment • Brand-name drugs with a price increase ≥ $3,000 in a year or course of treatment • Biosimilars with a launch WAC that is not ≤ 15% lower than the referenced biologic • Generic drugs with a WAC ≥ $100 for a 30-day supply • Generic drugs with a WAC increase ≥ 200% in the previous 12 months[29]	Prescription drugs that have been on the market for at least seven years, are not designated as rare disease treatments by the FDA and are one of the following: • Brand-name drugs and biologics with a WAC ≥ $60,000 per year or course of treatment • Brand-name drugs and biologics with a WAC increase ≥ 15% in a year • Brand-name drugs and biologics with a WAC increase ≥ 50% in three years • Biosimilars with a launch WAC that is not ≤ 15% lower than the referenced biologic • Generic drugs with a WAC ≥ $100 for a 30-day supply • Generic drugs with a WAC increase ≥ 200% in the previous 12 months[30]

To date, only Colorado has released a list of drugs selected for affordability review and possible UPL. However, Maryland notes in its annual cost review report that when the PDAB drug evaluation criteria are applied to their all-payer claims data (APCD), 707 brand-name national drug codes (NDCs) with WAC of over $30,000, 884 brand-name NDCs with increases of over $3,000, two NDCs of biosimilars not at least 15% less than the reference biologic and 483 NDCs of generic drugs costing $100 or more for a 30-day supply would be eligible for this review.[31]

Ongoing Legislative Efforts and IRA Implementation

In 2023 legislative sessions, at least five states have debated legislation to establish PDABs and UPLs (Minnesota, New Jersey, New Mexico, Vermont and Virginia) with Minnesota enacting its PDAB law in April 2023. All states with laws establishing PDABs with UPL authority prior to 2023 (Colorado, Maryland and Washington) have debated modifications to the process in their 2023 state legislative sessions.[32]



Beyond state legislation, Congress enacted major drug pricing reform through the IRA in August 2022.[33] The IRA's Medicare "negotiation" provision targets high-spend drugs, which could have downstream impacts on state PDAB and UPL development. For example, under Medicare "negotiation," a list of eligible drugs was released in September 2023 and the Secretary of the Department of Health and Human Services (HHS) will negotiate a "maximum fair price" (MFP) for each of the selected drugs to be effective in 2026.[34]

The MFP for each selected drug could impact UPL setting in states that enact laws tying UPLs to Medicare-negotiated rates. While federal "negotiation" is specific to Medicare, price-setting at the national level could trickle down to affect drug prices in state-regulated markets, and it can be expected that other states, like Minnesota, will tie the MFP to UPLs.

Affordability Ecosystem and Future Outlook for State Drug Pricing

Intended Outcomes of UPL Setting

1 Reduction in State Spending on Prescription Drugs

The goal of UPL setting is to establish payment limits for certain products to protect payers from high drug prices in the state and increase drug affordability for patients.

However, in states such as Colorado and Washington, where UPLs are limited to 12 products per year for the first three years, states may see nominal savings only if the products selected are tied to large enough state spending and volume.

Colorado's and Washington's laws purport to allow the PDABs to set no more than 12 UPLs a year until 2027, after which an unrestricted number of UPLs may be set. Early (e.g., pre-2027) savings from UPLs could mirror those projected by the Congressional Budget Office (CBO) for the IRA's Medicare "negotiation" provision.[35] This is because drugs selected in the first few years will likely include drugs that have significantly higher utilization and state expenditures per year than drugs selected in later years. For example, Maryland lists Humira as its top drug by spending for 2018-2019 in its annual cost review report, with the next product (Genvoya) listed as nearly half the total spending. By the tenth product listed on the report, the cost is less than one quarter of the top drug (Humira) by spend.[31] Within the next several years, states may see cost savings associated with UPLs on top drug expenditures. However, when UPLs are applied more broadly to unlimited products, their utility is likely to be limited.[36]

2 Patient OOP Cost Reductions

UPLs have also been touted as ways to lower patient out-of-pocket costs and improve patient adherence and access. In their initial efforts around UPLs, state policymakers anticipate, though they do not always mandate, that lowering payment rates for drugs will increase PBM "pass through" of rebates, allowing payers to pass on savings to patients through lower cost sharing or premiums. Historically, this has not happened.[28, 37] Within Colorado's statute, language states that any savings generated to the payer should be passed through to patients through out-of-pocket costs. However, how payers must do this, whether that be deductibles, premiums or lowered drug spending, has not been identified.[28]

Notably, since UPLs have typically only applied to state-regulated commercial health plans (e.g., exchange plans, small group), Medicaid and/or state employee plans, the broader impact on patient out-of-pocket costs may vary depending on whether other markets opt in (e.g., self-funded plans, large group). Though Medicaid may be included in UPL statutes, it is unlikely to have any impact due to low patient cost sharing and mandatory federal rebates for prescription drugs likely being lower than future UPL thresholds. Plans may be unlikely to make large changes to their benefit design structures for smaller markets, such as the exchange markets, leaving benefit design and patient access unchanged.

In addition, setting UPLs without consideration of overall plan economics and current market-based access incentives could inadvertently lead plans to favor non-UPL drugs over UPL drugs. Even if gross costs are lower for a UPL product, plans will base coverage decisions on the value of rebates and net cost to the plan, which could limit patient access to drugs with UPLs.

3

Increased Transparency

Mounting scrutiny on the drug pricing supply chain and increasing patient out-of-pocket costs have increased state efforts to improve transparency.[38] State policymakers are using PDABs to examine relationships between payers, PBMs, manufacturers and other stakeholders as they set UPLs.[39] Most notably, PBMs have been at the center of much of this scrutiny as their role in managing prescription drug benefits and negotiating payment rates is difficult to track. States, including Colorado and Washington, intend to leverage UPL setting information to reduce overall state drug costs and increase transparency and competition among manufacturers and payers.[40]

The PDAB and UPL process typically includes states requiring insurers to report top-spend drugs, either through existing or new reporting pathways, to inform PDAB review. However, much of the efforts to promote transparency through UPLs hinges on the information provided by an APCD. For example, the Colorado APCD is the state's most comprehensive source of health insurance claims information, representing lives across Medicare (Fee-for-Service and Advantage), Health First Colorado (Colorado's Medicaid program) and some commercial health insurance plans.[41] However, the APCD data has limitations, such as the ability to collect complete and accurate information without all ERISA plan contributions. This will impact the ability to use APCDs to support accurate analyses such as affordability reviews.[42]

Unintended Consequences of UPL Setting

UPLs have been enacted by state policymakers with the intention of lowering overall drug spending in the state, improving transparency across the supply chain and enhancing patient affordability. However, as UPLs ignore the interconnected market realities of the drug pricing ecosystem and supply chain, these price-setting thresholds may have unintended consequences across payer and PBM formularies, price-reporting metrics, provider reimbursement and patient plan and benefit options.

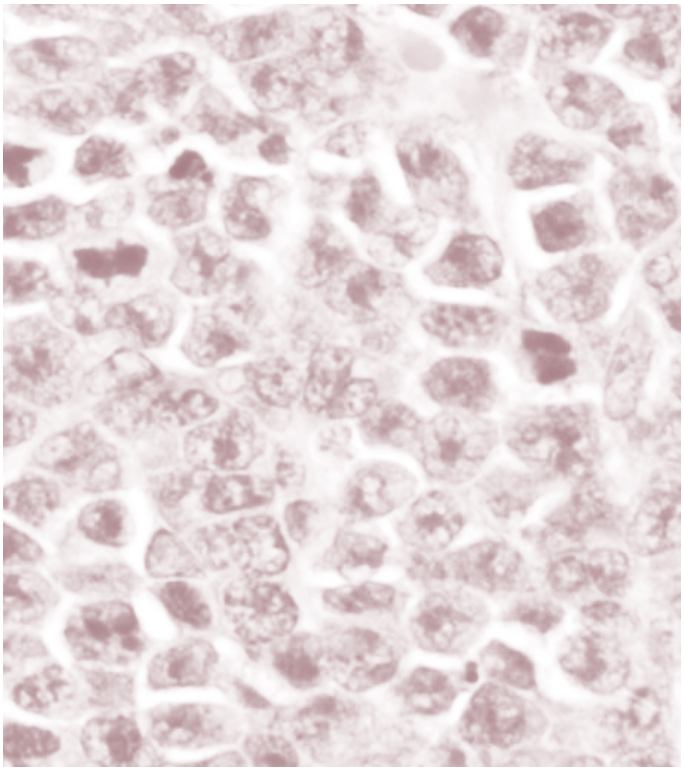
1

Benefit Design and Patient Access

UPL setting for select drugs may shape payer and PBM decision making in ways that could work counter to PDAB's primary intent and increase patient cost sharing or reduce patient access. For example, the process may act cyclically. Manufacturer-provided prescription drug rebates may alter how payers deliver and reform their benefit designs, and lower rebates may result in plans placing medications on higher formulary tiers, which means higher out-of-pocket costs for patients. In addition, this could then affect how patients access medication. The partial list of impacted stakeholders and unintended consequences are as follows:

Pharmacy Benefit Managers (PBMs)

The implementation of price setting in state-regulated commercial markets will have far-reaching effects on payer and PBM practices outside of states with UPLs. In response, PBMs may alter benefit designs to account for their changing rebate structure.[43, 44, 45] This, in turn, may impact patient access to medications and cost sharing, which are closely tied to a drug's placement on plan formularies (e.g., preferred vs. non-preferred).



Pictured: Lymph node.

Patient Cost Sharing

Firstly, UPLs do not necessarily ensure patients see reduced out-of-pocket costs. In addition, benefit design restructuring often results in increased patient cost sharing due to movement across tiers and could reduce patient access. Further, payers and PBMs may shape access by removing UPL products from formularies or reclassifying products to higher, non-preferred tiers. Any benefit design changes that move drugs into non-preferred or brand tiers or result in removal of a drug entirely from a plan's formulary will increase costs to patients (i.e., requires paying for the drug entirely or increases in cost-sharing amounts). Individuals seeking healthcare coverage on the exchanges are increasingly exposed to higher prescription drug cost sharing, as the individual and small group markets have more formulary tiers than large group plans. Nearly 95% of individual market and 93% of small group plans have four or more prescription drug tiers.[46] Additional tiers and PBM movement of drugs to higher tiers will mean higher out-of-pocket costs for patients, as cost sharing is higher for brand and specialty drugs. Additionally, according to HHS, the average deductible on an exchange plan increased from $2,405 to $2,825 in 2021, and the average annual deductible in employer-sponsored insurance has increased by more than 17% over the last five years, more than $2,000.[47, 48] Payer and PBM benefit design changes due to UPLs will have a higher likelihood of adversely impacting patient access, especially in states (e.g., Colorado, Washington) where UPLs will be applied to an unlimited amount of products post-2027.

Average Deductible on an Exchange Plan:

$2,405 2017

$2,825 2021

Average Deductible on Employer-Sponsored Insurance:

↑ 17% in the last 5 years

$2,000+ on average

Copay Assistance

As payers and PBMs implement benefit design changes following UPL application, there is likely to be an increased patient need for manufacturer cost-sharing (e.g., copay) assistance. Copay assistance helps to mitigate the impacts of increased plan and PBM cost-sharing requirements (e.g., deductibles, maximum out-of-pocket costs).[49] For many patients facing high out-of-pocket costs, manufacturer copay assistance programs provide a source of support that improves patient adherence and outcomes. For example, one study found that patients taking HIV or oncology brand medicines using copay assistance saved more than $1,700 in out-of-pocket spending in 2021.[50] As drugs are shifted to higher formulary tiers following UPL setting, increased patient demand for assistance could mean manufacturers reassess and alter eligibility considerations for their copay assistance programs and/or free drug/patient assistance programs (PAPs).

As additional patients seek out manufacturer copay assistance on commercial plans, the implementation of copay assistance diversion (e.g., copay accumulators or copay maximizers, which prohibit or limit manufacturer coupon assistance from counting toward a patient's deductible) could also rise. As such, copay assistance diversion programs could increase patient OOP burden further and prevent them from moving through their benefit.

Patient Choice

Additionally, depending on the volume of UPLs set in a given state, there is potential for market consolidation to limit patient choice. As UPLs grow, both across states and in volume as states become unrestricted in price setting, payers may consider removing themselves from state-regulated markets because of their decreased ability to make a profit based on the spread, decreasing plan choice among patients. Limited plan choice may make plans more sensitive to individuals with high-risk behaviors; as such, they may choose to deny coverage or increase premiums for these individuals.[51]

Plan Participation

While most employer-sponsored insurance is regulated by ERISA and therefore not subject to state PDABs and UPLs, UPL-setting states such as Colorado and Washington have allowed self-funded commercial employers to opt in to UPLs.[52] Self-funded employers could be more likely to opt into UPLs if the state sets a price threshold that is lower than the plan's existing negotiated price or if the plan's volume of UPL drugs is high enough. Higher product volume flowing through UPLs could further limit patient access through benefit design shifts.

Provider Reimbursement

UPL reimbursement pressures could also prompt providers to change referral, prescribing and acquisition patterns for drugs subject to price setting. Smaller practices may be disproportionately impacted by reimbursement cuts and could refer patients to larger sites of care (e.g., outpatient facilities). Where alternatives are available, providers may shift prescribing to other products where reimbursement is more stable.

In one literature review of prescribing habits in oncology, 15 of 18 studies found a correlation between reimbursement and care delivery and responsiveness to financial incentives, suggesting that some oncologists may alter treatment recommendations based on reimbursement considerations.[53]

Lowered reimbursement rates stemming from UPL setting may incentivize providers to prescribe pharmacy benefit drugs instead of medical benefit drugs or non-UPL drugs instead of UPL drugs. The negative financial impact on the traditional provider buy-and-bill system could play into a larger trend that encourages provider consolidation and referrals to larger entities and practices. Finally, UPLs may increase interest in alternatives to buy-and-bill, such as white-bagging, a practice where specialty pharmacies ship a patient's drug directly to the site of care.[54]

Investment in Research and Development

Finally, as manufacturers evaluate the therapeutic areas likely to be subjected to UPLs, they may reassess investment in research and development (R&D) for new therapies or biosimilar competitors to existing drugs. Similar to the potential impacts of the IRA's MFP on selected drugs, manufacturers may be unable to recoup R&D costs if the prices of selected drugs are capped. For example, if "negotiation" were to take place prior to a biosimilar entering the market, the MFP may be set low enough that it deters biosimilar market entry in general. Overall, this could reduce biosimilar launches and negate competition, which may in turn impact manufacturer investment decisions in high-value therapeutic areas that are likely to be subject to price limits such as UPLs.[55, 56]

2

Cascading Changes to Prescription Drug Price Reporting

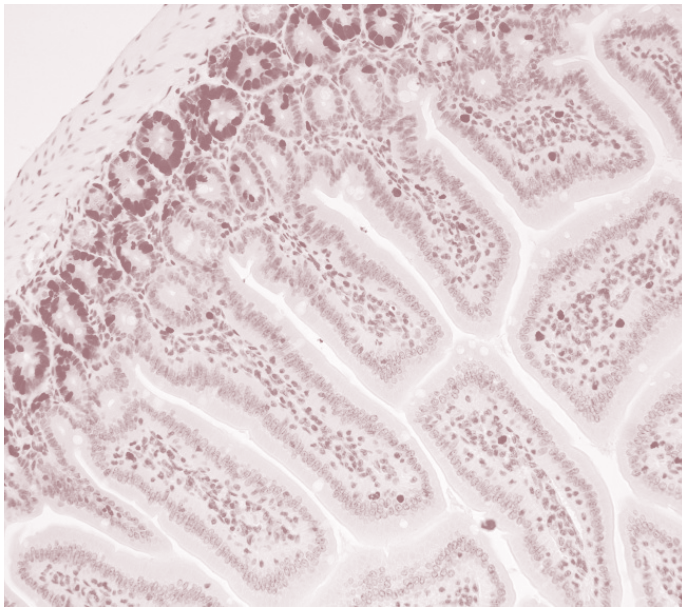
UPL implementation will place downward pressure on a broad range of healthcare stakeholders, including through price reporting metrics such as Medicaid Best Price (BP), Average Manufacturer Price (AMP) and Average Sales Price (ASP). The impact on price reporting metrics may vary, with changes to BP potentially having the largest ripple effect initially. Alternatively, UPL-induced changes to AMP and ASP would occur on a volume-weighted basis, which means that as additional states consider and implement UPLs, ASP and AMP would be affected to a greater degree. **These changes would have consequences that alter pricing outside of the intended markets.**

Medicaid Best Price	Focusing first on BP, base Medicaid Drug Rebate Program (MDRP) liability for brand name drugs is the greater of 23.1% of AMP or the difference between AMP and BP.[57] If a product's UPL were set lower than Medicaid BP, the UPL would set a new BP. If a UPL were to reset BP, markets outside of the UPL state would be affected as a lower BP would alter MDRP calculations and increase the manufacturer's MDRP liability in all states.[58] Additionally, UPL prices would also likely lower AMP on a volume-weighted basis, further altering the MDRP calculation. If BP is too low, it may disincentivize manufacturers from participating in the Medicaid channel.
ASP	Similar effects are expected for ASP for provider-administered drugs. If ASP is lowered due to a UPL, providers reimbursed on an ASP basis (e.g., ASP+6%) would face lower reimbursement, impacting providers outside of UPL states. This consequence is not unique to state UPLs and may be seen with MFP for "negotiated" drugs under the IRA. Once finalized, MFP may be lower than the current ASP, lowering provider reimbursement and creating cascading effects across commercial markets.[59] If provider reimbursement is too low, it may force providers to consolidate practices, contributing to the increasing workforce shortage and/or disincentivizing providers from prescribing or delivering appropriate medication to patients.
340B Pricing	UPL setting will also have cascading effects on the 340B drug pricing program. The 340B program requires manufacturers participating in Medicaid to offer outpatient drugs at a discounted price, no more than a calculated "ceiling price," to eligible entities.[60] Changes to best price and AMP resulting from UPLs will alter the 340B ceiling price (i.e., decreases in AMP could result in 340B entities nationwide purchasing drugs at higher prices). Further, as UPLs reduce insurers' payments for drugs and price reporting metrics, reimbursement for provider-administered drugs could also be negatively impacted, such as by setting a UPL that is lower than the 340B ceiling price, which will alter the margin.

Future of PDABs and UPLs

PDABs are debated and passed into law with the aspiration to be effective tools for states to address perceived rising drug prices and improve patient affordability. **However, much of their efficacy hinges on the ability to produce valuable solutions that work across the drug pricing supply chain and the unproven assumption that cost savings will be passed on to patients.**

To date, state stakeholder efforts to improve drug price transparency and lower costs have been stifled by a lack of long-term consideration and value initiatives. UPLs purportedly offer states a cost-effective short-term option for PDABs and states to lower overall branded drug spending; however, in the long term, their impacts across benefit design, patient access and pricing and contracting may further impede drug pricing reform across state-regulated commercial markets. Moreover, policy changes that focus exclusively on drug pricing at the manufacturer level do not always account for responses from other stakeholders, and hence may not deliver the intended shifts in patient access and affordability. As more states take this approach and select a greater number of drugs each year for UPLs, these issues may be compounded even further.



Pictured: Crypt cells.

In addition to the unintended consequences of UPLs described throughout this paper, future negative effects of price setting may include:

1. Alteration of payer and PBM benefit designs across states and markets (e.g., exchange, self-funded, Medicaid) to provide patients with less generous overall plan choice (e.g., adverse tiering) due to lowered reimbursement for products.
2. Changes in both payer and PBM contracting, as well as manufacturer contracting for products, altering provider reimbursement, 340B contracting and Medicaid rebates.
3. Reductions in manufacturer innovation and research in high-value areas subject to price limits, similar to the effects of the IRA.

In short, states evaluating UPLs may find that UPLs do not help them achieve all of their intended goals and create new negative consequences in the long term, often at the expense of patients and providers. States seeking to implement UPLs should consider the downstream consequences of price setting as UPLs' value may be limited—if not detrimental—in the long term.

Citations

1. Krutika Amin, Matthew McGough, Shameek Rakshi, Imani Telesford and Emma Wager, "How Has U.S. Spending On Healthcare Changed Over Time?" Peterson-KFF Health System Tracker. February 7, 2023. https://www.healthsystemtracker.org/chart-collection/u-s-spending-healthcare-changed-time/#Local%20and%20federal%20expenditures%20on%20public%20health,%20US%20$Billions,%201970-2021. Accessed December 7, 2023.
2. Murray Aitken, Julia Kern, Michael Klienrock, Bhagyashree Nawar and Urvashi Porwal, "Drug Expenditure Dynamics 1995–2020." IQVIA Institute From Human Data Science. October 2021. https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/drug-expenditure-dynamics/drug-expenditure-dynamics-19952020.pdf.
3. Kevin C. Adam, Cassandra Calderon and Constantin Nuernberger, "States Remain the Drivers of New Drug Pricing Legislation As Washington Weighs In." White & Case. August 23, 2021. https://www.whitecase.com/insight-alert/states-remain-drivers-new-drug-pricing-legislation-washington-weighs. Accessed December 7, 2023.
4. Martha Ryan and Neeraj Sood, PhD, "State Drug Pricing Transparency Laws: Numerous Efforts, Most Fall Short." USC Schaeffer Leonard D. Schaeffer Center for Health Policy & Economics. September 25, 2019. https://healthpolicy.usc.edu/research/state-drug-pricing-transparency-laws-numerous-efforts-most-fall-short. Accessed December 7, 2023.
5. Isaac D. Buck, "The Drug (Pricing) Wars: States, Preemption, and Unsustainable Prices." UNC School of Law, North Carolina Law Review, https://scholarship.law.unc.edu/cgi/viewcontent.cgi?article=6818&context=nclr. Accessed December 7, 2023.
6. National Academy for State Health Policy. "States Take Diverse Approaches to Drug Affordability Boards." February 12, 2021. https://nashp.org/states-take-diverse-approaches-to-drug-affordability-boards/. Accessed December 7, 2023.
7. New York State Assembly. "S02007 Summary." https://nyassembly.gov/leg/?default_fld=&leg_video=&bn=S02007&term=2017&Summary=Y&Text=Y. Accessed December 7, 2023.
8. Maryland Legislature. "House Bill 631." https://mgaleg.maryland.gov/2017RS/chapters_noln/Ch_818_hb0631E.pdf. Accessed December 7, 2023.
9. United States Court of Appeals for the Fourth Circuit. "Association for Accessible Medicines V. Brian E. Frosh." https://www.ca4.uscourts.gov/opinions/172166.P.pdf. Accessed December 7, 2023.
10. Bobby Clark and Marlene Sneha Puthiyath, "Can State Prescription Drug Affordability Boards Address High-Cost Drug Prices?" The Commonwealth Fund. October 11, 2022. https://www.commonwealthfund.org/blog/2022/can-state-prescription-drug-affordability-boards-address-high-cost-drug-prices#:~:text=What%20Is%20a%20Prescription%20Drug,varies%20from%20state%20to%20state. Accessed December 7, 2023.
11. National Academy for State Health Policy. "Prescription Drug Affordability Review Board Q&A." NASHP Center for State Rx Drug Pricing. https://www.nashp.org/wp-content/uploads/2019/04/Final-Prescription-Drug-Affordability-Review-Board-QA-4_1_2019.pdf. Accessed December 7, 2023.
12. National Academy for State Health Policy. "An Act to Reduce the Cost of Prescription Drugs by Establishing a Prescription Drug Affordability Board." https://eadn-wc03-6094147.nxedge.io/wp-content/uploads/2022/08/2022-PDAB-Model-Act_Form_080222.pdf. Accessed December 7, 2023.
13. National Academy for State Health Policy. "An Act to Reduce Prescription Drug Costs Using Reference-Based Pricing." November 29, 2022. https://nashp.org/an-act-to-reduce-prescription-drug-costs-using-reference-based-pricing/. Accessed December 7, 2023.
14. National Academy for State Health Policy. "Comparison of State Prescription Drug Affordability Review Initiatives." March 31, 2022. https://nashp.org/comparison-of-state-prescription-drug-affordability-review-initiatives/. Accessed December 7, 2023.
15. The Maine Prescription Drug Affordability Board. "Report of the Maine Prescription Drug Affordability Board:Recommendations to Reduce Prescription Drug Spending." March 2, 2022. https://www.maine.gov/bhr/oeh/sites/maine.gov.bhr.oeh/files/inline-files/2021%20Prescription%20Drug%20Affordability%20Board%20Annual%20Report.pdf.
16. Maine Legislature. "2041. Maine Prescription Drug Affordability Board Established." Maine Legislature, Maine Revised Statutes. https://legislature.maine.gov/statutes/5/title5sec2041-1.html. Accessed December 7, 2023.
17. Ohio Laws & Administrative Rules Legislative Service Commission. "Section 125.95 | Prescription Drug Transparency and Affordability Advisory Council." October 17, 2019. https://codes.ohio.gov/ohio-revised-code/section-125.95/10-17-2019. Accessed December 7, 2023.
18. National Academy for State Health Policy Establishing a Prescription Drug Affordability Board. "Q&A on NASHP's Model Act to Reduce the Cost of Prescription Drugs by Establishing a Prescription Drug Affordability Board." August 11, 2022. https://nashp.org/qa-on-nashps-model-act-to-reduce-the-cost-of-prescription-drugs-by-establishing-a-prescription-drug-affordability-board/. Accessed December 7, 2023.
19. State of Washington. "Certification of Enrollment Engrossed Substitute Senate Bill 5693." https://lawfilesext.leg.wa.gov/biennium/2021-22/Pdf/Bills/Senate%20Passed%20Legislature/5693-S.PL.pdf?q=20220328122927. Accessed December 7, 2023.
20. Minnesota Legislature Office of the Revisor of Statutes. "3rd Engrossment - 93rd Legislature (2023 - 2024)." February 8, 2023. https://www.revisor.mn.gov/bills/text.php?number=HF0017&version=latest&session=92&session_number=0&session_year=2023. Accessed December 7, 2023.
21. Colorado Division of Insurance. "CO PDAB 2023 Eligible Drug Dashboard." October 19, 2023. https://public.tableau.com/app/profile/colorado.division.of.insurance/viz/COPDAB2023EligibleDrugDashboard/0_Navigation?publish=yes. Accessed December 7, 2023.
22. Colorado Prescription Drug Affordability Review Board. "Board Resolutions." https://drive.google.com/drive/folders/1PYuErLjUpi5nP4FmoxJQaDEcGTcpLDFX. Accessed December 7, 2023.
23. Boram Kim, "Colorado Prescription Drug Affordability Board Discusses Criteria For Selecting Drugs To Review." State of Reform. February 22, 2023. https://stateofreform.com/featured/2023/02/colorado-prescription-drug-affordability-board-discusses-criteria-for-selecting-drugs-to-review/. Accessed December 7, 2023.
24. Maryland Prescription Drug Affordability Board. https://pdab.maryland.gov/. Accessed December 7, 2023.
25. Delegate Cullison, "House Bill 279 Emergency Bill." Maryland State Legislative Session. January 25, 2023. https://mgaleg.maryland.gov/2023RS/bills/hb/hb0279f.pdf.
26. Washington Governor Jay Inslee. "Prescription Drug Affordability Board." https://governor.wa.gov/boards-commissions/board-commission-profiles/Prescription%20Drug%20Affordability%20Board. Accessed on December 7, 2023.
27. Colorado Department of Health Care Policy & Financing. "2nd Edition Reducing Prescription Drug Costs in Colorado Cost Drivers and Strategies to Address Them." January 2021. https://hcpf.colorado.gov/sites/hcpf/files/Reducing%20Prescription%20Drug%20Costs%20in%20Colorado%20Second%20Edition.pdf.
28. Colorado General Assembly. "SB21-175 Prescription Drug Affordability Review Board." https://leg.colorado.gov/bills/sb21-175. Accessed December 7, 2023.
29. Maryland Legislature. "House Bill 768." https://mgaleg.maryland.gov/2019RS/bills/hb/hb0768e.pdf. Accessed December 7, 2023.
30. Washington State Legislature. "SB 5532 - 2021-22 Establishing a Prescription Drug Affordability Board." https://app.leg.wa.gov/billsummary?BillNumber=5532&Initiative=false&Year=2021. Accessed December 7, 2023.
31. Maryland Prescription Drug Affordability Board, "Section 21-2c-09(c) 2022 Annual Cost Review Report." December 31, 2022. https://dlslibrary.state.md.us/publications/Exec/PDAB/HG21-2C-09(c)_2022.pdf.
32. Avalere Health. "State Policy Prescription Drug Tracker." https://360.avalere.com/state-policy-360. Accessed December 7, 2023.
33. 117th United States Congress. "H.R.5376 - Inflation Reduction Act of 2022." https://www.congress.gov/bill/117th-congress/house-bill/5376/text. Accessed December 7, 2023.
34. Jordan Banks, Michael Ciarametaro, Sarah Moselle and Milena Sullivan, "Inflation Reduction Act Renews Focus on Value Assessment in the US." Avalere. October 10, 2022. https://avalere.com/insights/inflation-reduction-act-renews-focus-on-value-assessment-in-the-us. Accessed December 7, 2023.

35. Congressional Budget Office. "Estimated Budgetary Effects of H.R. 5376, the Inflation Reduction Act of 2022." August 3, 2022. https://www.cbo.gov/publication/58366. Accessed December 7, 2023.

36. Drew Gattine, Sarah Lanford and Jennifer Reck, "State Strategies To Lower Drug Prices: New Legislative And Medicaid Models." NASHP. December 13, 2021. https://nashp.org/state-strategies-to-lower-drug-prices-new-legislative-and-medicaid-models/. Accessed December 7, 2023.

37. The Commonwealth Fund. "Pharmacy Benefit Managers and Their Role in Drug Spending." April 22, 2019. https://www.commonwealthfund.org/publications/explainer/2019/apr/pharmacy-benefit-managers-and-their-role-drug-spending. Accessed December 7, 2023.

38. Kaiser Family Foundation. "2022 Employer Health Benefits Survey." October 27, 2022. https://www.kff.org/health-costs/report/2022-employer-health-benefits-survey/. Accessed December 7, 2023.

39. PDAB Staff, "Prescription Drug Affordability Board: Supply Chain Report and Policy Recommendations." Maryland Prescription Drug Affordability Board. July 22, 2022. https://pdab.maryland.gov/documents/meetings/2022/pdab_supply_chain_rpt_prst_07252022.pdf.

40. Jane Horvath, "State Prescription Drug Upper Payment Limits Explained." Maryland Prescription Drug Affordability Board. March 22, 2021. https://pdab.maryland.gov/documents/presentations/Horvath_Health_Policy_Upper_Pymt_Limits_03222021.pdf.

41. Center of Improving Value in Healthcare. "CO APCD Overview." https://civhc.org/get-data/co-apcd-info/. Accessed December 7, 2023.

42. Kevin McAvey, "Realizing the Promise of All Payer Claims Databases A Federal and State Action Plan." Manatt. December 2022. https://www.manatt.com/Manatt/media/Media/PDF/White%20Papers/RWJF_Realizing-the-Promise-of-APCDs_2022-12_d.pdf.

43. Javed Butler, Cynthia Chauhan, G. Michael Felker, Mona Fiuzat, Marvin A. Konstam, Christopher M. O'Connor, Mitchell A. Psotka, Shashank S. Sinha, Scott D. Solomon and John R. Teerlink, "Challenges and Potential Improvements to Patient Access to Pharmaceuticals." American Health Association Journals. August 24, 2022. https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.119.044976. Accessed on December 7, 2023.

44. NAIC. "Pharmacy Benefit Managers." June 1, 2023. https://content.naic.org/cipr-topics/pharmacy-benefit-managers#:~:text=Pharmacy%20Benefit%20Managers%20earn%20profits,or%20discounts%20negotiated%20with%20drug. Accessed December 7, 2023.

45. Hayden Consulting Group. "Understanding the PBM Compensation Model (Part 1)." https://haydencg.com/understanding-pbm-comp-i/. Accessed December 7, 2023.

46. Robert Wood Johnson Foundation. "Marketplace Pulse: Prescription Drug Benefit." December 18, 2022. https://www.rwjf.org/en/insights/our-research/2020/12/marketplace-pulse--prescription-drug-benefit.html. Accessed December 7, 2023.

47. D. Keith Branham, Nancy De Lew, Christie Peters and Benjamin D. Sommers, "Health InsuranceDeductiblesAmong HealthCare.Gov Enrollees, 2017-2021." Assistant Secretary for Planning and Evaluation. January 13, 2022. https://aspe.hhs.gov/sites/default/files/documents/748153d5bd3291edef1fb5c6aa1edc3a/aspe-marketplace-deductibles.pdf.

48. Gary Claxton, KFF, Matthew Rae, Emma Wager and Gregory Young, "Employer Health Benefits 2022 Annual Survey." Kaiser Family Foundation. 2022. https://files.kff.org/attachment/Report-Employer-Health-Benefits-2022-Annual-Survey.pdf.

49. PhRMA. "Patient Assistance." https://www.phrma.org/patient-assistance/patient-assistance. Accessed December 7, 2023.

50. PhRMA. "Faced with High Cost Sharing for Brand Medicines, Many Commercially Insured Patients with Chronic Conditions Use Manufacturer Copay Assistance." February 2023. https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/G-I/IQVIA-Condition-Specific-Report_Feb-2023.pdf.

51. Richard G. Frank, "Making Choice and Competition Work in Individual Insurance in Health Reform Proposals." The Commonwealth Fund. January 30, 2019. https://www.commonwealthfund.org/publications/issue-briefs/2019/jan/choice-competition-individual-insurance-health-reform. Accessed December 7, 2023.

52. Colorado Legislative. "Senate Bill 21-175." https://leg.colorado.gov/sites/default/files/2021a_175_signed.pdf. Accessed December 7, 2023.

53. Ethan Basch, Daniel A. Goldstein, Aaron P. Mitchell, Esita Patel, Daniel Richardson, Jason S. Rotter and Stephanie B. Wheeler, "Association Between Reimbursement Incentives and Physician Practice in Oncology A Systematic Review." JAMA Network. January 3, 2019. https://jamanetwork.com/journals/jamaoncology/article-abstract/2719759. Accessed December 7, 2023.

54. Value-Based Care Cancer Center. "Brown Bagging versus White Bagging." July 2013. https://www.valuebasedcancer.com/issues/2013/september-2013-vol-4-no-8/1341-brown-bagging-versus-white-bagging. Accessed December 7, 2023.

55. Craig Burton, "Opinion: The Inflation Reduction Act is a Step Backward for Biosimilar Competition." AJMC. August 18, 2022. https://www.centerforbiosimilars.com/view/opinion-the-inflation-reduction-act-is-a-step-backward-for-biosimilar-competition. Accessed December 7, 2023.

56. Joe Grogan, "The Inflation Reduction Act Is Already Killing Potential Cures." Wall Street Journal. November 3, 2022.https://www.wsj.com/articles/the-inflation-reduction-act-killing-potential-cures-pharmaceutical-companies-treatment-patients-drugs-prescriptions-ira-manufacturers-11667508291. Accessed December 7, 2023.

57. Medicaid Drug Rebate Program. 42 U.S.C. 1396r-8 (c)(1)(C).

58. Rachel Dolan, "Understanding the Medicaid Prescription Drug Rebate Program." Kaiser Family Foundation. November 12, 2019. https://www.kff.org/medicaid/issue-brief/understanding-the-medicaid-prescription-drug-rebate-program. Accessed December 7, 2023.

59. Reed Diskey, Ekemini Isaiah, Milena Sullivan and Amanda Tripp, "IRA Medicare Part B Negotiation Shifts Financial Risk to Physicians." Avalere. November 29, 2022. https://avalere.com/insights/ira-medicare-part-b-negotiation-shifts-financial-risk-to-physicians. Accessed December 7, 2023.

60. Health Resources and Services Administration. "340B Drug Pricing Program." https://www.hrsa.gov/opa. Accessed December 7, 2023.