VIA Electronic Delivery

August 24, 2022

Colorado Department of Regulatory Agencies
Division of Insurance
ATTN: Colorado Prescription Drug Affordability Review Board
1560 Broadway, Suite 850
Denver, CO 80202

Re: PRESCRIPTION DRUG AFFORDABILITY BOARD REGULATIONS

Dear DOI Board staff:

The Biotechnology Innovation Organization (BIO) and the Colorado Bioscience Association (CBSA) appreciate the opportunity to comment on the Colorado Prescription Drug Affordability Board (Board) Proposed Policies and Regulations.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions. BIO membership includes biologics and vaccine manufacturers and developers who have worked closely with stakeholders across the spectrum, including the public health and advocacy communities, to support policies that help ensure access to innovative and life-saving medicines and vaccines for all individuals.

Colorado BioScience Association (CBSA) champions a collaborative life sciences ecosystem and advocates for a supportive business climate on behalf of more than 720 life sciences companies and organizations in Colorado. Our life sciences community drives global health innovations that improve and save lives, from concept to commercialization. CBSA represents biotechnology and pharmaceutical, medical device and diagnostics, digital health, ag-bio and animal health, academic and research institutions, and the service provider companies that support the work of our ecosystem. CBSA remains committed to advancing affordability solutions that correct market failures, increase competition, and lower costs for patients while preserving patient access and supporting medical innovation.

As an overarching comment, we would like to note the following, BIO and CBSA have long been supportive of a more rational and transparent system of rebates – and specifically ensuring that patient cost sharing is based on the net cost of the drug to the payor. We are concerned, however, that the increasingly complex and opaque rebate dynamics, paired with the market power PBMs now yield, have created an environment in which patients are harmed and competition is stifled. Simply put, patients who take medicines are not benefiting from the significant discounts manufacturers provide to PBMs and the savings from manufacturer assistance programs are not always being passed along to the patient at the pharmacy counter.

Our comments are generally centered around ensuring that the Board remains faithful to the statute and its intent. More specifically, we encourage the Board to be clear that it must first identify drugs eligible for an affordability review by assessing drugs in accordance with the statutory criteria. Then, the Board must select drugs from the list of those that are eligible. In doing so, we encourage the Board to – be consistent with the legislative findings related to out-of-pocket costs for Coloradans – focus on data that analyzes out-of-pocket dynamics for different patient segments. The Board's selection should then seek to understand where patients are potentially not benefiting from the rebate dynamics described above. Therefore, we continue to advocate for lowering patients' out-of-pocket (OOP) costs. Please note our more detailed comments below.

Part 1: General Provisions:

1.1.C Definitions:

We have serious concerns that situations may arise with the vagueness of the definition of 'similar therapeutic effects' such as instances where an alternative drug is chosen that is less efficacious, has worse tolerability, and/or is meaningfully more challenging for patients to use (e.g., long infusions). We recommend the PDAB (the Board) include a more robust definition of 'therapeutic alternative', as 'similar therapeutic effects' creates too much uncertainty and subjectivity. We ask that (1) this definition include expectations for efficacy, safety, and drug profile to increase transparency, and (2) recommend the Board use a physician/provider panel to confirm whether products are truly alternatives.

Additionally, we recommend in the definition of 'therapeutic equivalence' the Board align to the FDA's orange/purple books, which is a publication of the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations.

The definition of "therapeutic equivalence" in the proposed rule is different from what is in the existing Colorado statute re: biosimilar substitution (§12-280-103). The state's current biosimilar substitution law includes the following as part of the definition of "interchangeable". In general, we would want the

definitions of 'therapeutic equivalence' to align—therapeutic equivalence should be designated by the FDA.

> 21."Interchangeable", in reference to a biological product, means:
> a. "Interchangeable" or "interchangeability", as determined by the FDA pursuant to 42 U.S.C. sec. 262 (k)(4); or
> b. That the FDA has deemed the biological product therapeutically equivalent to another biological product, as set forth in the latest edition or supplement of the FDA Approved Drug Products with Therapeutic Equivalence Evaluations, also referred to as the "Orange Book".

Part 3: Affordability Reviews of Prescription Drugs:

Establishment of Prescription Drug Affordability Priorities:

We are concerned that the process by which the Board will determine and set priorities is not clearly defined, nor is the duration of the priorities clearly articulated. The establishment of "Board Priorities" is not specifically contemplated by statute, and we note that the Board's priorities cannot usurp (takeover) the statutory criteria for drug selection. We would urge the Board to ensure it is in alignment with the statute in this section. Accordingly, we recommend reframing the rule to say: Section C.1: Establishment of Priorities: Recommend that the final sentence of this section be updated as follows: "These priorities may impact the selection of prescription drugs for an affordability review; provided, however, that the priorities will be set in accordance with any statutory criteria or limitations."

Identifying Prescription Drugs for Affordability Review (3.1.D in proposed rule):

CBSA and BIO are concerned with the use of the word 'inflation' as it relates to a brand-name drug or biological product that is adjusted annually for inflation. We ask the Board to clarify that the definition used will be consistent with "inflation" as it is defined in Colorado statute:

- 10-16-1401(14), C.R.S.) Inflation is defined as: "Inflation" means the annual percentage change in the United States department of labor's bureau of labor statistics consumer price index for Denver-Aurora-Lakewood for all items paid by all urban consumers, or its applicable predecessor or successor index.

Further, the phrase "adjusted annually for inflation" as written in the statute is ambiguous. We ask the Board to specify the following in the proposed rule:

- "Brand-name drugs or biologic products that meet the following requirements qualify for the list of prescription drugs eligible for an affordability review. A brand-name drug or biological product that, within the last year has:

a. An initial wholesale acquisition cost of thirty thousand dollars (as adjusted annually for inflation) or more for a twelve-month supply or for a course of treatment that is less than twelve months in duration; or
b. An increase in the wholesale acquisition cost of ten percent or more during the immediately preceding twelve months for a twelve-month supply or for a course of treatment that is less than twelve months in duration."

A clearer methodology and framework are needed before the Board moves forward with identifying certain prescription drugs for affordability review, as the proposed language is vague and leaves room for uncertainty and skewed results. We recommend the Board utilizes a starting point for referencing the WAC (e.g., January 1, 2022, or 2023) and NOT referencing the WAC prior to this point. We are concerned that without some sort of hard starting point, it could unfairly penalize manufacturers for previous pricing practices before the law went into effect.

Selection of Eligible Prescription Drugs for Affordability Review (E of proposed rule):

Overall, We are concerned with the data approaches listed throughout this section and strongly urge the Board to ensure its data collection process results in obtaining the right information, (i.e., spending versus manufacturer cost – costs should not include hospital markups in claims; health inequity proposals will not result in the evaluation of equity; and patient OOP cost should consider benefit design and total OOP cost, not just copayments/coinsurance, etc.).

E(1) – Class of the Prescription Drug and Therapeutic Equivalents:

It is unclear how the Board plans to treat those products that have "therapeutic equivalent" versus those that do not. If there are therapeutic equivalents and prices are similar, what is the Board's plan of action? For products with no therapeutic equivalent, what is the course of action? Additionally, there is a lack of clarity around where the rebate data (subpart E(1)(c)) will come from. The Board should clearly state if this data is from state/Medicaid or from commercial plans who also submit rebate information. It is important to note as the Board is working to select eligible drugs for review, that there is a lack of standards associated with dosing criteria across different products in a class.

E(2) – Aggregated Data:

We would like to highlight issues with APCD raw data files and note that they are not available for manufacturers. Hence, there should be some type of verification process on the aggregated data (e.g., sales, rebate, etc.)

E(3)- Average Patient's Out-Of-Pocket-Cost:

We are concerned with how the OOP costs will be factored into the affordability analysis. OOP costs are not set by the manufacturer. There should be clarity on how the Board plans to determine what portion of an enrollee's premium is because of drugs vs. other medical expenses. This is difficult and even experts in this field cannot do it.

Thinking through and further discussing these concerns will help the Board collect the right information when making decisions on what drugs should be subject to the affordability review process.

Conducting an Affordability Review (F of Proposed Rule):

In subpart F(4)(a) we recommend the Board to provide a minimum of 60 days from the date of selection of a prescription drug for affordability review to provide such information to the Board for its consideration from interested parties. Additionally, we recommend the Board clarify how it will solicit feedback. Particularly, in subpart F(2)(h), as it relates to soliciting input from "specified stakeholders". We urge the Board to define in the rule "specified stakeholders" – listing them each out under the subcategory's patients and caregivers and individuals with scientific or medical training. Specifically, we ask the Board to accept public comment from people identifying as patients or caregivers impacted by the disease/drug or list potential sources of feedback (e.g., seeking feedback from patient groups specifically representing that patient population) and solicit input from medical experts so they can provide insights into the patient experience and the time it takes to get the drug.

We are concerned with the intent of Section F(2)(c) related to the price effect on Colorado consumer access, does the Board intend to conduct a study to determine if access changed when price did? If evaluating over time, how will the Board determine what changes are due to price versus other clinical factors (e.g., additional data to support use, physician comfort in prescribing product)? We recommend the price effect on Colorado consumers should be based on actual OOP, which is driven more by insurance design and formulary placement. We also have concerns regarding language in Section F(3)(b)(ii) and (iii) and recommend adding "publicly available" to (ii) and (iii) as in (i). This will ensure that any pricing data subject to trade secret protections is not disclosed to other states or state entities.

Further, we recommend additional changes in Section F: `

- CBSA & BIO suggests the following changes to F(2)(c): "Price Effect on Colorado Consumer Access: The Board will consider the effect of price on Colorado consumers' access to the prescription drug by reviewing changes to WAC, patient out of pocket expenditure, and utilization over time in different segments of patients (e.g., uninsured, commercially insured (further analyzed, to the extent practicable, by benefit design (e.g., high-deductible plans, plans with copay caps, etc.)), and government insured."
- We recommend changing provisions in Sections F(2)(i) and F(4) specifying that the Board includes a requirement to affirmatively notify a manufacturer if it selects their drug for an affordability review. Specifically, we recommend changing "from the date of selection" to

"from the date on which the Board notifies the manufacturer that its drug has been selected."

- To ensure the language in the proposed rule is within the current statutory requirement, add the following language to Section F(2)(f) and F(2)(j)(iii)(2): we recommend adding language to F2f or F2j(iii)(2) that would require the Board to review 1) whether and to what extent safety net providers pass on the discounts to patients, 2) the extent of the discount received, and – potentially – 3) the utilization of the prescription drug by safety net providers relative to other therapeutic equivalents.

Notice and Comment Periods:

CBSA and BIO overall have concerns with the rulemaking process the Board has undertaken, the complexity of the Board's timelines, and the Board's general approach does not support meaningful comments from stakeholders. Throughout the entirety of this proposed rule, there are several instances that should be either subject to a notice and comment period or more specific parameters should be included around the process, they include the following sections:

- Identifying prescription drugs for affordability reviews – We recommend there be a notice and comment period subject to state APA notice and comment timelines for interested stakeholders to participate in when staff presents their methodologies and sources to the Board on how they plan to select drugs for affordability review.
- Selection of Eligible Drugs for Affordability Review – We recommend prior to the Board selecting which drugs, if any, from the approved list for which to conduct an affordability review should be subject to state APA notice and comment timelines for interested stakeholders.
- Conducting an Affordability Review – As the Board receives and considers comments regarding deliberations concerning whether prescription drugs id unaffordable for Colorado consumers, we recommend the notice and comment process should be subject to state APA notice and comment timelines.

Affordability Reviews of Prescription Drugs: Policies and Procedures Document:

Identifying Prescription Drugs for Affordability Review:

CBSA and BIO have serious concerns that the reliance on APCD utilization data (as specified in the draft Policies and Procedures document) could result in skewed costs as claims in the APCD will reflect amounts billed/paid, not the wholesale acquisition cost (WAC). We recommend that APCD should not be the only source of utilization information the Board uses to select eligible drugs for affordability review.

Specifically, in subpart 4(2)(b) the APCD costs should be verified against other sources as claims will include billed/paid amounts. CBSA and BIO suggest the Board utilize pricing compendia. For reference, drug pricing compendia are analogous to dictionaries of drug information, publishing specific fields for each NDC, UPC, or HRI listed.[1] Data published can include product names, pricing, package sizes, proprietary therapeutic categories, and a host of other data elements.[2]

The drugs identified for affordability review should be taken directly from a published list of drugs that are included in third-party pricing compendia.

If after this list is published (which is based on the WAC prices), the Board needs additional guidance to pare down this list, then discussions on APCD could guide the discussion. That said, it does not capture "affordability" for the patient which amounts to the cost of premiums and OOP costs.

Selection of Eligible Prescription Drugs for Affordability Review:

CBSA and BIO believe subpart 5(1) is too open-ended and should specifically state the "other similar classification systems" and "other therapeutic equivalence databases". We suggest the Board include USP as a classification system used for evaluating the class of prescription drugs and utilize the NDC because different packages of drugs can result in different prices. Certain NDCs have been around longer than others and can better speak to the pricing history of a product.

Subpart 5(2) utilization of aggregated data sources:

We have a few recommendations for the Board on the utilization of aggregated data sources:

- The combined expenditure and utilization of aggregated data needs to be compared to WAC during the same period as aggregated data may include mark-ups on claims, etc.
- The described analysis for health equity impact is unlikely to demonstrate the actual impact on health equity. The impact is likely to be more apparent in the treatments a patient did not receive. We recommend the Board re-evaluate the ability to assess health equity impact and ensure the Board has access to appropriate data. For example, this could be a comparison of treatments in claims for commercial versus Medicaid patients with the same diagnosis code.

Subpart 5(4) Patient's Out-Of-Pocket (OOP):

[1] Johnson, A., *The Importance of a Drug Pricing Compendia Strategy for Product Launch. Reference: https://medhealthoutlook.com/the-importance-of-a-drug-pricing-compendia-strategy-for-product-launch/*
[2] Ibid.

CBSA and BIO recommend that the Board should include looking at a patient's deductible, OOP per service/drug, and total OOP across various segments of the patient population (e.g., uninsured, commercially insured in various benefit designs, government-insured) when averaging the patient OOP cost for the prescription drug. Additionally, we urge the Board to set standards for other data sources. (i.e., peer review, etc.).

Conducting an Affordability Review:

CBSA and BIO have several concerns with the implementation of this section and ask the Board to address the following issues and consider suggested recommendations.

We are seriously concerned with confidentiality issues throughout this section. Specifically, as it relates to the Board and its staff when procuring pricing information from other states and obtaining information on rebates, discounts, and price concessions. The Board and its staff need to be held to the highest standard and any information obtained should be subject to Colorado § 7-74-101-7-74-110 on trade secrets. We recommend including specific trade secret statutes within this section. We recommend the Board includes the term "executive session", where confidential information can only be reviewed and discussed during executive sessions and governed by Colorado laws and regulations that govern these processes (C.R.S. § 24-6-402).

Furthermore, as staff engages with third-party consultants to assist in the compiling and/or analyzing of the data, we recommend that third-party consultants be subject to Conflict of Interest (COI) procedures and state procurement rules. This will ensure the information that is collected is transparent relative to the relationship/interest through COI disclosure. Additionally, third-party consultants and their contract agreements should be disclosed publicly per C.R.S. § 24-72-201 to 206.

CBSA and BIO recommend editing Section 7 as follows: "Confidentiality: A person submitting information for the Board's consideration pursuant to this Part 3 shall clearly designate the specific information it deems to be confidential, trade secret, or proprietary. The Board shall not disclose, in its summary report of affordability review created pursuant to this Part or otherwise, any information so designated.

General Comment: Upper Payment Limit Methodology:

CBSA and BIO have a few suggestions for the Board on the Upper Payment Limit (UPL) Methodology section. While the draft has yet to be released, we would like to flag a few items for the Board to consider.

- The Board's UPL determinations should have a defined process (i.e., issuing a proposed UPL and receiving comments on it).

- The Board should have more defined guardrails for setting the UPL. As the regulations are currently drafted, it appears the Board could pick an arbitrary price and then back into a justification by cherry-picking from the long list of factors it is required and permitted to consider.
- These regulations should be re-opened for comment after the UPL regulations are finalized. Asking for comment on these regulations before stakeholders understand the scope and impact of the UPL is putting the cart before the horse.

Overall, setting a UPL targets the most innovative medicines, disproportionately impacting patients with diseases where there is a high unmet need and where low-cost treatment options are not available (e.g., rare diseases), running counter to the aims of personalized medicine, and the availability of new treatments. Further troubling, the arbitrary nature of upper payment limits ignores the value that an innovative therapy can have to an individual patient—especially one who may have no other recourse—or the societal impact innovative technologies can have, including increased productivity and decreased overall healthcare costs (e.g., due to fewer hospitalizations, surgical interventions, and physicians' office visits).

Conclusion:

CBSA & BIO appreciates the opportunity to provide feedback to the Colorado PDAB through these proposed rules for comment. We look forward to continuing to work with the Board to ensure Coloradoans can access medicines in an efficient and timely manner. Should you have any questions, please do not hesitate to contact us at 303-592-4073(CBSA) or 202-962-9200 (BIO).

Sincerely,

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