COST-BENEFIT ANALYSIS

In performing a cost-benefit analysis, each rulemaking entity must provide the information requested for the cost-benefit analysis to be considered a good faith effort. The cost-benefit analysis must be submitted to the Office of Policy, Research and Regulatory Reform at least ten (10) days before the administrative hearing on the proposed rule and posted on your agency's web site. For all questions, please attach all underlying data that supports the statements or figures stated in this cost-benefit analysis.

DEPARTMENT: Regulatory Agencies (DORA) **AGENCY**: Division of Insurance

CCR: 3 CCR 702-9 Part 4 **DATE:** April 1, 2025

RULE TITLE OR SUBJECT: PART 4.3: CONCERNING AN UPPER PAYMENT LIMIT FOR ENBREL

Per the provisions of 24-4-103(2.5)(a), Colorado Revised Statutes, the cost-benefit analysis must include the following:

1. The reason for the rule or amendment;

By statute, the Prescription Drug Affordability Board (PDAB) may establish upper payment limits (UPLs) for prescription drugs it deems unaffordable, section 10-16-1407(1), C.R.S. The PDAB establishes UPLs through a rulemaking process and a notice has been published in the Colorado register that the Board will begin rulemaking to consider establishing a UPL for the prescription drug Enbrel.

The purpose of the UPL rule is to address high prescription drug costs and the impact these high costs have on patient access to drugs. The high cost of prescription drugs negatively impacts Coloradans' ability to purchase and adhere to the necessary medications they need to thrive. High drug costs also contribute to the unsustainable rise in health care costs and insurance premiums which further impacts the financial health of Coloradans,[1] [2] [3] threatening the health and safety of people in the state and disproportionately harming priority populations and Coloradans with low incomes.[4] *See* S.B. 175, 2021 Leg., 74th Gen. Assemb., 2nd Reg. Sess. (Co. 2021).

2. The anticipated economic benefits of the rule or amendment, which shall include economic growth, the creation of new jobs, and increased economic competitiveness;

UPLs are intended to achieve the following economic benefits:

- Reduce prescription drug costs for consumers. By statute, carriers must use savings from a UPL to reduce consumer costs via reduced out-of-pocket costs and lower premiums.
- Reduce prescription drug costs for consumers through increased competitiveness in the market and lower costs due to the availability of therapeutic alternatives. If the Board considers therapeutic alternatives to establish a specific UPL, this could result in increased use of targeted drugs and lower drug spending by consumers and payers, while maintaining access.[5]
- Increase consumer access to a drug by improving patient adherence and pharmacy fill rates, which can improve the health of consumers and limit increased use of additional medical services for worsening conditions.[6] [7]
- Improve affordability for the health care system by reducing health plan costs for the drug.

[1] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2773825
[2] https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet
[3] https://www.healthaffairs.org/doi/10.1377/hlthaff.2024.00469
[4] https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/
[5] https://eadn-wc03-8290287.nxedge.io/wp-content/uploads/2024/04/Upper-Payment-Limit-White-Paper.pdf
[6] https://pubmed.ncbi.nlm.nih.gov/37200029/
[7] https://pubmed.ncbi.nlm.nih.gov/17609491/

The anticipated economic benefit, including economic growth and the creation of new jobs, is difficult to quantify at this time for two main reasons:

- The Board has not yet specified a UPL amount - The Board is beginning a rulemaking process to review a significant volume of quantitative and qualitative data in determining whether to establish a UPL and what specific dollar amount the UPL should be. Without knowing the specific dollar amount the Board may eventually choose, it is difficult to make more precise estimates of economic benefits.[8]
- Unknown actions of prescription drug supply chain entities - Prescription drug regulations are created and updated at the federal and state levels frequently. The exact impact of such regulations depends on how the various, and often complex and opaquely related, prescription drug supply chain entities respond. The current anticipated economic benefit of the UPL to entities involved in the purchase of and reimbursement for a prescription is best assessed by the entities themselves. As the Board conducts rulemaking to establish a UPL, the Board encourages direct input from prescription drug supply chain entities during the rulemaking process to better understand the economic benefits of a UPL.

3. The anticipated costs of the rule or amendment, which shall include the direct costs to the government to administer the rule or amendment and the direct and indirect costs to business and other entities required to comply with the rule or amendment;

If the Board establishes a UPL, the following direct costs to the government may occur:

- Board staff time - If a UPL is established, staff time will be spent inquiring whether manufacturers intend to make the prescription drug available for sale in the state and rationale, notifying consumers of a decision to establish a UPL, and reporting on UPL and manufacturer responses to the General Assembly. It is anticipated these costs would be minimal.
- Attorney General Office (AGO) staff time - Pursuant to section 10-16-1411(3), C.R.S., the attorney general is authorized to enforce the UPL. The amount of resources needed to enforce a UPL is unknown at this time.

It is anticipated the following businesses and other entities may be impacted: consumers, health care providers, pharmacies, and health insurance carriers. While it is generally difficult to estimate the direct and indirect costs to businesses and other entities because of the two reasons (listed below and in the previous answer), generally it is estimated that the direct and indirect costs will be minimal since the UPL applies to one prescription drug, whereas health care providers, pharmacies, and health insurance carriers typically deal with thousands of prescriptions drugs:

- The Board has not yet specified the UPL amount - The Board is beginning a rulemaking process to review a significant volume of quantitative and qualitative data in determining whether to establish a UPL and what specific dollar amount the UPL should be. Without knowing the specific dollar amount the Board may eventually choose, it is difficult to make more precise estimates of anticipated costs.[9]
- Unknown actions of prescription drug supply chain entities - Prescription drug regulations are created and updated at the federal and state levels frequently. The exact impact of such regulations depends on how the various, and often complex and opaquely related, prescription drug supply chain entities respond. The current anticipated economic benefit of the UPL to entities involved in the purchase of and reimbursement for a prescription is best assessed by the entities themselves. As the Board conducts rulemaking to establish a UPL, the Board encourages direct input from prescription drug supply chain entities during the rulemaking process to better understand the economic benefits of a UPL.

While there may be actual costs to the drug supply chain associated with the implementation of a UPL, those costs are unknown and are unlikely to be substantial

[8] Oregon's PDAB has acknowledged it is difficult to estimate potential savings until a specific UPL is established (see: Prescription Drug Affordability Board (PDAB) Upper Payment Limit (UPL) Report to Legislature).
[9] Oregon's PDAB has acknowledged it is difficult to estimate potential savings until a specific UPL is established (see: Prescription Drug Affordability Board (PDAB) Upper Payment Limit (UPL) Report to Legislature).

4. Any adverse effects on the economy, consumers, private markets, small businesses, job creation, and economic competitiveness; and

It is not anticipated that the UPL will have an adverse effect on consumers, nor that there will be adverse effects on the economy, private markets, small businesses, job creation, and economic competitiveness for two reasons (listed below and in previous answers). Generally it is estimated that the direct and indirect costs will be minimal due to the scope of the rule and its applicability to one prescription drug specifically. While there are currently a total of three prescription drugs the Board has identified for a UPL, the Division anticipates initial effects of the UPL will be incrementally felt among the market in the initial stages of this work. Additionally, it should be noted one potential effect is that a manufacturer may withdraw the drug from the Colorado market, however Colorado Statute provides safeguards for consumers and fines for manufacturers who do not comply with noticing requirements.

- The Board has not yet specified the UPL amount - The Board is beginning a rulemaking process to review a significant volume of quantitative and qualitative data in determining whether to establish a UPL and what specific dollar amount the UPL should be. Without knowing the specific dollar amount the Board may eventually choose, it is difficult to make more precise estimates of adverse effects.[10]
- Unknown actions of prescription drug supply chain entities - Prescription drug regulations are created and updated at the federal and state levels frequently. The exact impact of such regulations depends on how the various, and often complex and opaquely related, prescription drug supply chain entities respond. The current anticipated economic benefit of the UPL to entities involved in the purchase of and reimbursement for a prescription is best assessed by the entities themselves. As the Board conducts rulemaking to establish a UPL, the Board encourages direct input from prescription drug supply chain entities during the rulemaking process to better understand the economic benefits of a UPL.

5. At least two alternatives to the proposed rule or amendment that can be identified by the submitting agency or a member of the public, including the costs and benefits of pursuing each of the alternatives identified.

One alternative to the proposed regulation would be to not adopt this regulation and not establish an Upper Payment Limit for Enbrel. Without establishing a UPL for this prescription drug, various entities, including Colorado consumers, may not be able to access Enbrel at a lower cost. If this regulation isn't adopted, prescription drug supply chain entities would likely continue operating as usual and the unsustainable high costs of prescription drugs would continue to grow.

Another alternative to the proposed regulation is that the Board could recommend to the General Assembly payment-specific, legislative strategies to address Enbrel's unaffordability for Colorado consumers. While the Board already has the ability to make recommendations to the General Assembly, the Board could provide payer- and payment-focused recommendations specific to the prescription drugs it finds unaffordable. Examples of recommendations could include co-payment caps for unaffordable prescription drugs, limits on utilization management, etc.

[10] Oregon's PDAB has acknowledged it is difficult to estimate potential savings until a specific UPL is established (see: Prescription Drug Affordability Board (PDAB) Upper Payment Limit (UPL) Report to Legislature).