Addressing the Crisis of High Drug Costs in NM:
Prescription Drug Affordability Board

Health Action New Mexico
New Mexico Consumers for Affordable Prescriptions

LHHS Drug Pricing Hearing
November 22, 2021

The skyrocketing cost of medications in the U.S. have created a crisis for patients in New Mexico.

As the profits for drug manufacturers increase, life-saving medications become unaffordable for more and more consumers, with **44% of New Mexicans reporting skipping doses or not filling a prescription due to cost**. This also burdens the healthcare system, as manageable conditions become unmanageable because the appropriate medications are out of reach.

New Mexico has the opportunity to forge a path forward through legislation creating a **Prescription Drug Affordability Board**. This board of experts, advised by a stakeholder council and supported by staff, will have the authority to set Upper Payment Limits for drugs bought and sold in New Mexico. **These limits will bring down costs for the supply chain, ultimately resulting in more affordable and accessible medications for patients in our state.**

Together, we can make prescriptions more affordable for all New Mexicans.

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Prescription Drug Affordability Board (PDAB)

Why is a PDAB important?

New Mexicans are struggling to afford the prescription drugs they need, often having to choose between their medication and other necessities, like rent and groceries. Prescription drug companies are the only cost center in the health care industry whose rates are not regulated. But we can hold them to the same standard, by setting upper payment limits for high-cost drugs. New Mexico can ensure that all of us have access to affordable medications, because drugs don't work if people can't afford them.

How does a PDAB work?

A Prescription Drug Affordability Board (PDAB) is an independent body with the authority to evaluate high-cost drugs and set reasonable rates for consumers to pay.

The state regulates the cost of health insurance, electricity and other critical utilities and it ought to look out for consumers of prescription medications as well. A PDAB balances consumer affordability with revenue needs of suppliers – revenues that allow service improvements.

The Board has five members, appointed by executive and legislative elected officials. It will review drugs that meet specific criteria or any prescription medication that creates affordability challenges to the New Mexico health care system, including to patients.

The Board will consider a broad range of factors when setting appropriate payment rates for reviewed drugs, allowing pharmaceutical manufacturers the opportunity to justify existing drug costs. Once a fair payment rate is determined, the Board sets an upper payment limit that applies to all purchasers and payor reimbursements in New Mexico, ensuring that lower costs benefit consumers.

For more information visit www.newmexicocap.org

Patient Stories

Kristina C- Albuquerque For the past 28 years, I've taken various $300,000 per-year drugs to treat my Gaucher's disease. Like other patients, I appreciate the innovative breakthroughs for new treatments, but I can't help but wonder if the price tag has reached the point of being absurd. These drug companies are earning unreasonable amounts, and they're earning all of this profit off of people's misfortune. Americans pay more for their prescription drugs than anyone else in the world. These unreasonably high drug prices have encouraged me to start fighting back and advocate for lower drug prices. Patients like me deserve leadership that works for affordable drugs.

Steven A- Albuquerque, NM I am 69, a Medicare beneficiary, and a veteran who has suffered from severe migraines for the last four years. Migraines impair my eyesight and my balance. When they hit, I suddenly can't stand bright light and have to stay in a dark room lying down, sometimes for days. The drug Ubrelvy provides the relief I need to live my life, but just 10 pills are priced as much as $3,000. I simply can't afford it. For an entire year, I jumped through hoops in order to get this medicine. I've managed to come up with the money with some help from my church community, but it isn't easy.

Gloria T- La Cruces, NM

I take Ozempic and struggle to afford the cost of my drugs. I often don't get my drugs because they are too highly-priced. My health shouldn't suffer because I cannot afford my prescriptions. No patient should forgo taking drugs because of drug companies' desire to make an extra buck off our backs.

Robert M- Clovis, NM

Each month I take eight prescriptions. This past month, while picking up my prescriptions, I discovered my insurance no longer covered my sleeping pills. This was the first time I saw the list price of these pills. Having to purchase seven other pricey medications including Ranitidine meant I could not afford my sleeping pills at their full $46 per month cost. Not taking my sleeping pills has had detrimental effects on my health. Since running out of pills, I've barely been able to sleep. My health and wellbeing shouldn't be contingent on month to month changes in my prescription costs and my ability to afford my drugs.

Amos M- Albuquerque, NM

Both my mom and wife have diabetes and each month they both struggle with the high costs of their medications. My wife's medication costs about $250 per month. These medications greatly help her health, but we often can't afford them because of their high cost. We need changes that help families like mine who struggle to afford our medications.

Provider Stories

Moriah Mohoney, NP I have been a primary care provider in New Mexico since 2004. I couldn't stay silent when I heard the committee was looking at the issue of prescription drug prices.

One of the worst examples I have seen this year of PRICE before Patients in medicine is patients who have been on long-acting insulin for diabetes. If their insurance changes their formulary they likely have to change to another form of the product.

What patients faced in 2021: When they went to the pharmacy to get the same insulin that they take to control their diabetes, they were told it is not covered, and they need to get a prescription for something that is covered. So they leave the pharmacy empty-handed. Patients need to somehow get ahold of their provider, hopefully to get a new prescription for the brand or generic medicine that is covered just like the one they have taken for years to control their diabetes. It is a fact that people go without treatment because they don't know what to do. **They are not pharmacists, they are not benefit managers, they are diabetics needing treatment.** Patients get lost in this scenario, they have their medications changed possibly to something that does not work as well only because of formulary changes. These patients could face the same thing all over again if they change insurance.

In our system a patient losing their life or limb due to not being able to take the treatment is somehow accepted, though the drug to prevent this avoidable impact costs 10 or 20 dollars.

It is unjust and immoral to put the patient's needs last in these situations.

Kathleen Mosley, RN MS, retired registered nurse specializing in asthma education I worked as a nurse educator for the American Lung Association, helping people with asthma to stay healthy, for many years. I'd like to tell you one story about how NM is failing to manage rapidly rising drug costs. Even Medicaid covered children, who should have no barriers, struggle to get the treatment they need, due to the hurdles created by insurers' search for the cheapest medicines.

A few Novembers ago, a patient of mine with severe asthma turned 12. With the diligent support of his mother, his knowledgable provider, Medicaid coverage, a case manager and me, a nurse educator-he was doing well. But after his birthday, Mom goes to pick up her son's asthma med. She's surprised that coverage is denied. The Managed Care Organization's pharmacy benefit manager had found a less expensive medication for 12 and older, and changed the formulary of drugs they pay for. When the mother, who speaks only Spanish, returns to the pharmacy after some calls she is told there's no prescription for the drug for her son.

The twelve year old has now been off his successful controller for almost a month. **It's now cold and flu season, the holidays, and this child isn't being treated for a disease that kills 9 Americans a day. It takes three weeks or a month for the new controller to be fully effective.** He was fully insured, had team coverage and training to use his inhaler, yet his health was impacted. Because the rising costs of drugs push our providers and plans to make changes to what is covered and prescribed, patients can't get the medicine they need.

Please act on this issue to help New Mexicans of all ages, with all kinds of health coverage, to feel better.

Prescription Drug Affordability Board

Summary: This legislation creates a 5-person independent board of experts with the authority to establish Upper Payment Limits (UPLs) on drugs bought and sold in New Mexico. It also establishes a 15-person stakeholder council to help select drugs for review. The bill also outlines the procedures for selecting drugs for review and choosing a UPL. The purpose of this legislation is to address the burden rising prescription drugs costs imposes on the healthcare system and patients in New Mexico.

Section 1 - **Title**
Section 2 - **Definitions**
Section 3 – Establishes the Prescription Drug Affordability Board, establishes terms, meeting frequency, and responsibilities/powers

A) Establishing the board
B) Board composition - five members appointed by governor, president pro tempore of the senate, minority floor leader of the senate, speaker of the house, minority floor leader of the senate
C) Mileage and per diem, no other compensation
D) Demonstrated expertise, not employee of manufacturer
E) Diversity of members (to extent practicable)
F) Potential conflicts of interests disclosed at appointment
G) Appointments made within 6 months of effective dates. 4-year terms, initial terms different based on who appointed
H) Removal process and cause – 3 members in favor of removal
I) Replacing vacancies
J) Elect chair and vice chair for board
K) Quorum – majority of members
L) Meeting frequency – 6x per year minimum
M) Accessing pricing information – enter into MOI with other states and/or buy pricing data
N) Additional powers – make rules for implementation, including a procedure to notify public of UPL
O) Board may enter into contracts with third parties
P) Third parties not allowed to release information
Q) Activities during open session – affordability reviews, UPLs, other decisions
R) Executive session

S) Public notice and opportunity for comment

Section 4 - **Conflicts of Interest** – board members may not vote when they or a family member stand to gain a financial benefit. Establishes requirements for disclosure.

Section 5 – **Creates Stakeholder Council** for purpose of providing input on board decisions and deliberations

A) Establishes council

B) 15 members:

Speaker of the house appoints: healthcare advocate, senior healthcare advocate, diverse communities rep, labor union rep, prescription researcher.

President pro temp appoints: doctor, nurse, hospital rep, carrier rep

Governor appoints: Pharma rep, generic drug rep, employer rep, IHS rep, PBM rep, pharmacist rep

C) Expertise of reps

D) Diversity of reps (to the extent practicable)

E) Terms for members – three years. Speaker's reps serve initial one-year term, pro temp's reps serve initial two years, governor's reps serve initial three years

F) Board chair selects two co-chairs for stakeholder council

G) Per diem and mileage

Section 6 – **Prescription Drug Cost Affordability Review** conducted by PDAB

A) Identify drugs for potential review

1. Brand name drugs which: (innovator)
    i. A launch WAC of more than $30,000
    ii. Increase in WAC of more than $3,000 in 12-month period
2. Biosimilars that are not at least 15% lower in price (than innovator product)
3. Generic drugs which:
    i. Cost more than $100 for a supply of 30 days or less
    ii. Increased in cost by over 200% in last year
4. Other prescription drugs that create affordability issue

B) Board determines whether to do an affordability review for each drug

1. Stakeholder council input
2. Average patient cost share

C) Information for affordability review – research on prices, market context, cost-effectiveness

D) If a manufacturer fails to provide the information for the review, the board will still conduct the review

E) **Affordability review** – if used as directed creates an affordability challenge for the state health care system or for patients. They will consider:

1. Wholesale acquisition cost of the drug
2. Average manufacturer rebate/discount to state
3. Average manufacturer rebate/discount to PBM
4. Price of therapeutic alternatives
5. Average manufacturer rebate/discount to health plan payers and PBMs for therapeutic alternatives
6. Cost to health plans when used as directed
7. Impact of cost on patient access
8. Dollar value of a drug-specific patient access program
9. Financial impacts comparted to therapeutic alternatives
10. Average patient cost share
11. Impact on 340B of federal Public Health Service Act
12. Orphan drug status
13. Additional info from manufacturer
14. Anything else as outlined by board rules

F) If affordability challenge is identified, **board establishes an Upper Payment Limit** which considers:

1. Cost of administering drugs
2. Cost of delivering drug to consumer
3. Other admin costs

G) Methodology must consider impact to older adults. Cost-per-quality adjusted life year measures may not be used

H) UPL will take effect no sooner than 6 months after UPL established

I) UPL applies to all purchases and payer reimbursements for the drug

J) Independent pharmacies may not be reimbursed less than UPL

K) UPL shall not include dispensing fee for pharmacies

L) **Health plan savings from UPL shall be used to reduce cost, especially out-of-pocket costs for patients ___**

M) Information submitted to board only accessible to public as allowed by Inspection of Public Records Act

N) Manufacturers are not prevented from advertising a drug while it is being reviewed

<u>Section 7</u> - **Attorney General Remedy**

<u>Section 8</u> - **Appeal Process for Manufacturers**

<u>Section 9</u> - **Prescription Drug Affordability Fund** - license fee on manufacturers, distributors, repackagers, no more than $2000

Section 10 - **Legislative Reports** - PDAB will report annually to legislature on drug pricing trends, which and how many drugs were reviewed that year, recommendations on other legislation. Will also annually study and report on generic drug market, how accessible and affordable generic drugs are.

Section 11 – **Medicare**

Section 12 – Severability

Section 13 – Effective Date

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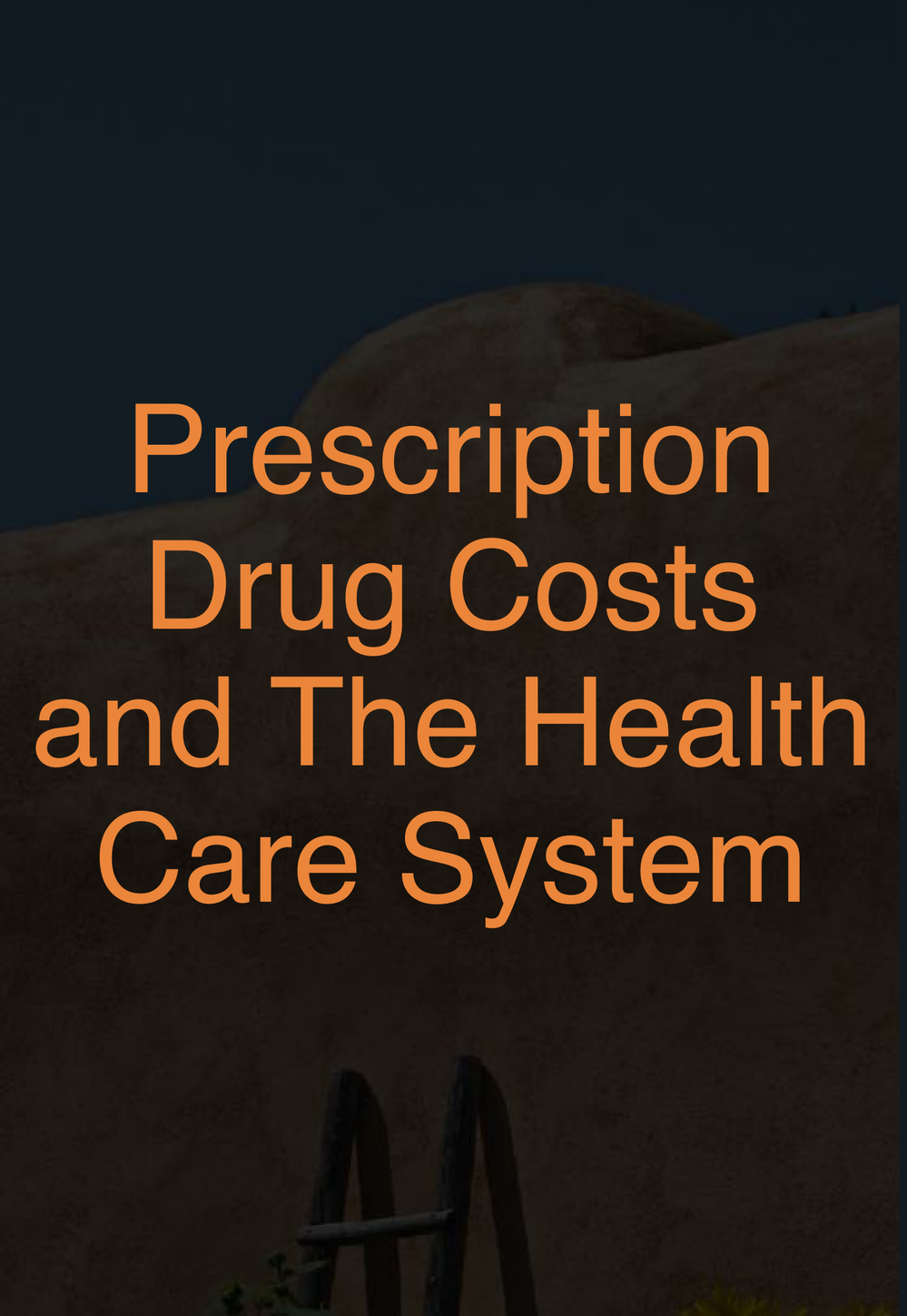
Prescription Drug Affordability Crisis in NM: Challenges & Solutions

Together, we can make prescriptions more affordable for all New Mexicans.

LHHS Drug Pricing Hearing, November 22, 2021



Prescription Drug Costs and The Health Care System

Prescription drug costs are the largest driver of rising health care system expenditures.

Drug pricing has not been addressed at the federal level, and prescription drug companies are the only cost center in the health care industry whose rates are not regulated.

Rising drug prices, beginning with the manufacturers, trickle down through the supply chain. Insurance carriers, for instance, account for the high cost of prescription drugs through higher premiums, copays, and deductibles.

Ultimately, these costs mean patients in our state don’t have access to the medications they need.

Drug costs were out of control before COVID, but studies show the pharmaceutical industry has taken advantage of the pandemic to further raise prices on 645 brands almost six percent in the first eight months of 2020.

How Prescription Drug Prices Affect New Mexicans

In October 2020, GBAO Polling firm conducted statewide polling in NM on medication issues:

44% of New Mexicans said they had not filled a prescription, or skipped taking medications as prescribed, because of cost concerns; more than twice the US rate of 18%.*

New Mexicans, regardless of race, ethnicity or party affiliation, rated the cost of drugs in their top 4 concerns:
1. Cost of Health Care; 2. Level of Poverty in NM; 3. Lack of good jobs; 4. **Cost of RX**.
(These concerns were higher than crime, school quality and funding, COVID-19, & taxes)

78% of respondents supported a Prescription Drug Affordability Board –
an effective state-level solution to address high drug costs.

*2021 Gallup poll, Kaiser Family Foundation

Patients Speak Out

Jeanne’s medication for MS has skyrocketed to from $18,000 to $90,000 a year, exhausting her retirement savings.

Martha, Santa Fe was scared for her family’s financial future once they recommended a medication to treat her rare cancer. $26,000 a month was not within her family’s means…the cost of treatment was unmanageable.

Kristen, Albuquerque, was diagnosed with an autoimmune disease after years of severe symptoms, but the treatment recommended by her doctor is not covered by her insurance & not affordable.

Kristina has Gaucher’s disease. She has been forced to make life and career choices out of fear of losing the coverage that she needs to afford her life-saving medication.

Patient Voices

Barbara W, Albuquerque

When the medication that worked for me jumped from $5 to $1700, my rheumatologist said 4-hour infusions in the hospital every 8 weeks would be covered by Medicare Part D.But while I waited to get on Medicare my joints became inflamed. The rheumatologist said that it was psoriatic arthritis – dormant with medication but now active. X-rays showed permanent, irreversible damage to my joints.

Robert M- Clovis, NM

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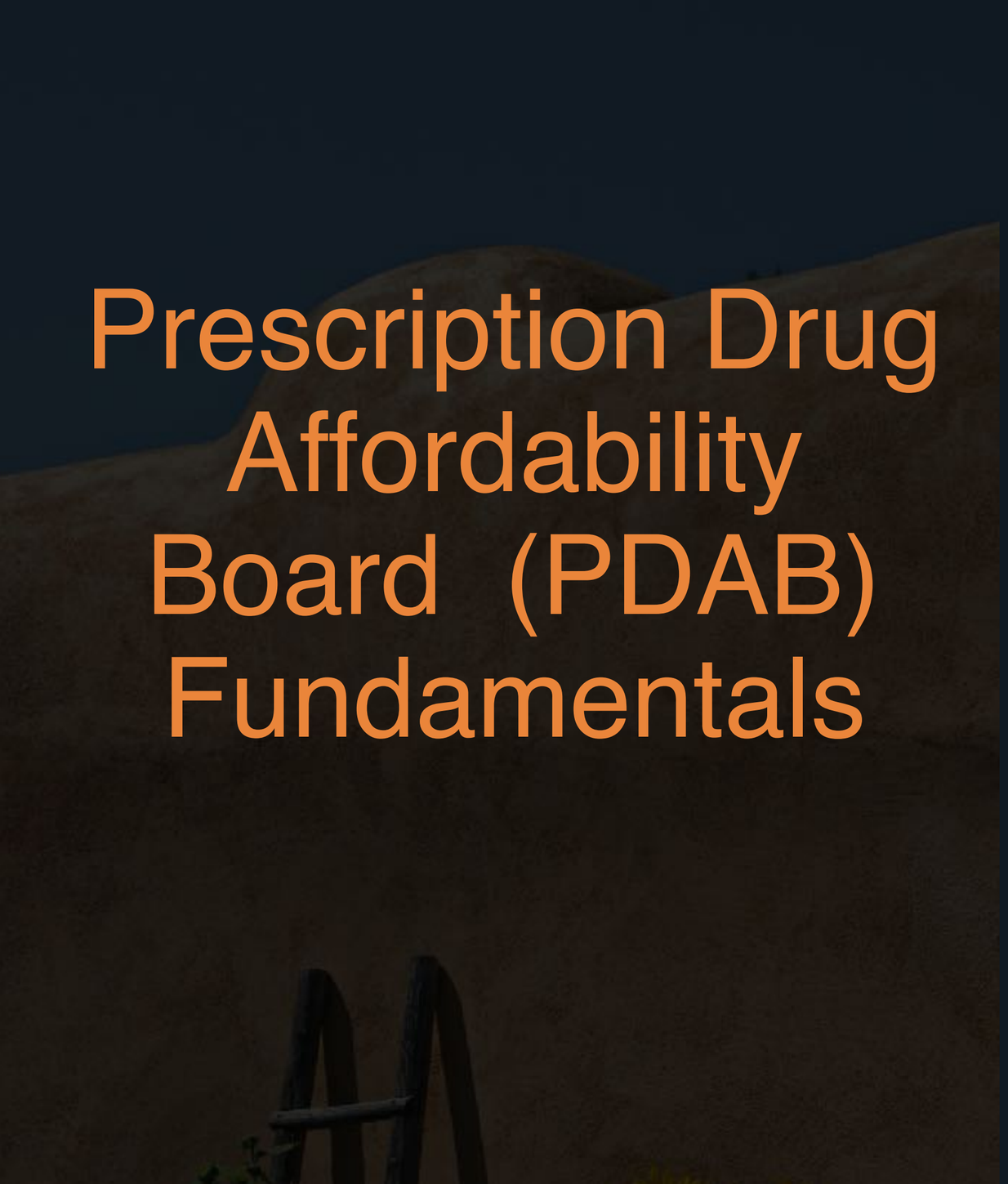
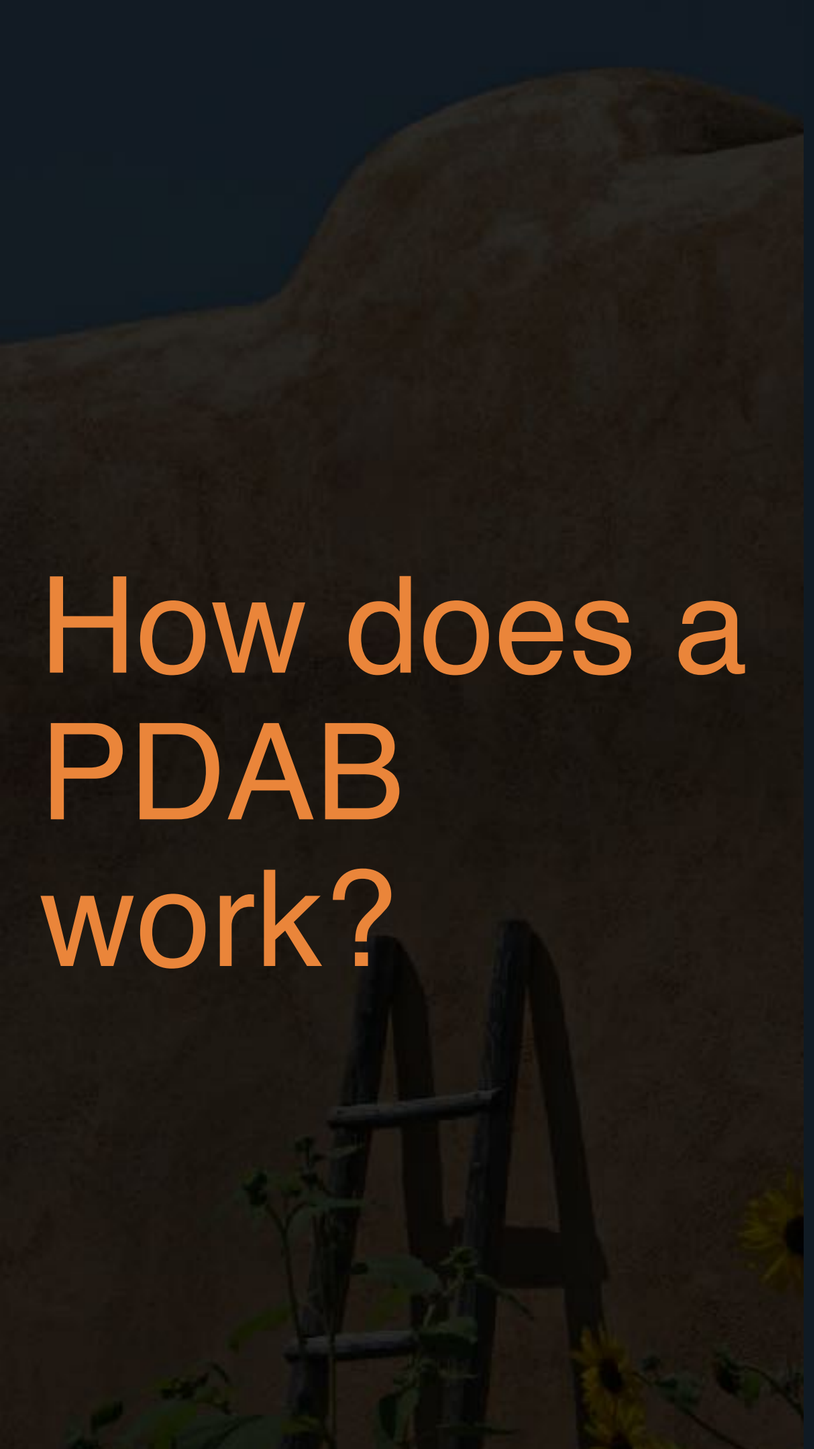
Prescription Drug Affordability Board (PDAB) Fundamentals



Just as public utility boards determine the most we can be charged for clean water, we need the same for prescriptions.

The PDAB will evaluate up to 12 high-cost drugs each year.

Using data provided by drug makers about costs to manufacture, and prices around the world, a PDAB can set an Upper Payment Limit (UPL) on those drugs for all buyers in NM. That limit applies to all buyers: patients, health plans, pharmacies, wholesalers, and manufacturers.



How does a PDAB work?

The Board

5 independent experts on clinical care and health care payments will be appointed by elected officials in staggered terms. The board has the authority to set upper payment limits for certain drugs, and acts as a clearinghouse for prescription drug policy expertise, reporting to the legislature.

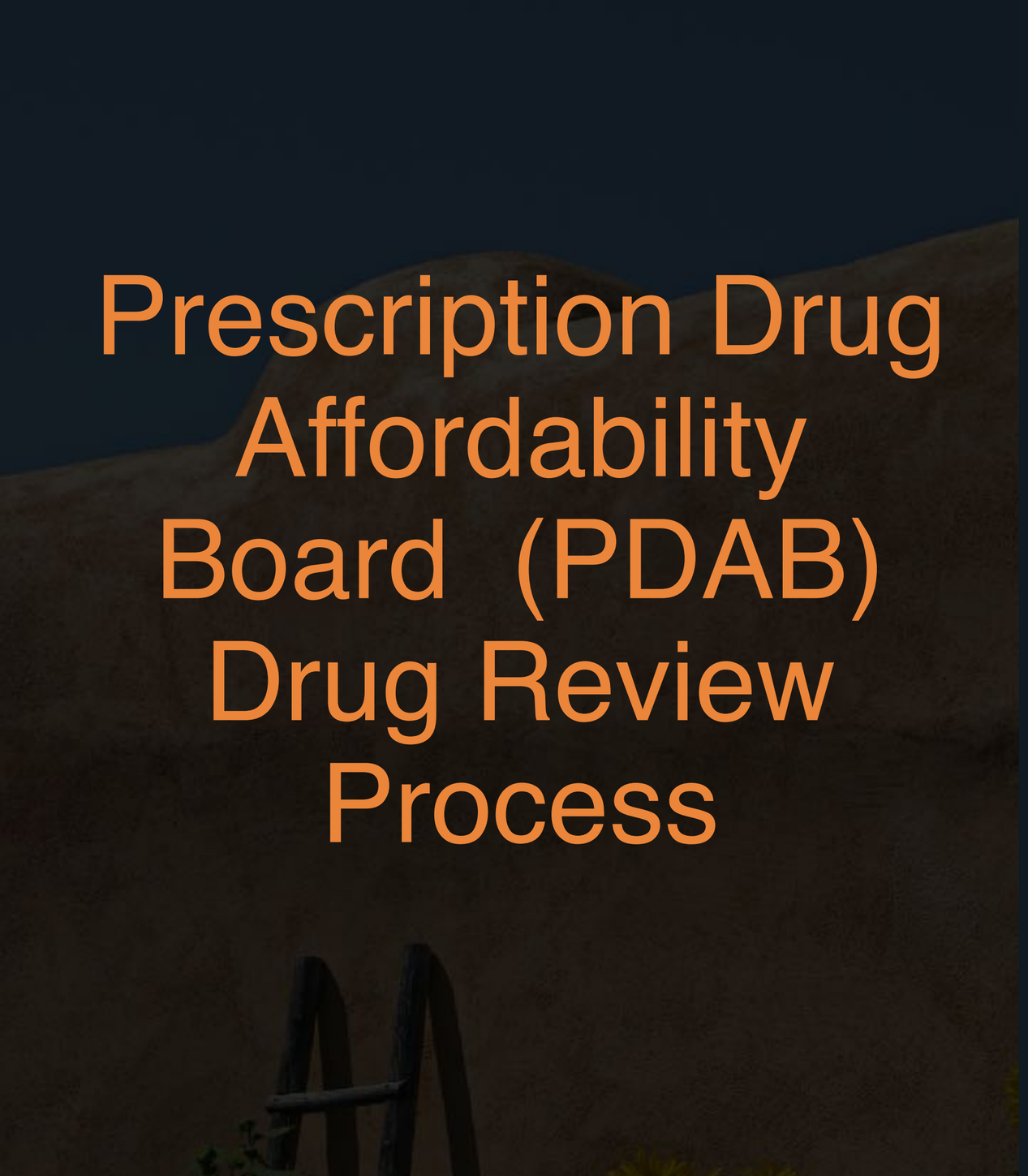
Stakeholder Council

15 stakeholders appointed by the governor and legislative leaders are advocates, health care providers, pharmacies, health plans, hospitals and market entities. They will recommend medicines for PDAB to review.

Statewide Scale

Statewide cost limits help patients and their health insurers to plan. Rebates, coupons and samples aren't needed for these drugs, so every buyer knows they are paying the same price for that medicine.

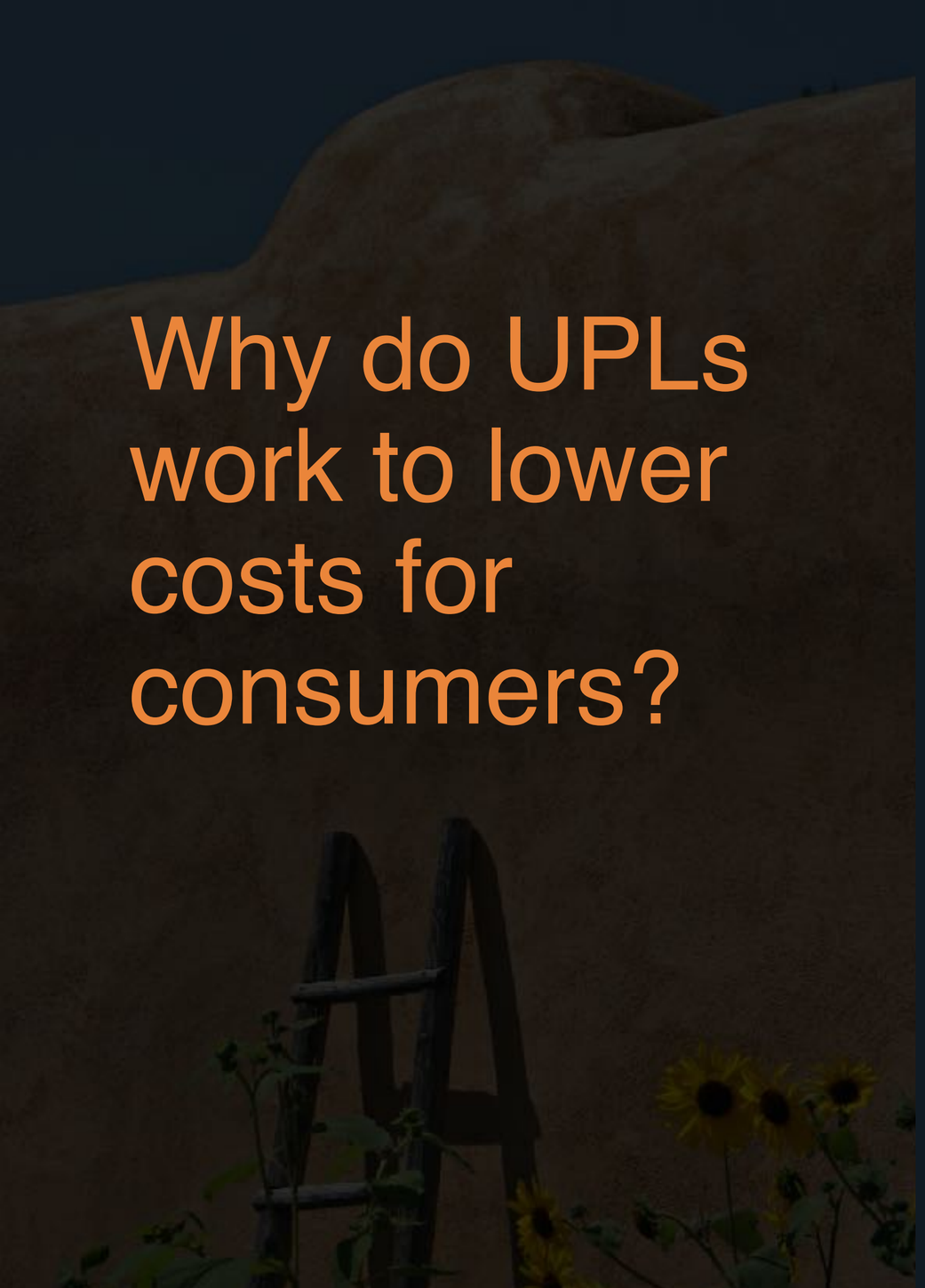
Prescription Drug Affordability Board (PDAB) Drug Review Process



The PDAB lowers costs by setting Upper Payment Limits–the most a specific drug can cost for any buyer in New Mexico–for some high-cost drugs.

Using manufacturer and market data on what prices are charged around the world, the PDAB can determine an affordable cost to patients and health plans.

Manufacturers will be asked to share data to support the prices that make the drug eligible for review. Any UPL set by the board accounts for those inputs about their costs.



Why do UPLs work to lower costs for consumers?

Upper Payment Limits (UPLs) set a cost limit for particular drugs that is the maximum that can be billed for those drugs by pharmacies, patients, and health plans that cover the prescription.

By setting a UPL that's effective throughout the supply chain, payments for medicine become more predictable and transparent.

Ultimately, this means more affordable and accessible medications for patients.

Common concerns about state action on prescription drug costs

Will this stifle innovation and prevent new drugs from entering the market?

In the U.S., drug manufacturers spend billions of dollars on marketing, often more than what they spend on research and development. Price limits on a small number of drugs will not endanger innovation.

Will manufacturers stop selling certain drugs in NM if they are assigned a UPL?

In other states with a PDAB, no drug that has been assigned a UPL has been pulled from the market, and there is still profit for manufacturers.

Will this prevent manufacturers, PBMs, insurance carriers, pharmacies, and other entities from making a profit?

No, for several reasons. First, of the over 20,000 FDA approved drugs in the U.S., this will only target those that create a significant affordability issue for a max of 12 reviews per year. Second, this will not replace the system of negotiation and contracts that exists between these entities, and drug prices will still normalize to a place where there is profit within the supply chain. Lastly, this gives each entity a formal voice on the Stakeholder Council to help set UPLs at a level that will work for the entire supply chain.

Drugs don't work if people can't afford them.

Barbara Webber, Executive Director, Health Action NM, barbara@healthactionnm.org

Sara Manns, Campaign Director, NM Consumers for Affordable Prescriptions, sara@healthactionnm.org

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