

1 HOUSE BILL 154

2 **55TH LEGISLATURE - STATE OF NEW MEXICO - FIRST SESSION, 2021**

3 INTRODUCED BY

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10 AN ACT

11 RELATING TO PRESCRIPTION DRUGS; ENACTING THE PRESCRIPTION DRUG  
12 AFFORDABILITY ACT; ESTABLISHING THE PRESCRIPTION DRUG  
13 AFFORDABILITY BOARD AND THE PRESCRIPTION DRUG AFFORDABILITY  
14 STAKEHOLDER COUNCIL; CREATING THE PRESCRIPTION DRUG  
15 AFFORDABILITY FUND; MAKING AN APPROPRIATION.

16  
17 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF NEW MEXICO:

18 SECTION 1. [NEW MATERIAL] SHORT TITLE.--This act may be  
19 cited as the "Prescription Drug Affordability Act".

20 SECTION 2. [NEW MATERIAL] DEFINITIONS.--As used in the  
21 Prescription Drug Affordability Act:

22 A. "biologic" means a drug produced or distributed  
23 in accordance with a biologics license application approved  
24 pursuant to 42 C.F.R. 447.502;

25 B. "biosimilar" means a drug that is produced or

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1 distributed in accordance with a biologics license application  
2 approved pursuant to Paragraph (3) of Subsection K of 42 U.S.C.  
3 262;

4 C. "board" means the prescription drug  
5 affordability board;

6 D. "brand name drug" means a drug that is produced  
7 or distributed in accordance with an original new drug  
8 application approved pursuant to Subsection C of 21 U.S.C. 355  
9 but does not mean an authorized generic drug as defined by 42  
10 C.F.R. 447.502;

11 E. "generic drug" means:

12 (1) a retail drug that is marketed or  
13 distributed in accordance with an abbreviated new drug  
14 application, approved pursuant to Subsection J of 21 U.S.C.  
15 355;

16 (2) an authorized generic drug as defined by  
17 42 C.F.R. 447.502; or

18 (3) a drug that entered the market before 1962  
19 that was not originally marketed under a new drug application;

20 F. "manufacturer" means an entity that:

21 (1) engages in the manufacture of a  
22 prescription drug product; or

23 (2) enters into a lease with another  
24 manufacturer to market and distribute a prescription drug  
25 product under the entity's own name; and

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1 (3) sets or changes the wholesale acquisition  
2 cost of the prescription drug product it manufactures or  
3 markets;

4 G. "prescription drug product" means a brand name  
5 drug, generic drug, biologic or biosimilar;

6 H. "stakeholder council" means the prescription  
7 drug affordability stakeholder council;

8 I. "therapeutic alternative" means a product that  
9 treats the same disease in similar but not identical manner;  
10 and

11 J. "wholesale acquisition cost" means the  
12 manufacturer's list price for a drug or biologic for  
13 wholesalers or direct purchasers in the United States, not  
14 including prompt pay or other discounts, rebates or reductions  
15 in price.

16 SECTION 3. [NEW MATERIAL] PRESCRIPTION DRUG AFFORDABILITY  
17 BOARD.--

18 A. The "prescription drug affordability board" is  
19 created. The purpose of the board is to protect state  
20 residents, state and local governments, commercial health  
21 plans, health care providers, pharmacies licensed in the state  
22 and other stakeholders within the health care system from the  
23 high cost of prescription drug products. The board is an  
24 instrumentality of the state. The exercise by the board of its  
25 authority pursuant to the Prescription Drug Affordability Act

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1 is an essential function.

2 B. The board consists of five members appointed as  
3 follows:

4 (1) one member appointed by the governor;

5 (2) one member appointed by the president pro  
6 tempore of the senate;

7 (3) one member appointed by the minority floor  
8 leader of the senate;

9 (4) one member appointed by the speaker of the  
10 house of representatives; and

11 (5) one member appointed by the minority floor  
12 leader of the house of representatives.

13 C. Members of the board are entitled to receive per  
14 diem and mileage pursuant to the Per Diem and Mileage Act and  
15 shall receive no other compensation, perquisite or allowance.

16 D. Board members shall collectively have expertise  
17 in health care economics or clinical medicine. A board member  
18 shall not be an employee of, a board member of or a consultant  
19 to a manufacturer or trade association for manufacturers.

20 E. Any potential conflict of interest, including  
21 whether a person has an association, including a financial or  
22 personal association, that has the potential to bias or has the  
23 appearance of biasing a person's decision in matters related to  
24 the board or the conduct of the board's activities, shall be  
25 considered and disclosed when board members are appointed.

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1 F. Board members shall serve four-year terms. The  
2 terms of the initial board members shall expire as follows:

3 (1) the members appointed by the minority  
4 floor leader of the senate and the minority floor leader of the  
5 house of representatives, December 31, 2023;

6 (2) the members appointed by the president pro  
7 tempore of the senate and the speaker of the house of  
8 representatives, December 31, 2024; and

9 (3) the member appointed by the governor,  
10 December 31, 2025.

11 G. A member of the board may be removed from the  
12 board by a vote of at least three members of the board if a  
13 member of the board fails to disclose a conflict of interest or  
14 for other good cause.

15 H. If there is a vacancy on the board, a new member  
16 of the board shall be appointed by the authority that appointed  
17 the former member to serve the remainder of the former member's  
18 term.

19 I. The board members shall elect a chair and a vice  
20 chair of the board.

21 J. A majority of the members of the board  
22 constitutes a quorum for the purposes of conducting the  
23 business of the board.

24 K. The board shall meet in open session at least  
25 six times per year to review prescription drug product

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1 information or other drug affordability pricing options. The  
2 chair may cancel or postpone a meeting if there are no  
3 prescription drug products to review or other board items for  
4 discussion.

5 L. To the extent practicable, the board shall  
6 access pricing information for prescription drug products by:

7 (1) entering into a memorandum of  
8 understanding with other states to which manufacturers already  
9 report pricing information; and

10 (2) accessing other available pricing  
11 information.

12 M. In addition to the powers set forth elsewhere in  
13 the Prescription Drug Affordability Act, the board may:

14 (1) promulgate rules for the implementation of  
15 the Prescription Drug Affordability Act; and

16 (2) enter into contracts with qualified,  
17 independent third parties for services necessary to carry out  
18 the powers and duties of the board.

19 N. Unless permission is granted by the board, a  
20 third party hired by the board shall not release, publish or  
21 otherwise use any information to which the third party has  
22 access pursuant to its contract with the board.

23 O. The following actions by the board shall be made  
24 in open session:

25 (1) deliberations on whether to subject a

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1 prescription drug product to a cost review pursuant to Section  
2 6 of the Prescription Drug Affordability Act;

3 (2) a vote on whether to impose an upper  
4 payment limit on purchases and payer reimbursements of  
5 prescription drug products in the state; and

6 (3) any decision by the board.

7 P. The board may meet in executive session to  
8 discuss proprietary data and information.

9 Q. The board shall provide public notice of each  
10 board meeting at least two weeks in advance of the meeting.  
11 Materials for each board meeting shall be made available to the  
12 public at least one week in advance of the meeting. The board  
13 shall provide an opportunity for public comment at each meeting  
14 of the board. The board shall provide the public with the  
15 opportunity to provide written comments on pending decisions of  
16 the board. The board may allow expert testimony at board  
17 meetings, including when the board meets in closed session.

18 SECTION 4. [NEW MATERIAL] CONFLICTS OF INTEREST.--

19 A. Members of the board shall recuse themselves  
20 from decisions related to a prescription drug product if the  
21 member, or an immediate family member of the member, has  
22 received or could receive either of the following:

23 (1) a direct financial benefit of any amount  
24 deriving from the result or finding of a study or determination  
25 by or for the board; or

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1 (2) a financial benefit from any person that  
2 owns, manufactures or provides prescription drug products,  
3 services or items to be studied by the board that in the  
4 aggregate exceeds five thousand dollars (\$5,000) per year.

5 B. As used in this section, "financial benefit"  
6 includes honoraria, fees, stock, the value of the member's or  
7 immediate family member's stock holdings and any direct  
8 financial benefit deriving from the finding of a review  
9 conducted pursuant to the Prescription Drug Affordability Act.

10 C. A conflict of interest shall be disclosed by:

11 (1) the board when hiring board staff;

12 (2) the appointing authority when appointing  
13 members to the board and members to the stakeholder council;  
14 and

15 (3) the board when a member of the board is  
16 recused in any final decision resulting from a review of a  
17 prescription drug product.

18 D. A conflict of interest shall be disclosed:

19 (1) in advance of the first open meeting after  
20 the conflict is identified; or

21 (2) within five days after the conflict is  
22 identified.

23 E. A conflict of interest disclosed pursuant to  
24 this section shall be posted on the website of the board unless  
25 the chair of the board recuses the member from any final

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1 decision resulting from a review of a prescription drug  
2 product. A posting pursuant to this subsection shall include  
3 the type, nature and magnitude of the interests of the member  
4 involved.

5 F. Members of the board, board staff and  
6 third-party contractors may not accept any gift or donation of  
7 services or property that indicates a potential conflict of  
8 interest or has the appearance of biasing the work of the  
9 board.

10 SECTION 5. [NEW MATERIAL] PRESCRIPTION DRUG AFFORDABILITY  
11 STAKEHOLDER COUNCIL.--

12 A. The "prescription drug affordability stakeholder  
13 council" is created. The purpose of the stakeholder council is  
14 to provide stakeholder input to assist the board in making  
15 decisions as required pursuant to the Prescription Drug  
16 Affordability Act.

17 B. The stakeholder council consists of fifteen  
18 members, appointed as follows:

19 (1) the speaker of the house of  
20 representatives shall appoint:

21 (a) one representative of a statewide  
22 health care advocacy coalition;

23 (b) one representative of a statewide  
24 advocacy organization for seniors;

25 (c) one representative of a statewide

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1 organization for diverse communities;

2 (d) one representative of a labor union;

3 and

4 (e) one health services researcher  
5 specializing in prescription drug products;

6 (2) the president pro tempore of the senate  
7 shall appoint:

8 (a) one representative of doctors;

9 (b) one representative of nurses;

10 (c) one representative of hospitals; and

11 (d) one representative of health

12 insurers; and

13 (3) the governor shall appoint:

14 (a) one representative of brand name  
15 drug corporations;

16 (b) one representative of generic drug  
17 corporations;

18 (c) one representative of employers;

19 (d) one representative of the Indian  
20 health service of the United States department of health and  
21 human services;

22 (e) one representative of pharmacy  
23 benefits managers; and

24 (f) one representative of pharmacists.

25 C. Members of the stakeholder council shall have

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1 knowledge of one or more of the following:

- 2 (1) the pharmaceutical business model;
- 3 (2) supply chain business models;
- 4 (3) the practice of medicine or clinical  
5 training;
- 6 (4) consumer or patient perspectives;
- 7 (5) health care costs trends and drivers;
- 8 (6) clinical and health services research; and
- 9 (7) the state's health care marketplace.

10 D. Members of the stakeholder council shall serve  
11 for three-year terms. The members of the stakeholder council  
12 appointed by the speaker of the house of representatives shall  
13 serve an initial term of one year. The members of the  
14 stakeholder council appointed by the president pro tempore of  
15 the senate shall serve an initial term of two years. The  
16 members of the stakeholder council appointed by the governor  
17 shall serve an initial term of three years.

18 E. The board chair shall appoint two members of the  
19 stakeholder council to be co-chairs of the stakeholder council.

20 F. Members of the stakeholder council are entitled  
21 to receive per diem and mileage pursuant to the Per Diem and  
22 Mileage Act and shall receive no other compensation, perquisite  
23 or allowance.

24 SECTION 6. [NEW MATERIAL] PRESCRIPTION DRUG PRODUCT COST  
25 AFFORDABILITY REVIEW.--

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1           A. The board shall identify prescription drug  
2 products that are:

3                   (1) brand name drugs or biologics that, as  
4 adjusted annually for inflation in accordance with the consumer  
5 price index published by the bureau of labor statistics of the  
6 United States department of labor, have:

7                           (a) a launch wholesale acquisition cost  
8 of thirty thousand dollars (\$30,000) or more per year or course  
9 of treatment; or

10                           (b) a wholesale acquisition cost  
11 increase of three thousand dollars (\$3,000) or more in any  
12 twelve-month period or course of treatment if less than twelve  
13 months;

14                   (2) biosimilars that have a launch wholesale  
15 acquisition cost that is not at least fifteen percent lower  
16 than the referenced brand biologic at the time the biosimilars  
17 are launched;

18                   (3) generic drugs that, as adjusted annually  
19 for inflation in accordance with the consumer price index  
20 published by the bureau of labor statistics of the United  
21 States department of labor, have a wholesale acquisition cost:

22                           (a) of one hundred dollars (\$100) or  
23 more for: 1) a thirty-day supply lasting a patient for a  
24 period of thirty consecutive days based on the recommended  
25 dosage approved for labeling by the United States food and drug

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1 administration; 2) a supply lasting a patient for fewer than  
2 thirty days based on the recommended dosage approved for  
3 labeling by the United States food and drug administration; or  
4 3) one unit of the drug if the labeling approved by the United  
5 States food and drug administration does not recommend a finite  
6 dosage; and

7 (b) that increased by two hundred  
8 percent or more during the immediately preceding twelve-month  
9 period, as determined by the difference between the resulting  
10 wholesale acquisition cost and the average of the wholesale  
11 acquisition cost reported over the immediately preceding twelve  
12 months; and

13 (4) other prescription drug products that may  
14 create affordability challenges for the state health care  
15 system and patients, in consultation with the stakeholder  
16 council.

17 B. After identifying prescription drug products as  
18 required by Subsection A of this section, the board shall  
19 determine whether to conduct an affordability review for each  
20 identified prescription drug product by:

21 (1) seeking stakeholder council input about  
22 the prescription drug product; and

23 (2) considering the average patient cost share  
24 of the prescription drug product.

25 C. The information to conduct a prescription drug

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1 product cost affordability review may include any document and  
2 research related to the manufacturer's selection of the  
3 introductory price or price increase of the prescription drug  
4 product, including life cycle management, net average price in  
5 the state, market competition and context, projected revenue  
6 and the estimated value or cost-effectiveness of the  
7 prescription drug product.

8 D. Failure of a manufacturer to provide the board  
9 with the information for a prescription drug product cost  
10 affordability review does not affect the authority of the board  
11 to conduct such a review.

12 E. If the board conducts a review of the cost and  
13 affordability of a prescription drug product, the review shall  
14 determine whether use of the prescription drug product that is  
15 fully consistent with the labeling approved by the United  
16 States food and drug administration or standard medical  
17 practice has led or will lead to affordability challenges for  
18 the state health care system or high out-of-pocket costs for  
19 patients. To the extent practicable, in determining whether a  
20 prescription drug product has led or will lead to an  
21 affordability challenge, the board shall consider the following  
22 factors:

23 (1) the wholesale acquisition cost for the  
24 prescription drug product sold in the state;

25 (2) the average monetary price concession,

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1 discount or rebate the manufacturer provides to health plans in  
2 the state or is expected to provide to health plans in the  
3 state as reported by manufacturers and health plans, expressed  
4 as a percent of the wholesale acquisition cost for the  
5 prescription drug product under review;

6 (3) the total amount of the price concession,  
7 discount or rebate the manufacturer provides to each pharmacy  
8 benefits manager operating in the state for the prescription  
9 drug product under review, as reported by manufacturers and  
10 pharmacy benefits managers, expressed as a percent of the  
11 wholesale acquisition costs;

12 (4) the price at which therapeutic  
13 alternatives have been sold in the state;

14 (5) the average monetary concession, discount  
15 or rebate the manufacturer provides or is expected to provide  
16 to health plan payers and pharmacy benefits managers in the  
17 state for therapeutic alternatives;

18 (6) the costs to health plans based on patient  
19 access consistent with United States food and drug  
20 administration labeled indications and recognized standard  
21 medical practice;

22 (7) the impact on patient access resulting  
23 from the cost of the prescription drug product relative to  
24 insurance benefit design;

25 (8) the current or expected dollar value of

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1 drug-specific patient access programs that are supported by the  
2 manufacturer;

3 (9) the relative financial impacts to health,  
4 medical or social services costs as can be quantified and  
5 compared to baseline effects of existing therapeutic  
6 alternatives;

7 (10) the average patient copayment or other  
8 cost sharing for the prescription drug product in the state;

9 (11) any information a manufacturer chooses to  
10 provide; and

11 (12) any other factors as required by rule  
12 promulgated by the board.

13 F. If the board finds the spending on a  
14 prescription drug product reviewed pursuant to this section has  
15 led or will lead to an affordability challenge, the board shall  
16 establish an upper payment limit after considering:

17 (1) the cost of administering the drug;

18 (2) the cost of delivering the drug to  
19 consumers; and

20 (3) other relevant administrative costs  
21 related to the drug.

22 G. The upper payment limit shall apply to all  
23 purchases and payer reimbursements of the prescription drug  
24 product dispensed or administered to individuals in the state  
25 in person, by mail or by other means.

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1           H. Information submitted to the board in accordance  
2 with this section shall be subject to public inspection only to  
3 the extent allowed pursuant to the Inspection of Public Records  
4 Act.

5           I. This section shall not be construed to prevent a  
6 manufacturer from marketing a prescription drug product  
7 approved by the United States food and drug administration  
8 while the product is being reviewed by the board.

9           **SECTION 7. [NEW MATERIAL] REMEDIES.--**The office of the  
10 attorney general may pursue any available remedy pursuant to  
11 state law when enforcing the Prescription Drug Affordability  
12 Act.

13           **SECTION 8. [NEW MATERIAL] APPEALS.--**

14           A. A manufacturer aggrieved by a decision of the  
15 board may request an appeal of the decision within thirty days  
16 after the decision by the board.

17           B. The board shall hear the appeal and make a final  
18 decision within sixty days after the appeal is requested.

19           C. A manufacturer aggrieved by a final decision of  
20 the board may petition for judicial review pursuant to Section  
21 12-8-16 NMSA 1978.

22           **SECTION 9. [NEW MATERIAL] PRESCRIPTION DRUG AFFORDABILITY**  
23 **FUND CREATED.--**

24           A. As used in this section, "fund" means the  
25 prescription drug affordability fund.

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1           B. The "prescription drug affordability fund" is  
2 created in the state treasury.

3           C. The board shall be funded by an assessment on  
4 licenses of manufacturers, virtual manufacturers, wholesale  
5 distributors, virtual wholesale distributors, third-party  
6 logistics providers and repackagers.

7           D. The board shall assess and collect fees as  
8 provided in this section. The board shall annually assess each  
9 manufacturer, virtual manufacturer, wholesale distributor,  
10 virtual wholesale distributor, third-party logistics provider  
11 and repackager based upon the manufacturer's, virtual  
12 manufacturer's, wholesale distributor's, virtual wholesale  
13 distributor's, third-party logistics provider's or repackager's  
14 relative share of gross revenue from drug sales in New Mexico.  
15 The annual assessment per license shall not exceed two thousand  
16 dollars (\$2,000).

17           E. Each year, manufacturers, virtual manufacturers,  
18 wholesale distributors, virtual wholesale distributors, third-  
19 party logistics providers and repackagers assessed a fee  
20 pursuant to this section shall pay that fee to the board.

21           F. The board shall pay all funds collected from the  
22 assessment into the fund.

23           G. The state treasurer shall hold the fund  
24 separately, and the state treasurer shall account for that  
25 fund.

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1           H. The fund shall be used only to provide funding  
2 for the board and for the purposes authorized pursuant to the  
3 Prescription Drug Affordability Act, including any costs  
4 expended by any state agency to implement that act.

5           I. The fund shall be invested and reinvested in the  
6 same manner as other state funds.

7           J. Any investment earnings shall be retained to the  
8 credit of the fund.

9           K. This section may not be construed to prohibit  
10 the fund from receiving money from any other source.

11           L. The board shall be established using general  
12 funds, which shall be repaid to the general fund with the  
13 assessments required pursuant to this section.

14           SECTION 10. [NEW MATERIAL] LEGISLATIVE REPORTS.--

15           A. On or before September 30 of each year,  
16 beginning in 2022, the board shall submit to the legislative  
17 finance committee and the legislative health and human services  
18 committee a report that includes:

19                   (1) price trends for prescription drug  
20 products;

21                   (2) the number of prescription drug products  
22 that were subject to board review, including the results of the  
23 review and the number and disposition of appeals and judicial  
24 reviews of board decisions; and

25                   (3) any recommendations the board may have on

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1 further legislation needed to make prescription drug products  
2 more affordable in the state.

3 B. On or before June 30, 2022, the board shall:

4 (1) conduct a study of the operation of the  
5 generic drug market in the United States that includes a review  
6 of physician-administered prescription drug products, which  
7 study shall consider:

8 (a) the prices of generic drugs on a  
9 year-over-year basis;

10 (b) the degree to which generic drug  
11 prices affect yearly insurance premium changes;

12 (c) annual changes in insurance cost  
13 sharing for generic drugs;

14 (d) the potential for and history of  
15 drug shortages;

16 (e) the degree to which generic drug  
17 prices affect yearly state medicaid spending; and

18 (f) any other relevant study questions;

19 and

20 (2) transmit its study and findings to the  
21 legislature.

22 SECTION 11. [NEW MATERIAL] FEDERAL EMPLOYEE RETIREMENT  
23 INCOME SECURITY ACT OF 1974 PLANS--MEDICARE DRUG PLANS.--The  
24 Prescription Drug Affordability Act obligates state-sponsored  
25 and state-regulated health plans and health programs to limit

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1 drug reimbursements and drug payment to no more than the  
2 board-established upper payment limit. Health plans regulated  
3 by the provisions of the federal Employee Retirement Income  
4 Security Act of 1974, as well as medicare part D plans, are not  
5 bound by decisions of the board and can choose to reimburse  
6 more than the upper payment limit. Providers who dispense and  
7 administer prescription drug products in the state to  
8 individuals in the state are bound to bill all payers no more  
9 than the upper payment limit to the patient without regard to  
10 whether or not a plan regulated by the federal Employee  
11 Retirement Income Security Act of 1974 or a medicare part D  
12 plan chooses to reimburse the provider above the upper payment  
13 limit.

14 SECTION 12. SEVERABILITY.--If any part or application of  
15 the Prescription Drug Affordability Act is held invalid, the  
16 remainder or its application to other situations or persons  
17 shall not be affected.

18 SECTION 13. EFFECTIVE DATE.--The effective date of the  
19 provisions of this act is September 30, 2021.