HOUSE BILL

55TH LEGISLATURE - STATE OF NEW MEXICO - SECOND SESSION, 2022

INTRODUCED BY

DISCUSSION DRAFT

FOR THE LEGISLATIVE HEALTH AND HUMAN SERVICES COMMITTEE

AN ACT

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

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

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

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

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

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

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

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

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

E. "generic drug" means:

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

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

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

F. "manufacturer" means an entity that:

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

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

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

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

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

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

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

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

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

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is an essential function.

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

(1) one member appointed by the governor;

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

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

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

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

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

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

E. To the extent practicable and consistent with federal and state law, the membership of the board shall reflect the racial, ethnic and gender demographics of the state.

F. A prospective board member shall disclose any foreseeable or known conflicts of interest, including financial

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or personal relationships that have the potential to bias or have the appearance of biasing a person's decision in matters related to the board or the conduct of the board's activities. The board shall consider the disclosed conflicts of interest of the prospective board member at the time of appointment.

G. All initial appointments shall be made within six months of the effective date of the Prescription Drug Affordability Act. Board members shall serve four-year terms. The terms of the initial board members shall expire as follows:

(1) the members appointed by the minority floor leader of the senate and the minority floor leader of the house of representatives, December 31, 2024;

(2) the members appointed by the president pro tempore of the senate and the speaker of the house of representatives, December 31, 2025; and

(3) the member appointed by the governor, December 31, 2026.

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

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

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J. The board members shall elect a chair and a vice chair of the board.

K. A majority of the members of the board constitutes a quorum for the purposes of conducting the business of the board.

L. The board shall meet in open session at least six times per year to review prescription drug product information or other drug affordability pricing options. The chair may cancel or postpone a meeting if there are no prescription drug products to review or other board items for discussion.

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

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

(2) accessing other available pricing information.

N. The board shall promulgate rules for the implementation of the Prescription Drug Affordability Act, including a procedure for notifying the public of the upper payment limit in a timely manner.

O. In addition to the powers set forth elsewhere in the Prescription Drug Affordability Act, the board may enter into contracts with qualified, independent third parties for

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services necessary to carry out the powers and duties of the board.

P. Unless permission is granted by the board, a third party hired by the board shall not release, publish or otherwise use any information that the third party has access to pursuant to its contract with the board.

Q. The following actions by the board shall be made in open session:

(1) deliberations on whether to subject a prescription drug product to a cost review pursuant to Section 6 of the Prescription Drug Affordability Act;

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

(3) the promulgation of rules by the board.

R. The board may meet in executive session to discuss proprietary data and information.

S. The board shall provide public notice of each board meeting at least two weeks in advance of the meeting. Materials for each board meeting shall be made available to the public at least one week in advance of the meeting. The board shall provide an opportunity for public comment at each meeting of the board. The board shall provide the public with the opportunity to provide written comments on pending decisions of the board. The board may allow expert testimony at board

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meetings, including when the board meets in closed session.

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

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

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

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

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

C. A conflict of interest shall be disclosed by:

(1) the board when hiring board staff;

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

(3) the board when a member of the board is recused in any final decision resulting from a review of a

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prescription drug product.

D. A conflict of interest shall be disclosed:

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

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

E. A conflict of interest disclosed pursuant to this section shall be posted on the website of the board unless the chair of the board recuses the member from any final decision resulting from a review of a prescription drug product. A posting pursuant to this subsection shall include the type, nature and magnitude of the interests of the member involved.

F. Members of the board, board staff and third-party contractors may not accept any gift or donation of services or property if acceptance would result in:

(1) a conflict of interest; or

(2) the appearance of biasing the work of the board.

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

A. The "prescription drug affordability stakeholder council" is created. The purpose of the stakeholder council is to provide stakeholder input to assist the board in making decisions as required pursuant to the Prescription Drug

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Affordability Act.

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

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

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

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

(c) one representative of a statewide organization for diverse communities;

(d) one representative of a labor union; and

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

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

(a) one representative of doctors;

(b) one representative of nurses;

(c) one representative of hospitals; and

(d) one representative of health insurers; and

(3) the governor shall appoint:

(a) one representative of brand name drug corporations;

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(b) one representative of generic drug corporations;

(c) one representative of employers;

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

(e) one representative of pharmacy benefits managers; and

(f) one representative of pharmacists.

C. Members of the stakeholder council shall have knowledge of one or more of the following:

(1) the pharmaceutical business model;

(2) supply chain business models;

(3) the practice of medicine or clinical training;

(4) consumer or patient perspectives;

(5) health care costs trends and drivers;

(6) clinical and health services research; and

(7) the state's health care marketplace.

D. To the extent practicable and consistent with federal and state law, the membership of the stakeholder council shall reflect the racial, ethnic and gender demographics of the state.

E. Members of the stakeholder council shall serve for three-year terms. The members of the stakeholder council

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appointed by the speaker of the house of representatives shall serve an initial term of one year. The members of the stakeholder council appointed by the president pro tempore of the senate shall serve an initial term of two years. The members of the stakeholder council appointed by the governor shall serve an initial term of three years.

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

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

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

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

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

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

(b) a wholesale acquisition cost increase of three thousand dollars ($3,000) or more in any

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twelve-month period or course of treatment if less than twelve months;

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

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

(a) of one hundred dollars ($100) or more for: 1) a thirty-day supply lasting a patient for a period of thirty consecutive days based on the recommended dosage approved for labeling by the United States food and drug administration; 2) a supply lasting a patient for fewer than thirty days based on the recommended dosage approved for labeling by the United States food and drug administration; or 3) one unit of the drug if the labeling approved by the United States food and drug administration does not recommend a finite dosage; and

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

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months; and

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

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

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

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

C. The information to conduct a prescription drug product cost affordability review may include any document and research related to the manufacturer's selection of the introductory price or price increase of the prescription drug product, including life cycle management, net average price in the state, market competition and context, projected revenue and the estimated value or cost-effectiveness of the prescription drug product.

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

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

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

(2) the average monetary price concession, discount or rebate the manufacturer provides to health plans in the state or is expected to provide to health plans in the state as reported by manufacturers and health plans, expressed as a percent of the wholesale acquisition cost for the prescription drug product under review;

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

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

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

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

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

(8) the current or expected dollar value of drug-specific patient access programs that are supported by the manufacturer;

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

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

(11) the impact on Section 340B of the federal Public Health Service Act and drug pricing program providers;

(12) orphan drug status as designated by the

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United States food and drug administration;

(13) any information a manufacturer chooses to provide; and

(14) other factors as required by rule promulgated by the board.

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

(1) the cost of administering the drug;

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

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

G. The methodology used by the board to establish the upper payment limit shall not place a lesser value on older adults or persons with disabilities. Pursuant to this subsection, the methodology shall consider:

(1) the impact to older adults and people with disabilities; and

(2) results indicating cost-effectiveness; provided that those results:

(a) are not used if the cost per quality-adjusted life year or similar measure used to identify

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subpopulations for which a treatment is less cost-effective due to severity of illness, age or preexisting disability; and

(b) weigh the value of increased life expectancy equally for all persons, regardless of the severity of an illness, age or preexisting disability for a treatment that extends life.

H. The upper payment limit will take effect no sooner than six months after the limit is established and announced.

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

J. Independent pharmacies may not be reimbursed less than the upper payment limit established for a drug.

K. The upper payment limit shall not include the dispensing fee for pharmacies.

L. Health plan savings from the upper payment limit shall be used to reduce enrollee costs, especially patient out-of-pocket costs.

M. Information submitted to the board in accordance with this section shall be subject to public inspection pursuant to the Inspection of Public Records Act.

N. This section shall not be construed to prevent a manufacturer from marketing a prescription drug product

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approved by the United States food and drug administration while the product is being reviewed by the board.

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

SECTION 8. [NEW MATERIAL] APPEALS.--

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

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

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

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

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

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

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

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

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

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

G. The state treasurer shall hold the fund separately, and the state treasurer shall account for the fund.

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

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

J. Any investment earnings shall be retained to the

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credit of the fund.

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

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

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

A. On or before September 30 of each year, beginning in 2023, the board shall submit to the legislative finance committee and the legislative health and human services committee a report that includes:

(1) price trends for prescription drug products;

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

(3) any recommendations the board may have on further legislation needed to make prescription drug products more affordable in the state.

B. On or before June 30, 2023, the board shall:

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

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

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

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

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

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

(f) other relevant study questions related to the generic drug market; and

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

SECTION 11. [NEW MATERIAL] FEDERAL EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974 PLANS--MEDICARE DRUG PLANS.--The Prescription Drug Affordability Act obligates state-sponsored and state-regulated health plans and health programs to limit drug reimbursements and drug payment to no more than the board-established upper payment limit. Health plans regulated by the provisions of the federal Employee Retirement Income Security Act of 1974, as well as medicare part D plans, shall not be bound by decisions of the board and can choose to reimburse more than the upper payment limit. Providers who dispense and administer prescription drug products in the state

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to individuals in the state shall be bound to decisions of the board and may bill all payers no more than the upper payment limit to the patient without regard to whether or not a plan regulated by the federal Employee Retirement Income Security Act of 1974 or a medicare part D plan chooses to reimburse the provider above the upper payment limit.

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

SECTION 13. EFFECTIVE DATE.--The effective date of the provisions of this act is September 30, 2022.

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