House Bill 931

By: Representatives Lupton of the 83rd and Lim of the 98th

A BILL TO BE ENTITLED

AN ACT

To amend Title 31 of the Official Code of Georgia Annotated, relating to health, so as to establish a framework to control the high costs of prescription drugs in this state; to provide for definitions; to establish the Prescription Drug Affordability Board; to provide for such board's membership, powers, duties, and meetings; to provide for assessments; to authorize the board to identify certain prescription drugs for affordability review; to provide for certain health benefit plans to submit information to the board; to authorize the board to conduct an affordability review of certain prescription drugs; to authorize the board to establish an upper payment limit on certain prescription drugs; to provide for rights of aggrieved persons; to provide for the use of savings; to provide for notice requirements for a manufacturer to withdraw a drug from this state; to provide for penalties; to provide for annual reports; to provide for rules and regulations; to provide for programs receiving certain funds to negotiate specialist rates; to provide for related matters; to provide for legislative findings; to provide for an effective date; to repeal conflicting laws; and for other purposes.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

SECTION 1.

(a) The purpose of this Act is to protect the safety, health, and economic well-being of

Georgians by taking steps to increase access to affordable prescription drugs. In enacting this Act, the legislature finds that:

(1) Access to prescription drugs is necessary for Georgians to maintain or acquire good health;

(2) Excessive costs negatively impact the ability of Georgians to obtain prescription drugs, and costs that exceed reasonable levels endanger the health and safety of Georgians and their ability to maintain or achieve good health;

(3) Lack of affordability of prescription drugs threatens the economic well-being of Georgians and endangers their ability to afford other necessary and essential goods and services, including housing, food, and utilities;

(4) Excessive costs for prescription drugs contribute significantly to healthcare and health insurance costs and threaten the overall ability of Georgians to obtain healthcare coverage and maintain or achieve good health;

(5) The high cost of prescription drugs contributes significantly to rising costs to the state for healthcare provided and paid for through health insurance programs for public employees, including employees of the state, municipalities and counties, school districts, institutions of higher education, and retirees whose healthcare costs are funded by public programs, thereby threatening the ability of the state to fund those programs adequately and further threatening the ability of the state to fund other programs necessary for the public good, such as public education and public safety; and

(6) The costs to consumers, health benefit plans, and the state for prescription drug coverage is higher than the costs in other countries because the prices charged by manufacturers and distributors of drugs in Georgia are higher.

(b) Based on these findings, the legislature finds that high costs of prescription drugs threaten the safety and well-being of Georgians and finds it is necessary to act in order to protect Georgians from the negative impact of excessive costs for prescription drugs.

SECTION 2.

Title 31 of the Official Code of Georgia Annotated, relating to health, is amended in Chapter 2, relating to Department of Community Health, by designating Code Sections 31-2-1 through 31-2-19 as Article 1.

SECTION 3.

Said title is further amended in said chapter by adding a new article to read as follows:

"ARTICLE 2

31-2-30.

As used in this article, the term:

(1) 'Affordability challenge' means a determination by the board that the costs of appropriate utilization of a prescription drug:

(A) Exceed the therapeutic benefit of such drug; or

(B) Are not sustainable to consumers or to public or private healthcare systems.

(2) 'Biological product' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine or any other trivalent organic arsenic compound, applicable to the prevention, treatment, or cure of a disease or condition of human beings.

(3) 'Biosimilar product' means a biological product highly similar to a reference biological product with no clinically meaningful differences in terms of the safety, purity, and potency of the product and with minor differences in clinically inactive components.

(4) 'Board' means the Prescription Drug Affordability Board established under Code Section 31-2-31.

(5) 'ERISA plan' means a plan qualified under the federal Employee Retirement Income Security Act of 1974, 29 U.S.C. Section 1001, et seq.

(6) 'Health benefit plan' means any hospital, health, or medical insurance policy; hospital or medical service contract; employee welfare benefit plan; contract or agreement with a health maintenance organization; subscriber contract or agreement; contract or agreement with a preferred provider organization; accident and sickness insurance benefit plan; or other insurance contract under any other name. Such term shall include any health insurance or benefit plan established pursuant to Part 6 of Article 17 of Chapter 2 of Title 20, Code Section 31-2-4, Article 1 of Chapter 18 of Title 45, and Article 7 of Chapter 4 of Title 49, the 'Georgia Medical Assistance Act of 1977.'

(7) 'Manufacturer' means an entity that engages in the manufacture, marketing, or distribution of a prescription drug or enters into an agreement with another manufacturer to manufacture, market, or distribute a prescription drug under such entity's name and sets or changes the wholesale acquisition cost of the prescription drug it manufactures, markets, or distributes.

(8) 'Participating ERISA plan' means an ERISA plan that has elected to participate in the requirements and restrictions as provided in Code Section 31-2-35.

(9) 'Pharmacy benefits manager' shall have the same meaning as set forth in Code Section 33-64-1.

(10) 'Pharmacy wholesale distributor' means any person engaged in the wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.

(11) 'Prescription drug' shall have the same meaning as set forth in Code Section 26-4-201. Such term shall include any biological product or biosimilar product.

(12) 'State entity' means any agency of state government that purchases prescription drugs on behalf of the state for a person whose healthcare is paid for by the state, including any agent, vendor, fiscal agent, contractor, or other party acting on behalf of the state.

(13) 'Wholesale acquisition cost' has the same meaning as set forth in 42 U.S.C. Section 1395w-3a(c)(6)(B).

31-2-31.

(a) There is hereby established the Prescription Drug Affordability Board for the purpose of protecting residents of this state, state and local governments, health benefit plans, healthcare providers, pharmacies, and other stakeholders within the healthcare system in this state from the high costs of prescription drugs.

(b)(1) The board shall consist of five members appointed by the Governor and confirmed by the Senate. The Governor shall designate the initial terms of the members of the board as follows: one member shall be appointed for one year, two members shall be appointed for two years, and two members shall be appointed for three years. Thereafter, all members shall serve for terms of four years and until their successors are appointed and qualified.

(2) When a vacancy occurs for any reason other than expiration of term, the Governor shall make an appointment to become immediately effective for the remainder of the unexpired term. Any appointment made by the Governor when the Senate is not in session shall be effective until the appointment is acted upon by the Senate.

(c) A board member shall:

(1) Be a resident of this state;

(2) Have an advanced degree, experience, or expertise in healthcare policy, healthcare economics, or clinical medicine; and

(3) Not be an employee or board member of or consultant to a manufacturer, pharmacy benefits manager, health benefit plan, pharmacy wholesale distributor, or related trade association.

(d)(1) The board shall elect a chairperson and a vice chairperson from among its members, each to serve for a term of one year commencing on the first day of July each year.

(2) The board shall have the authority to hire an executive director and staff necessary to conduct the board's activity as provided in this article.

(e) The commissioner or his or her designee shall serve as an ex officio member of the board, and the department shall provide staff support and may employ consultants, investigators, or other staff as necessary for the board to carry out its duties.

(f) The board shall assess and collect an annual assessment on manufacturers, health benefit plans, pharmacy benefits managers, and pharmacy wholesale distributors that sell or offer for sale any prescription drugs to persons in this state. The board shall specify the methodology for determining the amount of such assessment and the methodology and timeline for collecting such assessment pursuant to rules and regulations promulgated and adopted by the board.

(g) The board shall have the authority to enter into a contract with a third party for any service necessary to carry out the powers and duties of the board.

(h) The board may seek, accept, and expend gifts, grants, and donations from private or pubic sources for the purposes of this article; provided, however, that the board shall not accept any gift, grant, or donation that creates a conflict of interest or the appearance of any conflict of interest for any board member.

(i) Board members, department employees, and contractors providing services to or on behalf of the board shall recuse themselves from any board activity in which they have a conflict of interest. As used in this subsection, the term 'conflict of interest' means an association, including a financial or personal association, that has the potential to bias or

appear to bias an individual's decisions in matters related to the board or the activities of the board.

(j) The board may establish advisory groups consisting of relevant stakeholders.

(k) The board has the authority to promulgate and adopt rules and regulations to allow it to carry out its duties and powers under this article.

(l) A simple majority of the board's membership shall constitute a quorum for the purpose of conducting business. Decisions of the board shall be determined by majority vote of board members present.

(m) All meetings of the board shall be open to the public in accordance with Chapter 14 of Title 50, relating to open and public meetings, and all public records shall be subject to disclosure in accordance with Article 4 of Chapter 18 of Title 50, relating to open records; provided, however, that the board may hold executive sessions to discuss trade secrets or proprietary information, and such information shall be confidential by law and privileged; shall not be subject to disclosure under the provisions of Article 4 of Chapter 18 of Title 50, relating to open records; shall not be subject to subpoena; and shall not be subject to discovery or admissible in evidence in any private civil action.

(n) The board shall meet at least quarterly at a time and place determined by the chairperson. The board may also meet at other times and places specified by the call of the chairperson or a majority of the board members.

(o) Each board member shall receive the daily expense allowance and travel reimbursement as provided in Code Section 45-7-21 for actual attendance at board meetings in this state.

31-2-32.

(a) The board shall select prescription drugs for affordability review from the categories of prescription drugs identified pursuant to subsection (b) of this Code section.

(b) Beginning January 1, 2026, and annually thereafter, the board shall identify:

(1) Prescription drugs that, as adjusted annually by the increase or decrease in the cost of living for the previous calendar year, have:

(A) A wholesale acquisition cost of $3,000.00 or more per year; or

(B) A wholesale acquisition cost increase of $300.00 or more in the preceding 12 month period; or

(B) A wholesale acquisition cost increase of 200 percent or more in the preceding 12 months;

(2) Biosimilar products with an initial wholesale acquisition cost that is not at least 15 percent below the wholesale acquisition cost of the reference biological product at the time the biosimilar product is launched;

(3) Prescription drugs referred to the board as possessing potential affordability challenges;

(4) Prescription drugs referred to the board by any advisory group created by the board; and

(5) The following information on categories of prescription drugs and premiums, based on reports submitted annually from each health benefit plan:

(A) The 50 prescription drugs that are most frequently dispensed by pharmacies for claims covered under such plan and the total number of paid claims for each such drug;

(B) The 50 prescription drugs that are most costly with respect to such plan based on total annual spending and the annual amount paid for each such drug after any rebates or other price concessions;

(C) The 50 prescription drugs with the greatest increase in expenditures under such plan during the year preceding the year of the report, and, for each such drug, the change in the amount expended under such plan in each year after any rebates or other price concessions;

(D) The 50 prescription drugs that are most costly based on average out-of-pocket cost per insured, member, or covered person under such plan;

(E) Any impact on premiums of such plan from rebates, fees, and other remuneration paid by manufacturers to such plan or its administrators or service providers with respect to prescription drugs prescribed to insureds, members, or covered persons under such plan, including, but not limited to:

(i) The amounts paid by manufacturers for each therapeutic class of drugs; and

(ii) The amounts by paid manufacturers for each of the 25 drugs that yielded the highest amount of rebates and other remuneration under such plan during the prior year; and

(F) Any reduction in premiums and out-of-pocket costs to insureds, members, or covered persons under the plan.

(c) The reports submitted to the board by each health benefit plan as provided for in paragraph (5) of subsection (b) of this Code section shall include the following information for each prescription drug:

(1) Total annual spending by the plan after any rebates and other price concessions;

(2) Total annual spending by insureds, members, or covered persons under the plan;

(3) The number of insureds, members, or covered persons with a paid prescription drug claim;

(4) Total dosage units dispensed; and

(5) The number of paid claims.

31-2-33.

(a) In performing an affordability review of a prescription drug, the board shall be authorized to consider any documents and information relating to the manufacturer's selection of the introductory price or any price increase of such drug, including documents and information relating to:

(1) Life cycle management;

(2) The average cost of such drug;

(3) Market competition and context;

(4) Projected revenue;

(5) The estimated cost-effectiveness of the drug;

(6) Off-label usage of the drug;

(7) Development and manufacturing costs; and

(8) Any consumer assistance programs funded by the manufacturer.

(b) To the extent practicable, the board shall access pricing information for prescription drugs by:

(1) Accessing available information from the all-payer claims database in this state and other states;

(2) Entering into an interagency agreement with any state entity to share information collected by such entity;

(3) Entering into a memorandum of understanding with another state to which manufacturers already report pricing information; and

(4) Accessing other publicly available pricing information.

31-2-34.

(a) The board shall be authorized to conduct an affordability review of any prescription drug identified pursuant to Code Section 31-2-32 to determine whether the cost of such drug poses an affordability challenge.

(b) When conducting an affordability review for a prescription drug, the board shall be authorized to consider any of the following criteria:

(1) The relevant factors contributing to the price paid for the drug, including the wholesale acquisition cost, discounts, rebates, or other price concessions;

(2) The average patient co-pay or other cost-sharing for the drug;

(3) The effect of the price on consumers' access to the drug in this state;

(4) Whether the cost of the drug contributes to inequities in the availability of healthcare to underserved communities in this state;

(5) The dollar value and accessibility of patient assistance programs offered by the manufacturer for the drug;

(6) The price and availability of therapeutic alternatives;

(7) Input from any advisory groups established by the board;

(8) Input from patients affected by the condition or disease treated by the drug and individuals with medical or scientific expertise related to the condition or disease treated by the drug;

(9) Life cycle management;

(10) The average cost of the drug in this state;

(11) Market competition and context;

(12) Projected manufacturer revenue, if available;

(13) Off-label usage of the drug; and

(14) Any other relevant factors as determined by the board.

(c) Prior to conducting an affordability review under this Code section, the board shall publish which prescription drugs are subject to such review and shall notify the manufacturer of any prescription drug subject to review.

(d) At the conclusion of an affordability review under this Code section, the board shall determine whether the cost of a reviewed prescription drug presents an affordability challenge necessitating the establishment of an upper payment limit as provided for in Code Section 33-2-35.

31-2-35.

(a) Prior to setting any upper payment limits, the board shall establish by rule a methodology for setting upper payment limits.

(b) The board may set an upper payment limit for each prescription drug for which it determines there is an affordability challenge.

(c) The methodology used by the board to set an upper payment limit may take into consideration:

(1) The cost of administering the prescription drug;

(2) The cost of delivering the prescription drug to patients;

(3) The status of the prescription drug on the drug shortage list published by the United States Food and Drug Administration;

(4) The difference between the price of the drug in this state and other states and between the price in the United States and in other countries;

(5) Other relevant administrative costs related to the production and delivery of the prescription drug; and

(6) Other relevant criteria the board, accounting for any stakeholder input, determines is necessary.

(d) The methodology determined by the board shall consider whether an upper payment limit may help alleviate health disparities and inequitable outcomes for underserved communities, people with disabilities, older adults, or any other socially, economically, or environmentally disadvantaged group.

(e) The board shall not employ a measure or metric which assigns a reduced value to the life extension provided by a prescription drug based on a pre-existing disability or chronic health condition of the individuals whom the prescription drug would benefit.

(f) The board shall be authorized to suspend an upper payment limit if it determines that there is a shortage of the drug in this state, unless the board determines that such shortage was caused by a manufacturer or its agent.

(g) An upper payment limit for a prescription drug established by the board applies to all purchases of the prescription drug and reimbursements for a claim for the drug when such drug is dispensed or administered to an individual in this state in person, by mail, or by

other means. An upper payment limit does not include a pharmacy dispensing fee, and nothing in this article shall be interpreted to prevent a retail pharmacy from receiving a payment that includes a dispensing fee above the upper payment limit.

(h) An ERISA plan may elect to be subject to the upper payment limits established by the board.

(i) The board shall publish a list of prescription drugs for which it has set an upper payment limit.

(j) Unless the board prescribes a specific effective date, upper payment limits established by the board shall become effective six months after the adoption of the upper payment limit and apply only to purchases, contracts, and plans that are issued on or renewed after the effective date.

(k) The establishment of an upper payment limit shall constitute final agency action. Any person or entity may request a contested case hearing, in accordance with the procedures established for such hearings by Chapter 13 of Title 50, the 'Georgia Administrative Procedure Act,' no later than 30 days after the decision is issued. The board shall consider the appeal and issue a final decision concerning the appeal within 60 days after the board receives the appeal. Final decisions as a result of such appeals are subject to judicial review.

31-2-36.

Any savings generated by a health benefit plan, state entity, or participating ERISA plan that are attributable to the implementation of an upper payment limit established by the board shall be used to reduce costs to consumers, prioritizing the reduction of out-of-pocket costs for prescription drugs. No later than April 1 of each calendar year, each health benefit plan, state entity, and participating ERISA plan shall submit to the board, the commissioner, and the Commissioner of Insurance a report describing the savings achieved

as a result of implementing upper payment limits and how those savings were used to reduce costs to consumers.

31-2-37.

(a) Any manufacturer that intends to withdraw from sale or distribution within this state a prescription drug for which the board has established an upper payment limit shall provide a notice of withdrawal in writing at least six months before the withdrawal to the board, the commissioner, the Commissioner of Insurance, the Attorney General, and any state entity with which the manufacturer has a contract for the sale or distribution of the drug.

(b) The board shall assess a penalty not to exceed $500,000.00 if the board determines that a manufacturer failed to provide the notice required by subsection (a) of this Code section before withdrawing from sale or distribution within this state any prescription drug for which the board has established an upper payment limit.

31-2-38.

All assessments, penalties, and donations and grants received by the board and any interest earned on such shall be paid over into the general fund of the state treasury in accordance with Code Section 45-12-92.

31-2-39.

No later than December 1, 2026, and annually thereafter, the board shall submit a report to the commissioner, the Commissioner of Insurance, the Office of Health Strategy and Coordination, and the chairpersons of the House Committee on Health, the House Committee on Insurance, the House Committee on Public and Community Health, the Senate Health and Human Services Committee, and the Senate Insurance and Labor Committee. Such report shall include the following information:

(1) Publicly available data concerning price trends for prescription drugs;

(2) A list of the prescription drugs that were subjected to an affordability review by the board, including the results of such affordability review;

(3) A list of each prescription drug for which the board established an upper payment limit, including the amount of the upper payment limit;

(4) With respect to each prescription drug for which the board conducted an affordability review, how the board determined whether the cost of such drug contributes to health disparities and inequitable outcomes for underserved communities, people with disabilities, older adults, or any other socially, economically, or environmentally disadvantaged group;

(5) With respect to each drug for which the board set an upper payment limit, how the board assessed health disparities and inequitable outcomes for underserved communities, people with disabilities, older adults, or any other socially, economically, or environmentally disadvantaged group;

(6) The known impact of any upper payment limits established by the board on healthcare providers and pharmacies and the ability of Georgians to access such drugs;

(7) A summary of any appeals of decisions by the board and the outcome of any such appeal;

(8) A description of each conflict of interest that was disclosed to the board during the preceding year;

(9) A description of any violations of any of the provisions of this article, including an indication of any enforcement action taken in response to any such violation; and

(10) Any recommendations the board may have for legislative and regulatory changes to increase the affordability of prescription drugs and reduce the effects of costs on consumers and the healthcare systems in this state.

31-2-40.

The board shall promulgate rules and regulations necessary to implement the provisions of this article."

SECTION 4.

Said title is further amended in Chapter 8, relating to care and protection of indigent and elderly patients, by revising Code Section 31-8-154, relating to authorized expenditure of contributed funds, as follows:

"31-8-154.

All moneys contributed and revenues deposited and transferred to the trust fund pursuant to this article and any interest earned on such moneys shall be appropriated to the department for only the following purposes:

(1) To expand Medicaid eligibility and services;

(2) For programs to support rural and other ~~health care~~ healthcare providers, primarily hospitals, who serve the medically indigent, provided that such programs shall negotiate specialist care rates with primary healthcare programs described in paragraph (3) of this Code section;

(3) For primary ~~health care~~ healthcare programs for medically indigent citizens and children of this state; or

(4) Any combination of purposes specified in paragraphs (1) through (3) of this Code section."

SECTION 5.

This Act shall become effective upon its approval by the Governor or upon its becoming law without such approval.

SECTION 6.

All laws and parts of laws in conflict with this Act are repealed.