**South Carolina General Assembly**

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**H. 4984**

**STATUS INFORMATION**

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Summary: Prescription Drugs

**HISTORY OF LEGISLATIVE ACTIONS**

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**VERSIONS OF THIS BILL**

[01/31/2024](https://www.scstatehouse.gov/sess125_2023-2024/prever/4984_20240131.docx)

A bill

TO AMEND THE SOUTH CAROLINA CODE OF LAWS BY ENACTING THE “PRESCRIPTION DRUG AFFORDABILITY BOARD” BY ADDING CHAPTER 131 TO TITLE 44 SO AS TO ESTABLISH A PRESCRIPTION DRUG AFFORDABILITY BOARD AND TO PROVIDE FOR THE BOARD’S MEMBERSHIP, POWERS, AND DUTIES; TO REQUIRE THE BOARD TO CREATE A STAKEHOLDER COUNCIL AND TO PROVIDE FOR THE COUNCIL’S MEMBERSHIP AND DUTIES; TO REQUIRE THE BOARD TO UNDERTAKE DRUG COST AFFORDABILITY REVIEWS IN CERTAIN CIRCUMSTANCES; TO AUTHORIZE THE OFFICE OF THE ATTORNEY GENERAL TO ENFORCE THE PROVISIONS OF THE CHAPTER; TO REQUIRE ANNUAL REPORTING BY THE BOARD; AND FOR OTHER PURPOSES.

Be it enacted by the General Assembly of the State of South Carolina:

SECTION 1. Title 44 of the S.C. Code is amended by adding:

CHAPTER 131

Prescription Drug Affordability Board

 Section 44‑131‑10. As used in this chapter, unless the context requires a different meaning:

 (1) “Biologic” means a drug that is produced or distributed in accordance with a biologics license application approved under 42 U.S.C. Section 262.

 (2) “Biosimilar” means a drug that is produced or distributed in accordance with a biologics license application approved under 42 U.S.C. Section 262(k)(3).

 (3) “Board” means the Prescription Drug Affordability Board.

 (4) “Brand‑name drug” means a drug that is produced or distributed in accordance with an original new drug application approved under 21 U.S.C. Section 355(c). “Brand‑name drug” does not include an authorized generic drug as defined by 42 C.F.R. Section 447.502.

 (5) “Generic drug” means:

 (a) a retail drug that is marketed or distributed in accordance with an abbreviated new drug application approved under 21 U.S.C. Section 355(j);

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

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

 (6) “Manufacturer” means an entity that:

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

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

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

 (7) “Prescription drug product” means a drug or biological product receiving approval under a drug application pursuant to 21 U.S.C. Section 355(b) or under a biologics license application approved under 42 U.S.C. Section 262.

 (8) “Stakeholder council” means the Prescription Drug Affordability Board stakeholder council.

 Section 44‑131‑20. (A) There is hereby established in the Department of Health the Prescription Drug Affordability Board for the purpose of protecting citizens of the State and other stakeholders within the health care system from the high costs of prescription drug products.

 (B)(1) The board must be composed of five members to be appointed by the Governor and confirmed by the Senate. The Governor shall appoint three alternate members of the board who must be confirmed by the Senate prior to assuming a position on the board.

 (2) Members of the board must have expertise in health care, health care economics, or clinical medicine. One member of the board must be a representative of a local government in the State, and one member of the board must be a representative of a federally qualified health center.

 (3) A member or alternate member of the board may not be an employee of, a board member of, or a consultant to a manufacturer or trade association for manufacturers. Any conflict of interest must be disclosed and considered when appointing members and alternate members to the board.

 (C) The term of a member or alternate member of the board is five years. The expiration of the terms of the members and alternate members must be staggered.

 (D)(1) The board must hold a meeting open to the public with opportunity for public comment at least four times annually to review prescription drug product information, including whether to subject a prescription drug product to an affordability review under Section 44‑131‑50 and whether to impose an upper payment limit amount on purchases, payments, and payer reimbursements of prescription drug products in the State.

 (2) The board must provide public notice of each board meeting at least three weeks in advance of the meeting and materials for each board meeting must be made available to the public at least two weeks in advance of the meeting.

 (E)(1) Members of the board must recuse themselves from decisions related to prescription drug products if the member, or an immediate family member of the member, has received or could receive either of the following:

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

 (b) 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 per year.

 (2) For the purposes of this subsection, a 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 this chapter.

 Section 44‑131‑30. (A) The board shall assess pricing information for prescription drug products by accessing available pricing information based on state reporting and transparency requirements, including prescription drug product price transparency information collected and compiled by a nonprofit data‑services organization and the South Carolina Department of Health and Human Services or any other state agency assessing spending for prescription drug products in the State.

 (B) The board may enter into a contract with a qualified, independent third party for any service necessary to carry out the powers and duties of the board.

 (C) The board may promulgate regulations for the implementation of this chapter.

 Section 44‑131‑40. (A)(1) The board shall create a stakeholder council for the purpose of providing stakeholder input to assist the board in making decisions as required under this chapter.

 (2) The stakeholder council shall consist of eleven members appointed in accordance with this section. Members must include manufacturers of brand‑name drugs and generic drugs, providers that dispense or administer prescription drug products, suppliers of prescription drug products, and consumers of prescription drug products. More than one stakeholder council member must not be appointed to represent any single organization or entity.

 (3) The President of the Senate shall appoint three members, the Speaker of the House shall appoint five members, and the Governor shall appoint three members to the stakeholder council. The board chairman shall appoint one member of the stakeholder council to serve as chair of the stakeholder council.

 (B) The members of the stakeholder council must have knowledge in one or more of the following subjects: the pharmaceutical business model, supply chain business models, the practice of medicine or clinical training, consumer or patient perspectives, health care cost trends and drivers, clinical and health services research, or the health care marketplace in the State.

 (C) The initial term for members of the stakeholder council is three years, and the members shall serve staggered terms. A member of the stakeholder council may not receive compensation but is entitled to mileage, subsistence, and per diem as allowed by law for members of state boards, committees, and commissions.

 Section 44‑131‑50. (A) Nothing in this section shall be construed to prevent a manufacturer from marketing a prescription drug product approved by the U.S. Food and Drug Administration (FDA) while the product is under review by the board.

 (B) The board shall identify the following prescription drug products offered for sale in the State:

 (1) brand‑name drugs or biologics that, as adjusted annually for inflation in accordance with the Consumer Price Index, have a launch wholesale acquisition cost of sixty thousand dollars or more per year or course of treatment or a wholesale acquisition cost increase of three thousand dollars or more in any twelve‑month period;

 (2) biosimilars that have a launch wholesale acquisition cost that is not at least twenty percent lower than the referenced brand biologic at the time the biosimilars are launched and that have been suggested for review by members of the public, medical professionals, or other stakeholders;

 (3)(a) generic drugs that, as adjusted annually for inflation in accordance with the Consumer Price Index, have a wholesale acquisition cost of one hundred dollars or more for:

 (i) a thirty‑day supply lasting a patient for a period of thirty consecutive days based on the recommended dosage approved for labeling by the FDA;

 (ii) a supply lasting a patient fewer than thirty days based on the recommended dosage approved for labeling by the FDA; or

 (iii) one unit of the drug if the labeling approved by the FDA does not recommend any finite dosage;

 (b) generic drugs that, as adjusted annually for inflation in accordance with the Consumer Price Index, have a wholesale acquisition cost of at least one hundred dollars for a thirty‑day supply or a course of treatment less than thirty days and that increased by two hundred percent or more during the immediately preceding twelve‑month period; and

 (4) other prescription drugs that may create affordability challenges for the health care system in the State and high out‑of‑pocket costs for patients, including drugs used to address public health emergencies.

 (C) After identifying prescription drug products as required in subsection (B) and compiling preliminary information about the cost of the product, patient cost‑sharing for the product, health plan spending on the product, stakeholder input, and other information as determined by the board, the board shall determine whether to conduct an affordability review for each identified prescription drug product, taking into consideration relevant information about the prescription drug product, including information provided by the manufacturer.

 (D) An affordability review conducted by the board pursuant to this section must determine whether the prescription drug product is fully consistent with FDA labeling and other requirements and has led or will lead to affordability challenges for the health care system in the State or high out‑of‑pocket costs for patients.

 (E)(1) If the board finds that the spending on a prescription drug product reviewed under this section has led or will lead to an affordability challenge for the health care system in the State or high out‑of‑pocket costs for citizens of the State, the board shall establish an upper payment limit amount after considering the cost of administering the prescription drug product, the cost of delivering the prescription drug product to customers, and other relevant administrative costs related to the prescription drug product.

 (2) If the board establishes an upper payment limit amount pursuant to this subsection, the board must examine how the upper payment limit amount will affect entities operating pursuant to Section 340B of the federal Public Health Service Act.

 (F) An upper payment limit amount established by the board pursuant to subsection (E) must 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 any other means, exclusive of applicable pharmacy dispensing fees and provider administration fees.

 (E) State regulated health plans must inform the board of how the cost savings related to an upper payment limit amount are directed to the benefit of enrollees with a priority on enrollee cost‑sharing.

 Section 44‑131‑60. (A) The Office of the Attorney General may pursue any appropriate available remedy under state law in enforcing the provisions of this chapter.

 (B) Any person aggrieved by a decision of the board may request an appeal of the decision within thirty days after the decision of the board is made. Any person aggrieved by a final decision of the board may petition for judicial review as provided by the Administrative Procedures Act.

 Section 44‑131‑70. On or before December 31, 2025, and annually each year thereafter, the board must submit to members of the General Assembly a report that addresses price trends for prescription drug products in the State and nationwide, prescription drug products that were subject to board review during the previous twelve‑month period; and any recommendations the board may have regarding further legislation needed to improve prescription drug affordability in the State.

SECTION 2. This act takes effect upon approval by the Governor.

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