ASSEMBLY HEALTH COMMITTEE

STATEMENT TO

[First Reprint]

ASSEMBLY, No. 1747

with committee amendments

STATE OF NEW JERSEY

DATED: MAY 24, 2022

The Assembly Health Committee reports favorably Assembly Bill No. 1747 (1R), with committee amendments.

As amended by the committee, this bill establishes the Prescription Drug Affordability Board (Board), which will be charged with protecting New Jersey residents, State and local governments, health benefits plans, health care providers, licensed pharmacies, and other stakeholders within the State health care system from the high costs of prescription drug products, including brand name and generic drugs, and biological products. The Board will be established in, but not of, the Department of Law and Public Safety, and will be independent of any supervision or control by the department or any agency within the department.

The Board will comprise five public members and three alternate public members; the alternate public members will participate in Board deliberations in any case in which a public member is recused. All Board members will be required to have expertise in health care economics or clinical medicine. The Governor, the President of the Senate, the Speaker of the General Assembly, and the Attorney General will each appoint one public member, and the President of the Senate and the Speaker of the General Assembly will jointly appoint the fifth member, who will serve as chair of the Board. The Governor, the President of the Senate, and the Speaker of the General Assembly will each appoint one alternate public member. To the extent practicable and consistent with State and federal law, the membership of the Board is to reflect the racial, ethnic, and gender diversity of the State.

Board members will serve for a term of five years, with staggered appointments for the public members first appointed. Board members will be eligible for reappointment, and vacancies in the membership are to be filled in the same manner as is provided for the original appointment.

The chair of the Board is to hire an executive director, general counsel, and staff, and develop a five-year budget and staffing plan that will be subject to approval by the Board as a whole. The

executive director, general counsel, and board staff will receive a salary as provided in the Board's budget. Board members will be entitled to such compensation as may be approved under the State budget, and will be entitled to reimbursement for expenses reasonably incurred in the performance of their official duties.

The Board will meet in open session at least once every six weeks, except that the chair will have the authority to postpone or cancel any required meeting. Three Board members will constitute a quorum for the purposes of conducting official Board business. Generally, Board deliberations and proceedings are to take place in open session and will be subject to the requirements of the "Senator Byron M. Baer Open Public Meetings Act"; however the Board may meet in closed session to discuss information and data the Board determines to be a trade secret or confidential and proprietary. To the extent practicable, the Board is to access pricing information for prescription drug products by entering into memoranda of understanding with other states to which manufacturers already report pricing information, but it may seek out other available sources of pricing information as well.

The Board is to provide public notice of each Board meeting at least two weeks in advance of the meeting, and make materials for each meeting available to the public at least seven calendar days in advance of the meeting. The Board is to provide an opportunity for public comment at each open meeting and provide the public with the opportunity to submit written comments on pending decisions.

Board members will be prohibited from employment with, serving on the board of, or consulting for, pharmaceutical manufacturers, pharmacy benefits managers, pharmacy services administrative organizations, pharmacies, pharmacists, health benefits plan carriers, or wholesale distributors or related trade associations. Individuals appointed to the Board will be required to disclose, at the time of appointment, any conflict of interest, including whether the individual has any association that has the potential to bias or create the appearance of biasing the individual's decisions in Board matters.

The public members of the Board are to 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 a financial benefit deriving from the work of the Board or a benefit from a manufacturer that, in the aggregate, exceeds $500 per year. Board members, staff, and third party contractors will be prohibited from accepting any gift or donation of services or property that indicates a potential conflict of interest or has the appearance of biasing the work of the Board. The bill requires conflicts of interest involving Board staff, Board members, and mandatory recusals of Board members to be disclosed to the public on the board's Internet website, including information on the type, nature, and magnitude of the interests of the individual involved.

As amended, the bill provides that Board members will not be liable in an action for damages to any person for any action taken or recommendation made by the member within the scope of the member's functions as a member, if the action or recommendation was taken or made without malice. The members of the board will be indemnified and their defense of any action provided for in the same manner and to the same extent as employees of the State under the "New Jersey Tort Claims Act" on account of acts or omissions in the scope of their service.

The Board will be required to conduct hearings on possible violations of the provisions of the bill and determine appropriate penalties or other remedies to be assessed for substantiated violations, and refer non-compliance matters to the Attorney General for further legal action. The Board will be permitted to enter into contracts with qualified, independent third parties for any service necessary to carry out its powers and duties. A person aggrieved by a decision or order of the Board will have 30 days to seek a rehearing of the decision or order; thereafter, the decision or order becomes final. When so requested, the Board will conduct a new hearing on the decision or order and make a final decision or issue a final order no later than 60 days after the rehearing is requested. A final decision or order of the Board may be appealed to the Appellate Division of the Superior Court no later than 45 days after the decision or order becomes final. The Board's findings of fact will be deemed conclusive on appeal if supported by substantial evidence on the record. An appeal to the Appellate Division will not automatically stay enforcement of the final order or decision; however, the court will have the authority to issue a stay as it deems proper.

The Board will be initially established using $1 million appropriated under the bill for this purpose. Thereafter, the Legislature is directed to annually appropriate $1 million to support the Board's operations.

The bill additionally establishes the Prescription Drug Affordability Stakeholder Council (Council), which will provide stakeholder input to assist the Board in making decisions. The Council will comprise 27 members, with nine members each to be appointed by the Speaker of the General Assembly, the Senate President, and the Governor. Council members will represent various stakeholders throughout the pharmaceutical and healthcare system, and are to collectively have knowledge of the pharmaceutical business model, supply chain business models, the practice of medicine and clinical training, consumer and patient perspectives, health care cost trends and drivers, clinical and health services research, and the State health care marketplace. To the extent practicable and consistent with State and federal law, the membership of the Council is to reflect the racial, ethnic, and gender diversity of the State. The chair of the Prescription Drug Affordability Board will select two Council members to serve as

co-chairs of the Council. Members of the council will serve a term of three years, with staggered appointments for the members first appointed. Council members will be eligible for reappointment to the Council; vacancies in the membership are to be filled in the same manner as provided for the original appointment; and members will serve until a successor has been appointed. Council members will serve without compensation but may be reimbursed for expenses reasonably incurred in the performance of their official duties.

As amended, the bill requires the Prescription Drug Affordability Board to conduct a study of the entire pharmaceutical distribution and payment system in the State, as well as policy options being used in other states and countries to lower the list price of pharmaceutical drug products, including, but not limited to: establishing upper payment limits; revising the number of permitted cost sharing tiers and the limitations on cost sharing amounts; enhancing distribution of specialty drugs; developing, or adopting measures to facilitate the development of, new supply pipelines; adopting measures to facilitate the availability of new biological products; adopting measures to promote the administration of pharmaceutical drug products in the most cost-effective settings; using a closed formulary; allowing importation of pharmaceutical drug products from other countries; and implementing a bulk purchasing process. This study is to be completed no later than 18 months after the effective date of the bill.

The Board will also conduct a study of the operation of the generic, brand name, and specialty drug markets in the United States that includes a review of practitioner-administered drugs and that considers: the prices of generic, brand name, and specialty drugs on a year-to-year basis; the degree to which generic, brand name, and specialty drug prices affect yearly insurance premium changes; annual changes in insurance cost-sharing for generic, brand name, and specialty drugs; the potential for, and history of, drug shortages; the degree to which generic, brand name, and specialty drug prices affect annual State spending under the State Health Benefits Program, the School Employees' Health Benefits Program, the Medicaid and NJ FamilyCare programs, the Senior Gold program, and the Pharmaceutical Assistance to the Aged and Disabled program; and any other issues the Board deems relevant.

The Board will further be required to conduct a study of pharmacy benefit managers and pharmacy services administrative organizations, with a focus on practices used by pharmacy benefit managers and pharmacy services administrative organizations that may impact the cost of pharmaceutical drug products in New Jersey, as well as methods to regulate or otherwise restrict practices demonstrated to impact pharmaceutical drug product costs, including: (1) requiring disclosure of the sources and formulas used by pharmacy benefit managers and pharmacy services administrative organizations to determine multiple source generic drug pricing and brand-name drug

pricing; (2) reviewing whether health benefits plans, pharmacy benefit managers, and pharmacy services administrative organizations apply all manufacturer and pharmacy discounts, rebates, concessions, and fees at the point of sale or use the savings to reduce premiums to reduce the cost of pharmaceutical drug products for covered persons; (3) taking appropriate measures to eliminate, restrict, or revise practices that are designed to increase or sustain disproportionate profit margins within discrete points in the pharmaceutical supply chain without promoting improvements in the quality of care provided to, or reducing the cost of pharmaceutical products for, covered individuals; and (4) reviewing the effects of manufacturer couponing on premium costs as well as copay accumulator adjustments and copayment maximizers for such coupons, and ensuring that the value of manufacturer payments are counted against the patient's deductible and limits on out-of-pocket payments.

The studies of drug markets, pharmacy benefit managers, and pharmacy services administrative organizations are to be conducted within six months after the effective date of the bill.

The Board is also required, in consultation with the Council, to collect and review publicly-available information regarding prescription drug product manufacturers, health benefits plan carriers, wholesale distributors, pharmacy benefits managers, and pharmaceutical services administrative organizations; identify states that require reporting on the cost of prescription drug products; and initiate the process of entering into memoranda of understanding with those states to aid in the collection of transparency data for prescription drug products. The Board is to establish methods for collecting additional data necessary to carry out its duties, and identify circumstances under which the cost of a prescription drug product may create or has created affordability challenges for the State health care system and New Jersey patients.

The Board is to use the information and data collected under the bill to identify: (1) brand name drugs and biological products that have a significantly high wholesale acquisition cost or that have a wholesale acquisition cost that has increased by a significant percentage over a 12-month period; (2) biosimilar products that have a launch wholesale cost that is not at least 15 percent lower than the referenced brand name biological product; (3) generic drugs with a high wholesale acquisition cost or a wholesale acquisition cost that has significantly increased over the preceding 12 month period; and (4) other prescription drug products that the Board determines may create affordability issues. After identifying prescription drug products, the Board will be required to determine whether to conduct a cost review for each identified prescription drug product by seeking input from the Council about the product and considering the average cost share of the product. The information to conduct a cost review may include any document or research related to the manufacturer's selection of the

introductory price or price increase of the product, as well as additional information provided by various stakeholders upon request of the Board if other public information is not available.

A review of the cost of a prescription drug product is to determine whether use of the prescription drug product in a manner that is fully consistent with the labeling approved by the United States Food and Drug Administration (FDA) or standard medical practice has led or will lead to affordability challenges. In determining whether a prescription drug product has led or will lead to an affordability challenge, the board is to consider: the wholesale acquisition cost and any other relevant prescription drug cost index for the product; the average monetary price concession, discount, or rebate provided by the manufacturer and the total amount of the price concession, discount, or rebate; the price at which therapeutic alternatives have been sold in the State; the total amount of the monetary concession, discount, or rebate provided by the manufacturer for the prescription drug product; the cost of the product to health benefits plans; the effects on patient access resulting from the cost of the product relative to insurance benefit design; the current or expected dollar value of the drug-specific patient access programs that are supported by the manufacturer; the relative financial effects on health, medical, and social service costs; the average patient copay or other cost-sharing for the product; and any additional factors the Board establishes by regulation.

If the Board is unable to determine whether a prescription drug product will produce or has produced affordability challenges, the Board may additionally consider: the manufacturer's research and development costs in proportion to the manufacturer's sales in the State; the portion of direct-to-consumer marketing costs eligible for favorable federal tax treatment; gross and net revenues for the product; any additional factors proposed by the various stakeholders that the Board considers relevant; and any additional factors the Board establishes by regulation.

The Board's criteria for identifying prescription drugs and determining whether to conduct a cost review are to be established by regulation, which, along with any other requirements the Board establishes by regulation, will constitute the comprehensive operating plan governing the Board.

If the Board determines that it is in the best interests of the State to develop a process to establish upper payment limits for, or allow importation from other countries of, prescription drug products that it determines have led or will lead to an affordability challenge, the Board, in conjunction with the Council, will be required to draft a plan of action for implementing the process that includes, depending on the process being recommended, the criteria the Board will use to establish upper payment limits, consideration of certain cost and logistical factors that may affect importations from other countries, or both. The board may recommend both establishing upper payment

limits and allowing importation of pharmaceutical products from other countries.

The process for establishing upper payment limits will prohibit the application of an upper payment limit for a drug that is included in the FDA's prescription drug shortage list, and will require the Board to monitor the availability of any prescription drug product for which it establishes an upper payment limit and reconsider or suspend the upper payment limit if availability issues emerge. Upper payment limits will apply to prescription drug products purchased by or on behalf of State and local government entities, programs, and organizations.

The Board's action plan is to be submitted to the Legislature for approval no later than 24 months after the effective date of the bill. The plan will be deemed rejected unless legislation implementing the plan is adopted within 90 days after the date the plan is submitted to the Legislature. Legislation approving a plan may include modifications to the plan that was submitted by the Board, and in no case may a plan be deemed rejected solely because the implementing legislation includes technical or substantive differences from the plan that was submitted for approval. The Board will have no authority to establish upper payment limits for, or importations from other countries of, prescription drug products unless the action plan has been approved through the adoption of implementing legislation.

The bill requires the Board to submit various reports to the Governor and to the Legislature, including reports concerning price trends for prescription drug products; the number of products that were subject to board review and the results of the review; and recommendations for legislation or other action as may be needed to make prescription drug products more affordable in the State. Separate reports will include the Board's recommendations with regard to various policy options to address prescription drug product affordability; the legality, obstacles, and benefits of establishing upper payment limits, as well as recommendations as to whether the authority of the Board should be expanded; and recommendations concerning the importation of prescription drug products from other countries, including recommendations for legislation as may be necessary to authorize the practice and ensure the safety, security, quality, and integrity of imported prescription drug products.

All information and data obtained by the Board will be made publicly available unless the Board determines the information or data to be a trade secret, confidential, or proprietary. Information or data deemed to be a trade secret, confidential, or proprietary will be exempt from the State's open public records laws. Any person who knowingly divulges, discloses, or uses records or files containing information or data determined to be a trade secret or confidential or proprietary information will be guilty of a crime of the fourth degree, which is punishable by imprisonment for up to 18 months, up to a $10,000 fine,

or both. A person who knowingly examines records or files containing information or data determined to be a trade secret or confidential or proprietary information for any reason other than a reason necessitated by the performance of official duties will be guilty of a disorderly persons offense, which is punishable by imprisonment for up to 60 days, up to a $1,000 fine, or both.

As amended the bill provides that, whenever records and files are used in connection with the prosecution of a person for knowingly divulging, disclosing, using, or examining records or files containing information or data in a prohibited manner, the defendant will be given access to those records and files. The court will review the records and files in camera, and that portion of the court record containing the records and files will be sealed by the court.

COMMITTEE AMENDMENTS:

The committee amendments:

1) prohibit employees, board members, or consultants of a pharmacy benefit manager or pharmaceutical manufacturer from serving as an alternate public member of the board, and additionally prohibit pharmacy services administrative organizations, pharmacies, and pharmacists from serving on the Board;

2) require Board meetings to generally be subject to the “Senator Byron M. Baer Open Public Meetings Act”;

3) provide that Board members will not be civilly liable for actions taken or recommendations made by the members within the scope of the members’ functions, except in the case of malice, and will be indemnified and defended as employees of the State under the "New Jersey Tort Claims Act";

4) remove language indicating the council is “in but not of” the Board, and revise the membership of the council to specify that, instead of having three members of the public, the council will include one member of the public, one representative of Medicaid managed care organizations, and one representative of wholesale distributors;

5) remove a requirement for the Board to review the use of a reverse auction market place as a possible approach to reduce pharmaceutical drug product costs in the State, and additionally require the Board to review the options of: a) revising the number of permitted cost sharing tiers and the limitations on cost sharing amounts; b) enhancing distribution of specialty drugs; c) developing new supply pipelines; d) facilitating the availability of new biological products; and e) promoting the administration of pharmaceutical drug products in the most cost-effective settings;

6) expand the Board’s study of the generic drug marketplace to additionally include a study of the brand name and specialty drug marketplaces;

7) replace a provision requiring the Board to study whether pharmacy benefit managers establish high prices for payers and low

reimbursement rates for pharmacies with a provision requiring the Board to take appropriate measures to restrict practices that artificially inflate profits in specific areas of the pharmaceutical supply chain without delivering improvements in quality of care or reducing pharmaceutical drug costs;

8) make provisions relevant to pharmacy benefit managers apply to pharmacy services administrative organizations as well, including a requirement for the Board to conduct a study of practices used by these entities that may impact pharmaceutical drug product costs, include language requiring these entities to provide certain information when requested by the Board and for the Board to review data concerning those entities, and provisions concerning the confidentiality of information submitted by the entities;

9) make it a crime of the fourth degree to knowingly divulge, disclose, or use records or files containing information or data determined to be a trade secret or confidential or proprietary information, and make it a disorderly persons offense to knowingly examine records or files containing information or data determined to be a trade secret or confidential or proprietary information for any reason other than a reason necessitated by the performance of official duties;

10) require that, whenever records and files are used in connection with the prosecution of a person for knowingly divulging, disclosing, using, or examining records or files containing information or data in a prohibited manner, the defendant will be given access to those records and files, the court will review the records and files in camera, and the portion of the court record containing the records and files will be sealed; and

11) make technical changes involving internal cross-citations, to correct a typo, and to make a formatting change to the synopsis.