ASSEMBLY FINANCIAL INSTITUTIONS AND INSURANCE COMMITTEE

STATEMENT TO

ASSEMBLY, No. 2418

with committee amendments

STATE OF NEW JERSEY

DATED: JUNE 2, 2021

The Assembly Financial Institutions and Insurance Committee reports favorably and with committee amendments Assembly Bill No. 2418.

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, biological products, and interchangeable biological products. The Board will be established in, but not of, the Department of Law and Public Safety, but will be independent of any supervision or control by the department or by any agency, board, office, or individual within the department.

The Board will comprise five public members and three alternate public members, who 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 appointment 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 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; however the Board may meet in closed session to discuss trade secrets or confidential and proprietary data and information, which is defined in the bill to include any information that is not otherwise available from public sources. 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.

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, 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. Public Board members 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.

The Board may conduct hearings related to potential violations of the bill, refer non-compliance matters to the Attorney General, and 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 request a rehearing of the decision or order, or the order or decision will become final. A rehearing will constitute a new hearing on the decision or order, and the Board will have 60 days to make a final decision or issue a final order after the rehearing is held. 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 court will have the authority to grant such relief it deems appropriate. On appeal, findings of fact made by the Board that are supported by substantial evidence will be deemed conclusive. An appeal to the Appellate Division will not automatically stay a decision or order of the Board; the Board may choose to impose a stay, or a stay may be imposed upon application to the court.

All information and data obtained by the Board is to be made publicly available unless the Board determines it to be a trade secret and confidential and proprietary information.

The Board will be initially established using general funds. No later than 18 months after the effective date of the bill, the Board is to identify an independent funding source and, if appropriate, submit to the Legislature its recommendations concerning legislation or other action necessary to establish a funding source. In identifying an independent funding source, the Board may consider assessing fees on various pharmaceutical industry entities, using rebates received by State and local government entities from manufacturers, or using other appropriate methods. The Board is to repay the General Fund for the costs of its establishment from the independent funding source.

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.

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; using a reverse auction marketplace; 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 drug market in the United States that includes a review of practitioner-administered drugs and that considers: the prices of generic drugs on a year-to-year basis; the degree to which generic drug prices affect yearly insurance premium changes; annual changes in insurance cost-sharing for generic drugs; the potential for, and history of, drug shortages; the degree to which generic 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. This study is to be conducted within six months after the bill takes effect.

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, and pharmacy benefits managers; 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 prescription drug 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, as well as 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. The Board will be required to promulgate rules and regulations identifying the process and criteria for identifying prescription drugs and for determining whether to conduct a cost review of the drug. These rules and regulations will constitute the comprehensive operating plan governing the Board, and will include such other requirements as the Board determines necessary to implement the provisions of the bill.

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 average monetary concession, discount, or rebate provided by the manufacturer for therapeutic alternatives; 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.

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 the criteria the

Board will use to establish upper payment limits or consideration of certain cost and logistical factors that may affect importations from other countries. 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 be required to 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 there are availability issues. 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 price 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.

COMMITTEE AMENDMENTS:

The committee amendments provide that the Prescription Drug Affordability Board will be established in the Department of Law and Public Safety, rather than the Division of Consumer Affairs, and

specify that the Board will be independent of supervision or control by any entity or individual within the department.

The committee amendments clarify that the decisions of the Board that are to be conducted in open session include any enforcement, regulatory, or other decision.

The committee amendments add language permitting the Board to conduct hearings concerning possible violations of the bill and to refer non-compliance matters to the Attorney General for investigation.

The committee amendments require that the Board promulgate rules and regulations establishing the criteria for identifying prescription drugs and determining whether to conduct a cost review, which rules and regulations will constitute the Board's comprehensive operating plan.

The committee amendments provide that all data and information obtained by the Board is to be made publicly available unless the Board determines the information to be a trade secret or confidential or proprietary information, in which case it would not constitute a "government record" for the purposes of the "Open Public Records Act." As introduced, the bill provided that all information that is otherwise publicly available would be deemed to be a trade secret and confidential and proprietary information that is not subject to disclosure under the "Open Public Records Act."

The committee amendments revise the requirements to approve a plan submitted by the Board to implement upper payment limits or allow the importation of prescription drugs from other countries. As introduced, a plan could be approved by either the Legislature or the executive branch. As amended, the bill provides that a plan may only be approved through the adoption of implementing legislation.

The committee amendments revise the requirements for a person aggrieved by a decision of the Board to appeal the decision to: replace an appeal to the Board with a request for a rehearing; establish certain deadlines for filing a request for a rehearing or a court appeal; clarify the range of actions a court may take with regard to the order or decision; provide that if the Board's findings of fact are supported by substantial evidence, those findings of fact will be deemed conclusive; and provide that a court appeal will not automatically stay enforcement of the order or decision, but that the Board or the court may still impose a stay if requested.

The committee amendments revise an annual reporting requirement to remove a provision tolling the deadline for the first report by 18 months, and to require the report be submitted by March 31 of each year. The committee amendments revise a different reporting requirement to provide that it include an analysis and recommendations concerning the establishment of "payment limits," rather than "price limits."