FAQ - NJ's Prescription Drug Affordability Board (PDAB)

Why would states set up a prescription drug affordability board?

Prescription drugs are an essential component of medical treatment that have become increasingly unaffordable for the average consumer. Currently, there is no mechanism to ensure patients have access to the drugs they need in a sustainable, cost- effective manner. A PDAB offers New Jersey a targeted solution to the problem of escalating drug prices, which are currently going unchecked. Other states with PDABs are Maryland and Maine.

A PDAB reviews certain high-costs drugs that create "affordability challenges" for the State health care system or high out-of-pocket costs for patients. Because drug costs involve many complicated issues and affect numerous stakeholders, a PDAB is a regulatory mechanism that brings all the stakeholders together, increases procedural and substantive transparency regarding drug prices, and is able to set an upper payment limit (UPL) for certain drugs sold in the State and/or permit importation of those drugs at or below that price limit. This results in the lowering of overall healthcare costs for all.

How would NJ's PDAB work?

Pending state legislation, S.1066/A.2418, would establish an impartial review board comprised of five public members plus three alternates. Each member must meet certain professional qualifications, not be an employee, consultant or board member of an entity involved in the pharmaceutical industry, and, collectively, must reflect the racial, ethnic and gender diversity of the State. These members and alternates are appointed by the Governor, the Attorney General and the Legislative leadership. The Board is designed to function like our Board of Public Utilities (BPU) and will be supported by a 27-member advisory Stakeholder Council consisting of a wide range of healthcare stakeholders, who must have collective knowledge of the pharmaceutical business model, the practice of medicine and clinical training, consumer and patient perspectives and health care cost trends and drivers among other matters.

The Board will collect data, hold hearings, conduct its own research, and, based on its own analysis of the data, will issue reports and make recommendations to set limits on what NJ residents pay for specific drugs that are excessively priced or whose excess cost presents an affordability challenge to the State health care system, or leads to high out-of-pocket costs for patients. The board could also make a recommendation to pursue importation of specific drugs. Payment limits would be benchmarked against current U.S. market conditions to ensure NJ residents are getting a fair deal.

Would NJ's PDAB have oversight over all drugs?

No, New Jersey's PDAB is authorized to review only certain high-cost prescription drugs deemed by the Legislature to create affordability challenges in the State. Adhering to the criteria set forth in the National Academy for State Health Policy's (NASHP) model bill, the Board will review drugs that meet the following triggers/criteria:

- Brand name drugs or biological products that have a launch wholesale acquisition cost (WAC) of $30,000 or more per year or course of treatment;
- Brand name drugs or biological products that have a WAC cost increase of $3,000 or more in a 12-month period;
- Generic medicines costing at least $100 per 30-day supply or unit of the drug for a course of treatment with a 200% WAC increase or more in the preceding 12-month period;
- Interchangeable biological products or "biosimilars" with WAC prices that are discounted less than 15 % of their referenced brand name biologic; and
- In consultation with the Stakeholder Council, other prescription drugs that the Board determines may "create affordability issues for the State health care system and New Jersey patients."

How would NJ's PDAB decide the amount that can be billed or paid for a drug?

NJ's PDAB will examine a host of publicly available data in the U.S. market and, based on that existing market information, should be able to discern the best discounts in the existing market to set state-wide UPLs for certain drugs that create an affordability challenge. Once given the green light to exercise its regulatory authority, the Board is designed to regulate in-state charges and payments for a particular drug among state-licensed healthcare entities: wholesalers, other distributors, pharmacies, hospitals, physicians, and insurers, by setting a limit on what these payers will pay for a drug. This is not price fixing insofar as manufacturers are still able to set whatever price they wish to sell their product. The upper payment limit (UPL) concept employs the participants in the supply chain to negotiate price concessions which are fulfilled by wholesalers. Currently, manufacturers routinely adjust their price through negotiations with providers or the others in the supply chain when payer reimbursement (such as payment by insurers, government programs and other purchasers) is less than the product list price.

The Board will determine whether to conduct a cost review for a prescription drug product by seeking "input" from the Stakeholder Council about the product and after considering the "average cost share of the drug." The amount that will be paid for a drug will be based on publicly available pricing and cost information, some of which will come from subscription data services that track drug prices, price increases, and the availability of commercial rebates for brand name drugs. The Board is authorized to consult with state payers and purchasers to learn their net costs for drugs that the PDAB is studying, and to consider a manufacturer's research and development costs, as indicated on the manufacturer's federal tax filing or information filed with the Securities and Exchange Commission, among other public documents. To the extent that there is no publicly-available data to conduct a cost review, the Board shall request it from the manufacturer, but there is no obligation for the manufacturer to provide it.

Is there legal precedent for a PDAB? Will establishment of such board result in legal challenges?

Yes, historically, states, such as New Jersey, have the authority to regulate health care insurers and determine maximum payment levels for healthcare and other public goods and services in markets with little or no market competition. The PDAB would build on various regulatory precedents for

drugs that have had only a few suppliers, as well as, more generally, the rate-setting conduct of the BPU. New Jersey sets consumer rates for public utilities such as electricity and water because they are important to the public's well-being and controlled by just a few companies. Similar considerations are applicable to prescription drugs people need to maintain their health.

Previous attempts by a state, not the federal government, to control drug prices have been challenged under the Commerce Clause of the U.S. Constitution. This clause prohibits state laws and policies that place a *significant* burden on the interstate commerce of a company. Maryland passed its PDAB legislation in 2019 and its Attorney General issued an opinion that same year which concluded that its very similar PDAB legislation would likely be upheld against a Commerce Clause challenge. This opinion was most recently supported with the U.S. Supreme Court's December 2020 decision in Rutledge v. Pharmaceutical Care Management Association, which also held that state regulation of pharmacy benefit managers was not pre-empted by ERISA. Experts do not expect that an affordability review board, as proposed by S.1066/A.2418, would create such a burden and thus violate the Commerce Clause for the following reasons:

- regulating the payments of state-licensed healthcare entities and supply chain participants does not affect the manufacturer's national list price for a drug; and,
- a state-wide UPL also
    - provides benefits to consumer health and safety that outweigh the impact on trade outside of the state;
    - does not benefit in-state businesses to the detriment of out-of-state competitors operating in the state;
    - does not affect the manufacturer's price of drugs to any purchaser of drugs destined to another state;
    - does not exclusively target the in-state sales of businesses located outside the state; and has only an incidental impact on manufacturer operations outside the state.

What are the benefits of establishing a PDAB in NJ?

Consumers are seeing treatments of $1 to -$2 million per year per person for each course of treatment in a host of areas – including, but not limited to rare diseases, cancer, lupus, muscular dystrophy, sickle cell anemia, epilepsy, and COPD — rendering many drugs "financially toxic" to people who need them. A PDAB will establish the payment limit for such products at a point to both assure access and encourage innovation. Everyone benefits from the kind of fair, transparent, participatory public process a PDAB creates. The Board establishes a process that engages all stakeholders, provides due process to manufacturers, consumers, providers and others to be heard, and creates a review process that will shine a light on costs and prices.

How would the PDAB affect consumers?

There is little doubt that a PDAB that had the power to set UPL or import a particular drug (authority that NJ's PDAB does not have in S.1066/A.2418), would positively impact consumer

pocketbooks at the point of sale of that drug. Lower drug prices would also positively impact insurance premiums, hospital costs, and taxpayer funded programs.

How would an affordability review affect pharmacies and wholesalers?

Pursuant to S.1066/A.2418, NJ's PDAB is given the authority to conduct an affordability review, not to take action to set an UPL or import a drug. Neither the review nor the imposition of UPLs should have any effect on the standard operating procedures existing in the regular drug distribution systems throughout the state. Pharmacies would not segregate drugs that are regulated by the Board from drugs that are not regulated. The only difference being that there will be only one payment rate for a drug on which the Board has acted.

How would a PDAB be funded?

The costs to fund a PDAB can be budget neutral by imposing an assessment on drug manufacturers, wholesalers, Pharmacy Benefit Managers (PBM), and insurers. This is also the funding model used for Maryland's PDAB.

How can we improve the proposed PDAB legislation?

S.1066/A.2418 is a good start to introducing the concept of a PDAB and setting the Board on a path to conduct cost reviews of certain drugs that create an affordability challenge to New Jersey's health system and its patients. The Board is authorized to issue regulations, conduct cost reviews and issue several different reports, over different periods of time, recommending a course of action that must be approved by the Legislature and Governor before it can actually regulate any specific drug or permit importation of that drug. The Board's recommendations for government programs are separate from those governing private payers, and the legislation is difficult to read, understand and lacks clarity on key issues.

We suggest that the proposed statute give the PDAB the authority to regulate certain drugs by setting UPLs or permitting importation of certain drugs after a cost review, reduce the number of required reports, and reorganize sections for clarity.

There are several other changes that we would like to see made to improve the operation and outcome of the board to better protect NJ health care consumers:

- The Legislature should consider imposing an assessment as was done for the Maryland PDAB, of up to $2 million on drug manufacturers, wholesalers, PBMs, and insurers to enable the Board to operate;
- If information is submitted to the Board, it cannot be assumed to be confidential. The entity submitting the information has the burden to prove that it is trade-marked, patented or otherwise contains confidential information. The existing overly broad provision hinders transparency and defeats a major goal of this bill;
- The judicial review provision must be clarified regarding what decisions of the Board may be appealed and by whom; and
- The Attorney General must be given enforcement authority.