STATEMENT

PhRMA
RESEARCH • PROGRESS • HOPE

**Position: PhRMA respectfully opposes Prescription Drug Affordability Board ("PDAB") legislation because it allows the government to set the price of prescription drugs, which could limit the prescription options available to patients in Pennsylvania, discriminate against patients, stifle innovation, and raises significant legal concerns.**

The Pharmaceutical Research and Manufacturers of America ("PhRMA") represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. We appreciate the opportunity to submit our concerns regarding the consideration of Pennsylvania PDAB legislation.

Implementing price controls at a time when the industry has been tirelessly dedicated to finding treatments and vaccines for COVID-19 diverts industry resources elsewhere and risks current and future innovation. We are in a new era of medicine that is bringing revolutionary, innovative treatments, therapies, and cures to patients. Unfortunately, this radical policy could freeze new, life-saving innovation and force patients to face the uncertainty of a health care system where the government sets prices for critical medicines, similar to what is done in other countries.

**PDAB legislation ignores that there are meaningful policies for addressing affordability without importing government price setting that could reduce treatment options.**

PhRMA is increasingly concerned that the substantial rebates and discounts paid by pharmaceutical manufacturers, approximately $256 billion in 2022,[1] do not make their way to offsetting patient costs at the pharmacy counter. Patients need concrete reforms that will help lower the price they pay for medicines at the pharmacy, such as making monthly costs more predictable, making cost-sharing assistance count toward a plan's out-of-pocket spending requirements, and sharing negotiated savings on medicines with patients. These policies can be done without importing international price setting, which can reduce the options available to treat patients.

**This type of legislation does not account for insurance benefit design issues that prevent discounts from flowing to patients, and assumes incorrectly that the price a patient pays is determined solely by drug manufacturers.**

Legislation like this singles out the biopharmaceutical industry and ignores the variety of stakeholders involved in determining what consumers ultimately pay for a medicine, including insurers, pharmacy benefit managers (PBMs), wholesalers, and the government. The important role that these entities play in determining drug coverage and patient out-of-pocket costs is overlooked by the requirements of this kind of legislation. For example, PBMs and payers—which dictate the terms of coverage for medicines and the amount a patient ultimately pays—negotiate substantial rebates and discounts.

According to research from the Berkeley Research Group (BRG), rebates, discounts, and fees account for an increasing share of spending for brand medicines each year, while the share received by manufacturers has decreased over time. In 2020 manufacturers retained only 49.5% of brand medicine spending while members of

[1] Fein, A. "The 2023 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers," Drug Channels Institute. March 2023.

the supply chain retained 50.5%.[2] Increased rebates and discounts have largely offset the modest increases in list prices and reflect the competitive market for brand medicines.

The growth of net price prices, which reflects rebates and discounts, has been in line with or below inflation for the past five years. Factoring in discounts and rebates, prices for brand name medicines grew just 1.0% on average in 2021[3] – slower than the annual rate of inflation. This, of course, does not necessarily reconcile with what patients are feeling at the pharmacy counter, which is why looking at the whole system is so important. For example, despite manufacturers' rebates and discounts negotiated by health plans, nearly half of commercially insured patients' out-of-pocket spending for brand medicines is based on the medicine's list price rather than the negotiated price that health plans receive.[4]

In 2020, only 4.8% of Pennsylvania's Medicaid budget was spent on prescription drugs, including both brands and generics. Specifically, in 2020, pharmaceutical manufacturers paid more than $1.8 billion in rebates back to Pennsylvania and the federal government, which is 54% of the total Medicaid spending on drugs in the state.[5]

**Price controls can limit access to needed medicines.**

Allowing the government to set prices could restrict patients' access to medicines by reducing the availability of life-saving therapies in the state. For example, if a payor cannot obtain a therapy at the state-prescribed price, and/or if a pharmacy or dispensing provider cannot stock the drug because it too cannot meet the state-prescribed price, then the medicine will not be available to patients. Further, allowing the government to set a price could prevent a health care provider from choosing the best treatment for a patient, thus impacting patient health outcomes.

**Legislation like the PDAB bill from the 2021-2022 session also references utilizing cost-effectiveness analyses that are known to be discriminatory.**

Studies using cost-effectiveness analysis (CEA) rely on the use of discriminatory Quality Adjusted Life Years (QALYs) and cost-per-QALY thresholds. Developed from population averages, QALYs ignore important variability in patients' individual needs and preferences. Experts have identified that QALYs discriminate against people with disabilities by placing a lower value on their lives. A report issued by the National Council on Disability in 2019 "found sufficient evidence of the discriminatory effects of QALYs to warrant concern, including concerns raised by bioethicists, patient rights groups, and disability rights advocates about the limited access to lifesaving medications for chronic illnesses in countries where QALYs are frequently used."[6]

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2 BRG: The Pharmaceutical Supply Chain, 2013–2020. January 2022.

3 IQVIA. Use of Medicines in the U.S.: Spending and Usage Trends and Outlook to 2026, April 2022.

4 IQVIA Institute for Human Data Science. Medicine spending and affordability in the United States. Published August 2020. Accessed August 2020. https://www.iqvia.com/insights/theiqvia-institute/reports/medicine-spending-and-affordabilityin-the-us

5 Menges Group analysis of FFY2020 CMS Financial Management Reports (FMR) and State Drug Utilization (SDU) data files. Brand/generic expenditure totals net of rebates. Data predominantly derived from CMS FMRs. Brand/generic prescription drug costs derived through tabulations performed by Menges. Pre-rebate expenditures tabulated using FFY2020 CMS SDU data files and CMS brad/generic indicators for each NDC. Statutory rebates and fee-for-service supplemental rebate information obtained from CMS FMRs. MCO supplemental rebates available in FMRs for several states and estimated in remaining states at similar percentages as the published FMR data indicate. Generic rebates assumed to always be at the statutory 13% level – no supplemental rebates assumed. Total brand rebates are therefore derived as the difference between total rebates and the generic statutory rebates. Post-rebate expenditures derived through Menges tabulations using above information.

6 National Council on Disability, "Quality-Adjusted Life Years and the Devaluation of Life with Disability (letter of transmittal)." November 6, 2019.

In countries that rely on CEA to determine coverage and payment, like Canada, many patients face significant restrictions on access to treatments, including those diagnosed with cancer, diabetes, and rare diseases. An analysis noted that these types of cost-effectiveness assessments and recommendations based on population-averages fail to properly adjust to the demands of an evolving health care system and do not reflect the rapid pace of the science, or the needs and preferences of the patients.[7]

**PDAB legislation could threaten drug development and replaces market competition with government price setting.**

Legislation like this threatens to drastically reduce development of new medicines at a time of remarkable scientific promise, undermining U.S. global leadership in biopharmaceutical innovation. Government price setting diminishes the incentive for biopharmaceutical manufacturers to invest in the research and development of new medicines. By requiring state-regulated commercial insurance plans and pharmacies to cap the amount paid for prescription medicines at a set price, this creates a price control on these medicines that could have the long-term effect of decreasing access to medications.

On average, it takes more than 10 years and $2.6 billion to research and develop a new medicine. Just 12% of drug candidates that enter clinical testing are approved for use by patients. Efforts to impart price controls on innovative manufacturers could chill the research and development of new medicines by taking away the incentives that allow manufacturers to invent new medicines.

For years, Canada has imposed price controls and other measures that significantly undervalue innovative medicines developed in the United States. Research shows that U.S. patients enjoy earlier and less restrictive access to new therapies.[8] This is reinforced by the United States Department of Health and Human Services' own analysis of Medicare Part B drugs which showed that only 11 of the 27 drugs examined (41%) were available in all 16 comparator countries, nearly all of which have single payer health care systems.[9]

In fact, American patients have faster access to more medicines than patients anywhere else in the world, and doctors and patients work together to decide which medicine is right for them. In countries that use international reference pricing and other government price controls, patients can access fewer new medicines and face long treatment delays. Nearly 90% of new medicines launched since 2011 are available in the U.S. compared to just 50% in France, 46% in Canada and 41% in Ireland – countries that use some form of international reference pricing.[10] Even the medicines available in these countries take much longer to reach patients. On average, patients must wait at least 18 months longer in France, 15 months longer in Canada, and 20 months longer in Ireland than in the U.S.

**This type of legislation could harm Pennsylvania's economy.**

On average, it takes more than 10 years and $2.6 billion to research and develop a new medicine. Just 12% of drug candidates that enter clinical testing are approved for use by patients. Efforts to impart price controls on innovative manufacturers could chill the research and development of new medicines by taking away the

[7] Context Matters. NICE Limits Reimbursement for Oncology Products beyond EMA Product Labeling. May 2014.
[8] IQVIA Institute, Global Oncology Trends 2017, Advances, Complexity and Cost. May 2017.
[9] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation (ASPE). Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures. October 25, 2018.
[10] The Catalyst, Setting the record straight on international reference pricing. July 19, 2019. Available at https://catalyst.phrma.org/setting-the-record-straight-on-international-reference-pricing.

incentives that allow manufacturers to invent new medicines. Price controls also could severely reduce [insert state] patients' access to medicines, as is seen abroad.

The biopharmaceutical sector is committed to bringing new treatments and cures to patients. This commitment to innovation supports high-quality jobs and is a vital part of Pennsylvania's economy and its economic competitiveness. The biopharmaceutical sector directly accounted for 51,895 jobs in Pennsylvania in 2020 and supported another 219,398 jobs in Pennsylvania for a total of 271,293 jobs. These jobs generate over $4.8 billion in state and federal tax revenue for Pennsylvania in 2020. This type of bill could place these jobs, and tax revenue, in jeopardy.

**Legislation like PDABs raises significant legal concerns.**

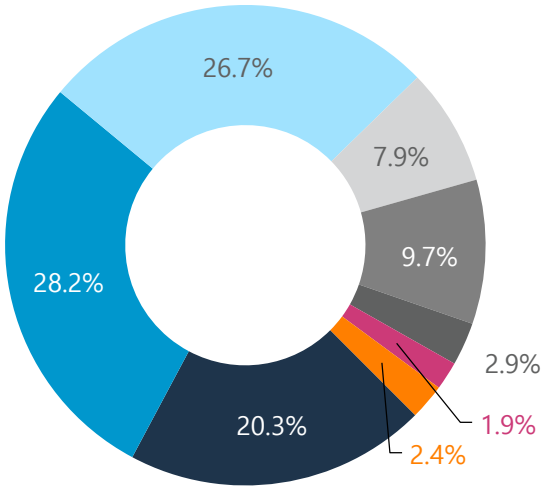
The proposed PDAB legislation raises constitutional concerns under the Supremacy Clause because it would restrict the goal of federal patent law, which is to provide pharmaceutical patent holders with the economic value of exclusivity during the life of a patent. Congress determined that this economic reward provides appropriate incentive for invention, and [State] is not free to diminish the value of that economic reward. Specifically, in the case of *BIO v. District of Columbia, 496 F.3d 1362 (2007)*, the U.S. Court of Appeals for the Federal Circuit overturned a District of Columbia law imposing price controls on branded drugs, reasoning that the law at issue conflicted with the underlying objectives of the federal patent framework by undercutting a company's ability to set prices for its patented products. The court's decision stated that "[t]he underlying determination about the proper balance between innovators' profits and consumer access to medication …is exclusively one for Congress."

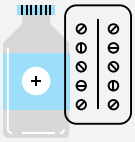
PhRMA recognizes the access challenges faced by patients in Pennsylvania with serious diseases. **However, this type of legislation could limit the treatments available to patients and stifle innovation.** PhRMA stands ready to work with the legislature to develop market-based solutions that help patients better afford their medicines at the pharmacy counter. **For these reasons, we respectfully oppose any proposed Prescription Drug Affordability Board legislation in the state.**

# The Facts About Medicaid in Pennsylvania

Medicines provide great value to Medicaid patients and society by saving and extending lives and preventing unnecessary hospitalizations and other costly health care services. According to National Health Expenditure estimates, national Medicaid spending on prescription drugs will grow roughly in line with overall national Medicaid spending growth from 2019 to 2028.[1]

## Breakdown of FFY2020 Medicaid Spending in Pennsylvania[2]



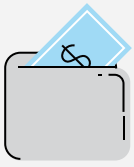



**Only 4.8%** of the total Medicaid budget in Pennsylvania is spent on retail brand and generic prescription drugs.

- Nursing, Rehabilitative Care / Home Health, Personal Support & Waivers
- Hospital Care
- Professional Services
- Other Health and Durable Medical Equipment
- Administrative
- Brand Rx
- Generic Rx
- Mental Health Facilities

## How Medicaid Pays for Drugs

All 50 states and the District of Columbia elect to cover prescription drugs as a benefit under the Medicaid Drug Rebate Program (MDRP). The MDRP is a federal-state-drug manufacturer program that provides significant rebates to Medicaid programs that offset the costs of prescription drugs while ensuring patients can access needed medicines. States, and managed care organizations or pharmacy benefit managers administering the prescription drug benefit on behalf of states, may also negotiate supplemental rebates with drug manufacturers, further reducing spending.



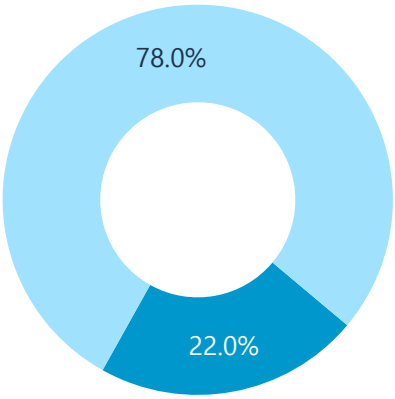
Manufacturers rebate **$1.8 Billion** back to Pennsylvania and the federal government, which is **54%** of the total Medicaid spending on drugs in the state.

1. Based on average spending growth between 2019 and 2028 according to U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of the Actuary 2020 National Health Expenditure Data (source: NHE Projections 2019-2028 - Tables 3 and 12).
2. Menges Group analysis of FFY2020 CMS Financial Management Reports (FMR) and State Drug Utilization (SDU) data files. Brand/generic expenditure totals net of rebates. Data predominantly derived from CMS FMRs. Brand/generic prescription drug costs derived through tabulations performed by Menges. Pre-rebate expenditures tabulated using FFY2020 CMS SDU data files and CMS brand/generic indicators for each NDC. Statutory rebates and fee-for-service supplemental rebate information obtained from CMS FMRs. MCO supplemental rebates available in FMRs for several states and estimated in remaining states at similar percentages as the published FMR data indicate. Generic rebates assumed to always be at the statutory 13% level – no supplemental rebates assumed. Total brand rebates are therefore derived as the difference between total rebates and the generic statutory rebates. Post-rebate expenditures derived through Menges tabulations using above information.

# The Facts About Medicaid in Pennsylvania

Medicaid and the Children's Health Insurance Program (CHIP) provide health care coverage to low-income, aged, and disabled individuals and families. Over one-in-five Americans are covered by Medicaid and CHIP.[1] Without Medicaid and CHIP, millions of Americans would not have access to necessary health care services, including prescription medicines.

## Medicaid Coverage in Pennsylvania[1]

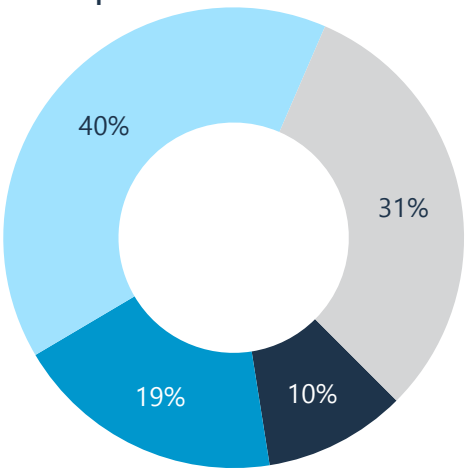



22% of Pennsylvanians were primarily covered by Medicaid in 2020.

Medicaid

Other/Uninsured

## Pennsylvania's Medicaid Population by Enrollment Group[2]



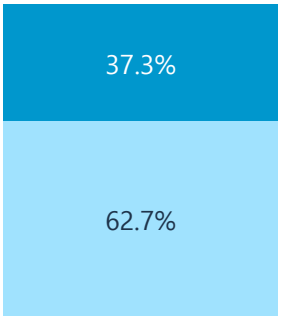

Aged

Disabled

Adults

Children

## Pennsylvania's Spending on Medicaid Services[3]




State

Federal

Pennsylvania spent $13.1 billion on Medicaid in FY 2020.

1. Menges analysis of state website data on enrollment and 2020 Census population data. Totals include CHIP enrollees in states where CHIP is folded into the Medicaid program.
2. Medicaid and CHIP Payment and Access Commission (MACPAC). MACStats: Exhibit 14. Medicaid Enrollment by State, Eligibility Group, and Dually Eligible Status (FY19). Analysis of T-MSIS data as of December 2020.
3. Kaiser Family Foundation. State Health Facts: Federal and State Share of Medicaid Spending, FFY20. Estimates based on data from CMS (Form 64), as of September 2020. Note: Medicaid expenditures do not include administrative costs, accounting adjustments, or the U.S. Territories.