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STATE OF MAINE MAINE PRESCRIPTION DRUG AFFORDABILITY BOARD 78 STATE HOUSE STATION AUGUSTA, MAINE 04333-0078

JANET T. MILLS

GOVERNOR

NOAH NESIN, MD

CHAIR

January 24, 2023 2022 Report of the Maine Prescription Drug Affordability Board: Recommendations to Reduce Prescription Drug Spending

The Maine Prescription Drug Affordability Board (MPDAB) was established in 2019 pursuant to MRS Title 5 Chapter 167-1.

Mission: To determine annual spending targets for prescription drugs purchased by Maine public payers and make recommendations to achieve the targets.

Vision: Board recommendations will target strategies to achieve prescription drug affordability while maintaining safety and ensuring clinically appropriate use. The spending targets will be based upon a 10-year rolling average of the medical care services component plus a reasonable percentage for inflation and minus a spending target determined by the board for pharmacy savings. In addition, spending targets will be determined on specific prescription drugs that may cause affordability challenges to enrollees.

MPDAB Membership:

Board Member:	Title/Occupation:	Nominated by:
Noah Nesin, MD	Innovation Advisor,	Governor of Maine
(Chair)	Penobscot Community Health Care	
VACANT		Governor of Maine
(alternate chair)		
Peter Hayes	President/CEO	President of the Senate
	Healthcare Purchaser Alliance of ME	
VACANT		President of the Senate
Jennifer Reck	Director	President of the Senate
(Alternate)	National Academy for State Health Policy	
Susan Wehry, MD	Geriatrics, Primary Care	Speaker of the House
	University of New England	
Julia Redding, DO	Family & Geriatric Medicine	Speaker of the House
	Maine Medical Partners	
Rhonda Selvin, FNP	Family Medicine	Speaker of the House
(Alternate)	Groups Recover Together	

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Advisory Council Members:

Bethany Beausang, Governor's Office; Anne-Marie Toderico, PharmD, Pharmacy Director, Office of MaineCare Services; Kristy Gould, Maine Municipal Employee Health Trust; Jennifer Kent, Maine Education Association Trust; Robert Nadeau, Maine Community College System; Kate Ende, Consumers for Affordable Health Care; Jonathan French, Maine State Employees Association; Ryan Low, University of Maine System; Christina Moylan, Assistant Attorney General; Heather Perreault, Deputy Commissioner of Finance, Department of Administrative and Financial Services; Shonna Poulin-Gutierrez, Executive Director, Maine Employee Health and Wellness; Karen Yeaton, Maine Department of Corrections

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I. 2022 Overview

The MPDAB met 9 times during 2022, all virtual meetings. Topics covered by presentations and discussions during these meetings included:

- Production of MPDAB 2021 Annual Report
- Development of Remote Public Proceedings Policy
- Discussions of Office of Affordable Health Care
- Adverse Impact of the use of the Quality Adjusted Life Year (QUALY) metric on people with disabilities
- Overview of health coverage for immigrants, refugees and asylees
- 340B drug pricing and its impact on costs

II. Spending Target Recommendation

Attached is a spread sheet that is aimed at addressing the charge to the MPDAB "to determine annual spending targets for prescription drugs purchased by Maine public payers based upon a 10-year rolling average of the medical care services component of the United States Department of Labor, Bureau of Labor Statistics Consumer Price Index medical care services index plus a reasonable percentage for inflation and minus a spending target determined by the board for pharmacy savings". The 10-year rolling average was determined to be 3.9 percent. The additional steps the Board must take to determine the annual spending target for prescription drugs are complex, and a number of confounding factors must be considered. These include the following points, developed in consultation with the Program on Regulation, Therapeutics, and Law (PORTAL) at Harvard Medical School:

- Consumer Price Index is a measure of price changes, and our charge is to benchmark spending. Levels of use is the other important contributor to spending. In addition, drug spending may change at a different rate from the CPI for all medical care services. Access to historic spending data for drugs will be vital to creating a meaningful target.
- Factoring in the last year's historically high inflation will require additional expertise.
- The need to define the term "annual spending":
 - Spending is a combination of prices and the use of medications, so spending can increase if prices increase or if use of medications increases. Spending can decrease if use shifts from high-price to low-price medications, as is often the case when a generic or biosimilar becomes available for an expensive drug. Also, generic drugs account for 90% of prescriptions but only 15% of spending, so brand name and generic spending may need to be separately measured.
 - Spending can be measured on an aggregate or per-capita basis. The latter allows for more detailed understanding of spending.
- Accounting for rebates is critical to creating accurate spending targets because there is a significant and growing gap between drug list prices and post-rebate net prices. It is very challenging to obtain accurate, comprehensive data from healthcare plans and from Pharmacy Benefit Mangers (PBMs).
- Both pharmacy dispensed drugs and clinician administered drugs (which may represent up to a third of prescription drug spending) must be considered.

III. Reference Rates

International Reference Rates

In its March 2022 report, the MPDAB recommended that the legislature consider instituting international reference rates, and continues to support that recommendation. On April 14, 2022, Governor Mills signed LD1636, a study bill requiring the Maine Health Data Organization (MHDO) to produce an annual report comparing US and Canadian pricing for the 100 costliest and the 100 most frequently used prescription drugs, as reported in the claims database. Publication of the MHDO report was pending as of January 24, 2023.

For context, related analyses estimating potential savings from Canadian prescription drug rates found the following:

- In one state where the international reference rate bill was introduced, the legislature's <u>fiscal office estimated</u> that referencing to Canadian prices could generate \$50 million in annual savings for the state employee health plan alone for the top 20 drugs.
- The National Academy for State Health Policy (NASHP) conducted a savings analysis for another state and determined that applying international referencing to the top 23 drugs would save their state employee health plan \$22 million.

Because Canadian drug prices are often a fraction of U.S. prices for the same drugs, it is anticipated that the Maine study will show results similar to those outlined above, representing substantial savings. By instituting international reference-based pricing, as outlined in model legislation by the NASHP, Maine's Bureau of Insurance could establish Canadian drug prices as upper payment limits for costly drugs, bringing down prescription drug costs for payers in the

state, and ensuring that savings be passed on to consumers through premium reductions, reducing or eliminating co-pays, or related strategies.

Medicare Reference Rates

On August 16, 2022, Congress enacted the Inflation Reduction Act, including historic measures enabling Medicare, for the first time, to negotiate prices for certain high-cost drugs which have been on the market for seven to eleven years, depending on product type. Negotiated prices for the first set of 10 drugs, known as Maximum Fair Prices (MFP), will be published September 2024. The MPDAB sees MFPs as an opportunity for Maine to leverage the work of the federal government, and recommends Maine adopts the MFPs as reference rates to set upper payment limits within a state. NASHP published model legislation to enable this approach in November 2022. Because the annual total of drugs for which there will be MFPs is a relatively small number (e.g., 10 in 2024, 15 in 2025, 15 in 2026, 20 in 2027), Maine should institute Medicare reference rates supplemented by Canadian reference rates where domestic MFPs are not available, to maximize savings. While the MPDAB's mandate focuses on public purchasers, reference rates could be extended beyond public purchasers to also realize savings for state-regulated commercial plans, as well as for ERISA-regulated plans that may select to participate.

IV. 340B Transparency

In 1992, Congress extended to safety-net providers the same kind of relief from high drug costs that Congress provided to the Medicaid program with the Medicaid rebate law. Congress enacted Section 340B of the Public Health Service Act, created under Section 602 of the Veterans Health Care Act of 1992. Section 340B requires pharmaceutical manufacturers to enter into an agreement, called a pharmaceutical pricing agreement (PPA), with the HHS Secretary in exchange for having their drugs covered by Medicaid and Medicare Part B. Under the PPA, the manufacturer agrees to provide front-end discounts on covered outpatient drugs purchased by specified providers, called "covered entities," that serve the nation's most vulnerable patient populations. According to congressional report language, the purpose of the 340B program is to enable covered entities "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." This has historically been used to benefit vulnerable populations. For example, Federally Qualified Health Centers (FQHCs) have typically used revenue from the 340B program to support sliding fee scales, reduce prescription costs, extend hours of operation, and enhance support services, and FQHCs are subject to detailed programmatic and reporting requirements to the Health Resources and Services Administration (HRSA). As the 340B program has been expanded to include other entities concern has grown over cost and the use of these revenues.

A December 20, 2022 Wall Street Journal article, "<u>Many Hospitals Get Big Drug Discounts</u>. <u>That Doesn't Mean Markdowns for Patients</u>," by Anna Wilde Mathews et al, included the following observations about the current status of the federal 340B drug program:

• "A decades-old federal program that offered big drug discounts to a small number of hospitals to help low-income patients now benefits some of the most successful nonprofit health systems in the U.S. Under the program, hospitals buy drugs at reduced prices and sell them to patients and their insurers for much more, often at facilities in affluent communities."

- "The federal drug-discount program, known as 340B after the statutory provision that created it, requires pharmaceutical companies to sell drugs to participating hospitals at reduced prices. The program has grown rapidly in recent years. It now includes about 2,600 nonprofit and government hospitals, which spent at least \$38 billion on discounted drugs last year, according to the Health Resources and Services Administration, the federal agency known as HRSA that oversees the program."
 - "What the hospitals do with their valuable discounts isn't always clear. The program doesn't require participating hospitals to pass on drug discounts to patients, insurers or Medicare. There is no rule limiting how much they can charge for the drugs. They don't have to report how much they make from such sales, nor do they have to spend any profits to benefit low-income patients."
 - "Partly because of the growing number of eligible hospitals, annual spending by hospitals on drug purchases through the program quintupled between 2015 and 2021, to at least \$38 billion, according to HRSA, though those numbers don't represent all sales. The prices hospitals pay for the drugs are confidential, and their proceeds from any markups aren't broken out in financial disclosures. The margins can be enormous"
 - "The data raise questions about the program's growth and purpose. In some cases, the program appears to be bolstering profits in well-off areas more than it is underwriting services in less-privileged neighborhoods."

Adam Fein, in his publication <u>Drug Channels</u>, summarizing the scope of the 340B program in 2021, stated the following:

• "The data tell a familiar story. For 2021, discounted purchases under the 340B program reached a record \$43.9 billion—an astonishing \$5.9 billion (+15.6%) *higher* than its 2020 counterpart. Hospitals accounted for 87% of these skyrocketing 340B purchases. What's more, the difference between list prices and discounted 340B purchases also grew, to \$49.7 billion (+\$7.0 billion). This figure approximates the money collected by 340B covered entities."

Accordingly, in order to promote and assure the appropriate use of 340B revenue as described in the original federal legislation the Maine Prescription Drug Affordability Board recommends that the Maine Legislature require greater transparency and accountability for the 340B program in Maine. A forthcoming reporting template along with model legislation under development by NASHP will enable this.

V. Collaborating with Prescription Drug Affordability Boards in Other States

The Maine Prescription Drug Affordability Board is part of a collaborative of six states (Colorado, Maine, Maryland, Oregon, New Hampshire, Washington) implementing Prescription Drug Affordability Boards, convened by the National Academy for State Health Policy, and receiving technical assistance (TA) from the Program on Regulation, Therapeutics, and Law (PORTAL) at Harvard Medical School and Brigham and Women's Hospital. MPDAB Chair Dr. Noah Nesin attends monthly meetings of this collaborative to learn across states, and to access TA from PORTAL.

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spending targets for public purchasers. Other PDABs, such as those in Colorado and Maryland, limits based on those reviews. Given the resource-intensity of this approach, in Maine it would are tasked with conducting affordability reviews and, when appropriate, setting upper payment be most expedient to set upper payment limits based on reference rates available from Canada Maine and New Hampshire have similar PDABs, both charged with setting prescription drug and/or Medicare price negotiations, - as described in the "Reference Rates" and "340B Transparency" sections of this report.

Board. The Department of Administrative and Financial Services staff's role was to convene and recommendations. The Department and Governor's Administration will review and react to any This report represents the positions and recommendations of the members of an independent support the independent Board; the Department has not taken any position on these proposals related to this report through the Legislative Committee Process.



Noah Nesin, MD, FAAFP

Chair, Maine Prescription Drug Affordability Board