

Introduction

Section 21-2C-09(c) of the Health-General Article, Annotated Code of Maryland, directs the Maryland Prescription Drug Affordability Board (Board) to submit an annual report on or before December 31 that includes: (1) price trends for prescription drug products; (2) the number of prescription drug products that were subject to Board review and the results of the review; and (3) any recommendations the Board may have on further legislation needed to make prescription drug products more affordable in the State.

I. Price Trends for Prescription Drug Products- 2022-2023

A. Net Prices Remain Stable, with Increased Spending Driven by New Products and Volume

The IQVIA Institute report *The Use of Medicines in the U.S. 2023* found that spending on medicines at net manufacturer prices in the United States rose 5.3% in 2022 to \$429 billion, with COVID vaccines and therapeutics remaining a cost driver. Specialty drugs made up 51% of spending. Total spending at net manufacturer prices increased by \$103 billion over the past five years, driven largely by new brand products and brand volume. In 2022, the increase of list prices have fallen to a low of 3.7% and net prices have largely remained unchanged, increasing less than 1%.¹

B. List Prices Continue to Increase, with Many Prices Increasing Faster than Inflation

The United State Department of Health and Human Services (HHS) Office of the Assistant Secretary for Planning and Evaluation HHS (ASPE) report on wholesale acquisition costs (WAC), or list price, covering January 2022 to January 2023, found that 4,200 drug products had price increases, with 46% of those increases being larger than the rate of inflation. The average drug price increase over the course of this period was 15.2%, which was about \$590 per drug.²

C. The Number of Biosimilars Providing Competition in the Biologics Market is Increasing

There has been a substantial increase in the number of biosimilars in the marketplace resulting in the brand sales of those products dropping by \$33 billion,³ and resulting in a savings of \$9.4

¹ IQVIA Institute. *The Use of Medicines in the U.S. 2023: Usage and Spending Trends and Outlook to 2027*. IQVIA. April 2023.

<https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2023>

² Bosworth A, Sheingold S, Finegold K, Lew ND, Sommers BD. *Price Increases for Prescription Drugs, 2017-2023*. United State Department of Health and Human Services (HHS) Office of the Assistant Secretary for Planning and Evaluation HHS (ASPE) Office of Health Policy Issue Brief. October 6, 2023. <https://aspe.hhs.gov/reports/changes-list-prices-prescription-drugs>

³ IQVIA Institute. *The Use of Medicines in the U.S. 2023: Usage and Spending Trends and Outlook to 2027*. IQVIA. April 2023.

billion.⁴ Generics and biosimilar medicines continue to make up over 90% of all prescriptions, while making up less than 18% of spending.⁵

D. Out-of-Pocket Costs Continue to Cause Affordability Challenges for an Important Number of Americans

Patient out-of-pocket costs rose to \$82 billion in 2022, and would have exceeded \$100 billion without nearly \$19 billion in manufacturer copay assistance.⁶ While KFF public surveys found that 80% of respondents indicated the cost of prescription drug products are unreasonable, 65% of respondents stated that affording a prescription drug is easy.⁷ Average out-of-pocket costs per script have decreased; however, there are a number of patients with significant out of pocket costs.⁶ According to public surveys, individuals with household incomes of less than \$40,000 per year and those taking four or more prescription drugs are likely to report affordability challenges.⁷

II. Maryland’s Cost Review Experience

A. Overview of Cost Review Study Process

Section 21–2c–08(c)(4) of the Health-General Article directs the Board to identify prescription drug products that meet certain statutory metrics and “[o]ther prescription drug products that may create affordability challenges for the State health care system and patients.” From the identified prescription drug products, the Board selects a drug or drugs for cost review—a study of specified statutory and regulatory factors to assess whether use of the prescription drug product “has led or will lead to affordability challenges for the State health care system or high out-of-pocket costs for patients.” Md. Code Ann., Health-Gen. §21-2c-09(b)(1). Over the course of 2022 and 2023, the Board developed regulations establishing procedures implementing the Cost Review Study Process. In developing the regulations, the Board published initial drafts in May, June, and July 2023 and solicited and received extensive public feedback. On July 24, 2023, the Board formally adopted the regulations, which were published as proposed regulations in the Maryland Register on September 22, 2023. The Board received two comments to the proposed regulations.

The Board anticipates the final regulations will be effective for the start of 2024 at which time the work in identifying and selecting drugs for cost review study will begin.

⁴ Association for Accessible Medicines. The U.S. Generic & Biosimilars Medicines Savings Report. September 2023. <https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf>

⁵ Association for Accessible Medicines. The U.S. Generic & Biosimilars Medicines Savings Report. September 2023.

⁶ IQVIA Institute. *The Use of Medicines in the U.S. 2023: Usage and Spending Trends and Outlook to 2027*. IQVIA. April 2023.

⁷ KFF. *Public Opinion on Prescription Drugs and Their Prices*. <https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/>. August 2023.

B. Number of Cost Reviews and Results

Because the cost review process is under development, including the drafting of regulations necessary to implement the process, no cost reviews were completed in 2023.

III. Recommendations

The Board does not recommend additional legislation at this time, but will continue to explore policy and legislative initiatives to make prescription drugs more affordable for Marylanders.