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November 3, 2025

Massachusetts Health Policy Commission
50 Milk Street, 8th Floor
Boston, MA 02109

Please see the attached response from Merck to the request for written testimony in preparation for the 2025 Health Care Cost Trends Hearing, *"Working Together to Safeguard the Commonwealth's Commitment to Health Care Affordability, Access and Equity"* that is scheduled for Wednesday, November 12, 2025.

I am legally authorized and empowered to represent Merck for the purposes of this testimony. The enclosed testimony is signed under the pains and penalties of perjury.

Sincerely,

Terri J. Lee

CC: Josh Harrell

MASSACHUSETTS
HEALTH POLICY COMMISSION

2025 Pre-Filed Testimony

As part of the *Annual Health Care Cost Trends Hearing*

Massachusetts Health Policy Commission
50 Milk Street, 8th Floor
Boston, MA 02109

INSTRUCTIONS FOR WRITTEN TESTIMONY

If you are receiving this, you are hereby required under M.G.L. c. 6D, § 8 to submit written pre-filed testimony for the 2025 Annual Health Care Cost Trends Hearing.

On or before the close of business on **Friday, October 31, 2025**, please electronically submit testimony as a Word document to: HPC-Testimony@mass.gov. Please complete relevant responses to the questions posed in the provided template. If necessary, you may include additional supporting testimony or documentation in an appendix. Please submit any data tables included in your response in Microsoft Excel or Access format.

Your submission must contain a statement from a signatory that is legally authorized and empowered to represent the named organization for the purposes of this testimony. The statement must note that the testimony is signed under the pains and penalties of perjury. An electronic signature will be sufficient for this submission. All submissions are public record and will be posted to the HPC's website.

If you have any difficulty with the template or have any other questions regarding the pre-filed testimony process or the questions, please contact HPC General Counsel Lois Johnson at HPC-Testimony@mass.gov or Lois.Johnson@mass.gov.

THE 2025 HEALTH CARE COST TRENDS HEARING: PRE-FILED TESTIMONY

The Massachusetts Health Policy Commission (HPC), along with the Office of the Attorney General (AGO), holds the Health Care Cost Trends Hearing each year to examine the drivers of health care costs and consider the challenges and opportunities for improving the Massachusetts health care system.

The 2025 Health Care Cost Trends Hearing offers a critical opportunity to discuss the pressing issues challenging the stability and sustainability of the Commonwealth's health care system. These include mounting affordability issues, workforce constraints, financial volatility, increasing prescription drug costs, and threats to health care access and coverage – and the ongoing efforts to address them.

Recent federal action has created uncertainties about the health care landscape in Massachusetts. It will require a renewed commitment among stakeholders and policymakers to work together towards a health care system that is more affordable, accessible, and equitable for all residents. The 2025 Health Care Cost Trends Hearing will convene industry leaders, clinicians, and community members to reflect on recent policy actions and invite further collaborative action in Massachusetts, advancing the Commonwealth's health care goals and values.

Amid the federal activity, Massachusetts is still contending with existing affordability hardships facing the Commonwealth's residents. Massachusetts now has the highest family health insurance premiums in the country. In 2024, the average annual cost of health care for a family exceeded $31,000 (including out-of-pocket spending). As health care spending grows as a portion of household income, more and more families incur medical debt and avoid using needed care. These rates become particularly dire when health care premiums and out-of-pocket spending reach 25% of total income – a reality that 41% of Hispanic families and 26% of black families in Massachusetts faced in 2023 compared to 9% of white families. Furthermore, the average annual cost sharing per person grew from $849 in 2019 to $1,049 in 2023 (a 29% increase), and residents paying $5,000 or more annually in cost sharing doubled from 2019 (1.5%) to 2023 (3.1%).

This is the first hearing since the enactment of two significant health care laws earlier this year (Chapters 342 and 343 of the Acts of 2024), which strengthen the health care market, address rising prescription drug costs, and enhance the public transparency and accountability of the Commonwealth's health care system – including requiring additional health care market participants to provide public testimony. As the HPC, the AGO, and other state agency partners continue implementation of these new laws, the 2025 Health Care Cost Trends Hearing will focus on working together to safeguard the Commonwealth's commitment to health care affordability, access, and equity.

The pre-filed written testimony affords the HPC and the AGO, on behalf of the public, an opportunity to engage with a broad range of Massachusetts health care market participants. In addition to pre-filed written testimony, the public hearing features in-person testimony from leading health care industry executives, stakeholders, and consumers, with questions posed by the HPC's Board of Commissioners about the state's performance under the Health Care Cost Growth Benchmark and the status of public and industry-led health care policy reform efforts.

QUESTIONS FROM THE HEALTH POLICY COMMISSION

1. In recent years, prescription drugs have been a key driver of spending growth in the Commonwealth, consistently growing at a faster rate than the state's health care cost growth benchmark, and contributing to challenges related to health care affordability, medication access, and health disparities among Massachusetts residents.

    a. What policies or strategies should policymakers and/or other market participants consider to (1) provide greater transparency and (2) address the growing cost of prescription drugs in Massachusetts, balancing patient access to needed medications and therapies with the imperative to offer affordable coverage for employers and residents?

PBM Reform

As more power and control has been consolidated into an ever-smaller number of vertically-consolidated players, their negotiating strength has increased dramatically. But patients are not benefiting from the discounts being negotiated by PBMs. Instead, their insurers often base their cost-sharing on the list price, even when PBMs and insurance companies are paying a heavily discounted fraction of that price.

Rather than passing the discounts they obtain to patients to lower their out-of-pocket costs at the pharmacy counter, we understand that insurance plans retain them to cover overhead costs and reduce insurance premiums for all their insureds. When they do this, rather than reducing medicine costs for those that need them, it means sick people end up effectively subsidizing healthy people. This dynamic is contrary to the basic idea of insurance, which should use the premiums of healthy people to help fund the care of those who are struggling.

PBMs can influence medicine affordability and availability for patients through their decisions about formulary coverage, utilization management, and formulary tier placement (which establishes patient cost sharing). PBMs can have misaligned incentives when the fees they charge are based on drug price. Reforms to the current system should be made with an aim to move toward a PBM compensation structure that is not linked to drug prices.

For this reason, we support the proposed reforms in H1082 that would delink PBM compensation

from the price of a medicine, eliminating incentives for PBMs to favor high-priced medicines over lower cost alternatives

Another critically important change is to require that the discounts provided by manufacturers be passed through to patients to lower their out-of-pocket costs at the pharmacy counter, rather than allowing insurance plans to retain them. Reforms like these are necessary and will help provide long-term solutions for patients' out-of-pocket costs and ensure they can take advantage of the full breadth of innovative medicines available to keep them healthy and alleviate their suffering. Patients should never pay more for their medications than their insurers do. We support measures like those outlined in H1364, which would help with patient affordability and access.

340B Program

The 340B Drug Pricing Program is a federal program that was designed to help vulnerable patients improve access to their medicines through manufacturer discounts to specific safety-net, non-profit hospitals and federally funded clinics. Unfortunately, the program has strayed far from its intended purpose, with more and more for-profit health care entities using these discounts for themselves.

The rapid growth and limited oversight of the 340B program has led to misaligned incentives and market distortions, which are contributing to higher health care costs for both patients and payers. In turn, these costs are contributing to the exponential growth of the program overall. There has been significant growth in the program with sales increasing from $3.9 billion in 2007 to $43.9 billion in 2021, making it the second-largest federal prescription drug program behind only Medicare Part D[1]. In addition, a recent analysis of HRSA data by BRG indicates that from 2019 to 2023, purchases of 340B drugs have increased by 22.1% annually, reaching $68 billion in 2023.[2] This rate of growth far outstrips the US pharmaceutical marketplace overall and demonstrates the broad scope and impact of 340B.

A recent analysis by IQVIA looked at 340B utilization across states and found that 340B utilization in Massachusetts is 19% higher than the national average of 12%. In addition, this research also estimates that the financial impact of the program on employers and workers in Massachusetts in terms of lost rebates is $240M annually.[3]

The 340B program's rapid growth, particularly the extreme growth of contract pharmacy arrangements, has allowed large, for-profit middlemen to capture the savings intended to help low income and underserved patients. Today, 340B covered entities and their contract pharmacies realize an average 72% profit margin on 340B purchased brand medicines – more than three times greater than the average margin realized by independent pharmacies.[4] A recent analysis found that

[1] Fein A., "The 340B Program Climbed to $44 Billion in 2021 – With Hospitals Grabbing Most of the Money," August 15, 2022. Drug Channels. https://www.drugchannels.net/2022/08/the-340b-program-climbed-to-44-billion.html

[2] Gross and net 340B sales figures and overall 340B program growth are based on BRG analysis of net program sales as reported by HRSA at: https://www.hrsa.gov/opa/updates/2023-340b-covered-entity-purchases.

[3] IQVIA" The Cost of the 340B Program to States, "February 4, 2025.

[4] Berkley Research Group, " For-Profit Pharmacy Participation in the 340B Program," October 2020.

more than half of all profits realized by the 27,000 contract pharmacies participating in the program are concentrated in just four companies: Walgreens, CVS, Walmart, and Cigna's specialty pharmacy.[5] Leveraging their enormous market power and vertically integrated structures, these corporations are able to negotiate high reimbursement rates from payers, even for deeply discounted 340B-purchased drugs.

Additionally, the growth in contract pharmacy arrangements may increase the risk of 340B statutory violations, including duplicate discounts. The 340B statute prohibits subjecting manufacturers to "duplicate discounts' in which drugs provided to Medicaid beneficiaries are subject to both 340B program discounts and Medicaid rebates. Despite this clear statutory prohibition, many covered entities do not have mechanisms in place to adequately identify 340B claims to prevent duplicate discounts. The GAO has found there to be a heightened risk of duplicate discounts in managed Medicaid where HRSA does not require covered entities to address them or work with manufacturers to repay them.[6]

The use of 340B drugs in Managed Medicaid may also have financial implications for the state. While fee-for-service Medicaid is required to reimburse 340B providers for drugs at the actual acquisition cost (AAC),[7] this requirement does not extend to managed care organizations (MCOs).[8] Instead, MCOs negotiate provider reimbursement rates that can exceed AAC. This means that in addition to the inability to claim a Medicaid rebate on 340B drugs, a state may be paying more when a 340B drug is used in Medicaid Managed Care.[9] A recent study by BRG estimated the reductions in Medicaid rebate revenue due to the 340B program and estimated the state share lost in Massachusetts to be $189.9 million.

Under its current structure, the 340B program may also create incentives for sites to use more expensive drugs. GAO highlighted this phenomenon in a 2015 report, which observed that per beneficiary Medicare Part B drug spending was substantially higher at 340B hospitals than non-340B hospitals.[10] Another recent study found that commercial payers also pay more for hospital outpatient medicines per beneficiary at 340B hospitals than non-340B hospitals.[11]

For these reasons, we disagree with efforts such as those outlined in H785, H1274, H 1296, and H1107 that would expand the 340B Program without addressing these concerns. Alternatively, Merck agrees with the assessments by the Government Accountability Office (GAO), the Office of Inspector General (OIG), and the Medicare Payment Advisory Commission (MedPAC) that 340B

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[5] Ibid

[6] Government Accountability Office (GAO), " Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement," January 2020

[7] Actual acquisition cost (AAC) means the agency's determination of the providers' actual prices paid to acquire drug products marketed or sold by specific manufacturers. 42 CFR 447.502

[8] 42 CFR 447.518(a)(2)

[9] Medicaid pays MCOs on a capitated basis and in many cases the 340B entities retain the value of the 340B discount and may be reimbursed by the MCO at an amount far above the 340B discount price. This then drives up MCO capitated rates and state Medicaid spending.

[10] Government Accountability Office (GAO)," Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals," Report to Congressional Requestors, June 2015.

[11] Hunter, M., Gomberg, J., C., " Commercial Payers Spend More on Hospital Outpatient Drugs at 340B Participating Hospitals," Milliman White Paper, March 2018.

reforms are needed at the federal level to address covered entity eligibility criteria and other aspects of the program design to ensure the integrity of the program and align with its intended purpose.[12] [13] [14] [15] [16]

We believe the key areas of reform include the following:

- **Enforcement of Prohibition Against Duplicate Discounts in Medicaid:** HRSA has completed a number of audits of covered entities that have shown deficits in the area of duplicate discount compliance.[17] Notably, the increase in contract pharmacies has contributed to oversight difficulties and may have limited 340B covered entities' abilities to prevent both drug diversion and duplicate discounts.[18] HRSA is required to establish a mechanism to prevent duplicate discounts. The current mechanism, the Medicaid Exclusion File (MEF), can only be used to prevent duplicate discounts in fee-for-service (FFS) Medicaid, and does not address the issue in Medicaid managed care, which accounted for 75 percent of total Medicaid enrollment in 2022.[19]

  To more effectively ensure compliance with the prohibition of duplicate discounts in the Medicaid program, the OIG recommended the use of a 340B claim modifier to identify claims for 340B purchased drugs.[20] Merck supports this approach and believes requiring this information in Managed Medicaid in addition to FFS could help detect, dispute, and prevent duplicate Medicaid discounts. We also believe a clearly established procedure for manufacturers to request and receive claims level data would improve the dispute resolution process.

[12] Government Accountability Office (GAO), " Drug Discount Program: Status of Agency Efforts to Improve 340B Program Oversight" Testimony before the US Senate Committee on Health, Education, Labor, and Pensions (HELP), May 15, 2018.
[13] Office of Inspector General (OIG), " Examining HRSA's Oversight of the 340B Drug Pricing Program," Testimony before the U.S. House of Representatives Committee on Oversight and Investigations, July 18, 2017.
[14] Medicare Payment Advisory Committee (MedPAC), " Report to the Congress: Overview of the 340B Drug Pricing Program," May 2015.
[15] Government Accountability Office (GAO), " Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement," January 2020.
[16] Government Accountability Office (GAO), " 340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements, " December 2019.

[17] Health Resources & Services Administration (HRSA), "Program Integrity: FY23 Audit Results," last updated July 7, 2023.
[18] Office of Inspector General (OIG), "Contract Pharmacy Arrangements in the 340B Program," February 4, 2014.
[19] The Kaiser Family Foundation " Total Medicaid MCO Enrollment," 2022.
[20] Office of Inspector General (OIG), "State Efforts to Exclude 340B Drugs for Medicaid Managed Care Rebates," June 2016.

2. Direct-to-consumer ("DTC") sales of prescription drugs is a growing trend in the United States, enabling pharmaceutical companies to sell their drug products to patients directly or through a third party or government platform, often at discounted prices. If your company currently offers or has publicly announced plans to offer any DTC programs, either directly or through a third-party, for the sale and distribution of any of your prescription drug products, please respond to the following questions:

    a. How do you select the drug products offered in your DTC programs? Which drug products do you offer through your DTC programs and which do you plan to offer?

Merck currently has one direct-to-patient program in the market for COVID-19. COVID-19 was selected for this channel since, due to the infectious nature of COVID-19, patients may not seek medical care and patients starting COVID-19 treatments must do so within a certain number of days of symptom onset, therefore it is important that patients are able to locate and receive treatment quickly (if treatment is appropriate). To support patient access, Merck will continue to assess if other programs could be appropriate for a direct-to-patient program.

    b. For each drug product that you currently sell through your DTC programs, indicate the DTC price for a one-month supply, and the DTC price's percentage discount off list price (if prices differ by dosage, please respond separately for each).

The direct-to-patient program for COVID-19 is not a cash offer program and is not intended to work outside of an eligible patient's insurance. It is only for patients with commercial insurance so the patient out-of-pocket price for the medication is set by the patient's insurer.

    c. Please describe any eligibility requirements that consumers must meet to purchase drug products through your DTC programs, and which payment methods your programs accept or will accept, including cash pay, insurance, FSA/HSA accounts, and other payment methods.

One example of the eligibility requirements of the direct-to-consumer program for COVID-19 is that the patient must be commercially insured. Patients who have Medicare, Medicaid, or any other government program insurance are not eligible.

d. Please describe any prescriber consultations that you facilitate, either directly or through a partnership with a provider organization, for consumers seeking to purchase a drug product through your DTC programs.

If a commercially insured patient chooses to utilize a telehealth visit within the program, they may choose to connect with an independent HCP who will exercise autonomous clinical judgment in evaluating any medical conditions and resulting care decisions which may or may not include COVID-19 medication. The telehealth providers have no obligation to prescribe any manufacturer's product during the patient's visit.

3. Massachusetts now has the highest family health insurance premiums in the United States. In 2024, the average annual cost of health care for a family exceeded $31,000 (including out of pocket spending). This reflects the growth in underlying health care costs. As health care spending grows as a portion of household income, more and more families incur medical debt and avoid using needed care. Collaborative, urgent action across market participants is needed to reverse these trends. How can your organization contribute to this effort?

At Merck, our purpose is to use the power of leading-edge science to save and improve lives around the world. We develop and bring forward breakthrough medicines and vaccines and then make those treatments available to patients in the United States and worldwide. Based in Rahway, New Jersey, our company is one of the world's most advanced research-intensive biopharmaceutical companies, an organization at the forefront of providing innovative health solutions that advance the prevention and treatment of disease in people and animals.

We know that many Americans are struggling to afford health care, including prescription medicines, despite the best efforts of leaders in government, industry, academia, and the nonprofit community. Even though medicine costs are growing at the slowest rate in years, thanks in part to market competition, patients are too often being asked to pay more out-of-pocket for their medicines. And for some, that burden is simply too much to bear. As has often been observed, a lifesaving drug is not effective if the patient who needs that drug cannot afford it.

Merck has worked hard to help patients overcome access and affordability challenges. That work continues. We believe our company and our industry have a duty to act responsibly in our pricing practices and contribute to affordability solutions. That is why we supported changes to the Medicare Part D program to create an out-of-pocket cap and allow beneficiaries to pay their costs over time.

We also have programs designed to help patients who cannot afford their medicines. To reduce patient out-of-pocket costs at the pharmacy counter, we may provide coupons and other co-pay assistance for our products. And through our support of a separate charitable organization that administers our patient assistance program, we provide free medicines to Americans of limited means who do not have insurance coverage or have some other hardship and cannot otherwise obtain their prescribed medications.