MASSBIO

700 Technology Square, 5th Floor
Cambridge, MA 02139
617.674.5100 | massbio.org

June 24, 2025

The Honorable James M. Murphy, House Chair
Joint Committee on Financial Services
State House Room 254
Boston, MA 02133

The Honorable Paul R. Feeney, Senate Chair
Joint Committee on Financial Services
State House Room 112
Boston, MA 02133

Re: MassBio Statement of Opposition – State-Level Regulation of the 340B Drug Pricing Program - H.1107, H.1274, H.1296, H.785, S.779, S.819

Dear Chair Murphy, Chair Feeney, and Members of the Committee:

On behalf of over 1,800 members, including emerging biotechs, research institutions, and life sciences leaders headquartered in Massachusetts, MassBio respectfully submits this testimony in strong opposition to matters that propose to establish state regulation of the federal 340B Drug Pricing Program. These efforts represent a misguided intervention into a federal program already beset by oversight challenges, legal uncertainty, and growing evidence of systemic abuse.

Established by Congress in 1992, the 340B Drug Pricing Program was originally designed to help safety-net providers stretch limited resources by requiring drug manufacturers to provide outpatient drugs at significantly discounted prices. The intent was clear: support covered entities like community health centers and eligible hospitals serving low-income, uninsured, and vulnerable populations. Over time, however, the program's scope has grown far beyond its original mission. The number of qualifying and participating covered entities has surged by over 600% since 2000, with more than 60,000 covered entities and over 33,000 contract pharmacies participating nationally in 2023[1]. As noted in the U.S. Senate HELP Committee Majority Staff Report, issued this April, this growth has occurred in the absence of basic guardrails to ensure that patients, rather than supply chain intermediaries, fully benefit from the program's intended savings.

Exclusively administered by the federal Health Resources and Services Administration (HRSA), the 340B program today operates as a financial black hole, swallowing billions in manufacturer discounts with little visibility into where savings ultimately go. Also according to the Majority Staff Report, many hospitals generate hundreds of millions in 340B revenue yet provide minimal evidence of direct patient support. There is no requirement under the program for savings to be passed to patients at the point of sale, and most covered entities do not separately track or report how 340B dollars are used. Numerous hospitals, for example, were shown to retain discounts as general revenue rather than directing them to specific patient care initiatives.[1] Worse still, contract pharmacies often extract a large share of this revenue through complex, opaque fee arrangements. Major pharmacy chains can charge dispensing fees as high as $85 per prescription for mail-order drugs, and administrative fees are frequently layered in through third-party administrators.[1] Many of these fees are indexed to inflation and increase automatically each year, further draining the value of the program.

With HRSA auditing fewer than 1% of covered entities annually and lacking rulemaking authority, the system now operates with virtually no accountability, transparency, or assurance that vulnerable patients actually benefit. In 2024, only 0.33% of covered entities (1 out of every 303) were audited, and since

2015, 68% of reaudited covered entities continue to be noncompliant with federal 340B requirements.[2] Additional figures from 2023 indicate 12 states had no covered entity audits whatsoever and 63% of audited covered entities had at least one adverse finding.[2]

The Commonwealth is not immune to national trends. Contract pharmacy engagements in Massachusetts increased 12,000% since the federal government expanded their use in 2010, with 69% of arrangements with one of the three largest pharmacy benefit managers in the country.[3] Despite this growth, only 33 covered entities have been audited in Massachusetts since 2015, and 23 of those audits returned adverse findings including illegal distribution of 340B drugs. Of the over 5,200 arrangements between for-profit contract pharmacies and 340B covered entities in the Commonwealth, 1,500 are with pharmacies outside of Massachusetts, and only 21% are in zip codes with an average household income that is lower than the state median. [3] Even further expansion, absent clear accountability for vulnerable patients, threatens to further distort the healthcare market and undercut the viability of innovative biopharmaceutical investment in this state. We must not encourage a targeted safety-net program to remain a shadow reimbursement system that disproportionately benefits large hospital systems, contract pharmacies, and vertically integrated subsidiaries - regardless of their physical location - over actual patients in need in Massachusetts.

The proposals pending before your Committee, listed above, seek to further embed and expand this underregulated federal framework at the state level. Doing so not only threatens to lock in current dysfunction but also invites legal conflict. Several states are already facing legal challenges over 340B laws, and the broader question of state authority over a federally administered program remains unsettled in the courts. These cases center on the fundamental question of whether states have the authority to regulate the program. As litigation continues, advancing state legislation in Massachusetts risks entangling the Commonwealth in costly legal battles and regulatory confusion. Moreover, the bills before you fail to define how patients will ultimately benefit, how revenue will be correctly tracked, or how compliance will be strictly enforced, ignoring each of the core weaknesses that have plagued the program at the federal level for years.

Rather than insert state mandates, we urge Massachusetts lawmakers to support efforts at the federal level to realign the 340B program with its original purpose. MassBio stands ready to work with both federal and state partners to improve access and affordability for patients across the health and income spectrums. But these bills represent the wrong approach at the wrong time. State intervention in the 340B program will only compound the program's problems and divert attention away from the patients the program was created to serve. We respectfully urge the Committee to reject these proposals.

Thank you again for your work, time, and consideration of this statement. Should you have any further questions or concerns, please contact me directly at (617) 674 5100 or kendalle.oconnell@massbio.org.

Sincerely,

Kendalle Burlin O'Connell
President & CEO
Massachusetts Biotechnology Council (MassBio)

[1]U.S. Senate Committee on Health, Education, Labor & Pensions. *Congress Must Act to Bring Needed Reforms to the 340B Drug Pricing Program: Majority Staff Report*. April 2025. https://www.help.senate.gov/imo/media/doc/final_340b_majority_staff_reportpdf1.pdf.

[2]ADVI Health. "ADVI Analysis: HRSA 340B Covered Entity Audits." *ADVI Health*, March 10, 2025. https://advi.com/insight/advi-analysis-hrsa-340b-covered-entity-audits/.

[3]Pharmaceutical Research and Manufacturers of America. *2025 State Profile: Massachusetts – 340B Drug Pricing Program*. Washington, D.C.: PhRMA, 2025. https://cdn.aglty.io/phrma/fact-sheets/340b/2025/Fact%20Sheet%20-%20340B%20State%20Profiles%20Massachusetts.pdf.