State of Vermont
Green Mountain Care Board
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Act 134 of 2024
Preliminary Report on Implementing a Vermont Prescription Drug Cost Regulation Program

Prepared by the
Green Mountain Care Board

January 15, 2025

VERMONT
GREEN MOUNTAIN CARE BOARD

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To: Vermont General Assembly
From: Green Mountain Care Board
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Title: Preliminary Report on Vermont Prescription Drug Cost Regulation Program

Act 134 of 2024 (S.98) directs the Green Mountain Care Board (GMCB), in consultation with others, to explore and create a framework and methodology for implementing a program to regulate prescription drug costs in Vermont. The GMCB's preliminary plan is due to the General Assembly on or before January 15, 2025, with a final plan due on or before January 15, 2026.

In the summer of 2024, we hired a director of prescription drug pricing, Kathryn O'Neill, and a policy analyst for prescription drug pricing, Noah Montemarano. We issued an RFP for contractor services with expertise on prescription drug-related issues to assist us in this work. The contract with Onpoint Health Data and Horvath Health Policy, was executed on December 15, 2024, and they have begun conducting a national landscape review and data analyses to support the GMCB's prescription drug program.

This preliminary report highlights learning to date from other states' experiences and the work underway in Vermont to address potential regulation of prescription drug costs as required under Act 134. It also describes the methodology proposed for the development of a final report with recommendations for consideration. We remain deeply committed to serving as an unbiased source of information, and to monitor and evaluate options as Vermont determines the best path forward in this work.

Preliminary Report on Implementing a Vermont Prescription Drug Cost Regulation Program

Progress Update and Preliminary Findings

The Green Mountain Care Board seeks to improve the health of Vermonters through a high-quality, accessible, affordable, and sustainable health care system.

Submitted January 15, 2025

In accordance with Act 134 of 2024

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ACKNOWLEDGEMENTS

This report is a work product of the Prescription Drug Pricing staff at the Green Mountain Care Board with support from contracted staff at Onpoint Health Data and Horvath Health Policy.

Glossary of Acronyms

Acronym	Definition
APA	Vermont Administrative Procedures Act
CMS	Centers for Medicare & Medicaid Services
DFR	Vermont Department of Financial Regulation
HHS	U.S. Department of Health and Human Services
MFP	Maximum Fair Prices (the Medicare Drug Price Negotiation Program)
PBM	Pharmacy Benefit Manager
PDAB	Prescription Drug Affordability Board
UPL	Upper Payment Limit
VHCURES	Vermont Health Care Uniform Reporting and Evaluation System
VUHDDS	Vermont Uniform Hospital Discharge Data System
WAC	Wholesale Acquisition Cost

Additional terminology definitions are available at the National Academy for State Health Policy (NASHP), which maintains a "Glossary of All Terms Pharma." [1]

[1] https://nashp.org/a-glossary-of-all-terms-pharma/

Introduction

Act 134 of 2024 (S.98) tasks the Green Mountain Care Board with creating a framework and methodology for implementing a program to regulate the cost of prescription drugs for Vermont consumers and Vermont's health care system. In doing so, the Board is exploring a variety of options for regulating the cost of prescription drugs, including:

- the experiences of states that have developed prescription drug affordability boards;
- the Centers for Medicare and Medicaid Services' development and operation of the Medicare Drug Price Negotiation Program;
- other promising federal and state strategies for lowering prescription drug costs; and
- the Board's existing authority to set rates, adopt rules, and establish technical advisory groups.

In exploring these options we will consider potential impacts of regulation, including:

- the likely savings–or "net"–of implementation costs for the most promising program options;
- the potential impacts on Vermonters' access to medications; and
- the potential impacts on private sector entities and state agencies.

Current State Initiatives

States have been working to reduce the cost of prescription drugs and associated state spending for several years. One area of focus that has developed for more than a decade has been the regulation of anti-consumer market behavior by pharmacy benefit managers (PBMs), such as PBMs' treatment of non-network pharmacies, behaviors that disadvantage independent pharmacies and pharmacies situated in underserved communities, as well as other behaviors that limit consumer choice. Many states have returned repeatedly to modify their statutes to address evolving and often obscure PBM practices. Most recently, states have started to require that PBMs report all the rebates they receive from drug manufacturers.

Starting in 2017, states began taking another approach: mandating minimum levels of prescription drug price transparency. California, Oregon, and Nevada led the effort with laws that required that manufacturers report new drug launch prices as well as price increases of in-market drugs that exceed certain dollar thresholds. Vermont was an early adopter of price transparency, adopting similar laws to California, Oregon, and Nevada as well as laws that mandated drug price disclosures from commercial insurance carriers.[2] States' efforts to increase transparency have expanded such that some states now require reporting from all parts of the supply chain – including wholesalers, pharmacies, and other organizations. Although some states have seen promising progress in this area, it has generally been difficult to use this information for policy development, as most data collected is incomplete, too complex, or lacking consistency to support policy recommendations.

The next wave of activity has consisted of state efforts to pursue wholesale prescription drug importation from Canada.[3] These initiatives have not moved forward because required federal approval has not been forthcoming due to a variety of legal, operational, and political impediments

[2] Act 193 - Impact of Prescription Drug Costs on Health Insurance Premiums (2025 report)

[3] Vermont, Colorado, Maine, Florida, and New Mexico all have statutes that authorize the development of wholesale importation programs.

that have not been addressed to the satisfaction of the first Trump Administration, nor the Biden Administration.

Finally, states have moved forward with a diverse set of initiatives that:

- limit the growth of pharmacy benefit spending in Medicaid and state employee programs;
- attempt to identify and penalize state-defined drug price gouging;[4] and
- establish governmental boards to study pharmaceutical costs and make recommendations to the governor or state legislature. Many of these boards are called prescription drug affordability boards (PDABs) or something similar.
    - Among these states, Colorado, Minnesota, and Washington boards have the authority to establish statewide upper payment limits (UPLs) for certain high-cost drugs. Maryland and Oregon may pursue statewide upper payment limit authority in their 2025 legislative sessions.

Limitations of State Initiatives

State options and opportunities for prescription drug cost containment have been limited for a variety of reasons such as:

- Federal statutes and caselaw which preempt potential state regulations.
- The high probability that any substantive state activity will engender legal challenges from highly resourced industries.
- Opposition from parts of the market that benefit financially from high drug prices.[5]
- The limited ability of a state to consolidate its market to build leverage with pharmaceutical market players.
- Vertical integration of the healthcare sector, which has created opportunities for self-dealing around prescription drugs at the expense of consumers and proved difficult for states to address.[6]
- The complex nature of the pharmaceutical market, including the obscure nature of price competition, the large number of stakeholders, the multiple functions of stakeholders, and the distinct business models of stakeholders, each seeking to maximize profits relative to direct and indirect market competitors.

These impediments are not insignificant to effective prescription drug cost regulation, but they can be overcome with thoughtful, informed policymaking.

[4] Minnesota and Illinois have enacted similar price gouging statutes, and both are under challenge by the Association for Affordable Medicines – the trade association for generic and biosimilar manufacturers.
[5] Depending on the state, opposition can come from the drug industry, PBMs, hospitals, doctors, 340B clinics, and patient groups that receive industry funds.
[6] Vertical integration is where a corporate parent owns a PBM, an insurance company, mail order pharmacies, specialty pharmacies, retail pharmacies, outpatient clinics and clinical practices, and increasingly, private label prescription drugs manufacturing. Drug Channels has an illustrating graphic on the issue.

Impact of State Initiatives to Date

States have been developing their cost management strategies for almost two decades. Their strategies have become bolder over the years, both as state policymakers have learned from past policy iterations, and as state and federal courts have created caselaw that is more amenable to state regulatory authority regarding national entities that affect the health and safety of state residents.

- PBM laws have been effective in halting some consequential PBM market abuse which had previously driven independent pharmacies[7] out of business. While the number of independent pharmacies seems to be growing again, the PBM industry seems to have the ability to modify its business model to work around state laws.
- Drug price transparency reporting has not yet led to actionable public policy. The original intention behind transparency reporting was that the pharmaceutical industry would be shamed into reducing prices and price increases. Although the industry has reduced the frequency and level of price increases, it has not slowed the increase in launch prices. Much of the data collected by states is publicly available to Vermonters since manufacturer drug list prices and price increases are national, not local.
- No state has yet implemented a wholesale prescription drug importation program. Aside from the limitations of federal importation rules themselves, the pharmaceutical industry will undoubtedly challenge the operational approval of any state wholesale importation program by challenging the federal approval authority created under the rules of the first Trump Administration. The industry has also successfully generated Canadian governmental opposition to U.S. state efforts to import Canadian-licensed drug products. Some states and local government employee health plans have incentives in place for enrollees to personally import drugs from other countries, notably Canada.
- Efforts to lessen the impact of high cost/high spend drugs in Medicaid have been moderately successful but state Medicaid programs have no real tools to obtain cooperation from manufacturers should they refuse to assist in cost/spending management.

[7] https://www.drugchannels.net/2024/12/drug-channels-news-roundup-december.html

Project Approach

GMCB is engaged in a collaborative contract partnership with Onpoint Health Data and Horvath Health Policy to develop a comprehensive approach to fulfill the objectives of Act 134. This includes a national landscape review, robust data analyses, and the provision of high-quality deliverables for each element of the project. This approach will ensure that Vermont can determine the most effective and sustainable program to regulate prescription drug costs.

National Landscape Review

We have begun and will continue to identify and evaluate state policy initiatives across the United States that address prescription drug pricing and the efforts to constrain related costs and spending. We will provide a comprehensive written description of these state initiatives, including an in-depth examination of the strengths and weaknesses of various approaches, as well as alternative and innovative strategies for cost containment. We will prioritize strategies that are relevant to Vermont's healthcare landscape, such as payment reference rates, drug importation programs, and consumer cost caps, among others. This research will provide insights into how these and similar initiatives have impacted cost containment, access to medications, and administrative burden in other states. This analysis will offer a critical view of the effectiveness of these strategies, allowing for an informed assessment of their applicability to Vermont. We will translate these findings into actionable recommendations that will inform Vermont's strategy for developing a framework and methodology to address prescription drug costs.

Data Analytics

Onpoint's analytical expertise, combined with Vermont's rich data sources (e.g., VHCURES, VUHDDS), enables us to conduct comprehensive analyses that will inform both program feasibility and potential outcomes. Informed by the National Landscape Review, we will use a data-driven approach to identify key focus areas for new policies to address key questions (e.g., Are certain drug classes driving spending growth? Are certain markets paying disproportionately more for specific drugs?). We will also model the potential savings for program options, projecting cost savings for both the state and consumers, while evaluating impacts on medication access. In addition, we will estimate the impacts of potential regulatory options on Vermont's healthcare system, including the potential implications for state agencies, the private sector, and patients. Onpoint will review existing publicly available data to identify sources of potential national or regional benchmarks to compare to Vermont's drug pricing and utilization trends.

Preliminary Review of State and Federal Experiences

In the following subsections we provide a summary of what we have learned to date from other states' experiences as well as activity at the federal level. These efforts will help inform Vermont's approach.

State Experience with Prescription Drug Affordability Boards

As defined by The Commonwealth Fund, prescription drug affordability boards (PDABs) are independent bodies empowered to analyze the high cost of drugs and suggest effective ways to lower spending.[8] The scope of PDAB authority varies from state to state.[9] Board members are generally appointed by the governor and have expertise in health care and economics. Members also can be clinicians, insurers, and consumer advocates. Most boards have official advisory boards of various sizes and scope that meet separately to review board activity and make recommendations to the board.

Vermont Act 134 of 2024 directs the GMCB to consider the experiences of states that have developed PDABs as we consider options for and likely impacts of regulating the cost of prescription drugs in Vermont. We looked at eight states that currently have boards or councils specifically designed to address prescription drug affordability. Here, we provide a summary of each state in terms of authority, meeting cadence, staffed FTEs, and budget allocation, when available.

Colorado Prescription Drug Affordability Review Board

Description	Colorado's PDAB has the authority to review drug affordability and establish upper payment limits.
State Agency Location	The Division of Insurance in the Department of Regulatory Agencies.
Date Authorized	6/16/2021
Authority to Set Upper Payment Limit (UPL)	Yes, for all consumers. The Board can assign UPLs to up to 18 drugs annually. So far, the Board has selected several drugs for UPLs, which are currently under development. The State has been sued by Amgen, a company with a drug determined to be not affordable.
Meeting Cadence	Approximately every other month.
Total Board members and qualification requirements	Five board members. Board members must not be an employee, board member, or consultant of potential regulated entities or have other potential conflicts of interest.
Advisory Group	Yes. Market stakeholders.
Staffed FTEs	Approximately six.
Annual Budget/Details	The FY2021 budget act appropriated to the Board $730,311. Of this amount, $325,297 was appropriated for personal services, $22,650 was appropriated for operating expenses, and $382,824 was appropriated for legal services.

[8] https://www.commonwealthfund.org/blog/2022/can-state-prescription-drug-affordability-boards-address-high-cost-drug-prices

[9] Maryland is the only state with a board fully separate from any existing state agency or department. The boards of all other states are housed in an existing state agency or department: Healthcare Authority, Commerce, Insurance, or Treasury. The language of the laws of most states where boards are housed and supported by existing state agencies is that the board is "in but not of…" the agency where it is housed.

Maine Prescription Drug Affordability Board

Description	Maine's PDAB is required to set prescription drug spending targets for state payers and purchasers as well as develop policy recommendations.
State Agency Location:	The Office of Affordable Healthcare.
Date Authorized:	6/24/2019
Authority to Set Upper Payment Limit (UPL)	No.
Meeting Cadence	Approximately every other month.
Total Board members and qualification requirements	Eight board members.
Advisory Group	Yes. Government agency heads.
Staffed FTEs	No staff positions were established for the PDAB specifically. The Maine PDAB is supported by staff at the Office of Affordable Healthcare.
Annual Budget/Details	Not specified.

Maryland Prescription Drug Affordability Board

Description	Maryland's PDAB has the authority to review drug affordability and establish upper payment limits. However, the UPLs would only apply to state and local government purchasers.
State Agency Location	Independent Body.
Date Authorized	5/25/2019
Authority to Set Upper Payment Limit (UPL)	Yes, but UPLs will only apply to state and local government purchasers and employee benefit plans.
Meeting Cadence	Approximately every other month.
Total Board members and qualification requirements	Five board members. At least one member of the board must have expertise in the 340B program and the state's all-payer hospital program. Board members must not be an employee, board member, or consultant of potential regulated entities or have other potential conflicts of interest.
Advisory Group	Yes. Market stakeholders.
Staffed FTEs	Approximately five.
Annual Budget/Details	The Board was appropriated $831,900 in FY 2020. Board has authority to fund operations through collection of annual fees ($1000) on manufacturers, pharmacy benefit managers, carriers, and drug wholesalers. The fees are supplemented by State appropriations. The 2024 Board budget was $1.4 million.

Minnesota Prescription Drug Affordability Board

Description	Minnesota's PDAB has the authority to review drug affordability and establish upper payment limits.
State Agency Location	The Division of Insurance within the Department of Commerce.
Date Authorized	5/24/2023
Authority to Set Upper Payment Limit (UPL)	Yes, to all state licensed providers, suppliers, and health plans/PBMs. States cannot legally regulate Medicare plans, but Minnesota intends to bill Medicare at the UPL while allowing Medicare to pay a different amount. The same rule will apply to ERISA plans. In addition, when setting a UPL for a drug already subject to Medicare maximum fair pricing, the Minnesota PDAB plans to set the UPL at the maximum fair price.
Meeting Cadence	Monthly with exceptions.
Total Board members and qualification requirements	Seven board members. Board members must have knowledge and demonstrated expertise in pharmaceutical economics and finance, or in healthcare economics and finance. Board members must not be an employee, board member, or consultant of potential regulated entities or have other potential conflicts of interest.
Advisory Group	Yes. Market stakeholders.
Staffed FTEs	One (the Executive Director).
Annual Budget/Details	The board was appropriated $568,000 for FY2024 and $537,000 for FY2025 to create and maintain the Prescription Drug Affordability Board. The base appropriation for FY2026 is $500,000.

New Hampshire Prescription Drug Affordability Board

Description	New Hampshire's PDAB must set spending targets for government payers and purchasers as well as develop policy recommendations. Their authority is similar to Maine's PDAB.
State Agency Location	The Department of Health and Human Services.
Date Authorized	7/16/2020
Authority to Set Upper Payment Limit (UPL)	No.
Meeting Cadence	Approximately monthly.
Total Board members and qualification requirements	Five board members.
Advisory Group	Yes. Government agency heads.
Staffed FTEs	One (the Executive Director).
Annual Budget/Details	NH HB 1280 did not include an initial appropriation for the Board. As of 2022, New Hampshire's PDAB had a $350,000 annual budget.

New Jersey Drug Affordability Council

Description	The New Jersey Drug Affordability Council plans to collect pharmaceutical market data and issue policy recommendations to the state legislature.
State Agency Location	The Division of Consumer Affairs, Department of Law, and Public Safety.
Date Authorized	7/10/2023
Authority to Set Upper Payment Limit (UPL)	No.
Meeting Cadence	Unknown. The Council met twice in November 2024.
Total Board members and qualification requirements	Five council members.
Advisory Group	No.
Staffed FTEs	Unknown at this time.
Annual Budget/Details	The 2023-2024 budget appropriated $1,500,000 from New Jersey's General Fund.

Oregon Prescription Drug Affordability Board

Description	The Oregon PDAB must conduct an annual review on drug and insulin affordability and issue policy recommendations to the state legislature.
State Agency Location	The Department of Consumer and Business Services.
Date Authorized	7/19/2021
Authority to Set Upper Payment Limit (UPL)	Not at this time. In December 2024, they issued a report to the Oregon legislature with a methodology on how a statewide UPL could be implemented. [10]
Meeting Cadence	Approximately monthly.
Total Board members and qualification requirements	Eight board members. Members of the board may not be employees of, board members of, or consultants to a manufacturer or a trade association of manufacturers or have other potential conflicts of interest.
Advisory Group	No.
Staffed FTEs	Eight FTEs. Staff members include an executive director, policy analyst, project manager, two data analysts, and an executive assistant.
Annual Budget/Details	The 2023-2025 budget appropriation is $2,970,125, which is approximately $1,485,062 annually.

[10] https://dfr.oregon.gov/pdab/Documents/reports/PDAB-upper-payment-limit-report-2024.pdf

Washington Prescription Drug Affordability Board

Description	Washington's PDAB has the authority to review the affordability of certain drugs and establish statewide upper payment limits.
State Agency Location	The Washington State Healthcare Authority.
Date Authorized	3/24/2022
Authority to Set Upper Payment Limit (UPL)	Yes, for all purchases, billings and payments from which Medicare plans. ERISA plans are exempted and can pay more than the UPL providers would bill. UPLs can be assigned to up to 12 prescription drugs annually.
Meeting Cadence	Approximately every other month.
Total Board members and qualification requirements	Five board members with expertise in health care economics or clinical medicine. Board members must not be an employee, board member, or consultant of potential regulated entities, or have other potential conflicts of interest.
Advisory Group	Yes. Market stakeholders.
Staffed FTEs	Approximately four.
Annual Budget/Details	In FY2023, the Board was appropriated $1,491,000: $1,460,000 from the general fund and $31,000 from the insurance commissioner's regulatory account.

PDABs have gotten off to a slow start. Except for the Maryland and Minnesota boards, most PDAB members in various states have had a steep learning curve once appointed; most members across the states are not familiar with many of the key business models in the U.S. pharmaceutical market or the operations of the many pharmaceutical entities. Unlike other boards, Minnesota and Maryland have members who are researchers on pharmaceutical market behavior, as well as clinicians. In some states, PDABs have struggled to appoint board members without conflicts of interests and to avoid conflicts of interest in their deliberations. PDAB advisory groups tend to allow financial or personal conflicts because advisors represent their specific organizational or personal interests in reviewing board work.

Another reason for the slow start of PDABs is the strong opposition of the pharmaceutical industry in almost every state regardless of their board's scope of authority or level of activity. Additionally, the pharmaceutical industry funds and works with patient advocacy groups generating fear that if a UPL is applied, a drug may no longer be available in the state or, alternately, it will stifle introduction of new drugs to the market. The threat of market availability seems premature, however, given that UPLs are designed to increase patient access and therefore increase product sales. On the threat of innovation, the branded pharmaceutical industry must innovate or go out of business over time. It is a remarkably potent industry argument but one that does not reflect the core business necessity of innovation. Regardless, the drumbeat of pressures has impeded the work of some boards with or without UPL authority.

Building on the CMS Medicare Drug Price Negotiation Program

The Inflation Reduction Act of 2022 created the Medicare Drug Price Negotiation Program, which grants the Secretary of Health and Human Services (HHS) the authority to negotiate prices for certain high-spend, single-source drugs under Medicare Part D and, starting in 2028, Medicare Part B. In accordance with the statute, HHS has negotiated prices for ten drugs which take effect in 2026. In the future, HHS will negotiate prices for up to 15 additional drugs for 2027, 15 more for 2028, and 20 more each year beginning in 2029.

To qualify for negotiation, drugs must meet several criteria. They each must be among the top spend drugs in Medicare. Chemical drugs (a.k.a. "small molecule drugs") must have been licensed for at least seven years, and biological products (a.k.a. "large molecule drugs") must have been licensed for at least 11 years. Drugs must face no biosimilar nor generic competition. Certain types of drugs are fully or temporarily exempted from the process, such as for instance, plasma-derived products, certain rare-disease products, or drugs that provide the majority of the revenue of a small biotechnology company.

HHS has successfully negotiated prices for ten drugs starting in 2026: Januvia, Fiasp, Farxiga, Enbrel, Jardiance, Stelara, Xarelto, Eliquis, Entresto and Imbruvica. The negotiated prices for these drugs, also known as the Medicare Maximum Fair Prices (MFPs), constitute the highest price that a Medicare plan or beneficiary will pay for a product. According to the Centers for Medicare & Medicaid Services (CMS), the ten drugs selected for negotiation were prescribed to about 8.8 million Medicare beneficiaries in 2023 and accounted for about $56.2 billion (~20%) of total Part D gross drug costs. In the same year, the drugs accounted for about $3.9 billion in out-of-pocket spending for Medicare beneficiaries. Had the negotiated prices been in effect in 2023, CMS estimates that Medicare would have saved an estimated $6 billion in net covered drug costs.[11]

MFPs will be available at the pharmacy counter to Vermonters who elected to enroll in Medicare Parts B and D or C which is most, but not all, Vermont Medicare beneficiaries.[12] Some states have begun passing legislation to allow other residents to get similar reductions in pricing. For example, Minnesota law allows for the adoption of the MFP as a statewide UPL. In 2023, the Nevada legislature passed AB 250 to make the MFP the statewide UPL, but the bill was vetoed by the Governor.

A state PDAB may want to adopt the Medicare MFP as a statewide payment limit for the drug for all residents or possibly, just a subset of residents. Assuming that the state payment limit will have to be the same as the MFP and cannot be implemented earlier than the MFP (because of possible Medicare preemption challenges), a supply chain approach may suit the interests of most of the supply chain by building on existing operational and business processes. Alternatively, a state could consider a rebate approach which will be used for Medicare MFPs. Such approaches are described in further detail below.

[11] https://www.cms.gov/newsroom/fact-sheets/medicare-drug-price-negotiation-program-negotiated-prices-initial-price-applicability-year-2026

[12] Only Medicare Part A (inpatient hospital care and sub-acute nursing care) is an automatic entitlement for adults with a work history the includes payment of the Medicare payroll tax.

Approaches to Implementing a UPL at the MFP

The default MFP 'drug purchase and payment system' established by CMS creates new administrative requirements for pharmacies and providers. In it, the provider or pharmacy buys the MFP drug at market price, then dispenses and bills at the lower MFP which leaves the pharmacy underpaid for its acquisition cost. The pharmacy then provides additional data to seek reimbursement from the drug's manufacturer. CMS has created a standard formula for manufacturer reimbursement to providers and pharmacies: Wholesale Acquisition Cost (WAC) minus MFP, but manufacturers may choose alternative systems of reimbursement.[13]

Based on the system that CMS has created, if a state wants to extend the MFP to all residents, a supply chain approach may be helpful to pharmacies and providers. With a supply chain approach, the drug would come into the state at the MFP (the MFP would serve as the provider/pharmacy acquisition cost). Providers/pharmacies could then avoid the federal administrative process to verify that the sales were to eligible Medicare enrollees and would not need to seek reimbursement from the manufacturer for the difference between acquisition cost and MFP. There would be no new administrative burden on manufacturers for MFP/UPL drugs dispensed or administered in the state. Legally, manufacturers would first have to agree to this model on the Medicare MFP side since federal rules give manufacturers a choice, but there are administrative benefits to them to doing so.

Alternately, in a rebate approach, the MFP/UPL drug product would be purchased at market price by pharmacies or providers, which would receive a rebate once the drug is dispensed to anyone in the state. As in the supply chain approach, the rebate approach still lessens the burden of determining if a patient is eligible to access the MFP/UPL because access becomes universal in the UPL state. This rebate approach could be implemented from manufacturer to health plan/PBM, as is typical. Under the approach, plans/PBMs would manage their pharmacy claims systems to use the MFP/UPL as the basis of patient cost sharing at point of service, reimburse the pharmacy or provider based on market acquisition cost, and pursue a manufacturer rebate. Typical rebates – from manufacturer to the health plan/PBM – would not include uninsured people whereas the supply chain approach does create access to the MFP/UPL for people without insurance. For Medicaid, the manufacturer MFP/UPL rebate would become a supplemental rebate – reflecting the difference between Medicaid pharmacy payment and the MFP/UPL.[14]

There are likely additional ways to implement the UPL/MFP. Regardless of approach, a key implementation issue is the ease with which pharmacies and administering providers can manage their role in a unified MFP/UPL system versus in separate UPL and MFP administrative systems.

Some potential questions for future analysis and reporting include:

- How common are each of the MFP-applicable drugs within Vermont (e.g., how many prescriptions were filled and for how many patients)?
- To what extent will Medicare MFPs lower out-of-pocket costs for Vermont Medicare enrollees, particularly with the $2,000 annual Part D out-of-pocket limit as of January 2025?
- How might a universal/statewide MFP lower costs for Vermont residents not eligible for Medicare (both out-of-pocket costs and premium costs for people with insurance)?
- How might a universal/statewide MFP lower costs for Vermont agencies and programs?

[13] The CMS guidance anticipates that some providers or pharmacies may access the MFP drug at or below the MFP, in which case no reimbursement from the manufacturer is due. CMS includes this possibility in manufacturer reimbursement reporting codes.

[14] Medicaid supplemental rebates are generally voluntary for manufacturers, although some states have policies in place to make them difficult for manufacturers to refuse.

A Review of Other Federal and State Strategies

Market Transparency

The goal of transparency should be to better understand the prescription drug market and collect data that is useful for policy making. To date, much of the transparency data collected by states about price increases and launch prices has largely not been useful for policymaking. However, some of the data collected by states have the potential to be useful in the future, including:

- As reported by health plans or PBMs: the 25 most frequently prescribed drugs, the 25 costliest drugs as determined by total amount of spending (in state or by insurer/PBM), the 25 highest price drugs, and the 25 drugs with highest consumer cost sharing.
- The amount of rebates paid by manufacturers to health plans/PBMs for a drug, a class of drugs, or in total.[15]
- The amount of 340B revenue (total and net) generated by 340B covered entities in the state.[16]

Caps on Out-of-Pocket Costs

Many states limit insured consumer prescription cost sharing for certain drugs. Most notably, it has become more common for states to limit insulin to $35 per 30-day supply, epinephrine auto-injector devices to $25 per 30-day supply, and prescription asthma inhalers to $50 per 30-day supply. States have different limits and apply them to different drugs. Currently, Vermont limits out-of-pocket costs for insulin to $100 per 30-day supply.[17]

These state policies do not seem to have resulted in premium increases, but the results could be different if applied to very high-cost drugs with marginal manufacturer health plan/PBM price concessions, or to an overall limit on prescription drug out-of-pocket spending that is lower than current laws and industry practice. The new Medicare Part D 2025 annual out-of-pocket limit of $2,000 would have caused a significant premium increase across all Part D plans such that the government stepped in with a policy to increase the Part D plan premium subsidies which avoided a spike in premium costs for the 2025 plan year.

International Drug Importation

18 V.S.A. § 4651 directs the Agency of Human Services (AHS) to design a program for wholesale importation of predetermined, high-cost prescription drugs into Vermont from Canada that complies with federal requirements. For more information and a progress update on this initiative we defer to the Agency of Human Services Office of Health Care Reform.

There are challenges with importing drugs on a broad scale. Federal law allows the wholesale importation of prescription drugs exclusively from Canada under a set of limited conditions found in federal law and federal rules. The law requires that the wholesale program reduces costs for consumers and creates no health risk greater than the current U.S. drug supply system. Federal rules generated by the first Trump Administration require a program that is fairly onerous and is likely to

[15] Early states like Colorado and Texas capture aggregate/all rebate data from health plans because of concerns about trade secrets. States could capture by drug class so long as there are enough drugs within a class to preserve trade secrets. Oregon has received rebates by drug, but the data cannot be made public.
[16] Minnesota recently started to collect this data and issued its first report.
[17] 8 V.S.A. § 4089i

reduce the amount of savings. In brief, the rules require the participation of the original drug manufacturers as well as limit the Canadian supplier to one company and the U.S. distributor to one company which, together, may facilitate manufacturer control to prevent the distribution of their drugs. There are other limits such as package sizes that can be imported which could reduce the amount of savings and possibly limit the scope of the program. Florida has developed an importation program, which was approved by the Biden Administration but has yet to be operationalized and will likely be subject to legal challenge when launched.

On a smaller scale, some states and local governments have successfully designed programs to incentivize drug importation for limited populations. Schenectady NY and other state or local government employee health plans currently incentivize personal prescription drug importation by state and local workers.[18] The purchases are covered by the employer plan and out of pocket consumer cost is lower than it is for the drugs purchased from a U.S. pharmacy.

Multi-State Drug Purchasing Pools

The idea of multi-state drug purchasing pools has been circulating among states for many years for many different products and services. The goal of such pools is to maximize the purchasing power of states for specific items or services by teaming together with several states or with multiple entities within states. Two such state-focused organizations already exist to provide drug products or pharmacy benefit management services for any state.

- ArrayRx[19] is a service created jointly by Oregon and Washington State several years ago. In brief, it provides services that a PBM might provide such as pharmacy claims payment, pharmacy network management, and formulary management. It also provides 100% rebate pass through to client health plans.[20] ArrayRx offers a drug discount card which can be used by cash paying consumers in any state. The cards are currently available as state-sponsored programs in OR, WA, NV, and CT. ArrayRx also offers a full complement of Medicaid pharmacy management services.
- MMCAPInfuse[21] is operated by Minnesota and is open only to state and local government entities. The procurement service offers a wide array of prescription drugs and related supplies or services ranging from branded and generic drug products, and vaccines, to dispensing and pharmacy management for state facilities. The service is used in state-run hospitals, long term care facilities, public health, and other facilities, although use of MMCAPInfuse services may not be consistent within a state. The service allows states to track which in-state programs and facilities access MMCAPInfuse procurements.

[18] https://www.schenectadycountyny.gov/sites/default/files/hr-cs/Schenectady%20Meds%20Enrollment%20Package%20for%20ProAct%20Transition_09_15_2016.pdf
[19] https://www.arrayrxsolutions.com/
[20] The large commercial PBMs generally now say they pass through 100% of their rebates if the client prefers. Industry skeptics are concerned that new offshore companies owned by PBMs or the corporate parent company allow the US company to move funds offshore in order to reduce the amount of money that is "100%".
[21] https://infuse-mn.gov/about/index.jsp

Leveraging New Market Business Model Innovations

Recently, there have been several innovative market activities aimed at lowering the cost of drugs to payers/health plans and consumers. These innovations are growing in scope and volume. Most of the innovation attempts to overcome the market control of the largest PBMs which have a documented history of driving up costs for health plans and consumers through vertically integrated corporations with complex business models that use corporate components to enrich the corporation at the expense of competitor pharmacies, health plans, and consumers. These large corporations generally guarantee client health plans a rebate percentage off total pharmacy spend without guaranteeing control of the underlying health plan pharmacy spend. Branded manufacturers, new model PBMs, and employers are creating workarounds to overcome the adverse market practices of PBMs.

- Brand manufacturers are bringing products to market with two list prices – one for PBMs that refuse to cover the product at the lower list price (and less rebate) and another list price for the uninsured and PBMs willing to cover the product at lower list price with less or no rebate.
- Employers are demanding and sometimes creating new PBMs that allow greater payer control, greater flexibility to work with market disrupters, and better market behavior.
- Brand insulin makers dramatically dropped their list price and created dedicated distribution channels to move the lower priced product to consumers.
- Generic drug suppliers are creating closed distribution channels where channel participants commit to limit the price of the product to consumers.

States as payers and purchasers may be able leverage the innovation for themselves and/or create greater awareness of opportunities for private sector employer plans or others to leverage the current innovative models. One feasible approach would be to promote low-cost generic drug sourcing.

- Employer plans (government or private) could access new sources of drug spend cost containment such as the Mark Cuban Cost Plus Drug Company[22] which offers low-cost generic (and some brand) drug pharmaceutical products to cash-paying individuals as well as health plans. The pharmacy offers generics at the cost of manufacturing plus a set, publicly disclosed, percentage add-on. The pharmacy can offer its own PBM-type service to payers for billing of dispensed drugs or can "bolt onto" a health plan's existing PBM services. It has also begun to offer brand drugs near patent expiration at deeply discounted prices.
- CIVICAScript[23] is an organization that works with generic drug manufacturing facilities to lower the cost of otherwise high-cost generic products. It works with manufacturers, participating health plans, and retail and mail order pharmacies to provide lower cost generics to enrollees of participating health plans.

Drug Cost/Payment Limits

In addition to setting statewide UPLs or expanding access to Medicare MFPs, as mentioned earlier in this document, states have looked at proposals that would automatically apply one of a variety of cost limits on drugs bought, billed, or reimbursed in a state such as:

- the base rate for drugs established by the U.S. Department of Veterans Affairs (VA); or
- Canadian or other international payment rates.

[22] https://www.markcubancostplusdrugcompany.com/
[23] https://civicascript.com/

There are impediments to implementing these current proposals which automatically adopt the VA or international prices to a large list or group of high-spend drugs. One impediment may be Medicaid best price. If the automatically applied payment rate is lower than Medicaid best price, it could be that a state accidentally creates a new Medicaid best price. Existing federal law could then require the manufacturer to make that price available to all state Medicaid programs, which could create a legal challenge. Another impediment is that the state would be responsible for continuously tracking the changes in the non-US market prices so that purchases, payments, and reimbursements remain in compliance with state law. These ideas need more operational and legal analysis as well as consultation with the federal government before serious consideration.

Maximizing State Use of 340B Deeply Discounted Products

Some states have linked health services in prisons and jails to healthcare providers participating in the 340B drug discount program. Perhaps the most prevalent approach makes incarcerated people patients of 340B facilities. Generally, the arrangement accesses the services of government 340B entities including participating FQHCs and hospital clinics. Depending on the agreements, smaller 340B entities could benefit from more visit volume at potentially higher visit rates while 'sharing' the savings on 340B outpatient drugs for incarcerated patients.

However, there is growing scrutiny of the 340B program from state and federal policymakers, as well as litigation by stakeholders, and proposed federal legislation to change the program. State action to expand use of the program at this time could generate controversy and prove premature.

Limiting, licensing, or regulating pharmacy benefit managers

Vermont already has laws that pertain to PBMs, including licensure with the Department of Financial Regulation (DFR) and registering with the GMCB. Additionally, PBMs must provide a variety of data to the state agencies and meet several market conduct requirements.[24]

Vermont Act 127 of 2024 enhanced the state's purview over PBMs.[25] The Act establishes standards and criteria for licensure and regulation of PBMs, creates a PBM licensure requirement, and authorizes the Department of Financial Regulation to regulate PBMs. The act establishes the following:

- fee structure for PBM licensure application and renewal.
- requirement that PBMs and health insurers attribute all amounts paid by or on behalf of a patient for a prescription drug, including coupons and discounts, toward the patient's deductible and out-of-pocket limits (with the exception of third-party payments when there is a generic version of the drug and when there is no specific reason why the patient needs to use the brand-name version of the drug).
- ban on "spread pricing," the practice by which PBMs profit by charging more to an insurer or other payer for a prescription drug than the PBM reimbursed the pharmacy for dispensing the drug.
- ban on misleading or deceptive health insurance marketing and advertising among other practices.

[24] https://legislature.vermont.gov/assets/Legislative-Reports/DFR-Act-131-Report-on-PBMs.pdf
[25] https://legislature.vermont.gov/Documents/2024/Docs/ACTS/ACT127/ACT127%20As%20Enacted.pdf

- prohibition on regulating prescription drugs, pharmacies, or pharmacists in a manner that is more restrictive than, or inconsistent with, State or federal law or State Board of Pharmacy rules.
- ban on PBM and network pharmacies from unsolicited direct patient contact for the purpose of marketing the pharmacy's services, except under certain circumstances.
- requirement for patient consent to change a prescription (generic substitution excepted) or the patient's choice of pharmacy.

The conduct of PBMs has been a growing arera of interest across the U.S., particularly around issues of price transparency. We will continue to monitor states' policies as they develop.

GMCB's Existing Authority to Set Rates, Adopt Rules, and Establish Technical Advisory Groups

GMCB Existing Authority to Set Rates

Through 18 V.S.A. §9376(b)(1), the Vermont Legislature authorized the GMCB to set reasonable rates for health care professionals, health care provider bargaining groups, manufacturers of prescribed products, medical supply companies, and other companies providing health services or health supplies based on methodologies pursuant to 18 V.S.A. §9375, in order to have a consistent reimbursement amount accepted by these entities.

The Legislature specified that its intent was to:

- ensure that payments to health care professionals are consistent with efficiency, economy, and quality of care and will permit them to provide, on a solvent basis, effective and efficient health services that are in the public interest; and
- eliminate the shift of costs between payers to ensure that the amount paid to health care professionals is sufficient to enlist enough providers to ensure that health services are available to all Vermonters and are distributed equitably.

The Board has been directed to approve payment methodologies that encourage cost-containment; provision of high-quality, evidence-based health services in an integrated setting; patient self-management; access to primary care health services for underserved individuals, populations, and areas; and healthy lifestyles. Such methodologies shall be consistent with payment reform and with evidence-based practices and may include fee-for-service payments if the Board determines such payments to be appropriate. In establishing rates, the Board may consider legitimate differences in costs and the need for health care professionals in particular areas, particularly in underserved geographic or practice shortage areas.

State Rate Setting and Lingering Legal Concerns

As referenced above, the GMCB has authority under 18 V.S.A. §9376 to set reasonable rates for healthcare professionals, and for manufacturers of prescribed products. Under statute, the term "health care professional" means an individual, partnership, corporation, facility, or institution licensed or certified or otherwise authorized by Vermont law to provide professional health services.[26]. The term "manufacturers of prescribed products" means manufacturers of pharmaceuticals, biological products, or medical devices or any other person who is engaged in the production, preparation, propagation, compounding, processing, marketing, packaging, repacking, distributing, or labeling of prescribed products, but not a wholesale distributor of biological products, a retailer, or a pharmacist licensed under 26 V.S.A. chapter 36. [27]Setting rates is distinct from setting upper payment limits.

The Board would likely provoke a legal challenge if it attempted to set prices at which pharmaceutical manufacturers must sell their products. The concern is based on caselaw stemming from a legal challenge of 20 years ago, *Biotech Industry Organization vs. District of Columbia (*2007). The D.C. City Council had adopted legislation prohibiting any patented drug from being sold in the District for an

[26] 18 V.S.A. § 9373(6)
[27] 18 V.S.A. §§ 4373(11), 4631a(a)(9)

excessive price. The District law was found to violate the Constitution's Commerce Clause to the extent that it applied to transactions between parties there were not located within the District's borders. The law was also found to violate the Constitution's Supremacy Clause because it undermined the objective of federal patent laws by limiting the full exercise of the exclusionary power that derives from a patent.

GMCB Authority to Adopt Rules and Establish Technical Advisory Groups

GMCB already has the authority to adopt rules and establish technical advisory groups and has experience in performing both duties. This authority would also apply to any future statute that would give GMCB the responsibility to implement a program to regulate prescription drug costs in Vermont.

18 V.S.A. § 9380 gives GMCB the authority to adopt rules pursuant to 3 V.S.A. chapter 25 as needed to carry out the provisions of Title 18, Chapter 220, including 18 V.S.A. § 9375, which lists most of GMCB's duties. GMCB drafts and publishes rules in accordance with the Administrative Procedures Act (APA). As the process begins for each rule, we provide information regarding drafts, scheduled meetings, and the status of the rule when it enters the APA process. GMCB currently operates under numerous administrative rules that it has adopted since its inception.

18 V.S.A. § 9374(e)(2) also gives GMCB the authority to establish advisory groups as needed to carry out its duties. GMCB currently has two active advisory bodies: the General Advisory Committee and the Primary Care Advisory Group. GMCB also maintains a third committee, a Data Governance Council. In 2020, GMCB established a Prescription Drug Technical Advisory Group to examine potential state solutions to help curb the rising costs of prescription drugs. This technical advisory group phased out in 2022.[28]

[28] For more information, visit the GMCB website at https://gmcboard.vermont.gov/prescription-drug-technical-advisory-group

Relevant Vermont Activities and Statutes

Vermont has pursued an array of initiatives and regulatory activities to promote pharmaceutical affordability, accessibility, and market transparency, some of which resemble the nationwide reforms discussed in this report. Below is a summary – not an exhaustive list – of the state's activities to date, organized by statute. In the coming year, we will thoroughly evaluate Vermont's activities in consultation with other state agencies to understand their merits and limitations.

- **Title 8, Chapter 107: Health Insurance:** Per this chapter, major commercial health insurers disclose pharmaceutical spending data to the GMCB as part of their annual rate-reviewal process.[29] In addition, the chapter mandates that commercial health insurers abide by explicit protections for consumers and pharmacies: requiring that they cover certain drugs, cap out-of-pocket expenses for insulin, reimburse pharmacies at comparable rates regardless of their affiliation to the health insurer, and more.

- **Title 18, Chapter 77: Pharmacy Benefit Managers (PBMs)**: Recent laws empower the Department of Financial Regulation to license PBMs and regulate their market behaviors, including by forbidding PBMs from engaging in spread pricing, prohibiting PBMs from shielding data from commercial health insurers, mandating that PBMs abide by explicit protections for consumers and pharmacies, and more. This chapter consists of statutes implemented as a result of Act 127 (2024);[30] as a result, the Department of Financial Regulation has not yet begun regulation of PBMs in full force.

- **Title 18, Chapter 91: Prescription Drug Cost Containment:**
    - **Subchapter 1: Generic Drugs:** This subchapter empowers pharmacists to substitute generic drugs or interchangeable biological products for cheaper alternatives to promote consumer savings. As of 2022, eighteen other U.S. states had similar laws to encourage generic substitution at the pharmacy. They seem to have produced modest cost savings.[31]
    - **Subchapter 2: Evidence-Based Education Program:** Per this chapter, the Agency of Human Services operates a program that educates prescribers on cost-effective prescription practices.
    - **Subchapter 3: Information Requirements:** Since 2018, this subchapter has directed two government offices to publish reports on the Vermont pharmaceutical market. It directs the GMCB to publish an annual report on the effect of pharmaceutical spending on commercial insurance premiums,[32] and it directs the Attorney General's Office to publish an annual report on major prescription drug price increases.[33] It mandates that insurers, manufacturers, and the Department of Vermont Health Access disclose spending and market data to inform these reports. This subchapter also includes several miscellaneous statutes that mandate manufacturers disclose gifts to healthcare providers as well as prohibit manufacturers from engaging in improper types of market behavior.

[29] https://gmcboard.vermont.gov/rate-review
[30] https://legislature.vermont.gov/Documents/2024/Docs/ACTS/ACT127/ACT127%20As%20Enacted.pdf
[31] https://www.valueinhealthjournal.com/article/S1098-3015(22)00154-1/fulltext#fig3
[32] https://gmcboard.vermont.gov/publications/legislative-reports/Act165
[33] https://ago.vermont.gov/attorney-generals-office-divisions-and-unit/consumer-protection/health-and-product-safety/prescription-drug-cost-transparency-manufacturer-and-health-insurer-annual-reporting

- **Subchapter 4: Wholesale Prescription Drug Importation Program:** This subchapter directs AHS to design and implement a wholesale prescription drug importation program for select prescription drugs from Canada for sale within Vermont.

- **Subchapter 5: Unused Drug Repository Program:** Per this chapter, the Agency of Human Services has the authority to contract with a third-party entity to collect and distribute unused drugs within Vermont. The agency was granted this authority and the necessary funding over one year ago through Act 61 (2023).[34]

- **Title 33, Chapter 19: Medical Assistance:** This chapter directs the Department of Vermont Health Access to manage and oversee pharmaceutical spending for Medicaid and other state health benefit plans: to maintain a rigorous 'best practices and cost control program', to negotiate rebates and discounts on behalf of state plans, and to abide by certain consumer protections when offering state plans.

  The latter part of the chapter directs the State to operate two programs in particular: the VPharm program, which provides discounts on pharmaceutical products for Medicare Part D enrollees below a certain income threshold, as well as the Healthy Vermonters program, which provides discounts on pharmaceutical products to individuals below a certain income threshold and who otherwise lack coverage.

[34] https://legislature.vermont.gov/Documents/2024/Docs/ACTS/ACT061/ACT061%20As%20Enacted.pdf

Analysis

This initial report highlights the various approaches that states have taken to address prescription drug affordability and options available to Vermont. In the next phase of the project, we will narrow down potential options to those that seem feasible and appropriate for Vermont based on what we have learned to date and anything new that we might discover as we prepare our final report to the legislature.

Once we identify the most feasible options, we will analyze the potential cost savings and impact on access of each option, as well as costs of implementation and other potential challenges. We expect that this effort will likely require one or more analytic approaches, with the specific analyses contingent on the specific option or policy under review.

The type of analyses that will be conducted could include:

- Impact on prescription drug spend for
    - state agencies
    - consumers
    - health insurers/payers
    - direct purchasers
- Costs/Administrative burden of implementation on
    - providers
    - suppliers
    - public and private health insurers/payers
    - state agencies
- Impact on Vermonters' access to prescription drugs
- Potential legal issues/legal challenges
- Potential logistical impacts

Summary

In the past months we have learned a great deal about prescription drug pricing and regulatory and cost-containment practices across the United States and at the federal level. In the next phase of our work, we will continue to deepen our understanding of options with a focus on what may best serve Vermonters. In our final report in January 2026, we expect to issue recommendations that build upon Vermont's current infrastructure, including within the GMCB, the Department of Financial Regulation, the Department of Vermont Health Access, the Agency of Human Services, and the Office of the Vermont Attorney General.

The next phase of our work will benefit from input from the Vermont State Legislature about concepts that are not included but should be, ideas that legislators think might be most promising, and conversely, ideas that the legislature believes would not be appropriate for Vermont.