VERMONT

DEPARTMENT OF FINANCIAL REGULATION

Act No. 131 (2022) Report: Pharmacy Benefit Management

January 15, 2023

Submitted by
Kevin Gaffney, Commissioner of Financial Regulation

Executive Summary

Section 5 of Act 131 of 2022, An act relating to pharmacy benefit management, directed the Commissioner of the Department of Financial Regulation (DFR), in consultation with interested stakeholders, to study certain issues related to pharmacy benefit managers (PBMs), which act as an intermediary between health plans and pharmacies, and to deliver a report with findings and recommendations to the House Committee on Health Care and the Senate Committees on Health and Welfare and on Finance on or before January 15, 2023.

In preparing this report, DFR conducted extensive research and engaged with stakeholders in the insurance, pharmacy, and pharmacy benefit management industries, as well as regulators in other states and consultants. Stakeholders and regulators that we spoke with included representatives of: Vermont Retail Drug Association, Freedom Pharmacy, CVS Health, Navitus Health Solutions, LLC, Office of the Health Care Advocate, Office of the Attorney General, Office of Professional Regulation, MVP Health Care, Blue Cross Blue Shield of Vermont, New Mexico Office of the Superintendent of Insurance, Delaware Department of Insurance, and the Virginia Bureau of Insurance.

As explained in the report, Vermont already has laws that pertain to PBMs, including that they register with DFR and with the Green Mountain Care Board, and several market conduct-related requirements. However, PBMs continue to be a growing area of interest, especially around transparency, and evaluating impacts on prescription drug costs.

For those that want to take action in this space, this report outlines considerations and ways for increased oversight of PBMs in Vermont, and to improve transparency. Requiring that PBMs obtain a license from DFR and requiring that PBMs be subject to the same trade practices requirements, examination, and enforcement provisions that apply to health insurers, would help fill regulatory gaps and provide greater consumer protection.

Legislative Charge and Recommendations

Section 5 of Act 131 of 2022, *an act relating to pharmacy benefit management*, directs the Commissioner of the Department of Financial Regulation (DFR or the Department), in consultation with interested stakeholders, to consider the following issues related to pharmacy benefit management:

1. Should pharmacy benefit managers be required to be licensed to operate in Vermont?
2. Should pharmacy benefit managers be prohibited from conducting or participating in spread pricing?
3. What are the cost impacts of pharmacy benefit manager licensure and related regulatory measures in other states that have enacted such legislation?
4. In collaboration with the Board of Pharmacy, are any amendments to the Board's rules needed to reflect necessary distinctions or appropriate limitations on pharmacist scope of practice?
5. Should there be a minimum dispensing fee that pharmacy benefit managers and health insurers must pay to pharmacies for dispensing prescription drugs?
6. How should a pharmacy be reimbursed for a claim if a pharmacy benefit manager denies a pharmacy's appeal in whole or in part? Should the pharmacy be allowed to submit a claim to the health insurer for the balance between the pharmacy benefit manager's reimbursement and the pharmacy's reasonable acquisition cost plus a dispensing fee?
7. Is there a problem in Vermont of pharmacies soliciting health insurance plan beneficiaries directly to market the pharmacy's services? If so, how best to address the problem?
8. Are there other concerning issues relating to pharmacy benefit management and its effects on Vermonters, on pharmacies and pharmacists, and on health insurance in Vermont?

In accordance with the Legislature's directive in Act 131, Commissioner Gaffney hereby submits to the House Committee on Health Care and the Senate Committees on Health and Welfare and on Finance the following report of the Department's findings and recommendations related to the issues described above.

Based on our findings, detailed below, the Department recommends requiring Pharmacy Benefit Managers (PBMs) to receive a license from the Commissioner to operate in Vermont,

consistent with the forthcoming National Association of Insurance Commissioners (NAIC) model to establish a licensing or registration process for PBMs.

While the Department will not be requesting a bill to do the following, the Legislature could consider the below policy options to address issues identified in the report:

1. Prohibiting third parties, such as PBMs, from altering prescription drug orders or the pharmacy chosen by the patient without the patient's consent.
2. Applying the advertising standards applicable to health insurers in 8 V.S.A. § 4084 prohibiting "solicitation which is materially misleading or deceptive" to PBMs.
3. Requiring the Department to approve all solicitations sent by PBMs to patients.
4. Expanding required disclosures to health plans entering into spread pricing arrangements to include aggregate revenue derived from spread pricing by drug class at least biannually and, at the request of the Commissioner or the health plan client, the spread on specific prescription drugs. Either the aggregate spread or the disaggregated spread on specific drugs would be protected from public disclosure if such information satisfies the requirements of 1 V.S.A. § 317.
5. Entitling pharmacies to reimbursement at their acquisition cost if the PBM does not provide a reasonable maximum allowable cost (MAC) appeal process.
6. Tying the existing spread pricing disclosure in 18 V.S.A. § 9472(d) with new reporting about aggregate rebates and amounts received from fully-insured health plan clients to support a new requirement imposing a minimum loss ratio of 85% on PBMs.

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1. Introduction.

a. Research and Stakeholder Outreach.

In preparing this report and making recommendations, the Department conducted extensive research. Links to all sources are included in footnotes. The Department also engaged with stakeholders in the insurance, pharmacy, and pharmacy benefit management industries, as well as regulators in other states, including:

- Jeff Hochberg, President, Vermont Retail Drug Association
- Corey Duteau, Owner, Pharmacy Manager, Freedom Pharmacy
- Steven Larabee, Lead Director, State Government Affairs (MA, RI, VT), CVS Health
- Robyn S. Crosson, Vice President – Government Relations, Navitus Health Solutions, LLC
- Charles Becker, Staff Attorney, Vermont Legal Aid, Office of the Health Care Advocate
- Jill Abrams, Assistant Attorney General, Vermont Office of the Attorney General
- S. Lauren Hibbert, Director, Office of Professional Regulation
- Jordan Estey, Senior Director, Government Affairs, MVP Health Care
- Sara Teachout, Government Relations, Blue Cross Blue Shield of Vermont
- Paige Duhamel, Healthcare Policy Manager, New Mexico Office of the Superintendent of Insurance
- Christina Haas, Senior Policy Advisor, Delaware Department of Insurance
- Stephen Hogge, Policy Advisor–Insurance, Virginia Bureau of Insurance

The Department also worked with Risk and Regulatory Consulting (RRC) to prepare an informational request to pharmacy benefit managers (PBMs) which disclosed retaining money on claims charged to the health insurer for prescriptions filled during the preceding calendar year in excess of the amount the PBM reimbursed pharmacies under 18 V.S.A. § 9472(d). Although the specific information obtained from each PBM is confidential under 8 V.S.A. §§ 22, 23, 3573, & 3574 the Department references the aggregated data in Section 4.b of the report.

The Department extends its sincere thanks to Pai Liu, Eryn Campbell, and Kelly D. Edmiston from the National Association of Insurance Commissioners' (NAIC) Center for Insurance Policy and Research (CIPR) for their invaluable advice and research assistance.

b. Pharmacy Benefit Managers and Their Role in the Prescription Drug Supply Chain.

Prescription drugs represent a significantly expensive and exceptionally complicated sector of the American health care system. A 2021 RAND Corporation report commissioned by the federal Department of Health and Human Services (HHS) estimated that annual spending on prescription drugs ranged between $450 and $477 billion in 2018.[1] According to a 2021 analysis performed by the Green Mountain Care Board, prescription drug costs account for approximately 11.2% of commercial health insurance premiums in Vermont in 2020.[2] The increase in prescription drug prices is one of the largest drivers of rising health care costs in the United States: prescription medication prices have increased 35% since 2014 and 1.8% since the start of the COVID-19 pandemic.[3] At the same time, the supply chain for both brand-name and generic[4] prescription drugs dispensed and sold to patients is complex and the pricing practices of many of the entities involved in the drug supply chain are opaque, both to regulators and to other stakeholders in the supply chain.

While the focus of this report is on Pharmacy Benefit Managers (PBMs), it is important to understand the role of each of the different entities involved in the prescription drug supply chain. In general, there are six key parties who play a part in taking a prescription drug from the manufacturer to the patient:[5]

- **Pharmaceutical Manufacturers** are the entities with federal Food and Drug Administration approval to sell a prescription drug. In their most basic form, manufacturers purchase the ingredients and materials necessary to manufacture the drug, formulate the ingredients into a finished drug product at a specific dosage, and finally package and label the finished drug product for distribution themselves. Manufacturers may outsource one or all these activities to third parties. Crucially,

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[1] Andrew W. Mulcahy and Vishnupriya Kareddy, RAND Corporation, Research Report, Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships, 1 (2021), *available at* https://aspe.hhs.gov/sites/default/files/documents/0a464f25f0f2e987170f0a1d7ec21448/RRA328-1-Rxsupplychain.pdf

[2] Green Mountain Care Board, Impact of Prescription Drug Costs on Health Insurance Premiums, 2 (June 11, 2021), *available at* https://gmcboard.vermont.gov/sites/gmcb/files/documents/Act193_2021Report_PostedJune2021.pdf.

[3] *See* Tori Marsh, *Prices for Prescription Drugs Rise Faster than Prices for Any Other Medical Good or Service*, GoodRx Health (Sept. 17, 2020), *available at* https://www.goodrx.com/healthcare-access/drug-cost-and-savings/prescription-drugs-rise-faster-than-medical-goods-or-services.

[4] Generic Drugs are defined under Vermont law as "a drug listed by generic name and considered to be chemically and therapeutically equivalent to a drug listed by brand name[.]" 18 V.S.A. § 4601(3).

[5] *See* Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships, *supra* note 1 at 5-20.

manufacturers set the list price, or *wholesale acquisition cost* (WAC), for their prescription drugs. The WAC represents the price paid by distributors and wholesalers exclusive of any price concessions or rebates.

- **Wholesalers** perform the task of moving prescription drugs from the point of manufacture to the point of dispensing. Wholesalers typically retain enough inventory from manufacturers to manage any variations in supply and demand, and ship products directly to the pharmacies they serve, rather than to separate distribution centers. Some prescription drugs, such as biologics[6], may be distributed directly from the manufacturer to the point of dispensing. Wholesalers typically sell prescription drugs to pharmacies at or below their own WAC, making the bulk of their revenue from manufacturer price concessions, stocking fees, sale of business intelligence data such as analyses of prescription drug spending in a given market, and sale of logistics services to their pharmacy customers.
- **Pharmacies** dispense prescription drugs to patients. To obtain prescription drugs, pharmacies contract with wholesalers either directly, as in the case of large chain pharmacies, or through third-party buying groups known as Pharmacy Services Administrative Organizations (PSAOs) for smaller independent pharmacies. The contracts control prices, payment terms, logistics, and financial incentives for meeting certain distribution thresholds. Pharmacies have some discretion in setting retail prices (also known as the "cash price") for patients without insurance. However, the amount that a pharmacy is reimbursed for dispensing prescription drugs to insured patients is entirely determined by the pharmacy's contract with pharmacy benefit managers. As described below in Section 7, smaller pharmacies have little choice but to accept the reimbursement rates set by pharmacy benefit managers.
- **Pharmacy Benefit Managers**: (PBMs)[7] act as an intermediary between health plans and pharmacies, and perform a variety of functions in the prescription drug supply chain.

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[6] Biologic products are defined under Vermont law as "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition in human beings." 18 V.S.A. § 4601(a).

[7] Pharmacy Benefit Management is defined under Vermont law as:

> an arrangement for the procurement of prescription drugs at negotiated dispensing rates, the administration or management of prescription drug benefits provided by a health insurance plan for the benefit of beneficiaries, or any of the following services provided with regard to the administration of pharmacy benefits: (A) mail service pharmacy; (B)

They negotiate price concessions (rebates) from a drug's list price (WAC) with manufacturers. Some of these price concessions may be passed along to the health insurance plan or other third-party payer, although a portion may be retained by the PBM as revenue. PBMs create and manage formularies, which are lists of pharmaceutical drugs covered by health insurance plans. Formularies are divided into pricing tiers, each with a separate level of patient cost sharing to differentiate between preferred and non-preferred products.[8] PBMs also process pharmacy claims on behalf of health insurance plans, performing essentially the same function for pharmacy claims that the plans do for medical claims.[9] PBMs are generally compensated for their services in one of two ways: spread pricing or administrative fees.[10] Under spread pricing (which will be discussed later), PBMs charge a health plan more for prescription drugs than they reimburse the pharmacy for dispensing those same drugs, retaining the difference. Under a pass-through arrangement, a health plan or other third-party payer will pay a PBM for a prescription drug at the same amount the PBM has agreed to pay a pharmacy for the drug when the pharmacy dispenses it to a patient, in addition to an administrative fee to reimburse the PBM for its services. Savings, such as rebates negotiated by the PBM with the manufacturer, are thus passed through fully to the dispensing pharmacy. Even under a spread pricing arrangement, PBMs also charge health care plans an administrative fee for other services such as creating the plan's formulary, access to the PBM's pharmacy network (which is subject to adequacy

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> claims processing, retail network management, and payment of claims to pharmacies for prescription drugs dispensed to beneficiaries; (C) clinical formulary development and management services; (D) rebate contracting and administration; (E) certain patient compliance, therapeutic intervention, and generic substitution programs; and (F) disease management programs.

8 V.S.A. § 4089j(a)(2).

[8] For example, a brand name drug may be placed in a less favorable tier, and have a higher level of cost sharing, than its generic equivalent. *See Health Affairs*, Health Policy Brief: Formularies, 2 (Sep. 14, 2017), *available at* https://www.healthaffairs.org/do/10.1377/hpb20171409.000177/full/hpb_2017_09_14_formularies.pdf.

[9] One such function is utilization review, which PBMs argue allows them to control costs by steering patients to clinically equivalent, but less expensive drugs. Researchers at the USC Schaeffer Center for Health Policy & Economics contend that this poses a conflict of interest for PBMs since PBMs charge the client health plans a fee for performing prior authorization (PA) services "while at the same time choosing how many and which drugs on their formulary require PA." Geoffrey Joyce, Darius Lakdawalla, *et al.*, USC Schaeffer Center for Health Policy and Economics, letter to Lina Khan, Chair, U.S. Federal Trade Commission, 10 (May 25, 2022), *available at* https://healthpolicy.usc.edu/wp-content/uploads/2022/06/Van-Nuys-et-al.-Public-Comments-to-FTC-on-PBMs.pdf.

[10] As further explained in Section 9.b *infra*, PBMs also make money from direct and indirect renumeration (DIR) fees.

requirements imposed by state and federal regulators), and for processing drug claims. Most PBMs operate their own mail order and specialty pharmacies, which patients are required or incentivized to use.[11]

- **Payers:** include health insurers, employers, governments, and other entities that pay for the health care of their subscribers or beneficiaries. In the context of prescription drugs, the most important role payers have is to design their pharmacy benefit, usually in consultation with their PBM, including setting co-payments, out-of-pocket maximums, utilization management strategies, pharmacy networks, unit or quantity limits, and formularies. Payers negotiate reimbursement to PBMs for prescription drugs dispensed to their subscribers or beneficiaries, and depending on the specific contractual arrangement, the PBM may pass along some, all, or none of the rebates it negotiated with the drug manufacturers to the payer.
- **Patients/Prescribers:** Prescription drugs are dispensed to patients and are prescribed by their health care provider. When receiving drugs at a pharmacy, the patient pays the co-payment determined by their health plan, or the cash price determined by the pharmacy if the patient does not have any form of insurance coverage. Providers are not required to consider cost of or coverage for prescription drugs they order for patients as a factor in their treatment decisions.

c. Market Consolidation.

The PBM market, like other sectors within the health care industry, is heavily consolidated, both horizontally and vertically.[12]

Horizontal consolidation refers to mergers and acquisitions of direct competitors within the same level of a supply chain. An example of this would be a PBM purchasing another PBM, as Express Scripts did in 1998 when it purchased ValueRx, making it the biggest PBM in the country at the time.[13] Horizontal consolidation allows the combined businesses to produce greater revenue through improved economies of scale and greater market share, but it also

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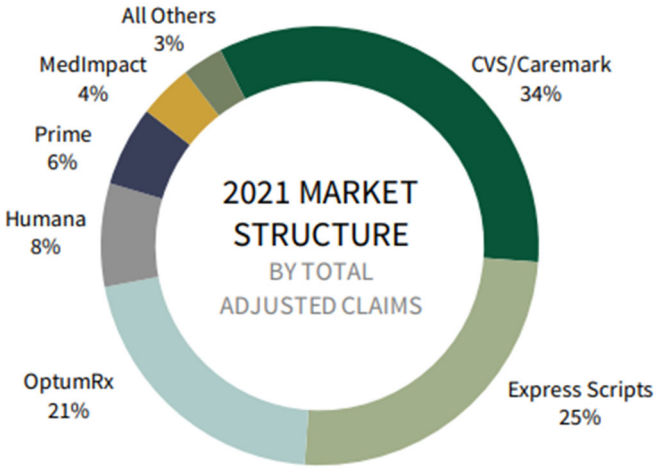
[11] As discussed further in Section 2.a, however, Vermont has a "mail-order parity" statute under which health insurers and PBMs must allow retail pharmacists to fill prescriptions for all prescription drugs "in the same manner and at the same level of reimbursement as they are filled by any other pharmacist or pharmacy, including a mail-order pharmacy or a pharmacy benefit manager affiliate, with respect to the quantity of drugs or days' supply of drugs dispensed under each prescription." 8 V.S.A. § 4089j(b).
[12] José R. Guardado, American Medical Association, Policy Research Perspectives, Competition in Commercial PBM Markets and Vertical Integration of Health Insurers with PBMs, 9-10 (2022), *available at* https://www.ama-assn.org/system/files/prp-pbm-shares-hhi.pdf.
[13] Calmetta Y. Coleman, *Express Scripts Agrees to Buy Columbia/HCA's ValueRx Unit*, Wall Street J. (Feb. 22, 1998), *available at* https://www.wsj.com/articles/SB887985464376608500.

reduces competition in the market. For health care payers and patients, "[T]here is no evidence to say that horizontal integration of health care entities results in absolute price decreases or enhanced quality outcomes. Furthermore, horizontal integration of large organizations that result in the domination of market share or elimination of competition within an industry can be classified as a monopoly."[14] According to a 2022 report by the Health Insurance Resource Center (HIRC) three major players controlled 80% of the total market for PBM services, which includes Medicare (Part D) and Medicaid, in 2021, as shown below:[15]

Figure 1: National PBM Market Share by Total Adjusted Claims, 2021.



This pattern of horizontal integration continues at the state and local level, where the AMA's analysis found a high degree of market concentration for PBM services: More than three of four (about 78%) states and four of five (85%) of metropolitan areas had "highly concentrated" PBM markets,[16] under the Herfindahl-Hirschman Index ("HHI") used by the Federal Trade Commission (FTC) and Department of Justice (DOJ) to analyze market competitiveness.[17] In

[14] Jacqueline Hanna, *Vertical Integration in Heath Care: The Next Stairway to Heaven?*, Pharmacy Times (July 16, 2019), *available at* https://www.pharmacytimes.com/view/vertical-integration-in-health-care-the-next-stairway-to-heaven.

[15] Health Industries Research Center (HIRC), Pharmacy Benefit Managers: Market Landscape and Strategic Imperatives (2022), *available at* https://www.hirc.com/system/files/public/MM_PBM%20Landscape_2022.pdf.

[16] Guardado, Competition in Commercial PBM Markets, *supra* note 12, at 8.

[17] HHI is calculated by taking the squares of each individual firms' market share in a given market, approaching zero in a market with many fierce competitors and reaching a maximum of 10,000 points

2020, Express Scripts and CVS Caremark made up a combined 96% of the market for PBM services in Vermont, giving the state an HHI of 6181 for commercial claims adjudication and retail pharmacy services and 6310 for the commercial rebate negotiation services. Vermont is among the most highly concentrated markets in the country:[18]

Table 1, Concentration in State PBM Markets, as of January 1, 2020.

Top 5 States by HHI	Rebates	Retail Pharmacy	Claims
Michigan	7879	7705	7879
Alabama	7389	7389	7389
South Carolina	6948	6984	6948
Delaware	6384	6384	6384
Vermont	6310	6181	6181

As opposed to simply increasing market share, vertical consolidation, refers to "the integration of suppliers of different components of health care services, such as hospitals and physicians, as well as integration of health systems and health plans, which collectively supply different elements of the health care product to the ultimate consumer."[19] In the PBM market, vertical integration has taken the form of PBMs acquiring or being acquired by health insurers and pharmacy chains. As a result, the largest insurers in the country and even some of the smaller ones already have their own PBM or share the same owner as one.[20] The below chart from Drug Channels Institute provides an illustration of the major vertical business relationships among the largest companies in the U.S. healthcare system:[21]

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when a market is monopolized. HHIs between 1,500 and 2,500 points are considered "moderately concentrated," while an HHI of more than 2,500 points is highly concentrated. Typically, competition is believed to decline as market concentration increases. *See* U.S. Department of Justice & Federal Trade Commission, Horizonal Merger Guidelines, 19 (Aug. 19, 2010), *available at* https://www.ftc.gov/sites/default/files/attachments/merger-review/100819hmg.pdf.

[18] Guardado, Competition in Commercial PBM Markets, *supra* note 12, at 19-63.

[19] Erin C. Fuse Brown and Jaime S. King, *The Double-Edged Sword of Health Care Integration: Consolidation and Cost Control*, 92 Ind. L. J. 55, 62 (Winter 2016), *available at* https://www.repository.law.indiana.edu/ilj/vol92/iss1/2/.

[20] Guardado, Competition in Commercial PBM Markets, *supra* note 12, at 1.

[21] Adam J. Fein, Mapping the Vertical Integration of Insurers, PBMs, Specialty Pharmacies, and Providers, a 2022 Update, Drug Channels (Oct. 13, 2022), *available at* https://www.drugchannels.net/2022/10/mapping-vertical-integration-of.html.

Figure 2, Vertical Business Relationships Among Insurers, PBMs, Specialty Pharmacies and Providers, 2022.

Because the health care sector is particularly vulnerable to anticompetitive effects from vertical consolidation, with extremely high costs and regulatory barriers to entry, federal regulators have expressed concern that mergers between PBMs and health insurers or PBMs and pharmacies will harm competition or patients by substantially lessening competition in the sale of PBM services or raise the cost of PBM services to health insurers.[22] Federal regulators have also expressed concern about the business practices enabled by vertical integration. On June 7, 2022, the Federal Trade Commission announced that it was launching an inquiry into the business practices of the six largest PBMs in the U.S., investigating: 1) fees and clawbacks charged to unaffiliated pharmacies; 2) steering patients to PBM owned or affiliated pharmacies; 3) auditing practices; 4) pharmacy reimbursement; 5) prior authorizations and other administrative restrictions; 6) specialty drug policies; and 7) the impact of rebates on formulary design.[23]

The market for specialty drugs represents one of the most striking examples of the potential harms of vertical consolidation between PBMs and pharmacies. Specialty drugs are used to treat complex, chronic conditions, and sometimes require special handling and administration, or

[22] *See* U.S. Department of Justice, Statement of the Department of Justice Antitrust Division on the Closing of Its Investigation of the Cigna–Express Scripts Merger (Sep. 17, 2018), *available at* https://www.justice.gov/atr/closing-statement.

[23] Federal Trade Commission, Press Release, FTC Launches Inquiry Into Prescription Drug Middlemen Industry (June 7, 2022), *available at* https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry.

oversight from a health care provider monitoring for side effects and ensuring that the treatment is effective. Most often, however, the term "specialty drug" is used to refer to high-cost medication.[24] Growth in spending for specialty drugs has far outpaced spending for non-specialty generic and brand drugs, with specialty spend growing at 11.5%, while non-specialty growth has remained relatively flat.[25] Since most "specialty" pharmacies are owned and operated by PBMs, wholesalers, providers, or integrated delivery networks,[26] PBMs often steer high-cost specialty claims to their own pharmacies by creating plan designs that require patients to fill specialty scripts at their own pharmacies or providing a discount for doing so.[27] These plan designs effectively prevent patients from getting all but the cheapest prescription drugs dispensed at the pharmacy of their choice and make it extremely difficult for non-affiliated pharmacies to compete.[28]

2. Whether Pharmacy Benefit Managers Should be Required to be Licensed to Operate in Vermont.

a. Current Law.

Under current law, PBMs are required to register with the Department on a form and in a manner to be prescribed by the Department by rule.[29] The Department has authority to adopt rules requiring PBMs operating in Vermont to notify health insurers that they offer contracts with full pass through of negotiated prices, rebates, and other financial benefits.[30] The Department also has authority to adopt rules allowing health insurers to conduct "complete and independent" audits of PBMs to verify any pricing arrangements or PBM activities required

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[24] *See* Patrick P. Gleason, *et al.*, *Health Plan Utilization and Costs of Specialty Drugs Within 4 Chronic Conditions*, J. of Managed Care Pharmacy, 1 (Sep. 2013) ("Although the definition of "specialty" will vary among health plans and PBMs, typically it is associated with a dollar amount"), *available at* https://www.jmcp.org/doi/10.18553/jmcp.2013.19.7.542.

[25] Loren Bonner, *The integrated pharmacy model: Specialty pharmacy's way forward?*, 25 Pharmacy Today 28, 29 (Nov. 1, 2019), *available at* https://www.pharmacytoday.org/article/S1042-0991(19)31227-7/fulltext.

[26] Elizabeth Seeley and Surya Singh, The Commonwealth Fund, Competition, Consolidation, and Evolution in the Pharmacy Market (Aug. 12, 2021), *available at* https://www.commonwealthfund.org/publications/issue-briefs/2021/aug/competition-consolidation-evolution-pharmacy-market.

[27] *See* Katie Thomas, *Specialty Pharmacies Say Benefit Managers Are Squeezing Them Out*, N.Y. Times (Jan. 9, 2017), *available at* https://www.nytimes.com/2017/01/09/business/specialty-pharmacies-say-benefit-managers-are-squeezing-them-out.html.

[28] This process is known as "market foreclosure." Brown and King, *The Double-Edged Sword of Health Care Integration, supra* note 19 at 69.

[29] 18 V.S.A. § 9421(a).

[30] 18 V.S.A. § 9421(b).

by the insurer's contract with the PBM.[31] The Department has additional authority to bill back any expenses associated with the statutory registration or disclosure requirements to PBMs in proportion to each PBMs' Vermont covered lives, with the exception of PBMs under contract with the Department of Vermont Health Access.[32] Because PBMs are already required to register with the Green Mountain Care Board (GMCB) for the purposes of submitting claims to Vermont's all-payer claims database,[33] the Department has not exercised its authority to adopt rules related to registration and disclosure. In 2022, there are 33 entities operating as PBMs registered to submit claims data according to GMCB data.[34]

PBMs are also subject to several market conduct requirements for their business practices regarding health insurers and pharmacies.[35] With respect to health insurers, PBMs are required to discharge their contractual duties with "reasonable care and diligence" and disclose the following to their health insurer clients: 1) financial and utilization information relating to the provision of benefits to beneficiaries; 2) potential conflicts of interest; 3) benefits directly or indirectly accruing to the PBM as the result of dispensing a substitute prescription drug for a prescribed drug to a beneficiary; 4) benefits from volume sales of any particular drug or classes or brands of drugs; and 5) rebates or other financial arrangements the PBM negotiated with drug manufacturers.[36] Additionally, PBMs are required to report to their health insurer clients, the Department, and GMCB, the aggregate amount the PBM retained on all claims charged to health insurers in excess of the amount the PBM reimbursed pharmacies in the preceding

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[31] 18 V.S.A. § 9421(c).
[32] 18 V.S.A. § 9421(d).
[33] 18 V.S.A. § 9410(j)(1)(B).
[34] Green Mountain Care Board, 2022 VHCURES Registration Report (Apr. 2022), *available at* https://gmcboard.vermont.gov/document/2022-vhcures-registration-report.
[35] *See* 18 V.S.A. Ch. 221, Subch. 9.
[36] 18 V.S.A. § 9472(b), (c). Financial information that must be disclosed to health insurers includes: "all financial and utilization information requested by a health insurer relating to the provision of benefits to beneficiaries through that health insurer's health plan and all financial and utilization information relating to services to that health insurer." 18 V.S.A. § 9472(c)(1); Rebating information that must be disclosed includes:

> all financial terms and arrangements for remuneration of any kind that apply between the pharmacy benefit manager and any prescription drug manufacturer that relate to benefits provided to beneficiaries under or services to the health insurer's health plan, including formulary management and drug-switch programs, educational support, claims processing, and pharmacy network fees charged from retail pharmacies and data sales fees.

18 V.S.A. § 9472(c)(5).

calendar year.[37] For calendar year 2021, nine PBMs submitted disclosure forms to the Green Mountain Care Board.[38]

With respect to pharmacies, PBMs are required to reimburse, deny, or contest pharmacy claims within fourteen days of receipt.[39] In addition, PBMs must allow retail pharmacies to fill prescriptions "in the same manner and at the same level of reimbursement" as mail order pharmacies.[40] PBMs are also prohibited from: 1) imposing higher co-payments for drugs than are applicable to the type of drug purchased under the patient's health plan; 2) imposing co-payments higher than the maximum allowable cost (MAC) [41] for a drug; 3) requiring pharmacies to pass through co-payments to the pharmacy benefit manager or other payer; 4) penalizing pharmacies for informing patients about their cost-sharing for a prescription drug; and 5) penalizing pharmacies for disclosing the cash price for a prescription drug or selling a lower cost drug to the patient, if one is available.[42] If a PBM establishes a MAC to determine reimbursement to pharmacies, the PBM is required to make the source of the MAC readily available to pharmacies, update it at least once per week, and ensure that drugs subject to MAC pricing are widely available for purchase by national or regional wholesalers.[43] Finally, PBMs are prohibited from: 1) requiring prescription drug claims to include modifiers to indicate that the drug is being purchased under the federal 340B program unless the claim is for payment by Medicaid; and 2) restricting access to a pharmacy network or adjusting reimbursement rates for pharmacies based on the pharmacy's participation in a 340B contract pharmacy arrangement.[44]

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[37] 18 V.S.A. § 9472(d).
[38] As explained at *infra* note 80, statutory spread pricing disclosures are not disclosed to the public.
[39] 18 V.S.A. § 9473(a).
[40] 8 V.S.A. § 4089j(b).
[41] Under Vermont law, maximum allowable cost (MAC) is "the per unit drug product reimbursement amount, excluding dispensing fees, for a group of equivalent multisource generic prescription drugs." 18 V.S.A. § 9471(6).
[42] 18 V.S.A. § 9473(b).
[43] 18 V.S.A. § 9473(c).
[44] 18 V.S.A. § 9473(c). Under the federal 340B program, "covered entities" such as hospitals can contract with an unlimited number of outside pharmacies to dispense drugs at substantially discounted rates. *See* Department of Financial Regulation, Act No. 74 (2021) Report: National Activity Affecting Participation in the 340B Drug Pricing Program, 6 (Jan. 15, 2022), *available at* https://dfr.vermont.gov/sites/finreg/files/doc_library/dfr-legislative-report-act74-340b-program.pdf.

Act 131 of 2022, whose operative provisions came into effect January 1, 2023, strengthens many of Vermont's existing market conduct statutes related to PBMs:

- Imposing a fiduciary duty on PBMs towards their health insurer clients to "be fair and truthful toward the health insurer, to act in the health insurer's best interests, and to perform its duties with care, skill, prudence, and diligence."[45]
- Prohibiting PBM contracts from giving the PBM sole discretion to change the formulary tier of a prescription drug or to remove a prescription drug from its formulary more than twice per year.[46]
- Limiting how much a patient pays for a covered prescription drug to the lesser of their plan's cost-sharing, the MAC for the drug, or the cash price, requiring any amount paid to apply to the patient's deductible.[47]
- Requiring PBMs to pass on any payments or benefits received based on volume of sales of a prescription drug to their health insurer clients.[48]
- Giving pharmacies additional rights during an audit conducted by a PBM.[49]
- Prohibiting "gag clauses," in which pharmacists may be contractually penalized for informing patients about "the nature of treatment, risks, or alternatives to treatment[,]" therapeutic alternatives, the process the PBM uses to authorize health care services, or the cost for pharmacist services for a prescription drug.[50]
- Barring contractual provisions that purport to penalize pharmacists for disclosing information about a PBM to the Department, law enforcement, or other state or federal officials.[51]
- Giving pharmacies additional rights when appealing the maximum allowable cost (MAC) price set by PBMs, who will be required to provide the reason an appeal was denied and identify a Vermont-licensed wholesaler where the prescription drug at issue can be purchased at or below the set MAC price.[52]

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[45] Act 131 of 2022, Sec.2, to be codified at 18 V.S.A. § 9472(a).
[46] *Id*, to be codified at 18 V.S.A. § 9472(e).
[47] *Id*, to be codified at 18 V.S.A. § 9472(f).
[48] *Id*, to be codified at 18 V.S.A. § 9472(c)(4).
[49] *Id.*, Sec. 3, to be codified at 18 V.S.A. § 3802.
[50] *Id.*, Sec. 2, to be codified at 18 V.S.A. § 9473(b).
[51] *Id*, to be codified at 18 V.S.A. § 9473(e).
[52] *Id*, to be codified at 18 V.S.A. § 9473(f)(4).

- Prohibiting PBMs from reimbursing pharmacies at a lower rate for drugs purchased through the 340B program or assessing any fees, charge-backs, or other monetary adjustments on the basis that a pharmacy participates in the 340B program, or from discriminating against 340B covered entities, such as hospitals, in a way that interferes with a patient's choice to receive drugs from the covered entity.[53]
- Extending mail-order parity to specialty pharmacy.[54]
- Prohibiting PBMs from implementing restrictive networks in their plan designs and requiring PBMs to reimburse outside pharmacies at least as much as pharmacies affiliated with the PBM are reimbursed for providing the same pharmacist services.[55]
- Barring PBMs from requiring "whitebagging" or "brownbagging" of prescription drugs.[56]

b. Regulatory Requirements in Other Jurisdictions.

As of this writing, all but six states and the District of Columbia require PBMs to be licensed or registered in some form with a state regulator.[57] State regulatory requirements with respect to PBMs vary wildly, especially in the wake of the Supreme Court's decision in *Rutledge v. Pharmaceutical Care Management Association*, concluding that state laws regulating payments to pharmacies are not preempted by the Employee Retirement Income Security Act of 1974 (ERISA).[58] In Arkansas, a state that has taken one of the most aggressive approaches to

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[53] *Id*, to be codified at 18 V.S.A. § 9473(h).
[54] *Id.*, Sec. 4, to be codified at 8 V.S.A. § 4089j(a)(5). As noted above, the specialty designation for prescription drugs largely reflects that a drug is expensive. *See* Patrick P. Gleason, *et al.*, *Health Plan Utilization and Costs of Specialty Drugs*, *supra* note 24.
[55] Act 131 of 2022, Sec. 2, to be codified at 18 V.S.A. § 9473(i).
[56] *Id.*, Sec. 4, to be codified at 8 V.S.A. § 4089j(d)(3), (4). "Whitebagging" refers to the practice of a pharmacy dispensing patient-specific prescription drugs to a health care setting for administration. "Brownbagging" refers to the practice of a pharmacy dispensing prescription drugs to a patient for later administration in a health care setting. *See* Carmen A. Catizone, Natl. Assn. of Bds. of Pharmacy, White and Brown Bagging Emerging Practices, Emerging Regulation, 2 (Apr. 2018), *available at* https://nabp.pharmacy/wp-content/uploads/2018/04/White-Bagging-and-Brown-Bagging-Report-2018_Final-1.pdf.
[57] A compilation of all state registration and licensure laws specific to PBMs is appended to this report in Appendix A: State Laws Requiring Pharmacy Benefit Manager Licensure or Registration.
[58] *See Rutledge v. Pharm. Care Mgmt. Assoc.*, 141 S. Ct. 474, 480 (2020) ("ERISA does not pre-empt state rate regulations that merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage."). For more information regarding ERISA preemption, please refer to the Department's memorandum re: Progress of Rulemaking Required by Act 54 of 2019 (Feb. 15, 2020), *available at* https://legislature.vermont.gov/assets/Legislative-Reports/TPA-Legislative-Memorandum-signed.pdf.

regulating the PBM market, the state regulates cost disclosures/gag clauses; maximum allowable cost (MAC) lists; network adequacy; pharmacy auditing standards; pharmacy reimbursement; spread pricing; and utilization management.[59] In contrast, until 2022, Michigan had no specific requirements outside of requiring PBMs to obtain a license to operate as a third-party administrator.[60]

In New England, every state except Massachusetts requires PBMs to be licensed or registered.[61] In general, Vermont's regulatory approach is roughly on par with that of Maine.[62] Maine requires health insurers that contract with PBMs to ensure that the PBM acts as the insurer's agent and owes it a fiduciary duty.[63] It also prohibits insurers from entering into contracts that restrict pharmacies from offering patients prescription drugs at the cash price (if less than their cost-sharing) or disclosing information to state and federal authorities.[64] Like Vermont, Maine requires disclosure of MAC lists to pharmacies and establishes procedures for pharmacies to appeal the MAC for a given prescription drug.[65] The only provisions of Maine's PBM law that are not present in Vermont relate to "copay accumulators" in which PBMs and health insurers prevent patients from applying manufacturer coupons towards their deductibles. Maine requires insurers and PBMs apply manufacturer coupons to patient's deductibles for brand-name drugs without a generic equivalent.[66]

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[59] *See* Ark. Stat. Ann. §§ 17-92-507 (MAC Lists); 17-92-1201 (Pharmacy Auditing Standards); 23-92-505 (Network Adequacy, Reporting/Transparency, Spread Pricing); 23-92-507 (MAC Lists, pharmacy reimbursement).

[60] Mich. Comp. Laws. Ann. § 550.910. On February 23, 2022, Michigan Governor Gretchen Whitmer signed HB 4348, which requires PBMs operating in Michigan to become licensed and prohibits gag clauses and spread pricing. *See* Press Release, Gov. Whitmer Signs Bipartisan Bills to Lower Prescription Drug Costs for Michiganders (Feb. 23, 2022), *available at* https://www.michigan.gov/whitmer/news/press-releases/2022/02/23/gov--whitmer-signs-bipartisan-bills-to-lower-prescription-drug-costs-for-michiganders.

[61] *See* Conn. Gen. Stat. § 38a-479bbb; Me. Rev. Stat. Ann. tit. 24-A, § 4348; N.H. Rev. Stat. Ann. § 402-N:2; R.I. Gen. Laws § 27-20.7-12.

[62] The Department cross-referenced state PBM laws using the National Conference of State Legislatures (NCSL) online database at: https://www.ncsl.org/research/health/state-policy-options-and-pharmacy-benefit-managers.aspx#/.

[63] Me. Rev. Stat. Ann. tit. 24-A, § 4349(2).

[64] Me. Rev. Stat. Ann. tit. 24-A, § 4349(3).

[65] Me. Rev. Stat. Ann. tit. 24-A, § 4350.

[66] Me. Rev. Stat. Ann. tit. 24-A, § 4349(6); Vermont's approach to copay accumulators is discussed further in Section 9.a., *infra*.

3. The Cost Impacts of Pharmacy Benefit Manager Licensure and Related Regulatory Measures in Other States that have Enacted Such Legislation.

a. Governmental Costs.

If required to be licensed, PBMs would add a major new class of regulated entity to the Department's regulatory portfolio.

As of June 2022, the Department has a total of seven positions in its Company Licensing and Examination sections, four positions in Consumer Services, and five positions in Market Conduct. These personnel are responsible for the day-to-day work of regulating every line of insurance except Captives, and do not have the capacity to manage a new regulatory program — particularly one that raises novel and complex issues like pharmacy benefit management — without additional support.

To get a sense of the costs of adopting a comprehensive licensing and regulatory program for PBMs, the Department examined fiscal notes for legislation enacted in other states and had conversations with regulators in Delaware, New Mexico, and Virginia, which have all implemented similar programs. All three state regulators advised the Department that PBM regulation cannot achieve its intended policy goals without sufficient resources dedicated to the task. New Mexico, which has regulated PBMs since 2014, emphasized the need to have personnel specifically tasked with PBM regulatory issues. In Florida, which proposed giving its Office of Insurance Regulation (OIR) authority to conduct market conduct examinations of PBMs in 2021, OIR estimated that it would need to hire a pharmacist to provide oversight of PBM activities and respond to complaints at a cost of $125,000 to $200,000 annually.[67] In Nebraska, the Department of Insurance estimated that it would need four full-time equivalents to provide oversight, respond to complaints, and request corrective action from PBMs, including a market conduct examiner, consumer affairs investigator, financial analyst, and a staff attorney at a combined annual cost of $293,360 in FY 2022-2023 for salaries and benefits.[68] Although the Department does not anticipate the need to hire a pharmacist to provide oversight of PBMs, additional positions will be necessary to bring PBMs into compliance and effectively regulate the market.

As in other states, the Department would anticipate offsetting some portion of the cost of additional positions through licensure fees, billback for examinations, and penalties. Like state PBM laws themselves, the licensure or registration fees charged by each state vary considerably.

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[67] Florida Senate, Bill Analysis and Fiscal Impact Statement, SB 1476 (Feb. 15, 2022), *available at* https://www.flsenate.gov/Session/Bill/2022/1476/Analyses/2022s01476.aeg.PDF.
[68] Neb. Legislature, LB 375 Fiscal Note (Jan. 14, 2021), *available at* https://nebraskalegislature.gov/FloorDocs/107/PDF/FN/LB375_20210301-122456.pdf.

West Virginia requires an initial application licensure fee for PBMs of $5,000 for a two-year license with a $5,000 renewal fee that may be refunded if a renewal is not approved.[69] New York requires PBMs to pay an annual $4,000 registration fee.[70] New Mexico imposes a $1,000 fee for initial licensing, $500 for renewal, and $200 for required annual reports.[71] Wisconsin only imposes a fee of only $100 for initial licensure applications.[72] The Department would support an annual or biannual application fee that would be enough to largely offset the budgetary impact of additional personnel. Like insurance licensure requirements, an exception could be included for small PBMs to help prevent market departures and reduced competition resulting from disproportionate fee impact.[73]

b. Market Effects.

It is inherently difficult to measure intended and unintended consequences of licensure on a complex market that operates without the kind of state oversight that the insurance industry operates under. Studies examining the economic impact of PBM regulation tend to be funded by the PBM industry itself or pharmacists and reach opposing conclusions.[74] However, since most states, including Vermont, already require licensure or registration of PBMs in some form, the Department does not expect that licensure alone would disrupt Vermont's market for PBM services. Likewise, the Department does not believe that Vermont's current laws with respect to PBM services have the effect of increasing prescription drug prices or insurance premiums because those laws either work to increase transparency in the market or prohibit PBMs from effectively locking out independent retail pharmacies. Many of these laws, such as mail-order parity, have been in effect for years and have not been cited by health insurers as a factor in increasing prescription drug prices or insurance premiums.[75] Enacting laws prohibiting spread

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[69] W.Va. Ins. Bulletin 22-08, *available at* https://www.wvinsurance.gov/Portals/0/IB22-08_PAE_PBM_Licensing_Fees.pdf.
[70] N.Y. Ins. L. § 2903(a).
[71] Section 59A-61-1 et. seq. N.M.S.A.; N.M.A.C. § 13.10.30.
[72] Wis. Stat. § 632.865(3).
[73] Under Vermont's "de minimis" statute, 8 V.S.A. § 3368(a)(4)(B), insurers with fewer than twenty-five certificate holders in Vermont are not required to obtain a license from the Commissioner.
[74] *See generally,* Visante, Increased Costs Associated with Proposed State Legislation Impacting PBM Tools (Jan. 2019), *available at* https://www.pcmanet.org/wp-content/uploads/2019/01/Visante-Study-on-the-Increased-Costs-Associated-With-State-Legislation-Impacting-PBM-Tools-Jan-2019-FINAL.pdf; National Community Pharmacists Assoc., PBM Reform Has Not Raised Costs for Patients and Payers (Mar. 4, 2022), *available at* https://ncpa.org/newsroom/qam/2022/03/04/truth-about-meaningful-pbm-reform-it-does-not-raise-costs.
[75] All rate filings for fully-insured health plans going back to 2014 may be found online at https://ratereview.vermont.gov/.

pricing or requiring a minimum dispensing fee for pharmacists, however, will likely have a more direct market impact, as discussed further below.

4. Whether Pharmacy Benefit Managers Should be Prohibited from Conducting or Participating in Spread Pricing.

a. Definition of Spread Pricing.

PBMs engage in two different business practices that have been referred to by the term "spread pricing." The most widely accepted definition, and the one that will be discussed in this section, is encapsulated in a 2019 Centers for Medicare and Medicaid Services (CMS) press release:

"Spread pricing occurs when health plans contract with pharmacy benefit managers (PBMs) to manage their prescription drug benefits, and PBMs keep a portion of the amount paid to them by the health plans for prescription drugs instead of passing the full payments on to pharmacies. Thus, there is a spread between the amount that the health plan pays the PBM and the amount that the PBM reimburses the pharmacy for a beneficiary's prescription."[76]

Although the CMS press release pertains to spread pricing in Medicaid, similar definitions are also used in much of the literature that addresses spread pricing in the commercial health sector.[77] As will be explained in Subsection b, this kind of spread pricing is a profit source for PBMs when functioning as a middleman between health plans and pharmacies in the sale of generic drugs.[78]

The practice of rebating, discussed later in Section 9.d, can also generate revenue for PBMs. Rebates are price concessions on prescription drugs that manufacturers offer PBMs in return for the PBM's agreement to place the drug on a preferred tier in the PBM's formulary. When a PBM retains a portion of the manufacturer's rebate, rather than passing it along to the client health plan, this is also a kind of spread, although it differs from the more traditional spread pricing described above in that it represents a financial benefit arranged directly between a PBM and a drug manufacturer, rather than a reimbursement arrangement between a PBM and a pharmacy that involves the transmission of health plan payments.

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[76] Press Release, Centers for Medicare and Medicaid Services, CMS Issues New Guidance Addressing Spread Pricing in Medicaid (May 15, 2019), *available at* https://www.cms.gov/newsroom/press-releases/cms-issues-new-guidance-addressing-spread-pricing-medicaid-ensures-pharmacy-benefit-managers-are-not.

[77] *See* The Commonwealth Fund, Pharmacy Benefit Managers and Their Role in Drug Spending (Apr. 22, 2019), *available at* https://www.commonwealthfund.org/publications/explainer/2019/apr/pharmacy-benefit-managers-and-their-role-drug-spending.

[78] *See supra* note 4 for the definition of generic drugs.

b. Effects of Spread Pricing.

As noted above, spread pricing occurs when a PBM charges a health plan more for a prescription drug than it reimburses a pharmacy for the same drug and retains the difference. The opposite of spread pricing is pass-through pricing, where the price paid by the health plan to the PBM for a prescription drug is the same as the price paid by the PBM to a pharmacy that dispenses the drug, plus a fixed dispensing fee per script. In a pass-through model, the PBM makes the bulk of its revenue by charging the health plan an administrative fee for its services.[79]

In Vermont, of the thirty-three PBMs that have registered with the Green Mountain Care Board, four reported retaining a combined total of over ten million dollars on all claims charged to health insurer clients in excess of what pharmacies were reimbursed between July 2020 and July 2021.[80]

The PBM industry calls spread pricing "risk-mitigation pricing," and states that it offers health plans "cost predictability by giving them a price-certain for prescription drug benefit payments to pharmacies."[81] According to the PBM trade group Pharmaceutical Care Management Association (PCMA): "If what the pharmacy charges the PBM is more than the rate agreed between the plan sponsor and the PBM, the PBM takes a loss. If the pharmacy charges less, the PBM earns a margin."[82] However, it is hard to assess whether the costs outweigh the value of

[79] Navitus Health Solutions, for example, has a business model entirely predicated on pass-through pricing. It produced the linked guide to help potential clients understand the differences between spread pricing and pass-through pricing: https://www.navitus.com/getattachment/ae760712-6507-4414-a489-28fbcfd53c05/understanding-pass-through-vs-traditional-model.pdf.

[80] Disclosure reports under 18 V.S.A. § 9472(d) are not available to the public but are on file with the Department. In a 2018 report by the Vermont State Auditor, Express Scripts, Inc., the PBM for the Vermont State Employees Health Plan, reported retaining a spread, the exact amount of which was redacted, for claims dispensed at retail pharmacies and charged to the State. The State Auditor recommended that the State require its PBM to accept pass-through pricing in future PBM contracts. *See* Vermont State Auditor, Recommendations for Improving the Performance of the State of Vermont's Prescription Drug Benefit Program, 12 (May 10, 2018), *available at* https://auditor.vermont.gov/sites/auditor/files/documents/Improving%20Vermont%27s%20Prescription%20Drug%20Benefit%20Program%20Report%20-%2009-17-2018.pdf.

[81] *See* Pharmaceutical Care Management Association, Infographic, How Risk Mitigation (Spread) Pricing Helps Drive Lower Drug Costs (2020), *available at* https://www.ncsl.org/documents/health/PCMA%20Spread%20Pricing%20Infographic%2035782.pdf.

[82] *Id.*

predictability because states and others have little data on spread pricing arrangements due to a lack of transparency.[83]

To learn more about the role spread pricing in the market, the Department sent an informational request to PBMs that submitted a spread pricing disclosure to the Green Mountain Care Board (GMCB) under 18 V.S.A. § 9472(d) in consultation with Risk and Regulatory Consulting (RRC). The Department received responses from several PBMs. Although the individual responses are confidential under 8 V.S.A. §§ 22, 23, 3573, & 3574, in the aggregate, the responses indicated that spread pricing arrangements are either offered during negotiation for PBM services or explicitly requested by prospective health plan clients. In cases where prospective clients specifically request pass-through pricing arrangements when soliciting PBM services, spread pricing arrangements are not offered at all.

The responses also indicated that PBMs count revenues derived from spread pricing as income for financial reporting purposes. This practice essentially allows a PBM to build the cost of its' services into the amount it charges health plans for prescription drugs, with revenue from the spread going to profits, administrative expenses, and ancillary and "value-added" services such as medication adherence initiatives and formulary management.[84] The addition of the cost of spread pricing within the regulatory medical loss ratio (MLR)[85] reporting for Medicaid managed care programs led the Centers for Medicare and Medicaid Services (CMS) to issue guidance in 2019 clarifying that medical claims could only include "the amount that the [PBM] actually pays the medical provider or supplier for providing Medicaid covered services to enrollees."[86]

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[83] *See, e.g.*, Robert Langreth, David Ingold and Jackie Gu, *The Secret Drug Pricing System Middlemen Use to Rake in Millions*, Bloomberg (Sep. 11, 2018), *available at* https://www.bloomberg.com/graphics/2018-drug-spread-pricing. (noting that CVS Health sued the state of Ohio in 2018 to prevent the release of a report divulging how much spread it had received for managing most of the state's managed Medicaid program).

[84] Scott Fry, Tze Min Lim & Gregory Warren, *What is the Price Anyway*, The Actuary Magazine (May 2020) (noting that "Pass-through pricing encourages an emphasis on low administrative fees, even though administrative fees are likely to be higher in the pass-through model than in the spread model. To stay competitive, PBMs might have incentive to cut back on ancillary services to the detriment of patients' long-term health and cost."), *available at* https://www.theactuarymagazine.org/what-is-the-price-anyway/.

[85] Medical Loss Ratio (MLR) represents the ratio of premium that goes to claims versus administrative expenses. Health plans are generally required to a maintain a high MLR. For example, under the Affordable Care Act, health insurers must spend at least 85% of premium on claims. 45 C.F.R. § 158.210

[86] Centers for Medicare and Medicaid Services, CMCS Informational Bulletin, Medical Loss Ratio (MLR) Requirements Related to Third-Party Vendors, 3 (May 15, 2019), *available at* https://www.medicaid.gov/federal-policy-guidance/downloads/cib051519.pdf.

According to the responding PBMs, health plans value spread pricing arrangements because they provide the lowest net cost, provide cost certainty, or shift pricing risk to the PBM. This sentiment is shared by health plans contacted by the Department, who reported that having cost stability in the form of long-term price guarantees for prescription drugs conveys benefits, such as allowing plan actuaries to price the plan's pharmacy benefit more accurately and insulating members from long-term pricing variability.

While it may be the case that spread pricing offers cost stability to health plans by passing the risk of rising drug prices to PBMs, the opacity of the pricing system makes this claim difficult to verify, even for sophisticated health economists and researchers.[87] The opacity of spread pricing extends to the stakeholders inside the pharmaceutical supply chain, "because neither the health plan nor the pharmacy knows what the other side was paid or charged,"[88] making it very difficult for health plans to accurately assess whether they are benefiting from spread pricing arrangements.[89] Not knowing the spread realized by the PBM or the amount paid by the health plan to the PBM for a specific drug also undermines pharmacies' ability to engage in informed contract negotiations with the PBM about prescription drug reimbursement, to the extent that reimbursement is negotiable.[90]

Several studies reviewed by the Department about use of spread pricing in managed Medicaid programs have raised questions about who benefits from spread pricing arrangements:[91]

- An analysis by the Ohio State Auditor of 2017-2018 data reported that the average spread retained by PBMs administering the state's managed Medicaid programs was

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[87] *See* Letter to Federal Trade Commission Chair Lina Khan, *supra* note 9 at 11 (noting that "[a]n overarching issue confounding all outside research seeking to understand the economics of PBM commercial practices is the lack of information about true transaction prices.").

[88] Erin Trish, Karen Van Nuys, & Robert Popovian, USC Schaeffer Center for Health Policy and Economics, U.S. Consumers Overpay for Generic Drugs, 6 (May 2022), *available at* https://healthpolicy.usc.edu/wp-content/uploads/2022/05/2022.05_US-Consumers-Overpay-for-Generic-Drugs.pdf.

[89] One health plan the Department consulted with reported that it nearly continuously performed benchmark analyses and audits on the spread pricing arrangement with its PBM to ensure that the prescription drug prices it paid were competitive to what other health plans were paying.

[90] As noted at *infra* note 153, PBM contracts with retail pharmacies are typically "adhesion" contracts, offered on a take-it-or-leave it basis with no meaningful opportunity for negotiation.

[91] The effect of spread pricing in some managed Medicaid programs is a reasonable proxy for its likely effect in commercial health plans because managed Medicaid programs are typically run by insurers and use PBMs to manage their pharmaceutical health benefits. *See* Massachusetts Health Policy Commission, HPC Datapoints, Cracking Open the Black Box of Pharmacy Benefit Managers: PBM Pricing for Generic Drugs in Massachusetts Medicaid Programs and the Commercial Market, 2 (June 5, 2019), *available at* https://www.mass.gov/doc/datapoints-issue-12-printable-version/download.

$5.71 per prescription, or 8.8% of the total amount paid by the plans on pharmaceutical benefits, totaling $224.8 million during the one-year period from April 1, 2017, through March 31, 2018.[92] According to the auditor's analysis, the state of Ohio could have obtained PBM services for an administrative fee of $0.95 to $1.90 per prescription under a pass-through pricing model.[93]

- In Indiana, Bloomberg determined that the average spread retained by the PBMs administering the state's managed Medicaid programs was over $13 per prescription in 2017.[94]
- In Kentucky, a report produced by the Kentucky Cabinet for Health and Family Services found that four insurers participating in that state's managed Medicaid program paid $957.7 million in 2018 to the PBMs administering their pharmaceutical benefit. Of that amount, the PBMs kept 13 percent, or approximately $123.5 million, through spread pricing. The size of the spread rose by more than a third from 2017 to 2018.[95]
- The Massachusetts Health Policy Commission (HPC), an independent state agency charged with monitoring health care spending growth in the Commonwealth, found that managed Medicaid organizations (MCOs) and commercial payers were overpaying PBMs for 95% of the generic drugs looked at by the HPC.[96] The HPC's analysis compared the prices paid for each drug by MCOs and commercial payers to the pharmacy acquisition costs contained in the National Average Drug Acquisition Cost (NADAC) survey published monthly by the Centers for Medicare and Medicaid Services (CMS).[97] In the commercial market, the price health plans paid for generic Gleevec, which is used in the treatment of leukemia, was an average of $1,811 more per prescription than the pharmacy acquisition cost.[98] For Suboxone, a prescription treatment for opioid use disorder, PBMs increased the price MCOs paid by 13% during the same two-year period that Suboxone acquisition costs fell by 60%.[99]

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[92] Ohio Auditor of State, Report, Ohio's Medicaid Managed Care Pharmacy Services, 4 (Aug. 16, 2018), *available at* https://ohioauditor.gov/auditsearch/Reports/2018/Medicaid_Pharmacy_Services_2018_Franklin.pdf.
[93] *Id.*
[94] *The Secret Drug Pricing System Middlemen Use to Rake in Millions*, *supra* note 83 at 2.
[95] Kentucky Cabinet for Health and Family Service, Office of Health Data Analytics, Medicaid Pharmacy Pricing: Opening the Black Box, 5 (Feb. 19, 2019), *available at* https://www.chfs.ky.gov/agencies/ohda/Documents1/CHFSMedicaidPharmacyPricing.pdf.
[96] Cracking Open the Black Box of Pharmacy Benefit Managers, *supra* note 91 at 3.
[97] *Id.*, at 5.
[98] *Id.*
[99] *Id.*, at 4.

These examples suggest that the terms of spread pricing arrangements can be highly favorable to PBMs, resulting in additional hidden costs to patients and pharmacies. For patients, higher prescription drug costs paid by health plans result in increased insurance premiums.[100] And, for pharmacies, spread pricing arrangements incentivize PBMs to set the lowest possible reimbursement rates for pharmacies in pursuit of a greater spread, which often results in pharmacies being reimbursed less than their acquisition costs, as further explained in Section 7 of this report.

c. Actions in Other Jurisdictions.

The Department is aware of at least four states – Delaware, Michigan, Oklahoma, and Virginia[101] – that categorically prohibit spread pricing by PBMs serving fully-insured commercial health plans as of this writing. However, regulators in Delaware and Virginia contacted by the Department were unable to provide data on the impact of prohibiting spread pricing on prescription drug prices or health insurance premiums. Regulators in one state shared that the prohibition legislation was primarily lobbied for by the pharmacy industry.[102]

Other states, such as Louisiana, prohibit PBMs and health plans from entering into spread pricing arrangements unless the health plan agrees in writing to the use of the practice and is provided with periodic reporting of the aggregate spread retained by the PBM.[103]

In the Medicaid context, as of July 1, 2019, eleven states prohibited spread pricing in their managed Medicaid programs, with four others set to prohibit spread pricing in Medicaid MCO contracts by 2020.[104] A preliminary report from the Ohio Department of Medicaid found that prohibiting spread pricing in its managed Medicaid program modestly increased reimbursement to pharmacists.[105] Additionally, a 2020 report by the Congressional Budget Office (CBO) on proposed federal legislation prohibiting spread pricing in all state Medicaid programs estimated that banning the practice would produce federal savings of $929 million

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[100] U.S. Consumers Overpay for Generic Drugs, *supra* note 88 at 6.
[101] 18 Del. C. § 3372A(1); Michigan's prohibition is contained in Mich. Act 11, Section 17(6) (effective January 1, 2024); 36 Okla. Stat. § 6962; Va. Code Ann. § 38.2-3467(A)(D).
[102] Telephone conference with Christina Haas, Senior Policy Analyst, Delaware Department of Insurance, Oct. 21, 2022; Telephone conference with Stephen Hogge, Virginia Bureau of Insurance, October 28, 2022.
[103] *See* La. Rev. Stat. § 22:1867.
[104] Center on Budget and Policy Priorities, Options to Reduce State Medicaid Costs: Prescription Drugs (Oct. 14, 2020), *available at* https://www.cbpp.org/sites/default/files/atoms/files/10-14-20health.pdf.
[105] Ohio Department of Medicaid, Executive Summary Assessing the Impact of Pass-Through Pricing, 3 (Sep. 2019), *available at* https://medicaid.ohio.gov/wps/wcm/connect/gov/2ef5a8b4-0f15-4ef4-8883-11fd6238e101/ODM-HDS-Summary.pdf?MOD=AJPERES&CONVERT_TO=url&CACHEID=ROOTWORKSPACE.Z18_K9I401S01H7F40QBNJU3SO1F56-2ef5a8b4-0f15-4ef4-8883-11fd6238e101-nAkMJJ4.

over 10 years.[106] However, according to a Kaiser Family Foundation (KFF) overview of proposals to cut Medicaid drug spending, this figure represents a less than a 1% drop in federal Medicaid prescription drug spending.[107] Citing the Ohio and Massachusetts audits of MCO spread pricing discussed in the previous section, as well as a similar Michigan analysis which concluded that the state's Medicaid program had been overcharged $64 million as a result of spread pricing, KFF suggested the possibility "that CBO's estimates [of the savings that would be realized by prohibiting spread pricing] assumes state activity to curb spread pricing has already addressed some of these costs."[108] The KFF report concluded that "[s]tate actions that focus on increasing transparency around PBM pricing could enable more precise estimates of federal savings."[109]

d. Analysis of Potential Regulatory Solutions.

i. Prohibiting Spread Pricing.

One of the major problems confronting economic researchers, and any regulator seeking to make informed recommendations about spread pricing, is the opacity that prevents other stakeholders in the supply chain from having full information regarding PBM financing arrangements and revenues. Because of this opacity, prohibiting spread pricing could well increase costs in other parts of the pharmacy supply chain. For example, PBMs could "increase fees charged to . . . pharmacies, alter drug formularies to promote more profitable medications, or keep larger portions of the rebates they negotiate with drug companies."[110] Prohibiting spread pricing could have other unintended consequences as well, as noted in a Milliman white paper:

> Eliminating spreads and rebate margins in some cases can lead a PBM to cut back on its value-added services (in order to keep explicit fees lower and more competitive), to the long-term detriment of a health plan and its members. To maintain its services (and relatively thin profit margins) a PBM has to get its

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[106] Congressional Budget Office, Fiscal Note, Prescription Drug Pricing Reduction Act of 2019 (Mar. 13, 2020), *available at* https://www.cbo.gov/system/files/2020-03/PDPRA-SFC.pdf.

[107] Rachel Garfield, Rachel Dolan, & Elizabeth Williams, Kaiser Family Foundation, Costs and Savings under Federal Policy Approaches to Address Medicaid Prescription Drug Spending, 7 (June 21, 2021), *available at* https://www.kff.org/medicaid/issue-brief/costs-and-savings-under-federal-policy-approaches-to-address-medicaid-prescription-drug-spending/.

[108] *Id.* at 7.

[109] *Id.* at 8.

[110] Catherine Candisky and Marty Schladen, *State Warned Against Pharmacy Middlemen's Whack-a-Mole*, Columbus Dispatch (Sep. 26, 2018), *available at* https://www.the-daily-record.com/story/news/state/2018/09/16/state-warned-against-pharmacy-middlemen/10292630007/.

revenue from somewhere – and that means increased fees if fees are the only source of income (as under a pass-through arrangement).[111]

Prohibiting spread pricing would also prevent health plans from getting long-term price guarantees on prescription drugs—a key reason cited health plans for entering into these arrangements.

On the other hand, there is substantial evidence from state managed Medicaid programs that the financial rewards of spread pricing accrue primarily to PBMs and are not passed along to stakeholders on lower rungs of the prescription drug supply chain.[112] To ensure that their prescription drug prices remain competitive over time, health plans must perform near constant due diligence on their spread pricing arrangements.[113] While large and sophisticated health plans and self-insured employers have this capacity, smaller ones do not. Therefore, spread pricing arrangements should be predicated on giving regulators, health plans, and pharmacies full and ongoing transparency as to the costs and benefits of the arrangement.

ii. Increasing Transparency.

Since health care is a public good in Vermont,[114] the Department believes the public interest demands robust financial transparency in the health care delivery system, including the prescription supply chain. At the federal level, the Pharmacy Benefit Manager Transparency Act (S. 4293) (hereafter Cantwell-Grassley), introduced in 2022 by Senators Maria Cantwell and Charles Grassley, offers a unique approach to spread pricing.[115] Cantwell-Grassley would ban spread pricing by PBMs, unless a PBM passes all rebates and other price concessions received from manufacturers along to its client health plans and discloses all prescription drug cost, price

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[111] Thomas D. Snook and Troy M. Filipek, Milliman White Paper, Pharmacy Benefit Management: Pros and cons of various approaches, 2 (May 2011), *available at* https://www.milliman.com/-/media/milliman/importedfiles/uploadedfiles/insight/research/health-rr/pharmacybenefitmanagementprospdf.ashx.

[112] Letter to Federal Trade Commission Chair Lina Khan, *supra* note 9 at 1 ("Research on economic rents earned by different sectors of the distribution system indicates PBMs are earning excess profits."); *see also supra* notes 92-99.

[113] *See supra* note 89.

[114] *See* 18 V.S.A. § 9401(a). It is the policy of the State of Vermont that "health care is a public good for all Vermonters and to ensure that all residents have access to quality health services at costs that are affordable."

[115] Pharmacy Benefit Manager Transparency Act, S. 4293, 117th Cong. (2022), *available at* https://www.congress.gov/bill/117th-congress/senate-bill/4293/text.

and reimbursement information to both health plans and pharmacies.[116] The bill, which was forwarded to the full Senate on June 22, 2022 by a 19-9 bipartisan vote of the Senate Commerce Committee, would also require PBMs to report annually to the Federal Trade Commission the aggregate difference between the amount the PBM was paid by each client health plan for prescription drugs and the amount that the PBM reimbursed each pharmacy on behalf of the health plan.[117] By requiring PBMs that want to continue to engage in spread pricing to disclose the amount of the spread to both health plans and pharmacies, Cantwell-Grassley attempts to level the playing field across the prescription drug supply chain and provide stakeholders with the information they need to make their own informed contract decisions, thus increasing competition.

Other options to increase transparency in the market include the following:

- Maine requires reporting from state-licensed prescription drug wholesalers, which allows "analysis of pharmaceutical pricing from manufacturer to pharmacy counter and beyond."[118]
- California mandates public reporting of wholesale acquisition costs (WAC), including drug prices at launch and five-year schedules of price increases—creating one of the only publicly available sources of prescription drug pricing data in the country.[119]
- Oregon requires manufacturers and other entities, like wholesalers, that set the wholesale acquisition cost (WAC) of prescription drugs sold in the state to report annual price increases over 10% or $10,000 for brand name drugs and over 25% or $300 more for

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[116] As noted above in *supra* note 90, there is no analogous duty on the part of PBMs to disclose to pharmacies the cost that PBMs charge health insurers for specific drugs. This lack of bilateral transparency, which puts pharmacies at a competitive disadvantage, is rectified by the provisions in Cantwell-Grassley.

[117] Although 18 V.S.A. § 9472(d) requires PBMs to disclose annually to the client health insurer, the Green Mountain Care Board and DFR the aggregate amount of the spread for each insurer, it does not require the PBM to disclose the number of prescriptions on which the spread is based or the aggregate spread by drug class, i.e., generics, brand names and specialty drugs. The former figure would be helpful in comparing the spread in Vermont to the spread in larger states like Ohio or Massachusetts and the latter figure would help regulators identify drug classes where spread pricing resulted in especially high markups.

[118] Me. Rev. Stat. Ann. tit. 22, § 8703, *et seq.*; Maine Health Data Organization, Prescription Drug Transparency Report, 3 (Feb. 9, 2021), *available at* https://mhdo.maine.gov/_pdf/MHDO%20Rx%20Transparency%20Report%20210209%20FINAL.pdf.

[119] Cal. Code Regs. tit. 22, § 96060, *et seq.*; The California Department of Health Care Access and Information (HCAI) makes the WAC data available on its' website at: https://data.chhs.ca.gov/dataset/prescription-drug-wholesale-acquisition-cost-wac-increases.

generic drugs.[120] The Oregon Department of Financial Regulation is then required to hold an annual public hearing on prescription drug prices and submit an annual report containing the data collected and recommending legislative changes to ameliorate the effect of prescription drug price increases.[121]

Vermont could also expand its existing prescription drug transparency laws, specifically, 18 V.S.A. § 4635(b)(1), which requires the Green Mountain Care Board (GMCB) to identify annually up to 15 prescription drugs "on which the State spends significant health care dollars" and for which the WAC has increased substantially during the preceding twelve months. If PBMs were required to similarly disclose the 15 prescription drugs on which it made the most spread, such disclosure would help determine what impacts PBMs that engage in spread pricing in Vermont may have on prescription drug costs.

5. Whether any Amendments to the Board of Pharmacy's Rules are Needed to Reflect Necessary Distinctions or Appropriate Limitations on Pharmacist Scope of Practice.

On October 5, 2022, Department of Financial Regulation staff met with the Office of Professional Regulation (OPR) and Board of Pharmacy (Board). OPR and the Board advised that because state and federal law set clear standards for pharmacies dispensing prescription drugs[122] and specialty pharmacy represents a pricing distinction more than a pharmacological distinction,[123] there is no need to implement heightened credentialing or licensing for specialty pharmacies. Additionally, OPR advised that out of the 50 state Boards of Pharmacy, only four states required a specialty license. For these reasons, OPR reiterated its earlier recommendation, appended to this report as Appendix B, which the Department herein adopts, against limiting a pharmacist's scope of practice, defining specialty pharmacy, or otherwise requiring non-governmental specialty pharmacy accreditations as a matter of law.

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[120] Or. Bulletin No. DFR 2020-12 (Apr. 22, 2020), *available at* https://dfr.oregon.gov/laws-rules/Documents/Bulletins/bulletin2020-12.pdf.
[121] O.R.S. § 646A.689(13).
[122] The Office of Professional Regulation maintains a comprehensive list of pharmacy statutes, rules, and resources at: https://sos.vermont.gov/pharmacy/statutes-rules-resources/.
[123] Patrick P. Gleason, et al., *Health Plan Utilization and Costs of Specialty Drugs*, *supra* note 24.

6. Whether There Should be a Minimum Dispensing Fee that Pharmacy Benefit Managers and Health Insurers Must Pay to Pharmacies and Pharmacists for Dispensing Prescription Drugs.

In general, there are two components to pharmacy reimbursement for prescription drug claims: dispensing fees and ingredient costs.[124] Dispensing fees represent compensation for providing prescription drugs to the patient, overhead (e.g., payroll and facility fees), and patient counseling.[125] In New Hampshire and Vermont, a 2020 study prepared for national pharmacy associations found that the overall cost of dispensing was $13.08 per script across all payers in 2019.[126] Ingredient costs represent compensation for the prescription drug itself, and are typically paid based on a maximum allowable cost (MAC) set by the PBM for generic drugs, as discussed further in Section 7 below, or a percentage of average wholesale price (AWP) for brand drugs.[127] While the ingredient costs a pharmacy receives can vary considerably depending on the prescription drug being dispensed, dispensing fees are generally fixed.[128]

To get a sense of how the ingredient costs and dispensing fees relate to each other, it is instructive to briefly examine how state Medicaid programs reimburse pharmacies. In 2016, the federal government adopted rules requiring ingredient costs paid by state Medicaid programs to be based on actual acquisition cost (AAC).[129] Because AAC generally represents the lowest

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[124] Pharmacies also receive a vaccine administration fee for vaccine administration.

[125] See Allison Garret and Robert Garis, Leveling the Playing Field in the Pharmaceutical Benefit Manager *Industry*, 42 Val. U. L. Rev. 33, 40 (Fall 2007), *available at* https://scholar.valpo.edu/cgi/viewcontent.cgi?article=1131&context=vulr.

[126] ABT Associates, Cost of Dispensing Study, 18 (Jan. 2020), *available at* https://www.nacds.org/pdfs/pharmacy/2020/NACDS-NASP-NCPA-COD-Report-01-31-2020-Final.pdf.

[127] Garret, Leveling the Playing Field in the Pharmaceutical Benefit Manager Industry, *supra* note 125 at 40. This amount is typically close to wholesale acquisition cost (WAC).

[128] *Id.*

[129] 42 C.F.R. § 447.518(a)(2); In Vermont, the AAC is the lesser of:

- National Drug Average Acquisition Cost (NADAC) + Professional Dispensing Fee
- Wholesale Acquisition Cost (WAC) + 0% + Professional Dispensing Fee
- State Maximum Allowable Cost (SMAC) + Professional Dispensing Fee
- Federal Upper Limit (FUL) + Professional Dispensing Fee
- Average Wholesale Price - 19% + Professional Dispensing Fee
- Submitted Ingredient Cost + Professional Dispensing Fee
- Pharmacist's Usual and Customary (U&C) charge
- Gross Amount Due (GAD)

Department of Vermont Health Access, Pharmacy Benefit Management (PBM) Program Pharmacy Provider Manual, 10 (May 25, 2021), *available at* https://dvha.vermont.gov/sites/dvha/files/documents/providers/Forms/Pharmacy%20Provider%20Manual.pdf.

permissible pricing benchmark for ingredients,[130] most states increased dispensing fees under the AAC-based payment methodology to comply with federal minimum payment requirements under 42 C.F.R. § 447.518(d).[131] To determine an appropriate dispensing fee in Vermont, the Department of Vermont Health Access (DVHA) commissioned a study in 2017 which found that across all pharmacies under contract with Vermont Medicaid, the weighted cost of dispensing prescription drugs to Medicaid beneficiaries was $11.30 per prescription, inclusive of specialty drugs.[132] Based in part on the results of this study, DVHA set a dispensing fee for all retail pharmacies of $11.13 for generic and brand drugs and $17.03 for specialty drugs.[133] Across the country, most states set a single dispensing fee for all pharmacies, while a minority of states tier dispensing fees based on criteria such as prescription volume.[134]

Outside of Medicaid, at least one state, West Virginia, requires PBMs to reimburse pharmacies at least the NADAC for a prescription drug, plus a dispensing fee of $10.49 – equivalent to its Medicaid program.[135] If the NADAC is not available for a given prescription drug, West Virginia requires PBMs to reimburse pharmacies at least the wholesale acquisition cost (WAC) of the drug plus a dispensing fee of $10.49.[136] Finally, West Virginia, like Vermont, prohibits PBMs from reimbursing pharmacies less than it would reimburse a pharmacy it owns or is affiliated with for the same services.[137]

West Virginia's approach, however, represents a major departure from how pharmacies are typically reimbursed in the commercial market, in which pharmacies generate the bulk of their revenue through the ingredient cost.[138] Indeed, a 2020 study conducted by 3Axis Advisors

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[130] The Centers for Medicare and Medicaid Services (CMS) makes prescription drug reimbursement information for all state Medicaid programs available online at: https://www.medicaId.gov/medicaid/prescription-drugs/state-prescription-drug-resources/medicaid-covered-outpatient-prescription-drug-reimbursement-information-state/index.html.

[131] Kaiser Family Foundation, Issue Brief, Pricing and Payment for Medicaid Prescription Drugs, 4-5 (Jan. 2020), *available at* https://files.kff.org/attachment/Issue-Brief-Pricing-and-Payment-for-Medicaid-Prescription-Drugs.

[132] Department of Vermont Health Access, Survey of the Average Cost of Dispensing a Medicaid Prescription in the State of Vermont, 5 (Feb. 8, 2017), *available at* https://dvha.vermont.gov/sites/dvha/files/documents/providers/Pharmacy/4vt-2017-average-cost-of-dispensing-report.pdf.

[133] Pharmacy Benefit Management (PBM) Program Pharmacy Provider Manual, *supra* note 129 at 10.

[134] *See supra* note 130.

[135] W. Va. Code § 33-51-9(f).

[136] *Id.*

[137] W. Va. Code § 33-51-9(g).

[138] 3Axis Advisors, Responsiveness of Maximum Allowable Costs to Generic Drug Inflation, 6 (Apr. 3, 2020), *available at* https://www.3axisadvisors.com/projects/2020/4/14/responsiveness-of-maximum-allowable-cost-mac-prices-to-generic-drug-inflation.

found that the average dispensing fee for generic drugs nationwide was just $0.70 per script—representing a fraction of operating expenses for pharmacies.[139] Although Vermont has several protections in place to ensure that pharmacies can challenge inadequate reimbursement for ingredients, as described further in Section 7 of this report, because ingredient costs vary significantly, pharmacies cannot rely on them to make up for low dispensing fees.[140]

For these reasons, setting minimum dispensing fees in the commercial market represents a policy decision that balances the likelihood of increased prescription drug costs against the societal benefit of supporting the continued existence of small, independent pharmacies, especially in rural areas. A study conducted by the Pharmaceutical Care Management Association (PCMA), a PBM trade group, estimates that mandating a Medicaid-like dispensing fee of $10.50 per prescription would increase drug spending across the country by over $16 billion in the first year alone.[141] Although the Department has been unable to find research addressing the PCMA's projections, the study's methodology is simple; it subtracts the estimated current $2.00 commercial prescription fee from a hypothetical $10.50 dispensing fee and multiplies the result by the number of prescriptions filled countrywide in 2019, the most recent year for which such data is available.[142] Using the study's methodology, imposing a $10.50 dispensing fee in Vermont's commercial market would increase annual prescription drug spending by more than $25.6 million, assuming that ingredient costs are unchanged.[143]

As to pharmacies, multiple credible sources indicate that competition from large chain pharmacies has whittled away at the number of independent pharmacies countrywide. According to a report by the University of Iowa's Rural Policy Research Institute "[f]rom 2003 to 2018, 1,231 of the nation's 7,624 independent rural pharmacies closed . . . leaving 630 communities with no independent or chain retail drugstore."[144] Part of the advantage enjoyed

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[139] *Id.*

[140] Responsiveness of Maximum Allowable Costs to Generic Drug Inflation, *supra* note 138 at 6.

[141] Pharmaceutical Care Management Association, Mandating Pharmacy Reimbursement Will Increase Prescription Drug Spending (2020), *available at* https://www.pcmanet.org/wp-content/uploads/2022/02/DispensingFee-infographic.pdf.

[142] *Id.*; *see also*, Kaiser Family Foundation, State Health Facts, Number of Retail Prescription Drugs Filled at Pharmacies by Payer (2019), *available at* https://www.kff.org/health-costs/state-indicator/total-retail-rx-drugs/.

[143] $8.50 x 3,021.358=$25,681,543. Without additional regulation of ingredient costs, PBMs could potentially offset higher dispensing fees at independent pharmacies by reducing ingredient costs or excluding them from preferred networks.

[144] Al Cross, *Independent Pharmacies are Closing, Leaving Many in 'Drugstore Deserts,'* Kentucky Health News (Nov. 15, 2021), *available at* https://ci.uky.edu/kentuckyhealthnews/2021/11/15/independent-

by large retail pharmacies stems from their high volume of prescription drug sales, resulting in greater economies of scale. Another advantage is that chain stores like CVS and Walgreens sell large amounts of non-pharmaceutical merchandise on which the profit margins can be "15% higher than the margins on prescription sales."[145] The revenue generated from these sources helps offset what one study calls "the miniscule dispensing fees" in the commercial market.[146]

To the extent that the Legislature would be inclined to set a minimum dispensing fee as a means of bolstering independent and community pharmacies, the Department would make the following suggestions:

- Tiering the dispensing fee based on prescription volume or percentage of gross revenue derived from prescription drugs to ensure that independent and community pharmacies see more of the benefit from a minimum dispensing fee; and
- Setting a minimum ingredient cost in addition to a minimum dispensing fee.

7. How a Pharmacy Should be Reimbursed for a Claim If a Pharmacy Benefit Manager Denies a Pharmacy's Appeal in Whole or in Part.

As briefly discussed in Section 2 of this report, a PBM may set a maximum allowable cost (MAC) list or lists for prescription drugs subject to the requirements of 18 V.S.A. § 9473. The MAC list establishes the most the PBM will reimburse a pharmacy for a group of equivalent generic drugs.[147] Because the list prices that pharmacies set for generic drugs tend to be significantly higher than their acquisition cost because of pricing volatility caused by ingredient shortages, supply disruptions, and manufacturer consolidation,[148] PBMs overwhelmingly use MAC pricing as the basis of pharmacy reimbursement to avoid overpayment for generic drugs.

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pharmacies-are-closing-leaving-many-in-drugstore-deserts-2020-ky-law-insulates-them-from-predatory-competition/; Fred Thys, *Vermont's Independent Pharmacies are Disappearing*, VTDigger (Mar. 24, 2022), *available at* https://vtdigger.org/2022/03/24/vermonts-independent-pharmacies-are-disappearing-a-bill-aimed-at-saving-them-just-passed-the-house/; Markian Hawryluk, *How Rural Communities are Losing Their Pharmacies*, Kaiser Health News (Nov. 15, 2021) ("[a]n analysis by GoodRx, an online drug comparison tool, found that 12% of Americans have to drive more than 15 minutes to reach the closest pharmacy or don't have enough pharmacies to meet demand."), *available at* https://khn.org/news/article/last-drugstore-how-rural-communities-lose-independent-pharmacies/.

[145] PBA Health, Is Owning a Pharmacy Profitable? (Aug. 2018), *available at* https://www.pbahealth.com/elements/is-owning-a-pharmacy-profitable/.

[146] Responsiveness of Maximum Allowable Costs to Generic Drug Inflation, *supra* note 138 at 6.

[147] 18 V.S.A. § 9471(6).

[148] David A. Hyman, White Paper, The Unintended Consequences of Restrictions on the Use of Maximum Allowable Cost Programs ("MACs") for Pharmacy Reimbursement, 8 (Apr. 2015), *available at* https://www.pcmanet.org/wp-content/uploads/2016/08/hyman-mac-white-paper-april-2015.pdf.

The PBM industry considers MAC pricing information to be confidential and proprietary, arguing that disclosure would allow opportunities for price fixing and lead to higher prices for patients.[149] This lack of transparency can allow PBMs to set MAC rates in a way that benefits the PBM.[150] For example, a PBM could be slow to update MAC lists to reflect increased acquisition costs, which would result in the PBM reimbursing a higher amount for a given prescription drug, but quickly update the list to reflect decreased acquisition costs, which would reduce reimbursement.[151] And, because MAC reimbursement is only loosely correlated to acquisition costs,[152] pharmacists are essentially left to bear the risk of price volatility on generic drugs.[153]

To address this issue, several states, including Vermont, have laws that require PBMs to update their MAC pricing lists on a regular basis and gave pharmacists the right to appeal MAC reimbursement if it did not reasonably reflect a drug's acquisition cost.[154] Under Vermont law, PBMs that set a MAC list or lists for reimbursement must:

- Make the MAC available to pharmacists in a format that is readily accessible and understandable, including the source used to determine the MAC;
- Update the MAC at least once every seven days and ensure that prescription drugs subject to MAC pricing are widely available for purchase by Vermont pharmacies;
- Have an administrative process to allow pharmacies to contest a listed MAC price;
- Give pharmacists 10 days from the date its claim for reimbursement is submitted to file an appeal; and
- Respond to pharmacies within 10 days of receiving an appeal.[155]

Act 131 further expands MAC appeal rights:

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[149] *Id.*
[150] Linda Cahn, Managed Care Mag., *Don't Get Caught By PBMs' MAC Mousetraps* (September 1, 2008) *available at* https://www.managedcaremag.com/archives/2008/9/don-t-get-caught-pbms-mac-mousetraps.
[151] *Id.* ("Ohio pharmacies have experienced MAC price upgrades lag for weeks at a time for a number of medications whose acquisition costs go up").
[152] Responsiveness of Maximum Allowable Costs to Generic Drug Inflation, *supra* note 138 at 5.
[153] According to the Department's conversations with pharmacists, PBM provider agreements with retail pharmacies are often offered on a take-it-or-leave-it or "adhesion" basis. Because pharmacies are forced to accept the contractual terms offered by PBMs, it is unlikely that a PBM would offer a pharmacy reimbursement terms that carried significant financial risk to itself.
[154] *See generally*, American Health Lawyers Association, Pharmacy Maximum Allowable Cost (MAC) Laws: A 50 State Survey (June 1, 2017), *available at* http://garnerhealth.com/wp-content/uploads/2014/02/Final_AHLA_Pharmacy_MAC_50_State_Survey.pdf.
[155] 18 V.S.A. § 9473(c).

- Allowing pharmacies to appeal more than 10 days after a claim is submitted if the claim is the subject of an audit initiated by the PBM;
- Requiring PBMs to provide the reason for a denied appeal and identify the national drug code (NDC) and a Vermont-licensed wholesaler "of an equivalent drug product that may be purchased by contracted pharmacies at or below the [MAC price;]" and
- For appeals in which the pharmacy prevails, require the PBM to change the MAC price for the drug product at issue and allow the appealing pharmacy to reverse and rebill the claim in question.[156]

The Department is not aware of any state that requires PBMs or the health plans they contract with to reimburse pharmacies in excess of the MAC price set by the PBM in the event an appeal is denied. A minority of states that require PBMs to provide a MAC appeal process, including Arkansas, provide that a pharmacy is entitled to a "reasonable appeal process," or reimbursement at the level of its acquisition costs.[157] In Arkansas, the Insurance Department issued guidance advising licensed PBMs that denying appeals solely because a claim was paid at the "generic effective rate," or contracted rate was not reasonable when pharmacies were reimbursed below their acquisition cost.[158]

8. Whether There is a Problem in Vermont of PBMs Soliciting Health Insurance Plan Beneficiaries Directly to Market the Pharmacy's Services.

Nationwide, PBMs advertise their own mail-order and specialty pharmacies to members as a matter of routine. These solicitations often advise patients that they must fill scripts at the PBM's own mail-order pharmacy, a practice known as "patient steering."[159] With Act 131, Vermont joins Louisiana, Minnesota, Oklahoma, and several other states in barring PBMs from engaging in patient steering.[160] Under Act 131, health insurers and PBMs are prohibited from:

- Requiring patients to purchase pharmacy services exclusively through a mail-order pharmacy or PBM affiliate as a condition of coverage or reimbursement;

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[156] Act 131 of 2022, Sec. 2, to be codified at 18 V.S.A § 9473(f).
[157] *See* Ark. Code. Ann. §§ 17-92-507 et seq.
[158] Ark. Ins. Dept., Bulletin No. 11-2021 (July 8, 2021), *available at* https://insurance.arkansas.gov/uploads/pages/bulletin_11-2021.pdf.
[159] For a description of patient steering, *see* Earl L. "Buddy" Carter, *Pulling Back the Curtain on PBMs: A Path Towards Affordable Prescription Drugs*, 59 Harv. J. on Leg. 257, 275 (2022), *available at* https://harvardjol.com/wp-content/uploads/sites/17/2022/06/201_Carter.pdf.
[160] *See* La. Rev. Stat. § 40:2870(5); Minn. Stat. Ann. 62W.07(b); 36 Okla. Stat. § 6963 (E).

- Offering or implementing plan designs that require covered persons to use a mail-order pharmacy or a PBM affiliate;
- Ordering covered persons, whether orally or in writing, to use a mail-order pharmacy or a PBM affiliate;
- Establishing network requirements that are more restrictive or inconsistent with federal and state law, rules adopted by the Board of Pharmacy, or guidance issued by drug manufacturers or the Board of Pharmacy that limit or prohibit pharmacies from dispensing certain prescription drugs; and
- Offering or implementing plan designs that increase costs for covered individuals if they do not use a mail-order pharmacy or a PBM affiliate, including requiring covered individuals to pay the full cost of prescription drugs if they do not use mail-order pharmacy or a PBM affiliate.[161]

Outside of patient steering, the Department is aware of PBMs in Vermont and across the country engaging in a practice known as "claim hijacking," in which a PBM processing a prior authorization, typically for a high-cost prescription drug, communicates with the patient, the patient's medical provider, or both to get the prescription filled at a pharmacy owned or affiliated by the PBM.[162]

9. Other Issues Relating to Pharmacy Benefit Management and its Effects on Vermonters, on Pharmacies and Pharmacists, and on Health Insurance in Vermont.

a. Copayment Accumulators.

Drug manufacturers sometimes offer copayment assistance, typically in the form of a "co-pay card" or a coupon, to patients with private health insurance to allay the out-of-pocket cost of prescription drugs.[163] In addition to reducing a patient's out-of-pocket costs at the pharmacy,

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[161] Act 131 of 2022, Sec.4, to be codified at 8 V.S.A § 4089j(d)(2). This provision bars tiered cost-sharing structures in which a PBM's mail-order pharmacy has "preferred" cost-sharing relative to other pharmacies.

[162] For a description of claim hijacking, *see* Frier Levitt, LLC, Pharmacy Benefit Manager Exposé: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers, and Taxpayers, 40 (Feb. 2022), *available at* https://communityoncology.org/wp-content/uploads/2022/02/COA_FL_PBM_Expose_2-2022.pdf. Although details cannot be provided in this report, the Department has taken consumer complaints related to claim hijacking in Vermont.

[163] National Conference of State Legislatures (NCSL), Copayment Adjustment Programs (Nov. 1, 2022), *available at* https://www.ncsl.org/research/health/copayment-adjustment-programs.aspx.

copayment assistance also applies to the patient's annual cost-sharing.[164] Some health economists have argued that in offering copayment assistance, drug manufacturers undermine health plan formularies, incentivizing patients to use and stabilize on higher cost brand drugs when there are generic alternatives available, and thereby increase total prescription drugs spending.[165] Health plans and PBMs, concerned that manufacturer copayment assistance works to shift costs to themselves, responded by adopting "copay accumulator programs," under which the plan or PBM will not apply copayment assistance to a patient's deductible.[166]

As of this writing, 15 states and Puerto Rico prohibit copay accumulator programs, requiring that any payment or discount made on behalf of a patent apply to the patient's cost-sharing.[167] In 2019, the federal government issued proposed guidance to qualified health plans allowing copay accumulator programs only when there was a generic equivalent available. Due to stakeholder confusion, and conflicting guidance from the IRS regarding high-deductible health plans,[168] the federal government delayed enforcement of the proposed guidance. In 2020, the federal government reversed course and issued revised guidance clarifying that copayment assistance was not required to apply to a patient's cost-sharing. The revised guidance is the subject of ongoing litigation brought by the HIV and Hepatitis Policy Institute and other interest groups, who allege that the revised guidance is inconsistent with the definition of "cost-sharing" under the Affordable Care Act.[169]

In Vermont, Act 131 provides that "[a]ny amount paid by a covered person . . . shall be attributed toward any deductible and . . . the annual out-of-pocket maximums under the covered person's health benefit plan."[170] Although the statute does not explicitly address copay

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[164] *Id.*

[165] One study found that between 2007 and 2010, copayment assistance increased total spending by $30 to $120 million for branded drugs first facing generic entry. *See* Leemore Dafny, Christopher Ody, & Matt Schmitt, *When Discounts Raise Costs: The Effect of Copay Coupons on Generic Utilization*, 9(2) Am. Econ. J.: Econ. Policy, 91, 120-23 (May 2017), *available at* https://www.aeaweb.org/articles?id=10.1257/pol.20150588 . Both MVP Health Care and Blue Cross Blue Shield of Vermont cited copayment assistance as a key driver of prescription drug spending.

[166] Under a copay accumulator program, if a patient uses a $100 manufacturer coupon to cover their copayment that amount will not count towards meeting their deductible.

[167] *See* Copay Adjustment Programs *supra* note 163.

[168] Internal Revenue Bulletin: 2004-33, Q&A 9 (Aug. 16, 2004) (noting that discount cards do not disqualify individuals from being eligible for HSA purposes if "individual is required to pay the costs of the health care (taking into account the discount) until the deductible of the HDHP is satisfied."), *available at* https://www.irs.gov/irb/2004-33_IRB#NOT-2004-50.

[169] *See* Katie Keith, Health Affairs Blog, Lawsuit Challenges Federal Copay Accumulator Policy (Sep. 28, 2022), *available at* https://www.healthaffairs.org/content/forefront/lawsuit-challenges-federal-copay-accumulator-policy.

[170] Act 131 of 2022, Sec 2, to be codified at 18 V.S.A. § 9472(f)(2).

accumulator programs, read in a light most favorable to patients, the statutory language suggests that Vermont health plans must apply copayment assistance to patient deductibles. While the Department does not recommend amending Act 131 at this time, we note that increased prescription drug spending incentivized by copayment assistance results in increased premiums that are borne by all employers and ratepayers.[171]

b. Direct and Indirect Reimbursement (DIR) Clawbacks.

"[D]irect or indirect reimbursement" (DIR) fees have their origins in the Medicare Part D program (Part D), which provides a Medicare prescription drug benefit, as a means to increase awareness of the actual cost of prescription drug transactions in the program.[172] In Part D, the federal government contracts with third-party prescription drug plan (PDP) sponsors, typically commercial health insurers, to administer the benefit.[173] These PDP sponsors, in turn, contract with PBMs to process claims, establish formularies, and provide other services.[174]

Part D reimburses PDP sponsors and their contracted PBMs for the prescription drug claims expenses that are "actually paid" to pharmacies, based on the claim submitted by the pharmacies at the point-of-sale. However, because PBMs commonly receive manufacturer rebates and other price concessions for prescription drugs after pharmacies have submitted claims, the net cost of those drugs to the PBM can be lower than what it was reimbursed by Part D. To ensure that the government shares in any savings accruing to PBMs, the definition of "actually paid" accounts for any DIR renumeration received from any source that "would serve to decrease the costs incurred under the Part D plan."[175] As a condition of reimbursement, the government requires PDP sponsors to disclose all drug costs and DIR data, examine it, and then notify Part D of any overpayment.[176] Any overpayments are then returned to the government.

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[171] This is particularly true in Vermont, which has a relatively low maximum out of pocket maximum for prescription drugs, resulting in most of the prescription drug benefit being paid out of premium. *See* 8 V.S.A. § 4089i.

[172] *See* 42 U.S.C. § 1395w-102.

[173] *See* 42 U.S.C. § 1395w-112, *et seq*.

[174] 42 C.F.R. § 423.4; *see also* U.S. Gov't Accountability Office, Medicare Part D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization (July 2019), *available at* https://www.gao.gov/assets/gao-19-498.pdf.

[175] 42 C.F.R. § 423.308 (emphasis added).

[176] 42 U.S.C. § 1395w-115(f)(1)(A); Centers for Medicare & Medicaid Services, Final Medicare Part D DIR Reporting Guidance for 2021, 5 (Mar. 30, 2022), *available at* https://www.cms.gov/files/document/final2021dirreportingreqsmemo508v3.pdf.

To reconcile claims against overpayments to the government, Part D PBMs started to impose "DIR fees" on pharmacies that retroactively "clawback" some portion of paid claims.[177] These fees can be flat, representing some dollar amount per script or a set percentage of claims, or "performance-based," which incorporate metrics such as generic dispensing rates and medication adherence rates into the calculation of the fee.[178] According to a 2017 fact sheet issued by the Centers for Medicare and Medicaid Services (CMS), which administers Part D, as well as the rest of the Medicare program, "DIR [grew] about 22 percent per year and PMPM DIR [grew] nearly 14 percent per year between 2010 and 2015. During the same period, total Part D gross drug costs only grew about 12 percent per year and PMPM Part D gross drug costs only grew nearly 5 percent per year."[179] This resulted in moderated premiums and lower levels of liability for plans, at the cost of increased out of pocket spending, since cost-sharing under Part D is assessed as a percentage of the price of a prescription drug at point-of-sale.[180]

On May 9, 2022, the federal government issued a final rule, effective January 1, 2024, prohibiting retroactive application of DIR fees, and requiring that all DIR be reflected at the point-of-sale.[181] The rule change, while allowing Part D PBMs to continue imposing DIR fees, increases pharmacists' reimbursement predictability since they will no longer be subject to clawbacks sometimes months after claims are submitted.[182]

Although nothing in federal law requires PDP sponsors to clawback a portion of paid claims under the guise of DIR fees, federal law preempts states from regulating Part D PDP sponsors.[183] Therefore, to the extent that Vermont took any action to address imposition of DIR

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[177] Adam Fein, Behind Diplomat Pharmacy's Plunge: A Primer on DIR Fees in Medicare Part D, Drug Channels (November 8, 2016), *available at* http://www.drugchannels.net/2016/11/behind-diplomat-pharmacys-plunge-primer.html.

[178] *Id*.

[179] Centers for Medicare & Medicaid Services, Fact Sheet, Medicare Part D – Direct and Indirect Remuneration (DIR) (Jan. 19, 2017), *available at* https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir.

[180] *Id*.

[181] Centers for Medicare & Medicaid Services, Final Rule, Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, 87 F.R. 27704 (May 9, 2022), *available at* https://www.federalregister.gov/documents/2022/05/09/2022-09375/medicare-program-contract-year-2023-policy-and-technical-changes-to-the-medicare-advantage-and.

[182] *See* American Pharmacists Assn., Press Release, APhA appreciates CMS' elimination of retroactive DIR fees (May 2, 2022), *available at* https://www.pharmacist.com/APhA-Press-Releases/apha-appreciates-cms-elimination-of-retroactive-dir-fees.

[183] *See* 42 U.S.C. § 1395w-112.

fees, for example by prohibiting PBMs from imposing fees after the point-of-sale, it could not be applied to Part D PDP sponsors.

c. Reporting Requirements.

Several states that regulate PBMs also require submission of reports to regulators identifying the PBM's health plan clients and aggregating all payments collected from pharmaceutical drug manufacturers. A table listing all state reporting requirements for PBMs is appended to this report as Appendix C. As noted in Section 2, in Vermont, PBMs are only required to report the aggregate amount retained on claims in excess of the amount the PBM reimbursed pharmacies.[184] While the Department is highly supportive of increased transparency, it is important that any reporting required by the Legislature goes to directly support a regulatory process or otherwise provide both health plans, regulators, or legislators with the information necessary to make informed contract and policy decisions, that lead to lower costs for consumers.

d. Rebating.

i. Overview of Rebating.

One of the major functions PBMs play in the pharmaceutical supply chain is to negotiate rebates with drug manufacturers on behalf of health plans. Rebates are price concessions on prescription drugs that manufacturers offer PBMs in return for the PBM's agreement to place the drug on a preferred tier in the PBM's formulary. Manufacturers generally pay rebates on high-cost brand-name drugs rather than on generic drugs[185] and rebates are apt to be especially high when "there is a competing product that can act as a substitute."[186] While the cost of generic drugs has steadily declined,[187] sales of brand-name drugs, which are typically patent-protected, jumped from $20 billion in 1984 to $250 billion in 2009.[188] Not surprisingly, while generics represented 90% of all drugs dispensed in the U.S. in 2020, they accounted for only about 18% of total retail prescription drug expenditures.[189] In contrast, brand-name drugs

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[184] *See supra* note 37.
[185] Maggie Alston, Gabriela Dieguez, Milliman, Samantha Tomicki, Milliman White Paper, A Primer on Prescription Drug Rebates: Insights into why Rebates are a Target for Reducing Prices, 2 (May 21, 2018), *available at* https://www.milliman.com/en/insight/-/media/Milliman/importedfiles/uploadedFiles/insight/2018/prescription-drug-rebates.ashx.
[186] Delaware Department of Insurance, Prescription Drug Spending and Rebates in Delaware, 14 (July 7, 2022), *available at* https://insurance.delaware.gov/wp-content/uploads/sites/15/2022/07/DelawarePBMSummary_FINAL_REPORT.pdf; *see also* A Primer on Prescription Drug Rebates, *supra* note 185 at 2, 4;
[187] U.S. Consumers Overpay for Generic Drugs, *supra* note 88 at 4-5.
[188] *Id.* at 3.
[189] *Id.* at 2-3.

accounted for only 10% of prescriptions dispensed in 2018 but 80% of prescription drug expenditures.[190]

Rebates are calculated as a percentage of the manufacturer's list price for a drug. As of 2016, an estimated $89 billion in rebates on brand name drugs were passed along by PBMs to health plans, with the largest amounts being collected by Medicaid and Medicare Part D ($32 billion and $31 billion, respectively) and a smaller share ($23 billion) going to private health plans.[191] Between 2012 and 2016, according to one study, the share of manufacturer rebates PBMs passed through to health plans increased from 78 percent to 91 percent.[192] According to the Pharmaceutical Care Management Association (PCMA), a PBM trade group, by aggregating "the buying clout of millions of enrollees . . PBMs are expected to save $654 billion [in drug costs] in 10 years nationally."[193]

ii. Concerns about Rebating.

PBMs consider the rebates they receive from manufacturers to be trade secrets, making it difficult for regulators to determine the downstream impact that rebating has on costs in the prescription drug supply chain.[194] Due in part to the lack of transparency about the financial dimensions of rebating, several broad concerns have arisen about the contradictory incentives and market distortions it creates for stakeholders in the drug supply chain.

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[190] Peter G. Peterson Foundation, Blog, Why are Prescription Drug Prices Rising and How do They Affect the U.S. Fiscal Outlook (Nov. 14 2019), *available at* https://www.pgpf.org/blog/2019/11/why-are-prescription-drug-prices-rising-and-how-do-they-affect-the-us-fiscal-outlook.

[191] *See* Charles Roehrig, Health Affairs Blog, Rebates, Coupons, PBMs, and the Cost of the Prescription Drug Benefit, 3 (Apr. 26, 2018), *available at* https://www.healthaffairs.org/content/forefront/rebates-coupons-pbms-and-cost-prescription-drug-benefit. These estimates *exclude* rebates that were retained by PBMs.

[192] Pharmacy Benefit Managers and Their Role in Drug Spending, *supra* note 77 at 2.

[193] April Alexander, J.P. Wieske, Pharmaceutical Care Management Association (PCMA), Managing Prescription Drug Benefits, presentation to the National Association of Insurance Commissioners (NAIC) Regulatory Issues Subgroup, 7 (Aug. 29, 2019), *available at* https://content.naic.org/sites/default/files/inline-files/PCMA%20Presentation%20082919%20%20-%20Final.pdf; The study on which the $654 billion savings estimate is based was prepared for the PCMA by Visante, a pharmaceutical consulting company. *See* https://www.visanteinc.com/.

[194] *See* Neeraj Sood, Tiffany Shih, *et al*, Schaeffer Center White Paper Series, The Flow of Money Through the Pharmaceutical Distribution System, 8 (June 2017) ("PBMs carefully guard information about the size of negotiated rebates and discounts, which may enhance their ability to negotiate lower prices [from drug manufacturers], but also masks whether they are indeed lowering the prices paid by patients and insurers as claimed."), *available at* https://healthpolicy.usc.edu/wp-content/uploads/2017/06/The-Flow-of-Money-Through-the-Pharmaceutical-Distribution-System_Final_Spreadsheet.pdf.

A. Rebate-Driven Formulary Design.

PBM formularies were intended to lower drug costs by steering patients to generic drugs that were cheaper, and which occupied a preferred formulary tier with lower patient cost sharing. However, some critics have argued that the practice of rebating creates perverse incentives for PBMs since the revenue they receive from rebates (which are paid by manufacturers to secure preferred placement on a PBMs formulary) could lead them to favor more expensive drugs paying higher rebates over drugs that provide a better value at a lower cost. A discussion and accompanying chart, contained in a May 25, 2022, letter from researchers at the USC Schaeffer Center to the Chair of the Federal Trade Commission, makes the argument that every entity in the drug distribution system, except the manufacturer, is likely to earn more money under a rebate-driven pricing model than under a pricing system with no rebates.[195] Any costs added to the distribution system by the rebate pricing model are borne by the patient in the form of higher premiums.[196] Another study found circumstantial evidence that "in certain classes, rebates may play a role in influencing brand over generic drug use, although the exact relationship is unknowable given the proprietary nature of rebates."[197] Because PBMs keep a share of the rebates they obtain from manufacturers, "both commercial and Medicare drug plans often are slow to put new generics, which typically do not pay rebates, on the formulary."[198] (emphasis added).

B. Distortion of Health Plan Administrative Fees.

As of 2016, PBMs passed along an estimated $89 billion in rebates on brand name drugs to health plans.[199] Assuming a portion of retained rebate revenue and the revenue received from spread pricing is used by a PBM to help provide pharmacy management services for a health plan client, such revenue, which doesn't appear as an expense on the books of the health plan, "could artificially lower reported administrative costs and make it easier [for an insurer] to meet government MLR requirements."[200] Since "the PBM practice of retaining a share of rebates is often built into their health plan contracts and may occur largely in lieu of fees," [201] a starting point for determining the existence and extent of this phenomenon would be an examination of

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[195] Letter to Federal Trade Commission Chair Lina Khan, *supra* note 9 at 6-8. A copy of the chart is included in this report as Appendix D: Rebating Example.
[196] *Id.*
[197] Christine Buttorff, Yifan Xu, & Geoffrey Joyce, *Variation in Generic Dispensing Rates in Medicare Part D*, 26(11) Am. J. Manag. Care, e355, e355 (Nov. 13, 2020), *available at* https://doi.org/10.37765/ajmc.2020.88530.
[198] U.S. Consumers Overpay for Generic Drugs, *supra* note 88 at 6.
[199] Rebates, Coupons, PBMs, and the Cost of the Prescription Drug Benefit, *supra* note 191 at 3. These estimates *exclude* rebates that were retained by PBMs.
[200] *Id.* at 5.
[201] *Id.*

the contracts between PBMs and health plans. As with spread pricing, it is possible that regulatory action to limit rebating would have unintended consequences for a health plan's ability to provide needed services to its subscribers.

iii. Actions in Other States.

According to a *Compilation of State PBM Business Practice Laws* prepared by the National Association of Commissioners (NAIC) in 2022, five states (Arkansas, Maryland, Texas, Utah and Virginia) already have laws that require PBMs to report aggregate rebates received from a drug manufacturer and aggregate rebates passed on to a client health plan to either the plan itself or the state Department of Insurance.[202] Delaware, which also prohibits spread pricing, has a similar reporting requirement.[203] The Department is aware of only one state, West Virginia, that requires drug rebates to be passed along to the patient at the point of sale. West Virginia law requires that cost-sharing for an individual covered by a prescription drug plan be reduced at the point of sale "by an amount equal to at least 100 percent of all rebates received, or to be received, in connection with the dispensing or administration of the prescription drug." Any remaining portion of the rebate "would then be passed along to the health plan to reduce premiums."[204]

There has been considerable discussion among regulators and health care economists about whether rebates should instead be passed along to subscribers at the point of sale to lower their cost sharing. The argument in favor of this approach is that it lowers out-of-pocket costs for high utilizers of the prescription drug benefit[205] and thus, tends to increase drug adherence.[206] The main argument against this approach is that it may "slightly increase premiums, as rebates are no longer available as a source of funding."[207] The Department believes that the approach adopted by West Virginia, which uses passed-through rebates first at the point of sale to reduce cost sharing and then applies any surplus to the reduction of premiums,[208] is a novel compromise that deserves consideration in Vermont.

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[202] National Association of Insurance Commissioners, Compilation of State Pharmacy Benefit Manager Business Practice Laws, 132-134 (Mar. 2022), *available at* https://content.naic.org/sites/default/files/call_materials/Compilation%20of%20State%20PBM%20Business%20Practice%20Laws%203.2022.pdf.

[203] Prescription Drug Spending and Rebates in Delaware, *supra* note 186 at 6; 18 Del. C. § 3363A.

[204] W. Va. Code Ann. § 33-51-9(k).

[205] What is the Price Anyway, *supra* note 84 at 5.

[206] Prescription Drug Spending and Rebates in Delaware, *supra* note 186 at 15.

[207] What is the Price Anyway, *supra* note 84 at 5.

[208] *See supra* note 204.

e. Whitebagging and Brownbagging.

As briefly discussed above in Section 2.a, Act 131 prohibits PBMs from requiring whitebagging and brownbagging of prescription drugs. It also prohibits PBMs from adjusting reimbursement or otherwise imposing any financial penalty for discounted prescription drugs purchased through the 340B program. Because 340B covered entities, such as hospitals, are dependent on the 340B program for revenue,[209] the Department notes that Act 131 will further encourage 340B covered entities to direct prescriptions to their own 340B contract pharmacies and dispense prescription drugs in a manner that maximizes revenue gained from the difference between the 340B discount price and the reimbursement paid by the PBM.[210] This will have the effect of driving up the price that health plans pay for prescription drugs and correspondingly increase insurance premiums.

10. Recommendation and Other Policy Options.

a. Recommendation: Require Licensure and Increase Regulatory Oversight of PBMs.

As described above in subsection 2.a, the Department has authority to investigate and examine PBMs. However, that authority is limited to violations of Subchapter 9, Chapter 221 of Title 18. In contrast, health insurers, which are required to be licensed by the Commissioner to operate in Vermont, are subject to significantly more regulatory oversight. The Department may generally examine the fees, expenses, officers and books of insurers and require reporting of their financial condition and pricing practices.[211] Insurers and their subcontractors, including PBMs, are also subject to the requirements of the Insurance Trade Practices Act, 8 V.S.A. Ch. 129, which prohibits insurers from engaging in "unfair methods of competition or unfair or deceptive acts or practices," including: misrepresentations, false advertising, discrimination against individual policyholders, and unfair claims settlement practices.[212] These provisions, however, do not apply to PBMs serving non-insurer entities like self-funded employer health

[209] *See* Act No. 74 (2021) Report, *supra* note 44 at 11.
[210] *Id.*, at 12 (citing research suggesting that "that 340B may incentivize covered entity providers to use more expensive drugs to achieve higher spreads between 340B discounted prices and commercial and Medicare reimbursement rates.").
[211] *See* 8 V.S.A. Ch. 101, Subch. 7.
[212] *See* 8 V.S.A. Ch. 129.

plans, which account for a majority of privately insured individuals in Vermont.[213] As a result, a significant gap exists in Vermont's regulatory scheme.

To address this gap, the Department recommends that the Legislature adopt the forthcoming National Association of Insurance Commissioners' (NAIC) model to establish a licensing or registration process for PBMs. In 2020, a draft model establishing a standardized licensing or registration process was adopted by the NAIC's Pharmacy Benefit Manager Regulatory Issues Subgroup but was not adopted by the NAIC membership. The subgroup is currently drafting a white paper examining state regulatory approaches to PBM business practices to inform changes to the draft model.[214] Registration and licensing requirements for PBMs are increasingly common, and the Department sees value in taking a coordinated approach with other jurisdictions through use of the forthcoming model to facilitate a more uniform regulatory approach for this complex, multistate business model.

b. Other Policy Options.

i. Expanding Spread Pricing Disclosures to Health Plans.

Because there are situations where it would be beneficial for a health plan to have certainty as to the cost of its pharmacy benefit, a solution like that adopted by Louisiana, combined with comprehensive statutory examination and reporting requirements like those currently imposed on health insurance companies, is preferable to strictly prohibiting spread pricing. The legislature could therefore consider expanding required disclosures to health plans entering into spread rising arrangements to include aggregate revenue derived from spread pricing by drug class at least biannually and, at the request of the Commissioner or the health plan client, the spread on specific prescription drugs. Any disclosures to the State that meet the threshold of being a "trade secret" under 1 V.S.A. § 317(c)(9), should be exempt from public disclosure.

ii. Requiring a Reasonable MAC Appeal Process.

Act 131 requires PBMs to tell a pharmacy where it can obtain prescription drugs at a price that is at or below the PBM's MAC price in the event an appeal is denied. Therefore, pharmacies appealing a PBM's MAC price will either receive a favorable reimbursement adjustment if the appeal is successful or information about where to purchase drugs at a lower price if it is not. For this reason, the Department does not recommend requiring reimbursement to pharmacists

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[213] Green Mountain Care Board, Vermont All-Payer ACO Model Annual ACO Scale Targets and Alignment Report Performance Year 4, at 6 (June 29, 2022), *available at* https://gmcboard.vermont.gov/sites/gmcb/files/documents/Scale%20Targets%20and%20Alignment%20Report_FINAL_Redacted.pdf.

[214] *See* National Association of Insurance Commissioners, Pharmacy Benefit Managers (April 11, 2022), *available at* https://content.naic.org/cipr-topics/pharmacy-benefit-managers.

in excess of the MAC price set by the PBM if an appeal is denied. The Legislature could, however, take Arkansas's approach of entitling a pharmacy to reimbursement at its acquisition cost if the PBM does not provide a reasonable appeal process.

The Legislature could also take further steps to directly address the administrative burden on pharmacies of filing appeals. Since MAC pricing, as discussed above, generally applies to generic drugs, which are typically high-volume and low-cost,[215] appealing claims is not cost-effective for pharmacies. A potential solution to this issue would be to require PBMs to batch similar claims, similar to how the federal No Surprises Act requires health insurers to batch claims for independent review when provider reimbursement is disputed.[216]

iii. Increasing Oversight of PBM Solicitations.

To address the issue of claim hijacking, discussed above in Section 8, and strengthen the anti-steering provisions in Act 131, the Department recommends:

1) codifying that a patient's choice of pharmacy belongs solely to the patient and, as Nebraska has done, prohibiting third parties, such as PBMs, from altering prescription drug orders or the pharmacy chosen by the patient;[217]

2) applying the advertising standards applicable to health insurers in 8 V.S.A. § 4084 prohibiting "solicitation which is materially misleading or deceptive" to PBMs; and

3) requiring the Department to approve all solicitations sent by PBMs to covered persons.

iv. Setting Loss Ratios for PBMs.

To increase transparency in the PBM market and ensure that premium dollars that flow to PBMs go primarily towards paying pharmacy claims, the Legislature could tie the existing spread pricing disclosure in 18 V.S.A. § 9472(d) and rebating disclosure under 18 V.S.A. § 9472(c)(5) with new reporting on amounts received from fully-insured health plan clients to support a new requirement imposing a minimum loss ratio of 85% on PBMs, the same loss ratio required of health insurers under the Affordable Care Act.[218] As with health insurers, if a PBM had a loss ratio lower than required, it would be required to pay a rebate to affected health plan

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[215] *See supra* note 25; *see also* Andrew W. Mulcahy, *et al.*, RAND Corp., International Prescription Drug Price Comparisons Current Empirical Estimates and Comparisons with Previous Studies, 20 (2021)(finding that that prices for generic drugs made up for 84% of drugs sold in the United States by volume but only 12% of spending in 2018.), *available at* https://www.rand.org/pubs/research_reports/RR2956.html.

[216] *See* Consolidated Appropriations Act, 2021, P. L. 116-260, Sec. 103.

[217] Neb. Rev. Stat. § 38-2870(5)(a)(i).

[218] 45 C.F.R. § 158.210.

clients. Such a requirement would serve to ensure that required reporting goes to support a regulatory process that moderates the cost of PBM services.

Appendix A: State Laws Requiring Pharmacy Benefit Manager Licensure or Registration.

State	Citation	What	Who	Language
AL	Ala. Code § 27-45A-4	License	Ins. Dept.	[T]o conduct business in this state, a pharmacy benefit manager must be licensed by the Commissioner.
AR	A.C.A. § 23-92-504	License	Ins. Dept.	A person or organization shall not establish or operate as a pharmacy benefits manager in Arkansas for health benefit plans without obtaining a license from the Insurance Commissioner under this subchapter.
CA	Cal. Health & Safety Code §§ 1385.003-1385.005	Register	Dept. of Public Health	A pharmacy benefit manager required to register with the department pursuant to Section 1385.004 shall complete an application for registration with the department that shall include, but not be limited to, all of the information required by subdivision (c).
CT	Conn. Gen. Stat. § 38a-479bbb	Register	Ins. Dept.	No person shall act as a pharmacy benefits manager in this state without first obtaining a certificate of registration from the commissioner.
DE	18 Del. C. § 3353A	Register	Ins. Dept.	A pharmacy benefits manager shall register with the Commissioner as a pharmacy benefits manager before providing pharmacy benefits management services in this State to a purchaser.
FL	Fla. Stat. § 624.490	Register	Ins. Dept.	Effective January 1, 2019, to conduct business in this state, a pharmacy benefit manager must register with the office. Upon receipt of a completed registration form, the required documents, and the registration fee, the office shall issue a registration certificate.

GA	O.C.G.A. § 33-64-2	License	Ins. Dept.	No person, business entity, or other entity shall act as or hold itself out to be a pharmacy benefits manager in this state, other than an applicant licensed in this state for the kinds of business for which it is acting as a pharmacy benefits manager, unless such person, business entity, or other entity holds a license as a pharmacy benefits manager issued by the Commissioner pursuant to this chapter.
HI	HRS § 431S-3	Register	Ins. Dept.	Notwithstanding any law to the contrary, no person shall act or operate as a pharmacy benefit manager without first obtaining a valid registration issued by the commissioner pursuant to this chapter.
ID	Idaho Code § 41-349	Register	Ins. Dept.	A person may not perform, offer to perform, or advertise any pharmacy benefit management service in this state unless the person is registered as a pharmacy benefit manager with the department of insurance.
IL	215 ILCS 5/513b2	License	Ins. Dept.	Licensure Requirements. Beginning on July 1, 2020, to conduct business in this State, a pharmacy benefit manager must register with the Director.
IN	IC 27-1-24.5-18	License	Ins. Dept.	A person shall, before establishing or operating as a pharmacy benefit manager, apply to and obtain a license from the commissioner under this chapter.
KS	K.S.A. § 40-3823	Register	Ins. Dept.	No person shall act or operate as a pharmacy benefits manager without first obtaining a valid

				certificate of registration issued by the commissioner.
KY	KRS § 304.9-053	License	Ins. Dept.	In order to conduct business in this state, a pharmacy benefit manager shall first obtain a license from the commissioner. The license shall be in lieu of an administrator's license as required by KRS 304.9-052.
LA	La. R.S. § 22:1660	License	Ins. Dept.	No person shall act as, or offer to act as, or hold himself out to be a pharmacy services administrative organization (PSAO) in this state without a valid license as a PSAO issued by the commissioner of insurance. A PSAO is not required to hold a license as a PSAO if it: (1) has its principal place of business in another state; and (2) is not soliciting business as a PSAO in Louisiana. This measure requires every PSAO to be registered and licensed by the Department of Insurance and to act in good faith as a fiduciary for its contracting pharmacy.
ME	24-A M.R.S. § 4348	License	Ins. Dept.	Beginning January 1, 2020, a person may not act as a pharmacy benefits manager in this State without first obtaining a license from the superintendent in accordance with this section and paying the licensing fee required under section 601, subsection 28A.
MD	Md. Code Ann. § 15-1604	Register	Ins. Dept.	A pharmacy benefits manager shall register with the Commissioner as a pharmacy benefits manager before providing pharmacy benefits management services in the State to purchasers.

MA	M.G.L.A. 176O § 21	Register	Ins. Dept.	. . . a third party administrator, a pharmacy benefit manager or other similar entity with claims data, eligibility data, provider files and other information relating to health care provided to residents of the commonwealth and health care provided by health care providers in the commonwealth.
MN	Minn. Stat, § 62W.03	License	Ins. Dept.	Beginning January 1, 2020, no person shall perform, act, or do business in this state as a pharmacy benefit manager unless the person has a valid license issued under this chapter by the commissioner of commerce.
MS	Miss. Code Ann. § 73-21-157	License	Bd. Of Pharmacy	Before beginning to do business as a pharmacy benefit manager, a pharmacy benefit manager shall obtain a license to do business from the board.
MO	Mo. Rev. Stat.§ 376.393	License	Ins. Dept.	No entity subject to the jurisdiction of this state shall act as a pharmacy benefits manager without a license issued by the department. The department shall establish by rule the application process and license fee for pharmacy benefits managers.
MT	M.C.A. 33-2-2403(1)	License	Ins. Dept.	A person may not perform an act or do business in this state as a pharmacy benefit manager without a valid license issued under this part by the commissioner.
NH	N.H. Rev. Stat. § 402-N:2	Register	Ins. Dept.	A person or organization shall not establish or operate as a pharmacy benefits manager in this state for health benefit plans without registering with the insurance commissioner under this chapter.

NM	N.M. Stat. Ann. § 59A-61-3	License	Ins. Dept.	A person shall not operate as a pharmacy benefits manager unless licensed by the superintendent in accordance with the Pharmacy Benefits Manager Regulation Act and applicable federal and state laws.
NY	N.Y. Ins. Law § 2902(a)	Register	Ins. Dept.	No person, firm, association, corporation or other entity may act as a pharmacy benefit manager on or after 06/01/2021 and prior to 01/01/2023, without having a valid registration as a pharmacy benefit manager filed with the superintendent in accordance with this article and any regulations promulgated thereunder.
NC	N.C. Gen. Stat. Ann. § 58-56A-2(a)	License	Ins. Dept.	A person or organization may not establish or operate as a pharmacy benefits manager for health benefit plans in this State without obtaining a license from the Commissioner of the Department of Insurance.
ND	N.D. Cent. Code § 26.1-27.1-02	Register	Ins. Dept.	A person may not perform or act as a pharmacy benefits manager in this state unless that person holds a certificate of registration as an administrator under chapter 26.1-27.
OH	ORC Ann. §§ 3959.01, 3959.09; OH Bulletin No. 2018-2	License	Ins. Dept.	Upon approval of the application for an administrator license and payment of appropriate filing fees, the applicant shall be granted a license by the superintendent of insurance and an appropriate certificate of authority to operate as an administrator will be issued to the applicant.
OK	Okla. Stat. Ann. tit. 59, § 358	License	Ins. Dept.	In order to provide pharmacy benefits management or any of the

				services included under the definition of pharmacy benefits management in this state, a pharmacy benefits manager or any entity acting as one in a contractual or employment relationship for a covered entity shall first obtain a license from the Oklahoma Insurance Department, and the Department may charge a fee for such licensure.
OR	Or. Rev. Stat. § 735.532	Register	Dept. of Consumer & Business Servs.	To conduct business in this state, a pharmacy benefit manager must register with the Department of Consumer and Business Services and annually renew the registration.
PA	Pa. Stat. Ann. tit. 40, § 4521	Register	Ins. Dept.	To conduct business in this Commonwealth, a PBM or auditing entity must register with the department.
SC	S.C. Code Ann.§ 38-71-2210	License	Ins. Dept.	A person or organization may not establish or operate as a pharmacy benefits manager in this State for health benefit plans without obtaining a license from the Director of the Department of Insurance.
TN	Tenn. Code Ann. § 56-7-3113	License	Ins. Dept.	No person or entity shall administer the medication or device portion of pharmacy benefits coverage provided by a covered entity or otherwise act as a pharmacy benefits manager in this state unless the person or entity has obtained licensure through the department of commerce and insurance.
UT	Utah Code Ann. § 31A-46-303	License	Ins. Dept.	To conduct business in the state, a person who acts as a pharmacy benefit manager in the state shall

				be licensed by the Insurance Department.
VT	18 V.S.A. § 9421	Register	Dept. of Financial Regulation	A pharmacy benefit manager shall not do business in this State without first registering with the Commissioner on a form and in a manner prescribed by the Commissioner.
VA	Va. Code Ann. § 38.2-3466; Administrative Letter 2020-04	License	State Corporation Commission	Unless otherwise covered by a license as a carrier, no person shall provide pharmacy benefits management services or otherwise act as a pharmacy benefits manager in the Commonwealth without first obtaining a license in a manner and in a form prescribed by the Commission.
WA	Wash. Rev. Code Ann. § 19.340.030(effective until 1/1/22)	Register	Ins. Dept.	To conduct business in this state, a pharmacy benefit manager must register with the office of the insurance commissioner and annually renew the registration.
WV	W. Va. Code Ann. § 33-51-8	License	Ins. Dept.	A person or organization may not establish or operate as a pharmacy benefits manager in the State of West Virginia without first obtaining a license from the Insurance Commissioner pursuant to this section: Provided, That a pharmacy benefit manager registered pursuant to §33-51-7 of this code may continue to do business in the state until the Insurance Commissioner has completed the legislative rule asset forth in §33-51-10 of this code: Provided, however, That additionally the pharmacy benefit manager shall submit an application within six months of completion of the final rule.

WI	Wis. Stat. Ann. § 632.865(3)	License	Ins. Dept.	No person may perform any activities of a pharmacy benefit manager without being licensed by the commissioner as an administrator or pharmacy benefit manager under s. 633.14.
WY	Wyo. Stat. § 26-52-101	License	Ins. Dept.	No person shall act or hold himself out as a pharmacy benefit manager in this state unless he obtains a license from the department.

National Association of Insurance Commissioners (NAIC), PBM Licensure/Registration Tracking Document (Oct. 2021), *available at* https://content.naic.org/sites/default/files/inline-files/PBM%20License_Registration%20Tracking%2010.2021.pdf.

Appendix B: Office of Professional Regulation Recommendations

State of Vermont
Office of the Secretary of State

Office of Professional Regulation
89 Main Street, 3rd Floor
Montpelier, VT 05620-3402
sos.vermont.gov

James C. Condos, Secretary of State
Christopher D. Winters, Deputy Secretary
S. Lauren Hibbert, Director

To: Hon. Ginny Lyons, Chair, Senate Committee on Health & Welfare
From: S. Lauren Hibbert, Director of Professional Regulation;
Carrie Phillips, MS, PharmD, Executive Director, Board of Pharmacy
Date: April 13, 2022
Re:

It is understood that the Committee is considering an amendment of H.353, *An act relating to pharmacy benefit management*, to include aspects of S.242, *An act relating to prescription drugs dispensed by a health insurer designated pharmacy for administration to a patient in a health care setting.*

The following markup illustrates how salient language from S.242 could be merged into Sec. 4 to more effectively restrain white-bagging and brown-bagging.

Sec. 4. 8 V.S.A. § 4089j is amended to read:
§ 4089j. RETAIL PHARMACIES; FILLING OF PRESCRIPTIONS
* * *
(d)(1) A health insurer or pharmacy benefit manager shall permit a beneficiary of a plan offered by the health insurer to fill a prescription at the in-network pharmacy of the beneficiary's choice and, except with respect to pharmacies owned or operated, or both, by a health care facility, as defined in 18 V.S.A. § 9432, shall not impose differential cost-sharing requirements based on the choice of pharmacy or otherwise promote the use of one pharmacy over another.

(2) A health insurer or pharmacy benefit manager shall permit a participating network pharmacy to perform all pharmacy services within the lawful scope of the profession of pharmacy as set forth in 26 V.S.A. chapter 36.

(3) A health insurer or pharmacy benefit manager shall adhere to the definitions of prescription drugs and the requirements and guidance regarding the pharmacy profession established by State and federal law and the Vermont Board of Pharmacy and shall not establish classifications of or distinctions between prescription drugs, impose penalties on prescription drug claims, attempt to dictate the behavior of pharmacies or pharmacists, or place restrictions on pharmacies or pharmacists that are more restrictive than or inconsistent with State or federal law or with rules adopted or guidance provided by the Board of Pharmacy.

(4) A health insurer shall not, by contract, written policy, or written procedure, require that a pharmacy designated by the health insurer dispense a medication directly to a patient with the expectation or intention that the patient will transport the medication to a health care setting for administration by a health care professional.

(5) A health insurer shall not, by contract, written policy, or written procedure, require that a pharmacy designated by the health insurer dispense a medication directly to a health care setting for a health care professional to administer to a patient.

~~(4)~~(6) The provisions of this subsection shall not apply to Medicaid.

VERMONT

Stakeholders may wish to retain the flexibility associated with other sections of S.242. The Office would not find the inclusion of that language objectionable and considers the question a policy choice for the Committee.

We do, however, strongly recommend that H.353 avoid reifying the concept of "specialty pharmacy" or recognizing in law special, non-governmental pharmacy accreditations. Industry has on occasion employed private pharmacy accreditations as a pretext to restrain consumer choice. For this reason, requiring certification to DFR, for example, that "the health insurer-designated pharmacy is accredited by a national pharmacy accreditation organization," or that "the health insurer-designated pharmacy is accredited by a national pharmacy accreditation organization," would tend to undermine the legislative purpose of the bill. The Office recommends not including language that further creates the concept of "specialty pharmacy."

Thank you for the opportunity to weigh into these important bills.

Appendix C: State PBM Reporting Requirements

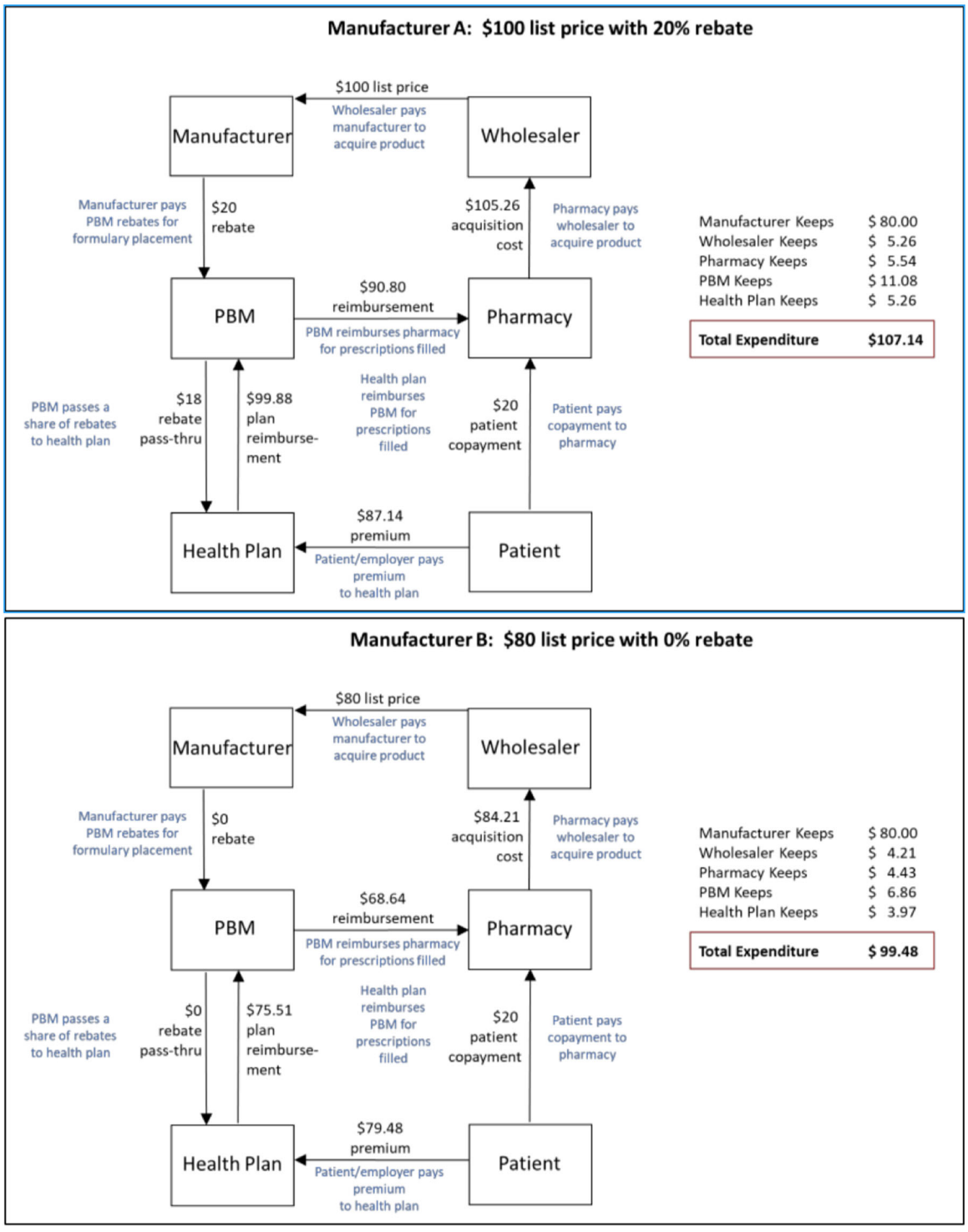
State	Citation	Statutory Language
DE	18 Del. C. § 3363A(b)	(b) A pharmacy benefits manager shall report to the Commissioner on a quarterly basis all of the following information for each insurer: (1) The itemized amount of pharmacy benefits manager revenue sources, including professional fees, administrative fees, processing fees, audits, direct and indirect renumeration fees, or any other fees. (2) The aggregate amount of rebates distributed to the appropriate insurer. (3) The aggregate amount of rebates passed on to insureds of each insurer at the point of sale that reduced the insureds' applicable deductible, copayment, coinsurance, or other cost-sharing amount. (4) The individual and aggregate amount the insurer paid to the pharmacy benefits manager for pharmacy goods or services itemized by all of the following: a. Pharmacy. b. Product. c. Goods and services. (5) The individual and aggregate amount a pharmacy benefits manager paid for pharmacy goods or services itemized by all of the following: a. Pharmacy. b. Product. c. Goods and services.
NH	N. H. Rev. Stat. § 402-N:6	I. Each pharmacy benefits manager shall submit an annual report to the commissioner containing a list of health benefit plans it administered, and the aggregate amount of all rebates it collected from pharmaceutical manufacturers that were attributable to patient utilization in the state of New Hampshire during the prior calendar year. II. Information reported to the commissioner pursuant to this section shall be confidential and protected from disclosure under the commissioner's examination authority and shall not be considered a public record subject to disclosure under RSA 91-A. Based on this reporting, the commissioner shall make public aggregated data on the overall amount of rebates collected on behalf of covered persons in the state, but shall not release data that identifies a specific insurer or pharmacy benefit manager.
TX	Tex. Ins. Code § 1369.502	(a) Not later than March 1 of each year, each pharmacy benefit manager shall file a report with the commissioner.

		The report must state for the immediately preceding calendar year: (1) the aggregated rebates, fees, price protection payments, and any other payments collected from pharmaceutical drug manufacturers; and(2) the aggregated dollar amount of rebates, fees, price protection payments, and any other payments collected from pharmaceutical drug manufacturers that were:(A) passed to:(i) health benefit plan issuers; or(ii) enrollees at the point of sale of a prescription drug; or(B) retained as revenue by the pharmacy benefit manager. (a-1) Notwithstanding Subsection (a), the report due not later than February 1, 2020, under that subsection must state the required information for the immediately preceding three calendar years in addition to stating the required information for the preceding calendar year. This subsection expires September 1, 2021. (b) A report submitted by a pharmacy benefit manager may not disclose the identity of a specific health benefit plan or enrollee, the price charged for a specific prescription drug or class of prescription drugs, or the amount of any rebate or fee provided for a specific prescription drug or class of prescription drugs.(c) Not later than June 1 of each year, the commissioner shall publish the aggregated data from all reports for that year required by this section in an appropriate location on the department's Internet website. The combined aggregated data from the reports must be published in a manner that does not disclose or tend to disclose proprietary or confidential information of any pharmacy benefit manager.
UT	Utah Code Ann. § 31A-46-307	(1) A pharmacy benefit manager may not enter into or renew a contract with an insurer on or after January 1, 2021, to administer or manage rebate contracting or rebate administration unless the pharmacy benefit manager agrees to regularly report to the insurer information regarding pharmaceutical manufacturer rebates received by the pharmacy benefit manager under the contract. (2) The quality and type of information required under Subsection (1) shall be detailed, claims level information unless the pharmacy benefit manager and insurer agree to waive this requirement in a separate written agreement.

WI	Wis. Stat. 632.865 (7)	(a) Beginning on June 1, 2021, and annually thereafter, every pharmacy benefit manager shall submit to the commissioner a report that contains, from the previous calendar year, the aggregate rebate amount that the pharmacy benefit manager received from all pharmaceutical manufacturers but retained and did not pass through to health benefit plan sponsors and the percentage of the aggregate rebate amount that is retained rebates. Information required under this paragraph is limited to contracts held with pharmacies located in this state. (b) Reports under this subsection shall be considered a trade secret under the uniform trade secret act under s. 134.90. (c) The commissioner may not expand upon the reporting requirement under this subsection, except that the commissioner may effectuate this subsection.
VT	18 V.S.A. § 9472(d)	At least annually, a pharmacy benefit manager that provides pharmacy benefit management for a health plan shall disclose to the health insurer, the Department of Financial Regulation, and the Green Mountain Care Board the aggregate amount the pharmacy benefit manager retained on all claims charged to the health insurer for prescriptions filled during the preceding calendar year in excess of the amount the pharmacy benefit manager reimbursed pharmacies.

National Association of Insurance Commissioners , Compilation of State Pharmacy Benefit Manager Business Practice Laws, 92-94 (Mar. 2022), *available at* https://content.naic.org/sites/default/files/call_materials/Compilation%20of%20State%20PBM%20Business%20Practice%20Laws%203.2022.pdf.

Appendix D: Rebating Example



Letter to Federal Trade Commission Chair Lina Khan, *supra* note 9 at 7.