VERMONT

DEPARTMENT OF FINANCIAL REGULATION

Act No. 74 (2021) Report: National Activity Affecting Participation in the 340B Drug Pricing Program

Section E.227.3 of Act No. 74 of 2021, Department of Financial Regulation; Essential Health Benefits; Benchmark Plan Review

REPORT

Report to the General Assembly

January 15, 2022

Submitted by
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Report overview

This report is organized into six parts:

(I) Summary of Legislative charge, stakeholder engagement, and data sources;
(II) An overview of the 340B drug pricing program;
(III) Medicaid and commercial rebates
(IV) Recent 340B controversies and their implications for Vermont stakeholders;
(V) Possible state responses; and
(VI) Recommendations.

I. Summary of Legislative charge, stakeholder engagement, and data sources

A. Legislative charge

Section E.227.3 of Act No. 74 of 2021, an act relating to making appropriations for the support of government, directs the Commissioner of the Department of Financial Regulation (DFR or the Department), in consultation with the Office of the Attorney General, to issue a report regarding national activity affecting participation in the 340B drug pricing program, including:

(1) recent changes to the manner in which prescription drug manufacturers pay rebates to pharmacy benefit managers (PBMs) for prescriptions filled through 340B contract pharmacies;
(2) the potential impacts of these changes on Vermont stakeholders, including individual Vermonters; and
(3) possible State responses to prescription drug manufacturer and pharmacy benefit manager actions related to participation in the 340B drug pricing program.

In accordance with the Legislature's directive in Act 74, Commissioner Pieciak 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 potential State responses related to the 340B drug pricing program.

B. Stakeholder engagement and data sources

In preparing this report and making recommendations, the Department engaged in extensive research to better understand the 340B drug pricing program, the intersection of the program with the Medicaid drug rebate program, the roles of contract pharmacies and PBMs, how and why commercial drug rebates are paid, the impacts of recent and potential changes to the 340B program, the status of federal litigation, and potential State responses. Links to all sources are included in footnotes. We also engaged with key State and industry stakeholders to better understand the impacts of the 340B program and recent and potential changes to it. The following is a list of stakeholders we consulted:

- Jill Abrams and Merideth Chaudoir, Assistant Attorneys General, Vermont Office of the Attorney General
- Nancy Hogue, Director of Pharmacy Services, Department of Vermont Health Access
- Christina McLaughlin, Health Policy Advisor, Green Mountain Care Board
- Devon Green, Vice President of Government Relations, Vermont Association of Hospitals and Health Systems
- Georgia Maheras, Vice President of Policy and Strategy, Bi-State Primary Care Association
- Nate Awrich, Director, Pharmacy Supply Chain, University of Vermont Health Care Network
- Jeff Hochberg, President, Vermont Retail Drug Association
- Heather Shouldice, President, William Shouldice & Associates LLC (on behalf of the Vermont Association of Chain Drug Stores); Mike Duteau, President, Noble Health Services, Inc., and Chair, Vermont Association of Chain Drug Stores; Anne Fellows, Regional Director, National Association of Chain Drug Stores; Scott Brewster, 340B Program Manager, Retail Business Services; Mike Fish, Regional Pharmacy Operations Manager- NY & VT, Retail Business Services; and Scott Guidinger, Vice President of Pharmacy, Price Chopper/Market 32
- Brian Murphy, Director of Pharmacy and Vendor Management, Blue Cross Blue Shield of Vermont
- Michael Fisher, Chief Health Care Advocate, Kaili Kuiper, Attorney, and Sam Peisch, Policy Analyst, Vermont Legal Aid

II. An overview of the 340B drug pricing program

The 340B drug pricing program was created by Congress in 1992 in Section 340B of the Public Health Service Act to allow health care providers that serve a disproportionately large share of uninsured or disadvantaged patients (known as covered entities) "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1] It does this by allowing covered entities to purchase covered outpatient prescription drugs from participating drug manufacturers at significantly discounted prices. The program is administered by the U.S. Health Resources and Services Administration (HRSA), part of the U.S. Department of Health and Human Services (HHS). The 340B program is unique among federal programs, in that it shifts costs from one group of private entities (health care providers) to another (drug manufacturers).

The 340B program is modeled on the Medicaid drug rebate program (MDRP), which requires drug manufacturers to pay rebates to states on drugs purchased for Medicaid. Congress intended for 340B to furnish safety net providers with "the same kind of relief from high drug costs" given

[1] 340B Drug Pricing Program | Official web site of the U.S. Health Resources & Services Administration (hrsa.gov). Section 340B of the Public Health Service Act is codified at 42 U.S.C. § 256b.

to states through the MDRP.[2] Protocols exist to help ensure drug manufacturers do not provide a covered entity with a 340B discount and pay a state an MDRP rebate on the same drug.

A. Participants in 340B

Direct participants in the 340B program include covered entities, prescription drug manufacturers, independent and chain pharmacies, and state Medicaid programs. Other interested parties include drug wholesalers, PBMs, and commercial insurers.

Covered entities

Health care providers eligible as covered entities to participate in 340B include federally qualified health centers (FQHCs), children's hospitals, critical access hospitals, freestanding cancer hospitals, sole community hospitals, rural referral centers, public and nonprofit disproportionate share hospitals, and specialized clinics receiving federal grant funding, such as Planned Parenthood and Ryan White HIV/AIDS program grantees. Each covered entity must register and annually certify its eligibility with HRSA. It may also register any "child sites," which are associated outpatient facilities included in the covered entity's Medicare cost report. In 2020, 12,700 registered covered entities throughout the country participated in the 340B program.[3] There are currently 89 registered Vermont covered entities (plus numerous child sites), including all hospitals and most FQHCs in the State.[4]

Drug manufacturers

To have its drugs covered by Medicaid, a drug manufacturer must participate in the 340B program by signing a pharmaceutical pricing agreement with HHS. As of January 1, 2015, there were 644 drug manufacturers participating in the 340B program.[5]

Contract pharmacies

Guidance issued by HRSA permits covered entities to contract with one or more outside pharmacies to dispense 340B drugs to patients. Covered entities must maintain oversight of their contract pharmacies, including by conducting period audits, and ensure each pharmacy's compliance with program requirements. As of November 30, 2021, the HRSA Office of Pharmacy Affairs Information System (OPAIS) lists 1039 active pharmacy contracts for Vermont covered entities.[6]

[2] Medicaid Drug Rebate Program (MDRP) | Medicaid; Detailed Overview - 340B Health
[3] GAO-21-107, DRUG PRICING PROGRAM: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements
[4] Vermont & the 340B Drug Pricing Program
[5] Federal Register: 340B Drug Pricing Program Omnibus Guidance
[6] Office of Pharmacy Affairs 340B OPAIS (hrsa.gov)

B. Program requirements

Under 340B, a manufacturer may not charge a covered entity more than the 340B ceiling price for a covered outpatient drug. Ceiling prices are calculated quarterly by HRSA and published on a secure website. The ceiling price for a drug is its average manufacturer price (AMP), minus the applicable unit rebate amount (URA), which is a minimum 23.1 percent for most brand name drugs, 17.1 percent for certain brand name pediatric drugs and clotting factor, and 13 percent for generic drugs. Brand name drugs are subject to a greater rebate amount if the manufacturer's best price for the drug (the lowest available price to any wholesaler, retailer, or provider, other than certain government programs) is lower than the AMP minus the URA. Both generic and brand name drugs are subject to a greater rebate amount if the drug's price has increased more quickly than the rate of inflation. This can result in some drugs being priced at one cent, commonly known as "penny pricing."[7]

Covered entities purchase 340B discounted drugs—either through a drug wholesaler or directly from a participating manufacturer—and dispense them to patients via in-house and/or outside pharmacies. If the patient receiving the drug is covered by a commercial insurance policy, the commercial insurer reimburses the covered entity for the list price of the drug (less the patient's co-pay amount). If the patient is covered by Medicare Part B, the federal Medicare program reimburses the covered entity for the drug at a rate set annually in rule. Importantly, in each case, the covered entity retains the difference between the 340B discounted price and the reimbursed amount. For patients covered by Medicaid, 340B discounts must be passed through to the state Medicaid program. According to HRSA, covered entities can realize substantial savings for drugs purchased through the 340B program.[8]

Neither the 340B statute nor program guidance specifies how covered entities must use 340B savings, except to say the program is intended to help covered entities "[reach] more eligible patients and [provide] more comprehensive services."[9] Covered entities are required to recertify their eligibility on an annual basis and "maintain auditable records documenting compliance with 340B program requirements."[10] However, HRSA has not imposed additional reporting requirements.

The 340B statute imposes specific restrictions on discounted drug purchasing. Certain hospital covered entities, including disproportionate share hospitals,[11] are prohibited from purchasing 340B drugs through group purchasing arrangements. In addition, manufacturers are not required

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[7] Detailed Overview - 340B Health

[8] GAO-21-107, DRUG PRICING PROGRAM: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements

[9] 340B Drug Pricing Program | Official web site of the U.S. Health Resources & Services Administration (hrsa.gov)

[10] Program Requirements | Official web site of the U.S. Health Resources & Services Administration (hrsa.gov)

[11] Disproportionate share hospitals serve a disproportionately high share of Medicaid-eligible and uninsured patients and are eligible to receive payments from the Centers for Medicaid and Medicare Services to cover the costs of providing care to that population. *See* 42 U.S.C. § 1395ww (d)(1)(B).

to offer 340B drug pricing on certain drugs designated by HHS for rare diseases or conditions (orphan drugs) to some covered entity hospitals.

The 340B program statute prohibits covered entities from diverting 340B drugs to persons other than patients. A patient is defined by HRSA as a person who:

- has an established relationship with the covered entity, such that the covered entity maintains records of the person's health care;
- receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity; and
- in case of a covered entity that is a federal grantee, the person receives a health care service or range of services from the covered entity that is consistent with the service or range of services for which grant funding or FQHC look-alike status has been provided to the entity.[12]

An individual is not considered a "patient" of a covered entity if the only health care service they receive is the dispensing of prescription drugs.[13]

In addition to preventing diversion of 340B drugs to non-patients, covered entities must ensure that manufacturers do not pay duplicate Medicaid discounts on 340B drugs (meaning they do not sell a drug at the 340B ceiling price to a covered entity and pay an MDRP rebate to a state Medicaid program on the same prescription). Preventing drug diversion and duplicate discounts becomes more complex when covered entities utilize contract pharmacies to dispense 340B drugs.

C. Contract pharmacy participation in 340B

The 340B program statute is silent as to how covered entities may dispense 340B discounted drugs to patients. Distribution methods have broadened over time. When the 340B program was created, covered entities distributed eligible drugs through in-house pharmacies only. In 1996, HRSA issued guidance allowing covered entities without adequate in-house pharmacies to contract with one outside pharmacy to dispense 340B drugs to patients. In 2001, HRSA began allowing covered entities to use a contract pharmacy to supplement an in-house pharmacy if they obtained advance approval. Finally, in 2010, HRSA updated its guidelines to permit covered entities to utilize an unlimited number of contract pharmacies, to facilitate participation in the 340B program and "increase patient access to 340B drugs."[14]

Using outside pharmacies allows providers without in-house pharmacies to participate in 340B. It also expands the reach of 340B by providing patients with access to multiple locations and expanded hours to fill their prescriptions. According to the American Hospital Association,

[12] 96-27344.pdf (govinfo.gov)
[13] *Id.*
[14] 2010-4755.pdf (govinfo.gov)

"contract pharmacies serve as an extension of the 340B provider and provide patients access to prescription drugs outside of the four walls of the hospital or community clinic."[15]

Many hospitals also contract with specialty pharmacies to dispense 340B drugs to patients. Drugs dispensed through specialty pharmacies are typically very expensive and prescribed to treat rare or complex health conditions. They may be administered to patients in outpatient settings (such as oncological infusions) or shipped directly to patients via mail order.

The Department of Vermont Health Access does not allow covered entities to utilize contract pharmacies to dispense drugs to patients covered by Medicaid.[16] However, Vermont covered entities may utilize contract pharmacies for 340B drug distribution to patients covered by commercial insurance. To dispense 340B drugs through an outside pharmacy, a covered entity must enter into a written contract with the pharmacy. Typically, the covered entity purchases discounted 340B drugs from a wholesaler or manufacturer and directs the wholesaler or manufacturer to ship the drugs to the contract pharmacy for dispensing to the covered entity's patients. The covered entity is ultimately responsible for the contract pharmacy's compliance with 340B program requirements, including by ensuring that it does not divert drugs to individuals who are not patients of the covered entity, and that it maintains complete records for audit by the covered entity or HRSA.

The Department spoke with representatives of both independent pharmacies and chain pharmacies. Independent pharmacies expressed a number of complaints about the program, mainly implicating PBMs, while chain pharmacies generally felt that the 340B program works well but has room for improvement. Covered entities and HRSA say contract pharmacies are important to the 340B program because they provide patients with increased access to prescription drugs at convenient locations with expanded hours. Manufacturers, on the other hand, argue that contract pharmacies generate significant profits through participation in 340B, while failing to provide discounts to patients, and increase the risks of drug diversion and duplicate discounts.

In 2014, the HRSA Office of Pharmacy Affairs reported that "the overwhelming majority (82 percent) of covered entities do not contract with pharmacies. Of the approximately 20 percent of covered entities that have an arrangement with a contract pharmacy, 75 percent have fewer than five contract pharmacy arrangements."[17] However, the number of participating pharmacies, particularly large chain pharmacy locations, has increased significantly over the past ten years and nearly all of the recent controversies and litigation related to the 340B program (discussed in sections III and IV) implicate contract pharmacies. *Drug Channels*, a website providing pharmaceutical economic analysis and commentary, states that there were 29,971 contract pharmacies in June 2021, a more than 2000 percent increase since 2010.[18] According to a University

[15] Fact Sheet: 340B Drug Pricing Program Contract Pharmacy Arrangements | AHA
[16] Vermont Medicaid does allow the use of outside pharmacies owned by covered entities.
[17] Contract Pharmacy Oversight | Official web site of the U.S. Health Resources & Services Administration (hrsa.gov)
[18] Drug Channels: Exclusive: 340B Continues Its Unbridled Takeover of Pharmacies and PBMs

of Southern California health policy paper, four of the largest pharmacy chains—Walgreens, CVS, Walmart, and Rite Aid—accounted for over 60% of 340B contract pharmacy locations in 2020.[19]

Specialty pharmacies, many owned by PBMs, dispense a disproportionate share of 340B drugs. According to *Drug Channels*, "the non-retail pharmacies [owned by the three largest PBMs, CVS Health, Express Scripts, and OptumRx] account for only 0.5% of 340B contract pharmacies—but 18% of 340B contract pharmacy relationships" and "340B sales through mail and specialty pharmacies grew by 55% in 2020."[20] This growth may be linked, in part, to the increasing consolidation of pharmacies, PBMs, insurance companies, drug wholesalers, and providers in a process known as vertical integration. Many health care industry commentators view vertical integration as problematic for providers and consumers of health care. For example, the AIDS Healthcare Foundation (AHF) joined other providers in urging the U.S. Department of Justice and the Federal Trade Commission to strengthen merger guidelines. The AHF stated that, "in part because of lack of regulation and transparency in the PBM industry, [vertically integrated] firms can operate secretly, which allows them to take outsized profits from rebates, spread-pricing and oppressive reimbursement practices."[21] Sections III and IV of this report refer to issues related to vertical integration, however, a full analysis is beyond its scope.[22]

III. Medicaid and commercial rebates

A. Medicaid rebates

To participate in Medicaid, drug manufacturers must both provide drug rebates to states under the MDRP and discounts to covered entities under the 340B program. Although closely connected, the MDRP and 340B are administered separately by HHS. The 340B program statute requires covered entities and states to have mechanisms in place to prevent Medicaid "duplicate discounts" or the provision of 340B discounts and MDRP rebates on the same prescriptions.

The Medicaid Drug Rebate Program was established by Congress two years before the 340B program, as part of the Omnibus Budget Reconciliation Act of 1990, to lower the cost of drugs reimbursed by state Medicaid agencies.[23] The MDRP requires each Medicaid-participating drug manufacturer to enter into a national rebate agreement with HHS. Under this agreement, a manufacturer must pay states quarterly rebates of their Medicaid payments on the manufacturer's drugs, and states must share a portion of these rebates with the federal government, determined by their current federal medical assistance percentage.

The MDRP and the 340B program utilize the same percentages to calculate discounts and rebates on brand name and generic drugs. Like 340B discounts, MDRP rebates are calculated quarterly

[19] The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments – USC Schaeffer
[20] Drug Channels: Exclusive: 340B Continues Its Unbridled Takeover of Pharmacies and PBMs
[21] AHF Sounds Alarm to FTC and DOJ on how Vertical Integration in Healthcare Harms Patients, Providers and Pharmacies | Business Wire
[22] Drug Channels: Specialty Pharmacy's Explosive 340B Growth
[23] 42 U.S.C. § 1396r–8

by HHS based on average manufacturer prices. However, unlike 340B discounts, which are provided by manufacturers to covered entities at the point of purchase, MDRP rebates are paid retroactively each quarter. To obtain each quarterly rebate, a state must track its Medicaid drug purchases and submit an invoice to the manufacturer.

To help states avoid duplicate discounts, HHS created the 340B Medicaid exclusion file (MEF) to "serve as the official data source to determine whether covered entities have opted to bill 340B drugs under Medicaid..."[24] When a covered entity enrolls in the 340B Program, it must inform HRSA whether it will "carve in" (i.e. include) or "carve out" its Medicaid fee-for-service (FFS) patients.[25] If it carves them in, the covered entity chooses to purchase and dispense discounted 340B drugs to its Medicaid FFS patients. If it carves them out, the covered entity agrees to dispense only drugs purchased outside of the 340B program to its Medicaid FFS patients. States refer to the MEF to determine whether or not covered entities have purchased drugs under 340B when submitting their MDRP rebate requests.

In Vermont, covered entities that carve in their Medicaid patients must submit all drug claims to the Department of Vermont Health Access (DVHA), which administers the State's Medicaid program. As required by the Centers for Medicare and Medicaid Services (CMS), DVHA reimburses covered entities for all drugs based on their actual acquisition cost (AAC) plus a professional dispensing fee.[26] On a monthly basis, DVHA produces a file for each covered entity that lists all drug claims paid in the prior month. Covered entities must identify each drug that was acquired under the 340B program and specify its AAC, which may not exceed the 340B ceiling price. If necessary, DVHA adjusts the total amount reimbursed for the month and charges the covered entity for any amount that DVHA overpaid.[27] This process is time consuming and difficult for both DVHA and covered entities.

B. Commercial rebates

Although 340B prohibits Medicaid duplicate discounts, there is no corresponding prohibition on the payment of duplicate discounts on drugs prescribed to commercially insured payments. The payment of commercial rebates is solely a matter of contract between a manufacturer and a PBM or commercial insurance company.

Most commercial health insurers contract with a PBM to serve as an intermediary between the insurance company and drug manufacturers. The purpose of a PBM is to help an insurer keep prescription drug costs down by creating and managing the insurer's drug formularies, administering its drug claims, and negotiating drug rebates with manufacturers on its behalf. In return, the PBM charges the insurer an administrative fee or retains portions of the rebates negotiated. There are currently 66 PBMs; the three largest, Express Scripts, CVS Caremark, and OptumRx, control approximately 89 percent of the market.[28]

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[24] 340B CIB (medicaid.gov)

[25] There is currently no such policy for drugs dispensed to Medicaid managed care patients.

[26] Att 4.19-B.pdf (vermont.gov)

[27] Microsoft Teams meeting with Nancy Hogue. October 29, 2021.

[28] aha-sens-alexander-rep-walden-express-support-340b-drug-pricing-program-letter-10-29-20.pdf

In negotiating drug prices with a manufacturer, a PBM often agrees to place a drug in a favorable position on a health plan's formulary in exchange for a rebate from the manufacturer equal to the difference between the negotiated price and the list price of the drug. The PBM passes all or a portion of the commercial rebate on to the insurer it represents, depending on the terms of their contract. Manufacturers may negotiate contracts that allow them to withhold commercial rebates on discounted 340B drugs. However, they say that a lack of transparency related to contract pharmacy arrangements often subjects them to "double dipping," or having to pay rebates on 340B drugs in violation of their contracts and they may even be forced to sell drugs at a loss. Large commercial insurers and PBMs may negotiate for the payment of commercial rebates regardless of a drug's 340B status and feel that commercial rebates are unrelated to the 340B program.

IV. 340B controversies and their implications for Vermont stakeholders

Although all 340B program participants and major stakeholders publicly support the program's intent—to ensure vulnerable patients' access to health care—they tend to disagree about how program revenue should be utilized or shared. In addition, the increasing role of contract pharmacies and PBMs in the program over the past decade has led to disputes over fees, revenue, and rebates. This section will overview issues and controversies related to 340B and cite the perspectives of each stakeholder group on the issues that impact them.

A. Uses of 340B savings and lack of program transparency

Most covered entities believe that the program has served and continues to serve its intended purpose of providing essential discounts to safety net hospitals and other health care providers, which helps those providers reach more vulnerable patients.[29] However, they argue that for-profit entities like manufacturers, pharmacies, PBMs, and commercial insurers are increasingly diverting crucial funds away from covered entities. Others, including many drug manufacturers, have accused hospitals of profiting off the 340B program while failing to offer discounts or expand services to uninsured and low-income patients. They argue that changes are necessary to realign the 340B program with its original objective of directly benefiting uninsured and otherwise vulnerable patients.[30]

Covered entities are not required to use savings to directly benefit low income and other underserved patients or to pass discounts through to patients. However, some (particularly FQHCs) choose to do so via sliding scale and other discounted fee structures. Many covered entities use savings to support their operations, expand programs and services, and make improvements to infrastructure.

When Congress created the 340B program in 1992, participation was limited to safety net providers such as FQHCs, disproportionate share hospitals, and specialized clinics receiving federal funding. These providers, which serve a large proportion of uninsured and indigent

[29] Pharmacy Benefit Managers (naic.org); About - 340B Health

[30] 2020-10-30-PhRMA-Response-to-Alexander-Walden-RFI_Modernizing-340B-Program.pdf; Drug Channels: How Hospitals and PBMs Profit—and Patients Lose—From 340B Contract Pharmacies

patients, say that 340B program revenues are necessary to sustain their ongoing operations. The program allows FQHCs to offer lower cost drugs or decrease cost sharing for patients and provides revenue to support other essential patient benefits such as food programs. A 2018 National Association of Community Health Centers policy paper states that, "due to their slim operating margins, many health centers report that without the savings from the 340B program they would be limited in their ability to support many of their core services for their patients."[31] Bi-State Primary Care, which represents Vermont FQHCs, agrees with this statement. The Department heard that, without savings from the 340B program, most or all Vermont FQHCs would have to cut patient benefits and the impact would be catastrophic.

In 2010, the Patient Protection and Affordable Care Act expanded 340B eligibility to include most types of public and private hospitals. Many of these hospitals also provide a safety net for their communities. They tend to operate at low margins and "the 340B program is essential to helping [them] stretch limited resources to better serve their vulnerable communities."[32]

Some Vermont hospitals say they are completely dependent on the program to remain financially stable; the program constitutes every Vermont hospital's operating margin. The University of Vermont Health Network, which includes 3 hospitals in northern New York, reported that, in fiscal year 2019, its margin for Vermont hospitals was only 2.5 percent, and Vermont hospitals saved over $100 million by participating in the 340B program. The 340B program appears to be an imperfect but meaningful solution to provide financial support for covered entities that provide health care services to Vermonters. The Department heard from a representative of UVM Health Network that, "without 340B, health care in Vermont would look very different and cost Vermonters a great deal more."[33] A 2019 study published in the *Journal of the American Medical Association Network Open*, found that nationwide in 2016, revenues from administering 340B drugs to Medicare beneficiaries alone accounted for 0.3% of hospital operating budgets and 9.4% of hospital uncompensated care costs.[34]

There are no statutory guidelines as to how covered entities must use 340B program revenues and little data is available to evaluate the costs and benefits of 340B, since covered entities are not required to report how they use 340B savings. Groups like PhRMA lobby for increased 340B program reporting by covered entities to ensure they are using revenues to expand access to care. Some reports have attempted to quantify the use of 340B savings, but results vary widely. A 2018 report in *The New England Journal of Medicine* states that "the [340B] program is intended to expand resources for underserved populations but provides no direct incentives for [disproportionate share] hospitals to use financial gains to enhance care for low-income patients."[35] A 2021 USC health policy paper cites studies that show 340B has positive impacts for both covered entities and consumers: one study showed that when HIV/AIDS patients receive their drugs from a 340B

[31] NACHC-2018-Policy-Paper-340B.pdf
[32] Fact Sheet: The 340B Drug Pricing Program | AHA
[33] Vermont & the 340B Drug Pricing Program
[34] Conti RM, Nikpay SS, Buntin MB. Revenues and Profits from Medicare Patients in Hospitals Participating in the 340B Drug Discount Program, 2013-2016. *JAMA Netw Open*. 2019;2(10):e1914141. doi:10.1001/jamanetworkopen.2019.1414
[35] Consequences of the 340B Drug Pricing Program | NEJM

covered entity, they tend to have higher medication adherence; and another demonstrated that 340B hospitals provide more medication access services and are more likely to provide drug treatment and HIV/AIDS outpatient services than non-340B hospitals.[36]

Because 340B lacks requirements for how covered entities must utilize savings or even report how savings are used, it is difficult to quantify the program's impacts on consumers. However, it is well known that many covered entities, particularly federally qualified health centers, provide medication assistance to consumers in the form of discounts or sliding-scale fees. Some Vermont hospitals, including the University of Vermont Medical Center (UVMMC), run health programs that help low-income Vermonter's access low- or no-cost prescription medications. These benefits are supported, at least in part, with 340B savings. On the other hand, the Department heard that 340B program revenues fund the growth of health care infrastructure, which increases covered entities' operating costs. In response, covered entities must negotiate higher reimbursements from commercial insurers and this may contribute to higher health insurance costs for consumers.

The lack of program transparency has become more apparent as covered entities' use of contract pharmacy arrangements has increased. In 2017, approximately 20,000 contract pharmacies participated in the 340B program, a more than 15-fold increase since 2010.[37] According to a 2017 GAO report, HRSA does not receive enough information on the use of contract pharmacy arrangements to oversee and prevent abuses of the 340B program. The GAO also calls HRSA's audit process insufficient, saying "weaknesses in its audit process impede the effectiveness of [HRSA's] oversight."[38]

Some stakeholders in Vermont's health care industry, including commercial insurers, also believe that 340B's misaligned incentives and lack of transparency is leading to increased list prices for drugs and, hence, increased health care costs for consumers. For example, a 2018 *Health Services Research* study found that 340B led to a shift in cancer care from physician's offices to more expensive hospitals and an increase in per-patient spending on cancer care.[39] An older *Journal of the American Medical Association* article suggested 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. It also suggested that manufacturers could increase list prices "to offset revenue losses incurred as a larger number of drug sales become eligible for 340B discounts (and thus fewer drugs are sold at full price)."[40] On the other hand, another study actually found that 340B contributed to list price *reductions* for certain drugs. A 2019 study published in the *Journal of the American Medical Association* found that they were able to sell a higher number of hepatitis C treatments through 340B and, even though they provided

[36] The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments – USC Schaeffer

[37] GAO-18-480, DRUG DISCOUNT PROGRAM: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement

[38] *Id.*

[39] Impact of the 340B Drug Pricing Program on Cancer Care Site and Spending in Medicare - Jung - 2018 - Health Services Research - Wiley Online Library

[40] Cost Consequences of the 340B Drug Discount Program (nih.gov)

those treatments at the 340B ceiling price, manufacturers were actually able to increase net revenues.[41]

B. Drug diversion

Drug manufacturers also argue that contract pharmacy use results in the diversion of 340B drugs to nonpatients, as most pharmacies use virtual inventory and replenishment models rather than separate physical inventories. Hence, they cannot be certain in each case that 340B drugs are dispensed solely to patients of covered entities.

Covered entities are ultimately responsible for contract pharmacies' compliance with 340B program rules. However, pharmacies must keep track of 340B drugs dispensed and properly identifying 340B claims can be challenging. Some pharmacies keep separate inventories of 340B and non-340B drugs to avoid concerns about diversion, but most utilize a virtual inventory and replenishment model. Under this model, when a pharmacy has dispensed a sufficient quantity of drugs on behalf of a covered entity, a software program or third-party administrator signals to the covered entity that it should purchase additional 340B drugs to replenish the pharmacy's stock. Some manufacturers argue that this method necessarily constitutes illegal diversion of 340B drugs to non-patients.[42]

C. Drug manufacturers' withholding of 340B discounts

The 340B program clearly provides much needed revenue for covered entities in Vermont. However, manufacturers say that it has grown too large, does not benefit patients, and lacks proper oversight. They contend that hospitals, contract pharmacies, and PBMs profit from 340B, which is not the intent of the program. Many manufacturers object to the use by covered entities of unlimited contract pharmacy arrangements. Beginning in July 2020, at least eight large drug manufacturers have begun withholding 340B discounts on drugs dispensed through contract pharmacies or taken actions to limit 340B participation by contract pharmacies.

Some manufacturers have refused to provide 340B discounts on drugs dispensed through contract pharmacies or altogether to covered entities that contract with more than one pharmacy. Some have required contract pharmacies to submit significant additional data reporting to identify 340B drug claims.

Many drug manufacturers argue that the 340B program is not intended to financially benefit pharmacies and that there is little evidence that contract pharmacy participation in 340B has positively impacted low-income patients. Some claim that contract pharmacies earn more revenue from 340B flat fees than they do from typical profit margins from dispensing non-340B

[41] Estimated Changes in Manufacturer and Health Care Organization Revenue Following List Price Reductions for Hepatitis C Treatments | Clinical Pharmacy and Pharmacology | JAMA Network Open | JAMA Network

[42] Eli Lilly argues this in its pending federal lawsuit against HHS (discussed in section IV).

drugs.[43] A report funded by Pharmaceutical Research and Manufacturers of America (PhRMA) indicated that a contract pharmacy's average profit margin for 340B drugs is approximately 72 percent, compared with 22 percent for non-340B drugs.[44]

Drug manufacturers also say they are being squeezed by PBMs obtaining commercial rebates on 340B drugs, often in violation of their contracts, because there is insufficient information to identify 340B drug claims. If a manufacturer issues a commercial rebate to a PBM on the wholesale acquisition cost of a drug that it has sold to a covered entity at the 340B ceiling price, it may ultimately lose money on that transaction. However, because contract pharmacies do not or cannot identify 340B drug claims as such at the point of sale, a manufacturer cannot know whether to pay the rebate. For this reason, some manufacturers are withholding commercial rebates altogether with respect to drugs sold through 340B contract pharmacies and, to offset this lack of rebate revenue, some commercial insurers and their PBMs are reducing reimbursements for 340B drugs.

It should be noted that the Department also heard from a vertically integrated chain drug store that owns a PBM that the issue of double dipping has been overstated. The chain states that 340B drugs are identified and Medicaid rebates are paid in a fairly timely manner, whereas commercial rebates are paid much later, when a drug claim has already been identified as a 340B claim. According to this commenter, PBMs use software to appropriately identify 340B drug claims and avoid duplicate rebate requests.

The withholding of 340B drug discounts by manufacturers has resulted in a number of 340B-related lawsuits that are pending in federal courts. Commentators and 340B participants hope that decisions in these cases will provide much-needed clarity around the intent and scope of the 340B program.

In July 2020, the major drug manufacturer Eli Lilly & Co. ceased providing 340B discounted drugs (other than insulin) to contract pharmacies. Manufacturers Merck, Sanofi, Novartis, AstraZeneca, and United Therapeutics took similar or related actions soon after.[45] In September 2020, HRSA sent a letter to Eli Lilly expressing concern with the policy, but declined to initiate any enforcement action, indicating that it lacks authority to enforce its own 340B guidance.[46]

At least three groups of covered entities, including Ryan White Clinics for 340B Access (the national association of HIV/AIDS clinics), the National Association of Community Health Centers, and the American Hospital Association have sued HHS in federal court for HRSA's

[43] Drug Channels: The Booming 340B Contract Pharmacy Profits of Walgreens, CVS, Rite Aid, and Walmart

[44] New Analysis Shows Contract Pharmacies Financially Gain From 340B Program with No Clear Benefit to Patients | PhRMA

[45] The manufacturer agreed to provide discounted insulin, but only if the contract pharmacy did not mark up the price or charge a dispensing fee.

[46] letter from Robert P. Charrow, General Counsel, HRSA to Anat Hakim, Senior Vice President and General Counsel, Eli Lilly and Co. (Sep. 21, 2020), *available at* https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hhs-eli-lilly-letter.pdf.

failure to act.[47] Several state attorneys general have sided with the covered entities. Vermont Attorney General TJ Donovan joined a group of 29 state AGs in sending a letter to HHS then-Secretary Azar in December 2020, asking him to address the drug manufacturers' refusal to provide 340B drug discounts. In the letter, the attorneys general asked HHS to use its existing enforcement authority to "immediately address flagrant and clear statutory violations by the drug manufacturers."[48] In December 2020, HHS issued a nonbinding advisory opinion stating that, "to the extent contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs."[49]

On Jan. 13, 2021, HRSA implemented a binding alternative dispute resolution (ADR) process for the 340B program. The rule states that "the purpose of the ADR process is to resolve (1) claims by covered entities that they have been overcharged for covered outpatient drugs by manufacturers and (2) claims by manufacturers, after a manufacturer has conducted an audit as authorized by the 340B statute, that a covered entity has violated the prohibition on diversion or duplicate discounts."[50] The creation of the ADR process has prompted many covered entities to file claims seeking redress against drug manufacturers.

In May 2021, HRSA sent letters directing the drug manufacturers to stop denying 340B discounts and notifying them that restricting covered entity access to 340B-discounted drugs through contract pharmacy arrangements has resulted in overcharges and directly violates the 340B statute. When the manufacturers continued to refuse, HRSA referred the violations to the HHS Office of the Inspector General under a rule that allows HHS to impose penalties of up to $5,000 for each instance of overcharging.[51] In response, each manufacturer sued HHS to block it from enforcing 340B and asking the court to rule that the 340B program statute does not require manufacturers to offer 340B discounted pricing for drugs dispensed through contract pharmacies. The Department of Justice filed a brief in support of HHS in one of the manufacturer's lawsuits, saying that covered entities are losing $3.2 billion per year in 340B program savings due to manufacturer restrictions on contract pharmacy access to 340B drugs.[52]

Decisions have been issued by federal courts in some of the cases and have varied widely. Some courts have upheld manufacturers' actions and others have supported enforcement measures undertaken by HHS. Notably, in a ruling in one of those manufacturer lawsuits against HHS, a U.S. District Court judge called for a "holistic legislative proposal to bring clarity to the scope of the regulated parties' obligations and entitlements under the statute with regard to contract pharmacy arrangements rather than… piecemeal interpretations and after the fact patchwork

[47] BREAKING: Hospitals Sue HHS Over Drug Companies' Denials of 340B Pricing – 340B Report
[48] 340B Multistate Letter FINAL 12.14.2020 (1) (ca.gov)
[49] 340B-AO-FINAL-12-30-2020_0.pdf (hhs.gov)
[50] 2020-27440.pdf (govinfo.gov)
[51] Program Integrity | Official web site of the U.S. Health Resources & Services Administration (hrsa.gov); 2016-31935.pdf (govinfo.gov)
[52] Pharma's 340B Contract Pharmacy Limits Are Costing Providers $3.2 Billion a Year, DOJ Tells Court – 340B Report

characterizing the history of the agency's attempts to manage this program."[53] Some decisions have been appealed and most cases remain pending. Unfortunately, at this point, it is unclear whether courts will reach a consensus or Congress will act.

D. Discriminatory reimbursement by PBMs

Some contract pharmacies report that PBMs are increasingly engaging in behaviors that make the pharmacies reluctant to continue participating in 340B. Many covered entities have accused PBMs of engaging in discriminatory reimbursement—reimbursing covered entities (through their contract pharmacies) for 340B drugs at lower rates than for non-340B drugs—or establishing barriers to pharmacy participation in the 340B program. Others may require contract pharmacies to identify 340B drug claims by using special codes at the point of sale in order to continue receiving 340B drug deliveries. In February 2021, for example, pharmacy benefit manager Express Scripts informed pharmacies that it would require them to implement new claims identification processes for 340B-eligible claims and require resubmission of claims that are later identified as being 340B-eligible. This identification system presumably allows the PBM to identify and pay lower reimbursement rates for 340B drugs. However, pharmacies told the Department that they do not have access to whether a drug is 340B-eligible at the point of sale. Pharmacies were given ten days to implement Express Scripts' new requirements, which pharmacy lobbyists argued would be complicated and burdensome.[54] The Department, however, did not specifically investigate whether and how these new requirements impacted Vermont pharmacies.

Pharmacy benefit managers may feel that reimbursing covered entities less for 340B drugs than for non-340B drugs is appropriate because contract pharmacy participation in the 340B program has contributed to a loss in rebate revenue. Manufacturer rebates are a significant source of PBM revenue and PBMs argue that they use these rebates to compensate pharmacies and reduce premiums for individuals insured by commercial insurance plans. PBMs claim that when manufacturers withhold rebates on 340B drugs, they must also reduce payments on these drugs.[55] However, by withholding 340B savings from covered entities or preventing them from accessing pharmacies to dispense 340B drugs to patients, covered entities say that PBMs "essentially transfer the benefit of the program from safety net providers to for-profit payers."[56]

E. Drug manufacturers' withholding of commercial rebates on non-340B drugs

[53] *Eli Lily and Co. v. U.S. Dep't of Health and Human Servs.*, No. 1:21-cv-00081-SEB-MJD, Order at 58-59 (Oct. 29, 2021).

[54] Express Scripts' New 340B Rules Will Have Big Impact on Contract Pharmacy and Drug Reimbursement, Providers and Consultants Say – 340B Report

[55] Opening Statement + PBMs and 340B White Paper (D0950558-2).DOCX (340breport.com)

[56] *Id.*

Many commercial insurers accuse manufacturers of using 340B to withhold or attempt to withhold rebates on *non*-340B drugs.[57] This is the opposite of what drug manufacturers allege—that they are being harmed by double-dipping.

Even if commercial insurers concede that a drug manufacturer should not be responsible for providing both a 340B drug discount and a commercial rebate on the same prescription, the Department heard that the program is indirectly causing many manufacturers to fail to pay negotiated commercial rebates on non-340B drugs. Since many pharmacies do not know whether drugs are 340B-eligible at the point of sale (or even after), the PBM must estimate the proportion of total claims that are 340B-eligible. The PBM may intentionally overestimate the number of 340B-eligible drugs to avoid "double dipping" and potential clawbacks of rebates by manufacturers. However, for this reason, PBMs may also lose out on the corresponding commercial rebates. There is currently no data clearinghouse or other way for 340B eligibility to be reported to a PBM or for a PBM to true up rebate eligibility with a manufacturer at a later date, so many negotiated rebates go unpaid. When a manufacturer does not pay a negotiated rebate to a PBM, the PBM does not pass this rebate onto the commercial insurer, and the insurer's overall drug costs may increase. In turn, this may also increase the cost of health insurance for consumers. The Department heard that if "double dipping" of 340B discounts and commercial rebates is occurring, it is not occurring at the same rate as insurers are losing out on rebates.

F. PBM clawbacks of contract pharmacy fees

Contract pharmacies claim that "direct and indirect renumeration" (DIR) fees charged to them by PBMs may be a hurdle to 340B participation, particularly for independent pharmacies. Direct and indirect renumeration fees were originally tied to Medicare Part D claims but are increasingly being charged on commercial claims as well. They may take the form of reconciliations between claims and negotiated drug prices, PBM pay-to-play fees for a pharmacy to participate in a preferred network, or fees based on a pharmacy's performance. It is the latter that appears to be the most problematic for contract pharmacies. A contract pharmacy earns a flat dispensing fee for each 340B prescription dispensed. They may also pay a fee based on the percentage of revenue generated for each 340B prescription. Since performance-based DIR fees often take the form of clawbacks, contract pharmacies may not accurately account for them when calculating the contractual percentage of 340B drug reimbursement to pay to a covered entity. If a PBM claws back a DIR fee four to six months after the pharmacy has remitted payment to a covered entity, then the pharmacy may ultimately suffer a loss that cannot be recouped. The amount of DIR fees may also be unpredictable. The Department heard from a stakeholder that performance metrics used are often unclear and inconsistent. According to a *Pharmacy Times* white paper, "at times, the [DIR] fee is based on the 'performance' of the pharmacy. This means that the PBM can take money back from the pharmacy and create a situation where the pharmacy does not receive adequate reimbursement to cover its costs due to arbitrary 'performance' standards that

[57] The University of Vermont Health Network and other covered entities have self-funded health plans and, like commercial insurers, may engage PBMs to negotiate rebates with drug manufacturers. In this way, their incentives are aligned with commercial insurers.

frequently serve as a moving goal post… The fees create losses in revenue that, at times, may surpass the acquisition cost of the drug itself."[58]

G. Prescription drug penny pricing

Some manufacturers argue that 340B drug pricing, particularly "penny pricing," may have unintended consequences such as inappropriate prescribing practices. Penny pricing is intended to discourage manufacturers from raising the prices of drugs too often or quickly.

When a manufacturer raises the price of a 340B drug more quickly than the rate of inflation, the drug's ceiling price decreases and it may become subject to penny pricing, meaning the manufacturer must sell the drug to covered entities for one cent. Manufacturers argue that penny pricing forces them to sell drugs at a loss and may contribute to drug shortages if manufacturers choose to cease manufacturing such drugs. For example, when HRSA proposed the penny pricing rule in 2010, Bayer stated:

> Requiring manufacturers to charge a penny is not materially different from requiring them to give their drugs away for free -- which HRSA has acknowledged is 'not reasonable.' Penny pricing is not only giving away the product for free but is also requiring the manufacturer to absorb losses generated by manufacturing, distributing, and shipping the products. At a minimum, the taking by the government of a manufacturer's products should cover for the cost of manufacturing and distributing the product.[59]

Manufacturers also claim that 340B drug pricing, particularly penny-pricing, may contribute to the overprescribing of medications by covered entities. According to *Health Affairs*, "340B pricing [arguably] encourages providers to choose a higher-cost agent, even when a lower-cost therapy is available, because the spread will be larger and the profit margin therefore higher."[60] Although some studies suggest that 340B may increase hospital drug spending,[61] the Department is not aware of data that would allow for an evaluation of this behavior by Vermont covered entities.

H. Medicaid issues

The Department of Vermont Health Access finds the 340B program to be difficult to manage and burdensome for both itself and covered entities. In addition, there is a lack of transparency for state Medicaid programs regarding 340B discounts. If a covered entity "carves in" its Medicaid FFS patients, it is difficult for a state to confirm that accurate 340B drug discounts are passed through to Medicaid. A mandatory carve-out of Medicaid FFS patients would simplify the

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[58] White Paper: DIR Fees Simply Explained (pharmacytimes.com)

[59] Despite Industry Opposition, HHS to Fine Drug Companies for Overcharging Hospitals | RAPS

[60] The 340B Drug Discount Program | Health Affairs

[61] GAO-15-442, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals; Commercial payers spend more on hospital outpatient drugs at 340B participating hospitals (milliman.com)

process and allow DVHA to collect rebates on all claims, which would improve transparency regarding the net cost of drugs. However, some Vermont covered entities are hesitant to carve out their Medicaid FFS patients because they are afraid that doing so may impact their purchasing power over non-340B drugs. There are several reasons cited for this, the primary one being that it is typically more cost effective for covered entities to purchase 340B drugs through a group purchasing arrangement. However, if certain types of covered entities participate in 340B, particularly disproportionate-share hospitals, HRSA prohibits their participation in a group purchasing arrangement. If DVHA were to mandate that all Vermont covered entities carve out Medicaid patients from 340B, these entities would have to purchase drugs for Medicaid patients at wholesale acquisition cost, rather than at 340B discounted prices, which would raise purchasing costs for them overall.

I. Reimbursement for 340B drugs under Medicare Part B

The Supreme Court is set to rule soon on a case regarding the amount Medicare is required to reimburse hospital covered entities for drugs purchased under the 340B program. The case concerns a rule passed by CMS in 2017 that reduced reimbursement rates by Medicare to hospital covered entities for "specified covered outpatient drugs."[62] Instead of 6 percent above the average sales price of the drug (which Medicare paid prior to 2018 and continued to pay to non-covered entities), covered entities began receiving reimbursement at 22.5 percent below the average sales price. In 2018, this change resulted in savings to Medicare of approximately $1.6 billion. HHS indicated that it is not appropriate for Medicare to subsidize the operations of hospital covered entities by paying the standard rate for drugs purchased by such entities at significantly discounted prices.[63] A group of nonprofit hospitals and hospital associations sued HHS in response to the rule. The Supreme Court heard arguments in the case, *American Hospital Association v. Becerra*, on November 30, 2021.

V. Potential state responses

The 340B program lacks clarity, including with respect to contract pharmacy participation, covered entities' use of program savings, and the scope of HHS's authority. Both Congress and the judiciary appear poised to address the program's shortfalls. However, until there is additional statutory guidance or binding case law, states may be able to pass legislation directly addressing 340B issues. For example, some states (including Vermont) have enacted laws to address discriminatory reimbursement or improve transparency by 340B program participants. Other novel approaches may be subject to federal preemption challenges. The following is a compilation of actions taken by states to date, as well as suggestions provided to the Department by Vermont stakeholders. The Department has not undertaken an analysis of the potential for federal preemption of any of the state actions outlined below.

A. State support of federal solutions

[62] R1-2017-23932.pdf (govinfo.gov)

[63] Supreme Court 340B Hospitals Discounts Medicare Part B Drugs | Commonwealth Fund

Many stakeholders suggested to the Department that Vermont should lend its support to the implementation of solutions at the federal level. The Legislature could voice support for laws that have been introduced in Congress to increase program transparency or encourage HRSA to issue more decisive program guidance. Other stakeholders favor support of a third-party database for 340B drug claims to prevent rebate duplication and ensure the burden of identifying 340B claims does not fall disproportionally to pharmacies.

The PROTECT 340B Act of 2021, introduced by Representatives McKinley of West Virginia and Spanberger of Virginia in July of this year, would require HHS to contract with a third-party vendor to request and review itemized claims data from covered entities and Medicaid rebate data from state agencies. This database would protect drug manufacturers from paying duplicate Medicaid rebates on 340B discounted drugs; however, some have voiced concerns about potential data mining by drug manufacturers. Importantly, however, this bill does not propose to address commercial claims.[64]

B. State laws to address discriminatory reimbursement

Vermont recently enacted Act No. 74 (2021), which prohibits PBMs from requiring 340B-specific claims modifiers or restricting access to a pharmacy network or adjusting pharmacy reimbursement rates based on participation in 340B.[65] Although it is a temporary measure scheduled for repeal on January 1, 2023, most stakeholders and the Department agree that this is an important first step to addressing issues with the 340B program. At least 16 other states have enacted similar laws, some significantly more expansive than Act No. 74.

In May 2021, Arkansas passed the comprehensive Arkansas 340B Drug Pricing Nondiscrimination Act (the Arkansas act), which prohibits commercial insurers and PBMs from providing different reimbursement rates to 340B-participating and nonparticipating pharmacies, usurping the benefit of 340B drug-pricing savings from covered entities, refusing to cover 340B drugs, or "charging more than fair market value or seeking profit sharing in exchange for services involving 340B drug pricing," among other things.[66] The Arkansas act was set to become effective in July of this year. However, the Arkansas insurance department stayed enforcement of the law in response to a petition from PhRMA citing the pending federal court cases by drug manufacturers against HHS.

Several stakeholders suggested that it would be helpful for the State to enact laws more broadly regulating PBMs. The National Academy for State Health Policy has issued model legislation, which goes beyond 340B issues to require PBM licensure, create a fiduciary duty for PBMs to their insurance company clients, require PBMs to disclose conflicts of interest, and ban "gag clauses," which restrict pharmacies from providing price information to consumers, among other things. Representative Mari Cordes introduced H.353, an act relating to pharmacy benefit management, which would implement many such measures for consideration during the Legislative session.

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[64] Text - H.R.4390 - 117th Congress (2021-2022): PROTECT 340B Act of 2021 | Congress.gov | Library of Congress

[65] 18 V.S.A. § 9473

[66] HB1881 as engrossed on 04-15-2021 11:26:54 (state.ar.us)

C. Increased program transparency

Almost all stakeholders indicated they were in favor of increasing 340B program transparency. Some suggested that the Green Mountain Care Board could require additional reporting by covered entities, including accountings of how 340B savings are used and whether and how the savings benefit patients. Some covered entities, although not opposed to standardized reporting, worried about subjecting already burdened providers to additional administrative requirements. One stakeholder suggested that Vermont could explore building compliance guardrails around appropriate community investments and other uses of 340B savings by covered entities.

Transparency is also lacking for drug manufacturers and PBMs. For example, PBMs routinely withhold information about what they pay for prescription drugs and the rebates they negotiate with manufacturers. As noted in a 2007 law review article:

> The PBMs are the common counterparty with health plans, retail pharmacies, and drug manufacturers. Thus, no single entity of these entities knows the economics of the transactions with the other counterparties. This lack of transparency has created an environment in which PBMs may engage in practices that involve self-dealing or that are prohibited under various laws.[67]

Other stakeholders suggested, however, that since that HRSA has implemented its binding ADR process, additional reporting requirements to increase transparency are no longer necessary.

D. Use of 340B revenues to offset patient drug costs

Some stakeholders have proposed that covered entities be required to use a portion of 340B savings to directly offset prescription drug costs for consumers. For example, DVHA has proposed that the State create a fund, to which all Vermont covered entities would contribute, that would be used to offset out-of-pocket prescription drug costs for income-eligible Vermonters. The University of Vermont Health Network recently created such a network-wide Health Assistance Program (HAP) that uses 340B savings to help low- and middle-income patients afford prescription drugs. If a patient or family qualifies for HAP, UVM Health Network will use its 340B savings to waive their prescription drug co-pays and coinsurance at participating pharmacies.[68] In addition, the Green Mountain Care Board Prescription Drug Advisory Group is exploring the possibility of modifying the Healthy Vermonters Program into a 340B contract pharmacy program similar to HAP, but on a larger scale. All Vermont covered entities would be required to contribute a portion of their 340B savings to a fund that would be used to cover out-of-pocket costs for all patients of covered entities, regardless of income, on eligible 340B prescriptions filled at contract pharmacies.[69]

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[67] Allison Dabbs Garrett and Robert Garis, *Leveling the Playing Field in the Pharmacy Benefit Management Industry*, 42 Val. U. L. Rev. 33, 61 (2007).

[68] UVM Health Network expands access to affordable medications | Vermont Business Magazine (vermontbiz.com)

[69] PowerPoint Presentation (vermont.gov)

Similarly, West Virginia enacted a novel law this year that requires PBMs and commercial insurers to offset patient cost-sharing for a prescription drug at the point of sale by an amount equal to 100 percent of the rebates they receive for the drug. The amount of rebate left over can be used by insurers to reduce plan premiums. Since this is a novel approach, it is not yet clear how it will impact overall prescription drug costs, but the Department recommends that Vermont closely monitor data and analysis of West Virginia's law.

E. State-run wholesaler or switch operator

Finally, a stakeholder suggested that the State explore the creation of a State-run drug wholesaler or pharmaceutical switch operator. In 2017, a working group led by DVHA explored the possibility of the State "enter[ing] into a competitive pricing contract with a single drug wholesaler to supply drugs to Medicaid-enrolled pharmacies for the Vermont Medicaid program[, which] would not change the distribution of medications from wholesalers to pharmacies, and pharmacies to patients[, but] would change the payment system whereby DVHA would directly reimburse the wholesaler for drugs that pharmacies utilize for Medicaid members."[70] Although limited to Medicaid, the working group posited that such an arrangement could be expanded to commercial payers. The working group issued a request for information to wholesalers to identify savings opportunities but received no responses. Although the working group anticipated that the State could ultimately achieve cost savings and improved transparency with this system, it also identified certain negative impacts. For example, while this option may be attractive for independent pharmacies, chain pharmacies (which dispense a majority of 340B drugs in Vermont), would likely oppose it. The Department heard that, since most chain pharmacies have their own distribution networks, converting to a State-run wholesaler would not benefit them financially or operationally.

A pharmaceutical switch operator (or clearinghouse) is an entity that routes prescription drug claims between a pharmacy and a PBM or insurance company. Some advocacy organizations accuse switch operators of thwarting efforts to lower insurers' efforts to lower prescription drug costs by allowing manufacturers to "systematically and surreptitiously undermine plans' copay and deductible requirements via electronic vouchers."[71] A State-run switch operator would be incentivized to better contain costs and would also gain a clearer understanding of behind-the-scenes payment processing. However, providing a full analysis of this proposal is beyond the scope of this report.

VI. Recommendation

As noted by Judge Barker in the *Eli Lilly* decision, the 340B program "can no longer be held together and implemented fairly for all concerned with non-binding interpretive guidelines and mixed, sometimes inconsistent messaging by [HRSA] regarding the source and extent of its

[70] Sec.11a-Act-193-Prescription-Drug-Cost-Savings-and-Price-Transparency.pdf (vermont.gov)
[71] Manufacturers Are Using "Switch Operators" To Undermine Your Plan's Cost Saving Efforts | National Prescription Coverage Coalition

authority to enforce statutory compliance in the area of contract pharmacies."[72] In the absence of clear federal guidance, it is up to the states to ensure that the 340B program works equitably to ensure access to prescription medication.

Vermont can best accomplish this goal by implementing a comprehensive regulatory scheme for PBMs similar to the Arkansas act, which prohibits differential pricing and discriminatory rebating practices. Although the Arkansas act is currently the subject of litigation, the U.S. Supreme Court's 2020 decision in *Rutledge v. Pharmaceutical Care Management Assoc.* gives states far more leeway to impose regulatory regimes on entities like PBMs without being preempted by the Employee Retirement Income Security Act of 1974 (ERISA).[73] A comprehensive PBM regulation would have the additional advantage of bringing needed transparency and oversight into the market conduct of such entities without requiring the state to directly participate in the pharmaceutical market as either a wholesaler or switch operator.

[72] *Eli Lily and Co. v. U.S. Dep't of Health and Human Servs.*, No. 1:21-cv-00081-SEB-MJD, Order at 59.

[73] "ERISA does not pre-empt state . . . regulations that merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage." *Rutledge v. Pharmaceutical Care Management Assoc.*, No. 18–540, slip op. at 6 (Dec. 10, 2020)