Vermont Medicaid Drug Wholesaler Savings Initiative

Report to the House Committee on Health Care and the

Senate Committee on Health and Welfare

Pursuant to Act 193, "An act relating to prescription

drug price transparency and cost containment."

Agency of Human Services

November 15, 2018

Prepared by:

Jennifer Egelhof, MBA-HCM

Nancy J. Hogue, Pharm.D.

Lisa Brouillette-Hurteau, Pharm.D.

Submitted by:

Al Gobeille, Secretary

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Section I: Guiding Legislation

There is growing recognition of drug wholesalers as key players in the drug supply chain. There is an interest in exploring alternative structures that will offer savings for Vermont consumers while increasing drug pricing transparency at all levels of the supply chain. There is a realization that the lack of transparency in the current drug delivery system can be hiding savings opportunities.

On May 30, 2018, Governor Phil Scott signed into law Act No. 193, "An act relating to prescription drug price transparency and cost containment." This report responds to the reporting requirements set forth in Section 11a., below:

> "Sec. 11a. WORKING GROUP ON PRESCRIPTION DRUG COST SAVINGS AND PRICE TRANSPARENCY; REPORT
>
> (a) The Secretary of Human Services or designee shall convene a working group comprising one representative each from the Department of Vermont Health Access, the Green Mountain Care Board, the Vermont Board of Pharmacy, the Vermont Association of Chain Drug Stores, the Vermont Pharmacists Association, the Vermont Retail Druggists, Bi-State Primary Care Association, and the Vermont Association of Hospitals and Health Systems to investigate and analyze prescription drug pricing throughout the prescription drug supply chain in order to identify opportunities for savings for Vermont consumers and other payers and for increasing prescription drug price transparency at all levels of the supply chain, including manufacturers, wholesalers, pharmacy benefit managers, health insurers, pharmacies and consumers.

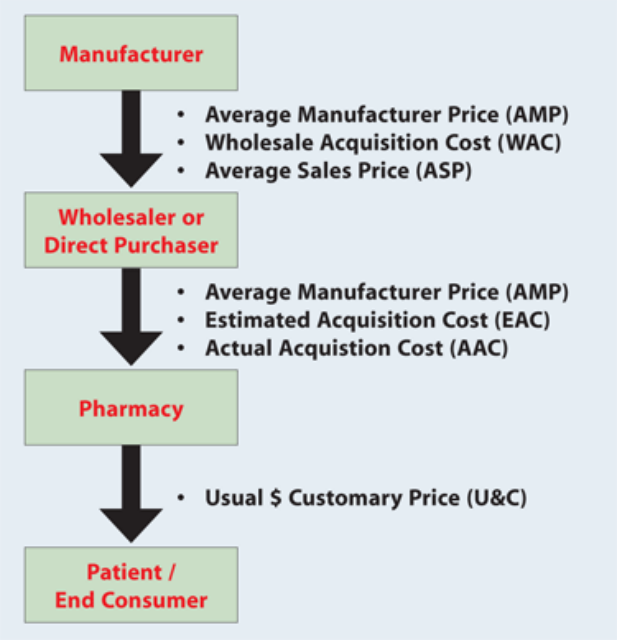
(b) On or before November 15, 2018, the working group shall provide its findings and recommendations to the House Committee on Health Care and the Senate Committee on Health and Welfare."

Section II: DVHA's Approach and the Project's Scope

The large number of drug manufacturers makes it difficult for pharmacies to purchase drugs directly from the plants where they are manufactured. "Wholesale drug distributors are a link between manufacturers and pharmacists. Their role is to ensure prescription medications are delivered safely and efficiently to thousands of health care practitioners and pharmacies nationwide." The pharmacies benefit from not having to coordinate with many manufacturers and enjoy reduced inventory carrying costs. (Mattingly, 2012)

The business model for drug wholesalers is simple: It relies on a wholesaler's ability to purchase large orders of drug products from manufacturers and then sell them to pharmacies at a higher price. This dynamic has created three transaction points of interest: 1) from manufacturer to wholesaler, 2) from wholesaler to pharmacy, and 3) from pharmacy to patient. The example below shows a standard supply chain – from manufacturer to consumer – along with some of the pricing acronyms and their relationship to the supply chain. This illustrates the complex nature of drug pricing in the United States and the role that drug wholesalers play.

(Mattingly, 2012)



(Mattingly, 2012)

Market Leaders

Three companies account for more than 90 percent of all revenues from drug distribution in the United States: AmerisourceBergen Corporation, Cardinal Health, Inc., and McKesson Corporation. According to Adam Fein, Ph.D. who publishes Drug Channels:

- It is estimated that in calendar year 2017, U.S. revenues from the drug distribution divisions of the "Big Three" wholesalers reached $425.1 billion, a 4.5 percent increase over the 2017 figure.
- Wholesalers' combined share of the market has grown in recent years, from 87 percent in 2013 to 92 percent in 2017.
- It is projected that the three companies' combined drug distribution revenues will reach $453.5 billion in 2018, a 6.7 percent increase from the 2017 figure. Note that these figures include sales of traditional, specialty, and generic drugs."

(Fein A. J., 2017)

U.S. Drug Distribution and Related Revenues at Big Three Wholesalers, Calendar Year 2017

Company (Stock Ticker)	U.S. Drug Distribution and Related Revenues[1] ($B)	% Change, 2017 vs. 2016	Share of Total U.S. Market[2]
AmerisourceBergen Corp. (ABC)	$149.6	+4.9%	32%
Cardinal Health, Inc. (CAH)	$114.1	+3.2%	25%
McKesson Corporation (MCK)	$161.4	+5.0%	35%
Total	**$425.1**	**+4.5%**	**92%**

Dollar figures in billions. Total may not sum due to rounding.
1. Revenues are presented for calendar year 2017. Note that fiscal years and segment definitions differ among the three companies. Revenue data include certain related businesses that are not reported separately. Revenue data exclude international drug distribution. Revenue is not adjusted for acquisitions or divestitures.
2. Total market includes sales via wholesale distribution and direct sales by manufacturers.
Source: Drug Channels Institute analysis of company filings; Drug Channels Institute estimates

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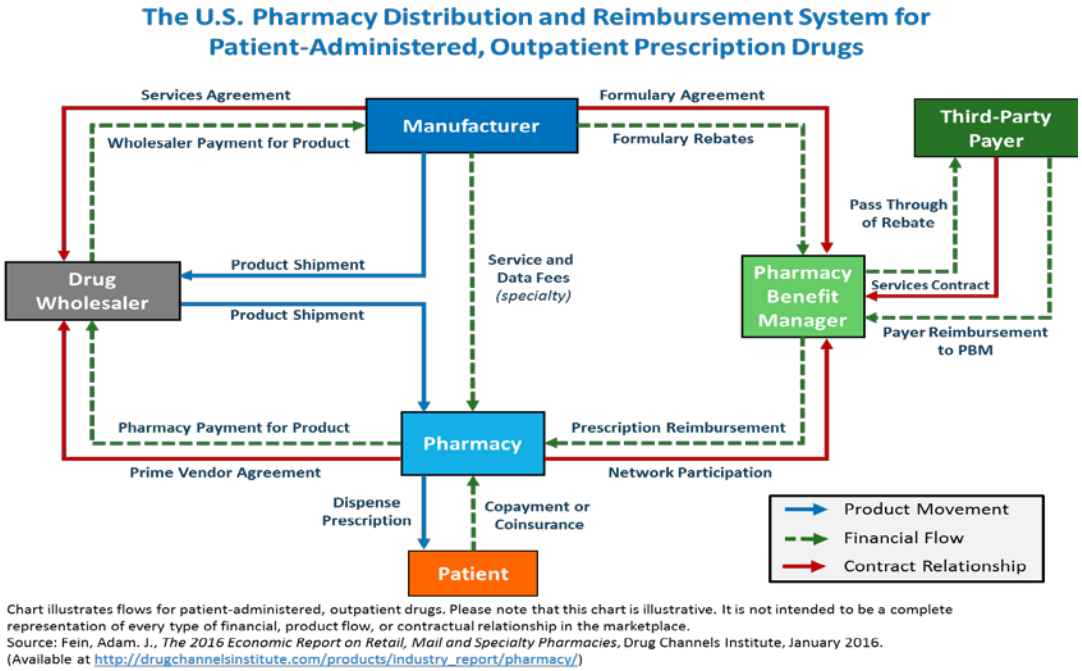
(Fein A. J., 2017)

Current Model of Wholesale Drug Distribution

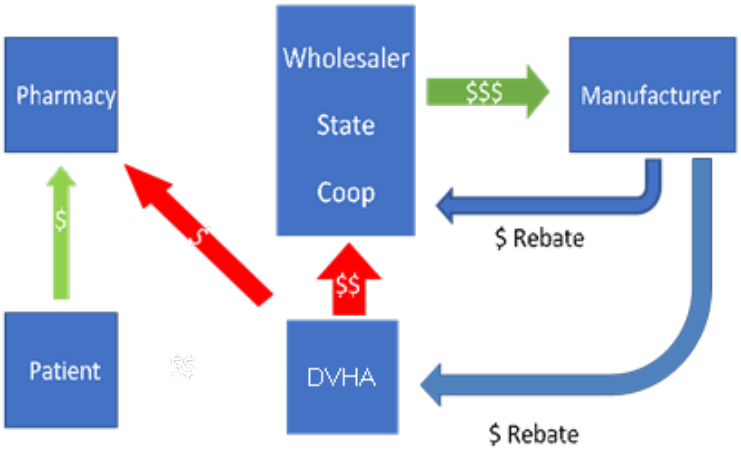
Currently DVHA-enrolled pharmacies purchase most drugs directly through drug wholesalers. When pharmacies fill prescriptions for Vermont Medicaid members, the pharmacy submits a claim to DVHA for reimbursement of the pharmacy acquisition cost of the drug and a professional dispensing fee.

The current complex pharmacy revenue path is represented in the following chart:



(Fein A. J., 2016)

DVHA has contemplated a new model (see next page) whereby the State of Vermont (hereinafter, the "State" or "DVHA," would enter into a competitive pricing contract with a single drug wholesaler to supply drugs to Medicaid-enrolled pharmacies for the Vermont Medicaid program. This would not change the distribution of medications from wholesalers to pharmacies, and pharmacies to patients. However, it would change the payment system whereby DVHA would directly reimburse the wholesaler for drugs that pharmacies utilize for Medicaid members. DVHA convened the workgroup to review this concept as well as other suggestions from workgroup members.



(Hochberg, Herrington, & Kennedy, 2018)

Section III: Request for Information (RFI)

On September 26, 2018, a Request for Information (RFI) was issued by the Department of Vermont Health Access (DVHA) to gather ideas and information from drug wholesalers on direct-contracting arrangements that could result in new cost-savings opportunities to Vermont Medicaid. DVHA is also interested in leveraging information gained in this RFI to benefit other payers and Vermont consumers. The original RFI response due date was October 12, 2018, which was then extended to November 2, 2018.

Objectives

The RFI requested that wholesalers respond to three key objectives:

- Identify if there are State savings to be realized through purchasing Vermont Medicaid outpatient drugs through a direct-wholesaler agreement;
- Quantify the estimated savings that could result from such an agreement; and

- Identify other savings opportunities (for example, value-based agreements, drug data management, 340B program, etc.) throughout the outpatient drug supply chain.

To aid wholesalers in performing a cost-savings analysis, the DVHA provided a link that contained utilization files for all covered outpatient drugs reimbursed by the Vermont Medicaid. We asked that all respondents utilize the **Calendar Year 2017** data file available via this link, which contains four quarterly files. We asked wholesalers to respond as follows:

1. Propose a concept(s) in which your organization (the wholesaler) would contract with DVHA as the wholesaler for Vermont Medicaid outpatient covered drugs. Explain the concept in terms pharmacy drug ordering, shipping, inventory tracking and invoicing to DVHA. Include a flow diagram if possible.

2. Propose cost savings analysis based on State of Vermont Medicaid utilization, which can be obtained via this link: https://www.medicaid.gov/medicaid/prescription-drugs/state-drug-utilization-data/index.html
3. What would DVHA need to manage this type of program (e.g. inventory management software, personnel, etc.)?

4. Propose an estimate of the cost for personnel and any other resources to provide such as service (e.g. software, etc.).

5. What discounts would be offered to DVHA: prompt pay discounts, rebates, etc.?

6. How would this impact pharmacies (e.g., chains with self-warehousing inventories and "store brands," independent pharmacies, specialty pharmacies, etc.), and what are the barriers of their acceptance or adaptation of this model?

7. DVHA seeks new ideas to optimize efficiencies in the healthcare supply chain. Are there other services, products or concepts that you offer and can propose to help the state save money? For example, data or information management; business process improvements or efficiencies that will deliver a return on investment for DVHA; 340B program management efficiencies; specialty/limited distribution drug management; further streamlining of the supply chain; drug shortage management; etc.

Section IV: Meetings of the Working Group (objectives and observations)

A. Meeting #1 Objectives

On October 19, 2018, DVHA convened the first meeting of the Working Group that was formed to respond to this legislative requirement. The meeting took place at the Waterbury State Office Complex. All entities required by the legislation were represented. Objectives of the meeting were to discuss, understand and come to agreement on:

- The Act 193 legislation and responsibilities of the Working Group
- The Request for Information (RFI) that DVHA issued on September 26, 2018 to drug wholesalers to explore savings opportunities
- Recommendations for this report, due to the legislature on November 15, 2018

A second meeting was held on November 9, 2018, to review the draft report to the legislature and make final recommendations.

B. Meeting #1 Agenda

The first part of the meeting was a presentation by Nancy Hogue, Pharm.D, DVHA Pharmacy Director which discussed:

- The current complex drug distribution and reimbursement system and a modified reimbursement model that would be simplified and more transparent;

- The new model that contemplates DVHA contracting with a single drug wholesaler to supply drugs to Medicaid-enrolled pharmacies for the Vermont Medicaid program. The proposed concept is as follows:
    - Efforts would begin with a Medicaid-only contract with a wholesaler.
    - If Medicaid is successful, this could be expanded to other books of business, such as commercial plans.

C. Meeting #1 Exercise

After the presentation, the Working Group performed a brainstorming activity to identify those entities that could benefit under such an arrangement and those would not. The results are as follows:

Entities that could/would benefit:

- Patients could benefit from decreased administrative hassle resulting in better coordination of care. For example, DVHA would be able to better identify and mitigate issues surrounding access to medications or medication shortages.
- Pharmacies would have a significantly smaller inventory costs (an estimated +/-25%) to manage and they would be protected from current pricing vulnerabilities on drug reimbursement.
- Pharmacists could spend less time on drug reimbursement issues and focus more on clinical care, where they are needed.
- The State should save money and achieve improved transparency on drugs costs.
- Wholesalers will have an opportunity to gain market share and achieve a more positive bottom line through more innovative and transparent financing arrangements.
- If this model could expand beyond Medicaid to commercial payers, the impact could disrupt any spread pricing practices of PBMs, which should benefit payers.

Entities that would be negatively affected:

- Chain drug stores will likely not benefit nor support direct-contracting relationships with the State because most have their own wholesaler arrangements based on their own unique ties. For example, Walgreens is tightly connected to AmerisourceBergen (ABC). It accounts for more than one-third of ABC's revenues, owns 26% of ABC's outstanding common stock, and controls one director on ABC's board; while CVS Health is McKesson's largest customer. (Drug Channels , 2018). In addition, many chains do their own central warehousing.
- Pharmacies would be negatively affected if the State ceased paying for the ingredient cost of drugs, as pharmacies make a profit margin on generic drugs.
- DVHA would incur additional expenses to manage such a payment system (perform inventory and payment tracking, for example). It is expected that additional staff and software will be needed.
- In reference to this statement in the presentation: "By eliminating the transaction-level financial challenges from the pharmacy, pharmacists can increase their efforts toward more value-based clinical services." The observer noted that "If that phrase is meant to suggest "pay for performance," then drug dispensing and costs may increase, not decrease. For example, patients with diabetes often benefit from more expensive therapies."
- There is concern among Bi-State and VAHHS providers that there could be significant administrative expenses and burden that pharmacies would incur if the State coordinates Medicaid pharmacy inventory. The additional costs for pharmacies are related to managing the inventory at the store level (replenishment, ensuring the appropriate inventory is used, etc.).
- Violation of the General Purchasing Organization (GPO) prohibition disqualifies hospitals from the entire 340B program, which could significantly impact access to services at some hospitals. (See Section E below for more information.)

- Hospital outpatient pharmacies generally partner with one wholesaler that provides GPO-specific discounts, so drugs outside of those parameters may present a barrier for their participation.

D. Other Observations and Feedback from Work Group Meetings

- DVHA's PBM contract would not be affected, as the contract is 100% transparent, based solely on administrative fees and does not include any sharing of rebates nor any spread pricing in the pharmacy network.
- Not all drugs could be included, such as some specialty drugs that are "limited distribution" and not available to all wholesalers.
- The Vermont Pharmacists Association representative offered these comments to the presentation:
    - The presentation should also describe the scenario of money leaving pharmacies and going back to PBMs through "direct and indirect remuneration" (DIR) fees and claw backs.
    - Medication dispensing does not equal medication adherence, as there is often significant waste when drugs are refilled not based on need, but on the refill schedule of the pharmacy.
- It needs to be determined whether a State Plan Amendment will be needed if the DVHA decides to go forward with a direct wholesaler agreement.

- Representatives from the Vermont Association of Chain Drug Stores offered a comment that reflected concern that the RFI was limited in scope to a single-source wholesaler arrangement with Medicaid, when it is understood that there are savings to be achieved in the commercial PBM environment, where transparency currently does not exist.

- Comments and recommendations received from Bi-State Primary Care Association a Vermont Association of Hospital and Health Systems:

- Return on investment after administrative costs:
  "According to DVHA, the direct wholesaler agreement could save Vermont Medicaid approximately $11 million. It is our understanding that this is before administrative costs are taken into account. Our providers have expressed concern that this new system will be administratively complicated and expensive to manage. Before moving forward with a direct wholesaler agreement, we ask that DVHA weigh the administrative costs and the cost of disruption against possible savings carefully."
- Availability of limited-distribution drugs:
  "Currently, hospital-owned pharmacies have access to prescription drugs that other organizations are restricted from purchasing. It is unclear whether a direct wholesaler agreement will fit into the existing authorized categories for purchasing these prescription drugs. In going forward, DVHA should consider an exception process to ensure that these hospital-owned pharmacies can dispense these drugs to Vermonters."
- 340B Group Purchasing Organization restriction:
  "Under the 340B program, certain hospitals cannot participate in a Group Purchasing Organization (GPO), which is defined as any organization that uses its bargaining power to obtain a better price for prescription drugs. See 42 U.S.C. 256b(a)(4)(L)(iii). Depending on how Vermont's direct wholesaler agreement works, it may violate the GPO prohibition. Violation of the GPO prohibition disqualifies hospitals from the entire 340B program, which could significantly impact access to services at some hospitals. We ask that DVHA structure this program as a pure wholesaler program to conform with the 340B GPO prohibition and allow hospital participation."

Section V: Summary of Responses to DVHA's RFI

DVHA received no responses to the RFI. At this time, we do not have any information that would help us understand the reasons for no responses directly from the wholesalers. However,

we are still attempting to collect additional information.

Section VI: Recommendations

The U.S. outpatient drug channels are extremely complicated, and DVHA believes that both savings and transparency can be achieved through channel simplification. While no responses were received from wholesalers, DVHA sees value in continuing to explore potential opportunities with wholesalers. The working group has agreed to reconvene and would like to be involved in future discussions if DVHA plans to go forward with any action related to a single-source wholesaler relationship for Medicaid.

Section VII: Works Cited

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