

Report of Attorney General to the Legislature Regarding
Pharmaceutical Cost Transparency Pursuant to 18 V.S.A. § 4635
February 23, 2018

OVERVIEW

This report is submitted pursuant to 18 V.S.A. § 4635(d) which directs the Attorney General, in consultation with the Department of Health Access, to provide an annual report to the General Assembly based on the information provided by drug manufacturers pursuant to 18 V.S.A. § 4635(c) (1).

18 V.S.A. § 4635 (b)(1) directs the Green Mountain Care Board (“GMCB”), in collaboration with the Department of Vermont Health Access (“DHVA”), to identify annually up to 15 prescription drugs representing different drug classes, “on which the State spends significant health care dollars and for which the wholesale acquisition cost has increased by 50 percent or more over the past five years or by 15 percent or more over the past 12 months, creating a substantial public interest in understanding the development of the drugs’ pricing.” The statute also requires that the manufacturers of the identified drugs provide a justification for the increase in the wholesale acquisition cost (“WAC”), including all relevant information and supporting documentation, and provide that information to the Attorney General on a confidential basis. 18 V.S.A. §§ 4635 (c)(1) and (e)

GMCB, in collaboration with DHVA, identified a list of 10 drugs (8 drugs are manufactured by different pharmaceutical companies and 2 are manufactured by the same company), 9 of which are branded and 1 of which is a generic drug (the “List”). The selection process used by GMCB and DHVA is outlined in the August 10, 2017 memorandum from DHVA to GMCB, attached to this report as Exhibit 1. The Attorney General published, on its website, an overview of the statute, the list of identified drugs, and instructions for the manufacturers to submit the information required by 18 V.S.A. § 4635(c) (1). <http://ago.vermont.gov/divisions/for-lawyers-and-businesses/drug-price-transparency-manufacturer-annual-reporting.php>. The List, which reflects the percentage changes in the WACs of the drugs, is attached to this report as Exhibit 2.

Each of the nine manufacturers submitted information to the Attorney General’s Office (“AGO”). The AGO reviewed the submissions and conducted follow-up calls, during which manufacturers were offered the opportunity to provide additional information. Pursuant to 18 V.S.A. § 4635 (e), the AGO cannot publicly disclose the information provided by the manufacturers in a manner that allows for the identification of a specific drug or manufacturer, or in a way likely to compromise the financial, competitive or proprietary nature of that information. In order to comply with the statute, this report presents the information in a summary manner.

As was the case in 2016, the drug manufacturers' reports focused on three main points:

1) The manufacturers expressed the view that pricing analyses should be made based on the prices actually paid, rather than WAC. WAC (the manufacturer's "list price" to a wholesaler) is the starting price set by a manufacturer and does not reflect the discounts and rebates negotiated by wholesalers and other drug purchasers such as pharmacies, hospitals, pharmacy benefit managers and payers;

2) Manufacturers do not determine the price an individual patient will pay for that patient's prescription and WAC does not typically reflect the price a patient actually pays for a drug; and

3) Manufacturers set prices based on a variety of factors and no specific percentage is assigned to any individual factor.

The information provided by the manufacturers is addressed below.

MEDICAID VERSUS PRIVATE PURCHASER PRICING

Manufacturers discussed the difference between Medicaid and private purchaser pricing structures, and how those differences affect drug prices. The Medicaid net price is the price paid to a pharmacy or other provider by a Medicaid program for its covered patients, minus all rebates received (both statutory and negotiated) for a given drug. Federally mandated rebates paid by manufacturers to Medicaid are adjusted by the Consumer Price Index-Urban ("CPI-U"), based on the product's price at the time it was launched and the current quarter average manufacturer price ("AMP"). As a result, if the list price of the product rises above inflation, the manufacturer's rebate liability rises accordingly. In other words, the State does not pay a price increase that exceeds CPI-U. It receives the excess amount as a rebate. According to the manufacturers, State Medicaid programs pay significantly less than WAC as a result of rebates provided under the Medicaid Drug Rebate Program.

Often, several products compete for positions on government and private formularies.¹ Manufacturers negotiate rebates based on factors that include clinical evidence, patient and physician experience, and the overall net cost of a drug compared to other drugs in the same therapeutic category.

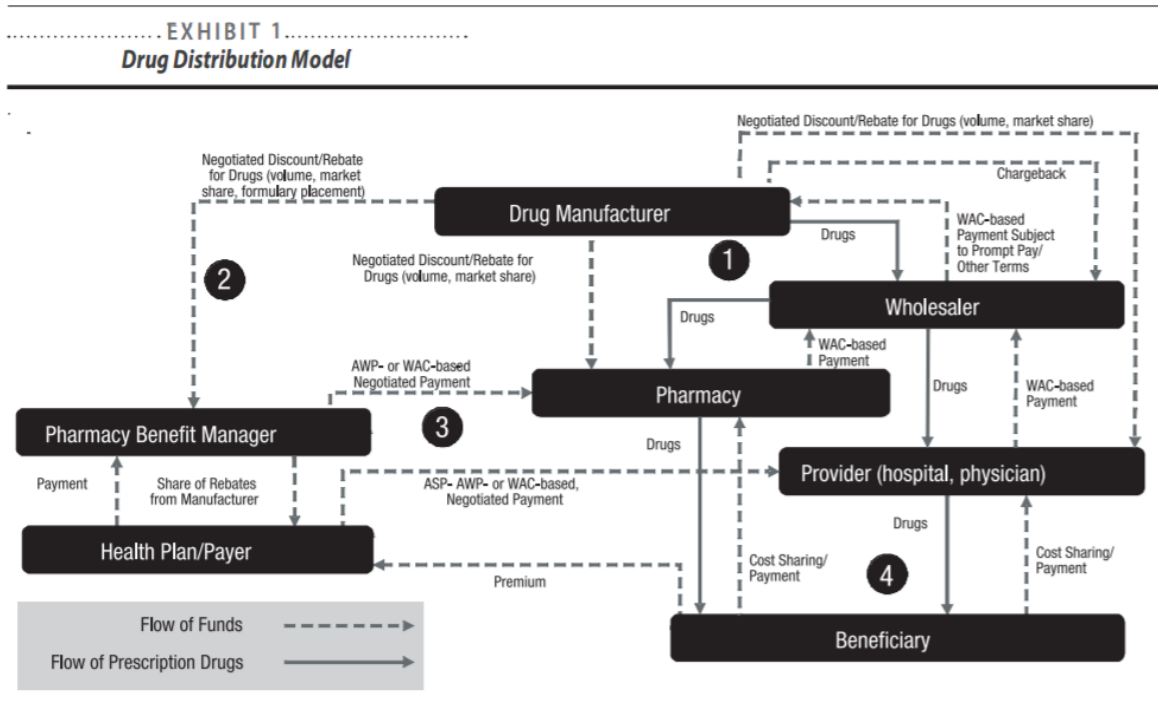
Included in the manufacturers' comments about pricing was that payers' increased rebate demands - in the context of "exclusive formularies"² - is a main driver of list price increases. In the case of an exclusive formulary, the drug company agrees to provide a higher

¹ A formulary is a list of drugs that are preferred by an insurance company or Medicare drug plan. Drugs that are less costly to the plan are placed in a lower cost tier or category on the formulary. They cost the patient less out of pocket, while higher cost drugs will result in a significantly higher copay for the patient. Formularies include both generic and brand drugs.

² When a drug is given "exclusive" formulary status, it is the only product in that therapeutic class available or covered by that formulary or formulary tier.

rebate in exchange for its drug being the sole therapy on the formulary for that class of drugs. When that happens, the rebate given by the manufacturer is higher, but the choice of medicines doctors can prescribe is limited. Manufacturers said that when one drug company raises the WAC (and normally, also raises the rebate to payers), other drug companies may also raise the WAC for a competing drug (and normally, they raise the rebate amount as well) to remain competitive.

The Academy of Managed Care Pharmacy (“AMCP”)³ has observed that there is less transparency in the payment methods used by private payers than public payers. The complex nature of the drug distribution chain is reflected in the flow chart below, found in the most recent version of the AMCP Guide to Pharmaceutical Payment Methods, 2013 Executive Summary, Version 3.0, together with an explanation of the flow chart, at <http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=16476>. This chart, which was included in the 2016 AGO Report, remains the current version, and is included for context.



AMCP GUIDE TO PHARMACEUTICAL PAYMENT METHODS | 2013 UPDATE

Based on the manufacturers’ submissions to the AGO and comments they made in discussions with the AGO, the State and those it serves pay significantly less for drugs than private payers, and receive the benefit (directly or through state-administered programs) of low

³ AMCP is the acronym for the Academy of Managed Care Pharmacy, a national professional organization of about 7000 pharmacies and other health care practitioners.

and sometimes no-cost drugs. Most manufacturers said that they fund assistance programs for people who lack health insurance or cannot afford treatment to access their drugs at very low or no cost.

The manufacturers believe that analyses of their pricing should be made on the basis of the prices actually paid, after the deduction of discounts, price concessions and rebates. Several manufacturers commented that there were relatively small increases in the net prices paid by Medicaid for the selected drugs, that the net prices of those drugs have remained fairly constant or decreased, or that the actual price increases are much smaller than WAC prices reflect.

PRICES PAID BY PATIENTS

Manufacturers said that patients' out-of-pocket-expenses for prescription drugs vary widely, driven mainly by their prescription drug insurance and the drug's position on the applicable formulary. Manufacturers' comments included their lack of control over payers' decisions concerning patients' out-of-pocket expenses under the various prescription pharmaceutical benefit plans.

The manufacturers said that a patient's out-of-pocket cost (the portion of the prescription cost paid by the patient) is set by the health insurance plan or pharmacy benefit manager ("PBM") that manages the drug benefit for the patient.⁴ Wholesalers and other drug purchasers (including pharmacies, hospitals, retailers, and other payers) negotiate for considerable discounts, price concessions and rebates from the WAC price. Manufacturers observed that these entities receive a portion of the negotiated discounts. The manufacturers also commented that discounts and rebates are rarely passed on to patients, so that net prices received by the manufacturers may differ from the final cost to payers and patients.⁵ When stakeholders in the supply chain apply additional charges, they increase drug prices above the discounted amount charged by the manufacturer.

FACTORS THAT INFLUENCE MANUFACTURERS' DRUG PRICING

The manufacturers identified a number of factors they consider in making pricing decisions. Different manufacturers seem to rely more or less heavily on different combinations of these factors. The factors commonly mentioned by the manufacturers as impacting their decisions to increase prices include (in no particular order)⁶:

⁴ A PBM is a third party administrator hired by a health plan, employer, union or governmental entity to manage prescription drug programs on behalf of beneficiaries.

⁵ Manufacturers say that PBMs may not always pass on discounts they receive to consumers and guard the size of their profits from rebates. In their view, there is a lack of transparency which, when combined with market consolidation (3 large PBMS reportedly control over 70 percent of the market), makes it difficult to determine the actual cost of many drugs.

⁶ One manufacturer also included the role of PBMs and other middlemen among its pricing considerations.

the value of innovative medicines;

cost effectiveness (meaning the economic value to patients given the effectiveness of the drug, compared to other drugs in the same class);

the size of the patient population for the drug;

investments made (including in research and development) and the risks undertaken;

return on investment and fiduciary responsibilities post-marketing regulatory commitments and ongoing pharmacovigilance(safety surveillance);

creation and maintenance of manufacturing facilities and capabilities, including the ability to address drug shortages caused by production issues;

cost of ingredients;

competition, including for drugs in the same class; and

the rate of inflation.

In addition to the factors listed above, most manufacturers highlighted the percentage of their sales in commercial versus Medicare or other government channels, and the funds they expended on assistance programs for people with limited resources or without insurance which, in some measure, offset their drug sales income.

DHVA'S OBSERVATIONS

DHVA observed that increasing WAC does not always result in more rebates for commercial payers, as rebates are not available on all drugs. Since rebates are sometimes based on a percentage of WAC, purchasers and payers may still pay more when WAC increases. In addition, uninsured and under-insured patients, such as those with high deductible health plans or limited coverage, often bear the full burden of price increases at the pharmacy. DHVA commented that while Medicaid is somewhat insulated against brand drug price increases due to the federal rebate structure, Medicaid net cost should not be the only benchmark for examining extremely large price increases. DHVA also said that others in the drug distribution system are adversely affected, potentially resulting in higher insurance premiums, higher co-pays and deductibles, and higher out of pocket costs for all Vermonters.

Respectfully Submitted,

Jill S. Abrams
Assistant Attorney General
Vermont Attorney General's Office

Exhibit 1

To: Green Mountain Care Board
From Susan Barrett, Executive Director
Re: Act 165 Drug List
Date: August 10, 2017

Background:

Act 165 of 2016, *see* Appendix A, requires that the Green Mountain Care Board (GMCB), in collaboration with the Department of Vermont Health Access (DVHA):

[i]dentify annually up to 15 prescription drugs on which the State spends significant health care dollars and for which the wholesale acquisition cost has increased by 50 percent or more over the past five years or by 15 percent or more over the past 12 months, creating a substantial public interest in understanding the development of the drugs' pricing.

18 V.S.A. § 4635(b).

Once identified, the GMCB must provide a list of the drugs, including the percentage of wholesale acquisition cost increase for each, to the Office of the Attorney General, and make the information available to the public on the GMCB website. *Id.*

Methodology used for selection of drug list for Act 165 of 2016:

The GMCB asked Nancy Hogue, BS, Pharm. D., Director of Pharmacy Services for DVHA, to provide data on drugs that meet the criteria set forth in Act 165. Nancy requested data from DVHA's Pharmacy Benefits Manager (PBM) and produced a final list of drugs based on the following criteria:

- 1) Drugs for which the wholesale acquisition cost (WAC) increased by 50 percent or more over the past five years or by 15 percent or more over the past 12 months. This was measured by comparing the Wholesale Acquisition Cost of each drug at the end of each fiscal year evaluated.
- 2) The five-year query compared the WAC on the last day of SFY2013 to the WAC on June 20, 2017 (almost the end of SFY2017). Drugs that had an increase in WAC of at least 50% were used.
- 3) The one-year query compared the WAC on the last day of SFY2016 to the WAC on June 20, 2017. Drugs that had an increase in WAC of at least 15% were used.

Exhibit 1

4) This query resulted in the following totals:

| Category | Total # NDC's Evaluate | # of NDCs Exceeded Threshold | % of Total |
|----------------------|------------------------|------------------------------|------------|
| WAC >= 50% last 5 Yr | 76095 | 6490 | 8.53% |
| WAC >= 15% last 1Yr | 85214 | 1876 | 2.20% |

5) The legislation also requests the list represent drugs on which the State spends significant health care dollars. Therefore, once the drug list was created, the total Medicaid paid amount for each drug that had utilization during SFY 2017 through June 20, 2017 was provided. In order to accurately reflect the amount that DVHA spends on drugs, each drug was ranked by its net cost to DVHA and drugs that had a high net cost were preferentially selected.

6) Once the initial drug list was finalized, the list was further refined to assure that both brands and generics and different therapeutic classes were represented.

A final list of 10 drugs was created and appears below:

| Ranking | PRODUCT_NAME | LABELER_NAME | BG_IN D | AVG_PERC ENT_INCR EASE | TOTAL_QU ANTITY | TOTAL_AMOU NT_PAID | List appeared on: |
|---------|------------------------|-------------------------------|---------|------------------------|-----------------|--------------------|-------------------|
| 1 | VYVANSE | SHIRE US, INC. | B | 58.60% | 639,728 | \$5,473,510.83 | 5 |
| 2 | METHYLPHENIDATE HCL ER | WATSON PHARMA, INC. | G | 50.14% | 615,342 | \$4,466,606.97 | 5 |
| | | | | 18.50% | | | 1 |
| 3 | HUMIRA PEN | ABBVIE INC | B | 102.80% | 2,806 | \$4,978,270.95 | 5 |
| 4 | LYRICA | PFIZER, INC | B | 105.79% | 724,390 | \$3,541,871.94 | 5 |
| | | | | 19.77% | | | 1 |
| 5 | FOCALIN XR | NOVARTIS | B | 80.32% | 252,509 | \$2,846,464.99 | 5 |
| | | | | 15.40% | | | 1 |
| 6 | ENBREL SURECLICK | AMGEN/IMMUNEX | B | 87.95% | 2,916 | \$2,417,969.47 | 5 |
| | | | | 19.13% | | | 1 |
| 7 | NOVOLOG FLEXPEN | NOVO NORDISK, INC. | B | 94.50% | 95,305 | \$2,409,488.27 | 5 |
| | | | | 16.43% | | | 1 |
| 8 | LATUDA | SUNOVION PHARMACEUTICALS, INC | B | 95.30% | 57,035 | \$1,754,771.27 | 5 |
| | | | | 20.76% | | | 1 |
| 9 | EPIPEN 2-PAK | MYLAN SPECIALTY L.P. | B | 152.89% | 4,171 | \$1,193,858.28 | 5 |
| 10 | NOVOLOG | NOVO NORDISK, INC. | B | 94.52% | 69,900 | \$1,583,541.29 | 5 |
| | | | | 16.43% | | | 1 |

Exhibit 1

Appendix A:

Pertinent language from Act 165:

(b)(1) The Green Mountain Care Board, in collaboration with the Department of Vermont Health Access, shall identify annually up to 15 prescription drugs on which the State spends significant health care dollars and for which the wholesale acquisition cost has increased by 50 percent or more over the past five years or by 15 percent or more over the past 12 months, creating a substantial public interest in understanding the development of the drugs' pricing. The drugs identified shall represent different drug classes.

(2) The Board shall provide to the Office of the Attorney General the list of prescription drugs developed pursuant to this subsection and the percentage of the wholesale acquisition cost increase for each drug and shall make the information available to the public on the Board's website.

(c)(1) For each prescription drug identified pursuant to subsection (b) of this section, the Office of the Attorney General shall require the drug's manufacturer to provide a justification for the increase in the wholesale acquisition cost of the drug in a format that the Attorney General determines to be understandable and appropriate. The manufacturer shall submit to the Office of the Attorney General all relevant information and supporting documentation necessary to justify the manufacturer's wholesale acquisition cost increase, which may include:

(A) all factors that have contributed to the wholesale acquisition cost increase;

(B) the percentage of the total wholesale acquisition cost increase attributable to each factor; and

(C) an explanation of the role of each factor in contributing to the wholesale acquisition cost increase.

(2) Nothing in this section shall be construed to restrict the legal ability of a prescription drug manufacturer to change prices to the extent permitted under federal law.

(d) The Attorney General, in consultation with the Department of Vermont Health Access, shall provide a report to the General Assembly on or before December 1 of each year based on the information received from manufacturers pursuant to this section. The Attorney General shall also post the report on the Office of the Attorney General's website.

(e) Information provided to the Office of the Attorney General pursuant to this section is exempt from public inspection and copying under the Public Records Act and shall not be released in a manner that allows for the identification of an individual drug or manufacturer or that is likely to compromise the financial, competitive, or proprietary nature of the information.

Exhibit 1

Appendix B:

| Category | Total # NDC's Evaluated | # of NDCs Exceeded Threshold | % of Total | Number of generic NDCs exceeding threshold | Generic % of total NDCs exceeding threshold |
|----------------------|----------------------------|------------------------------------|---------------|--|---|
| WAC >= 50% last 5 Yr | 76,095 | 6,490 | 8.53% | 3,764 | 58.00% |
| WAC >= 15% last 1Yr | 85,214 | 1,876 | 2.20% | 629 | 33.53% |

Exhibit 2

| Ranking | PRODUCT_NAME | LABELER_NAME | BG_IND | AVG_PERCENT_I NCREASE | TOTAL_QUANTITY | TOTAL_AMOUNT_PAID | List appeared on: 1YR/5YR |
|---------|-----------------------|-----------------------------|--------|--------------------------|----------------|-------------------|------------------------------------|
| 1 | VYVANSE | SHIRE US, INC. | B | 58.60% | 639,728 | \$5,473,510.83 | 5 |
| 2 | METHYLPHENIDATE HCL E | WATSON PHARMA, INC. | G | 50.14% | 615,342 | \$4,466,606.97 | 5 |
| | | | | 18.50% | | | 1 |
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