

Report of Attorney General to the Legislature Regarding
Pharmaceutical Cost Transparency Pursuant to 18 V.S.A. § 4635
December 1, 2016

This report is submitted pursuant to 18 V.S.A. § 4635(d) which directs the Attorney General, in consultation with the Department of Vermont Health Access, to provide an annual report to the General Assembly on or before December 1, 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 (“DVHA”), 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 DVHA, identified a list of 10 drugs, each of which is manufactured by a different pharmaceutical company, 8 of which are branded and 2 of which are generic. The selection process used by GMCB and DVHA is outlined in the August 19, 2016, memorandum 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>. A list of the selected drugs and the percentage change in their respective WACs is attached to this report as Exhibit 2.

Each of the 10 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. Several did so. Because the information is exempt from public inspection and cannot be released in a manner that permits the identification of a specific manufacturer or drug, the following is a summary of the information received from the manufacturers.

The manufacturers commented on the use of WAC as a yardstick and the fact that it represents the “list price” to wholesalers for a drug purchased from the wholesaler’s supplier. They said that wholesalers and other drug purchasers such as pharmacies, hospitals, physician groups and other payers negotiate for considerable discounts, price concessions and rebates from the WAC price. All seemed to agree that WAC does not typically reflect the price actually paid for a drug. In contrast, the Medicaid net price is the price paid to a pharmacy or other provider by a Medicaid program for their covered patients minus all rebates received (both statutory and

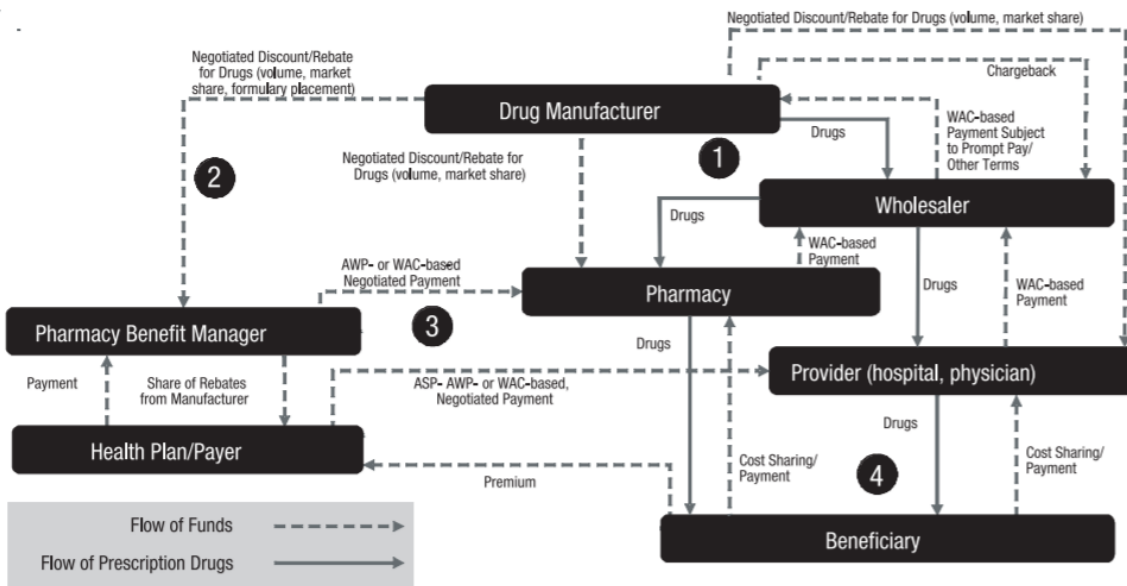
negotiated) for a given drug. Medicaid and private purchaser pricing structures are different, but they are both complicated.

Often, several products compete for positions on government and private formularies. Manufacturers pay rebates to obtain or maintain favorable positions on formularies. Some manufacturers reported that rebates paid to pharmacy benefit managers and commercial insurance companies are generally calculated as a percentage of WAC, and formulary position is based on both clinical considerations and the overall net cost of a drug compared to other drugs in the same therapeutic category. One manufacturer observed that when one drug company raises the WAC (and thus normally raises the rebate to payers), other drug companies may also raise the WAC for a competing drug (and thus normally the rebate amount) to remain competitive. Furthermore, state Medicaid programs pay significantly less than WAC due to rebates provided under the Medicaid Drug Rebate Program. The manufacturers reported that, in some cases, the net price to Medicaid increased at an extremely small percentage compared to the increase in the WAC.

The Academy of Managed Care Pharmacy (“AMCP”)¹ 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>.

¹ AMCP is the acronym for the Academy of Managed Care Pharmacy, a national professional organization of about 7000 pharmacies and other health care practitioners.

Drug Distribution Model



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 and sometimes no-cost drugs. In addition, 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.

Patients' out-of-pocket-expenses for prescription drugs vary widely, driven mainly by their prescription drug insurance and the drug's position on the formulary. Manufacturer comments included the fact they have no control over payers' decisions concerning patients' out-of-pocket expenses under the various prescription pharmaceutical benefit plans.

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. Most said that they have pricing committees that meet to discuss and approve prices, change those prices, and determine payer rebates. The factors commonly mentioned by the manufacturers as impacting their decisions to increase prices include (in no particular order): 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; 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; return on investment and fiduciary responsibilities; and the percentage of their sales in commercial, Medicare or other government channels.

The manufacturers believe that pricing analyses 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.

DVHA observed that increasing WAC does not always result in more rebates for commercial payers, as rebates are not available on all drugs. If it does, those rebates are generally based on a percentage of WAC, so purchasers, payers, and patients are still paying more. In addition, uninsured and under-insured patients, such as those with high-deductible health plans or limited drug coverage, often bear the full burden of price increases at the pharmacy. DVHA 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 justifying extremely large price increases. DVHA also said that others in the drug distribution model 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 19, 2016

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 SFY2012 to the WAC at the end of SFY2016. 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 SFY2015 to the WAC at the end of SFY2016. Drugs that had an increase in WAC of at least 15% were used.

4) This query resulted in the following totals:

Category	Total # NDC's Evaluated	# of NDCs Exceeded Threshold	% of Total
WAC >= 50% last 5 Yr	87,248	8,221	9.4%
WAC >= 15% last 1Yr	87,248	3,975	4.6%

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 2016 was provided. In order to accurately reflect the amount that DVHA spends on drugs, the GMCB felt it important to incorporate the significant rebates that pharmaceutical companies provide to the State. Since the first list DVHA provided to the GMCB did not include rebates, DVHA was asked to run a revised list that accounted for the rebates the State receives.

6) Once the initial drug list was finalized, the list was sorted in two different ways. First, by DVHA SFY2016 drug spend, and secondly by the percentage increase in WAC of each drug. This created two unique lists. These lists were further refined to assure that both brands and generics and different therapeutic classes were represented. A final list of 15 drugs was created and the GMCB chose the top 10 on the list which appears below:

IDENTIFIED DRUG LIST PER ACT 165					1 Year Avg.	5 Year Avg.	
Brand/ Generic	Brand Name**	Generic Name	Labeler	Therapeutic Class	WAC* % Change	WAC* % Change	SFY2016 Gross Drug Spend
Brand	ABILIFY	Aripiprazole	OTSUKA AMERICA	Quinolinone Derivatives		55.27%	\$6,500,094.29
Brand	LANTUS	Insulin Glargine	AVENTIS PHARMACEUTICALS	Human Insulin		89.83%	\$5,445,451.20
Brand	HUMIRA	Adalimumab	ABBOTT LABORATORIES	Anti-TNF-alpha - Monoclonal Ant	27.95%	113.79%	\$4,712,102.88
Brand	ENBREL	Etanercept	AMGEN/IMMUNEX	Soluble Tumor Necrosis Factor Re	16.42%	92.73%	\$3,194,724.72
Brand	CRESTOR	Rosuvastatin Calcium	ASTRAZENECA LP	HMG CoA Reductase Inhibitors	20.75%	75.98%	\$1,759,833.88
Brand	EPIPEN	Epinephrine	MYLAN SPECIALTY	Anaphylaxis Therapy Agents	32.02%	205.45%	\$1,697,383.74
Brand	LATUDA	Lurasidone HCl	SUNOVION PHARMACEUTICALS, INC.	Antipsychotics - Misc.	19.80%	99.68%	\$1,149,040.43
Brand	PREVACID	Lansoprazole	TAKEDA PHARMACEUTICALS AMERICA	Proton Pump Inhibitors	20.78%	103.32%	\$941,689.27
Generic	DOXYCYCLINE HYCLATE	Doxycycline Hyclate	MUTUAL PHARMACEUTICAL COMPANY	Tetracyclines		4787.61%	\$194,044.37
Generic	PERMETHRIN	Permethrin	PERRIGO PHARMACEUTICALS	Scabicides & Pediculicides	50.00%		\$69,949.22
*	WAC - Wholesale Acquisition Cost across various strengths, representing different brands/generics and therapeutic classes						
	1 Year Average increase > 15%						
	5 Year Average increase > 50%						
	Blank fields indicate drug did not exceed the threshold during that time period						
**	Includes all dosage forms that exceeded the threshold						

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.

Appendix B:
WAC Analysis Summary
Based on WAC price per unit

Category	Total # NDC's Evaluated	# of NDCs Exceeded Threshold	% of Total	# of NDCs that are Generic	% of NDCs that are Generic	Avg % Incr Generics	Avg % Incr Brands	Avg \$ Incr Generics	Avg \$ Incr Brands
WAC >= 50% last 5 Yr	87,248	8,221	9.4%	3,354	40.8%	442.6%	339.6%	\$4.44	\$337.51
WAC >= 15% last 1Yr	87,248	3,975	4.6%	2,177	54.8%	106.1%	68.6%	\$3.36	\$41.45

Note that a significant number of NDCs where the WAC has exceeded the threshold are generic, over 50% in the last year.

The average percent increase in generic drugs for both time periods is GREATER than the average percent increase in brand drugs.

While the average percent increase in generics is greater than brands, the average increase in actual dollars is much greater for brand drugs. This contributes to the impression that brand drugs are increasing in cost more quickly than generic drugs.

Exhibit 2

Drug List Per Act 165

IDENTIFIED DRUG LIST PER ACT 165

<u>Brand/</u>					<u>1 Year Avg.</u>	<u>5 Year Avg.</u>
<u>Generic</u>	<u>Brand Name**</u>	<u>Generic Name</u>	<u>Labeler</u>	<u>Therapeutic Class</u>	<u>WAC*</u>	<u>WAC*</u>
					<u>% Change</u>	<u>% Change</u>
Brand	ABILIFY	Aripiprazole	OTSUKA AMERICA	Quinolinone Derivatives		55.27%
Brand	LANTUS	Insulin Glargine	AVENTIS PHARMACEUTICALS	Human Insulin		89.83%
Brand	HUMIRA	Adalimumab	ABBOTT LABORATORIES	Anti-TNF-alpha - Monoclonal Antiboc	27.95%	113.79%
Brand	ENBREL	Etanercept	AMGEN/IMMUNEX	Soluble Tumor Necrosis Factor Recep	16.42%	92.73%
Brand	CRESTOR	Rosuvastatin Calcium	ASTRAZENECA LP	HMG CoA Reductase Inhibitors	20.75%	75.98%
Brand	EPIPEN	Epinephrine	MYLAN SPECIALTY	Anaphylaxis Therapy Agents	32.02%	205.45%
Brand	LATUDA	Lurasidone HCl	SUNOVION PHARMACEUTICALS, INC.	Antipsychotics - Misc.	19.80%	99.68%
Brand	PREVACID	Lansoprazole	TAKEDA PHARMACEUTICALS AMERICA	Proton Pump Inhibitors	20.78%	103.32%
Generic	DOXYCYCLINE HYCLATE	Doxycycline Hyclate	MUTUAL PHARMACEUTICAL COMPANY	Tetracyclines		4787.61%
Generic	PERMETHRIN	Permethrin	PERRIGO PHARMACEUTICALS	Scabicides & Pediculicides	50.00%	

* WAC - Wholesale Acquisition Cost across various strengths, representing different brands/generics and therapeutic classes
 1 Year Average increase > 15%
 5 Year Average increase > 50%