Attorney General's Report on Prescription Drug Cost Transparency
Pursuant to 18 V.S.A. § 4635
December 2, 2019

OVERVIEW

This report is submitted pursuant to 18 V.S.A. § 4635 ("Prescription Drug Cost Transparency"). The statute requires that the Attorney General's Office ("AGO") provide a report to the General Assembly on an annual basis. This report focuses on information provided to the AGO by the Department of Vermont Health Access ("DVHA"), Blue Cross and Blue Shield Vermont ("BCBS") and MVP Health Care ("MVP") for calendar year 2018.[1]

I. Information Provided by the Department of Vermont Health Access

Pursuant to 18 V.S.A. § 4635, DVHA and health insurers with more than 5,000 covered lives in Vermont for major medical health insurance (referred to below as "Health Insurers") are required to provide certain information annually about the increase in the price of prescription drugs.

The statute requires that DVHA annually create two lists. The first, required by 18 V.S.A. § 4635 (b)(1)(A), is comprised of 10 prescription drugs (at least one generic and one brand name) on which the State "spends significant health care dollars" and for which the wholesale acquisition cost ("WAC") [2] has increased by 50 percent or more over the past five calendar years or by 15 percent or more during the previous calendar year. DVHA must rank the drugs on the list from those with the largest to smallest increase, and state: whether it considers any of the drugs to be specialty drugs; whether the drugs were included based on their price increase over one year, five years or both; and provide DVHA's total expenditure for each drug. The WAC list provided by DVHA is attached as Exhibit A.

[1] This report was prepared after discussing with legislative leaders the challenges of complying with the reporting requirements of the statute. The AGO looks forward to working with the Legislature to address the compliance challenges presented by, among other things, federal law which prohibits Medicaid from providing drug-specific net cost information.

[2] WAC is a manufacturer's "list price" to a wholesaler and does not reflect the discounts and rebates negotiated by wholesalers and other drug purchasers such as pharmacies, hospitals, pharmacy benefit managers and payers.

The second list, required by 18 V.S.A. § 4635 (b)(1)(B), is comprised of 10 prescription drugs (at least one generic and one brand name) on which the State "spends significant health care dollars" and for which DVHA's net cost[3] has increased by 50 percent or more over the past five years or 15 percent or more during the previous calendar year. DVHA must rank the drugs on the list from those with the largest to smallest increase, state whether it considers any of the drugs to be specialty drugs, and whether they were included based on their price increase over one year, five years or both. (18 V.S.A. § 4635 (b)(1)(B)). The net cost list provided by DVHA is attached hereto as Exhibit B.

The methodology DVHA used to create its 2018 WAC and net price lists is attached as Exhibit C.

II. Information Provided by Vermont Health Insurers

Pursuant to 18 V.S.A. § 4635 (b)(1)(C), Health Insurers are also required to create a list of 10 prescription drugs (at least one generic and one brand name) on which the insurance plan "spends significant health care dollars" and for which the insurance plan's net cost[4] has increased by 50 percent or more over the past five years, 15 percent or more during the previous calendar year, or both. Each Health Insurer must rank the drugs on the list from those with the largest to smallest increase and state whether it considers any of the drugs to be specialty drugs. The public version of the 2018 net cost lists provided by BCBS and MVP are attached hereto as Exhibits D and E, respectively. [5]

III. Factors That Influence Manufacturers' Drug Pricing

As observed by the AGO in its February 2018 Pharmaceutical Cost Transparency report, manufacturers have identified several factors they consider in making pricing decisions, although the weight they place on those factors seems to vary. The factors commonly mentioned as impacting manufacture's decisions to increase prices are listed below, in no particular order:

[3] "Net cost" under 18 V.S. A. § 4635 (b)(1)(B) means the cost net of rebates and other price concessions.
[4] "Net cost" under 18 V.S. A. § 4635 (b)(1)(C) means the cost net of rebates and other price concessions.
[5] Health Insurers also provide the Attorney General's Office with a list that includes the insurer's actual net dollars spent on each drug. That list is exempt from public inspection pursuant to 18 V.S. A. § 4635 (b)(1)(C)(ii).

- 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 risks undertaken;
- return on investment;
- 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;
- the rate of inflation; and
- percentage of sales in commercial versus Medicare or other government channels, and the funds expended on assistance programs for people with limited resources or without insurance which, in some measure, offset drug sales income.

IV. Analysis of Cost Information Submitted by DVHA and Health Insurers

Health Insurers provide the AGO with their net expenditures on a confidential basis. Because federal law prevents DVHA from disclosing the net prices it pays for individual drugs, it is unable to provide the AGO with the prices actually paid, even on a confidential basis. 42 U.S.C. § 1396r-8(b)(3)(D). DVHA has provided the gross dollar amount (WAC) it paid for individual drugs, as depicted in Exhibit A, but those figures do not exclude any rebates and other price concessions it receives. As a result, it is not possible to compare the net drug costs to the Health Insurers and DVHA. As discussed below, there is no overlap between the drugs on the net cost lists submitted by DVHA and the Health Insurers.

A. How DVHA and the Insurers Selected the Drugs on the Lists

As mentioned above, 18 V.S.A. § 4635 permits DVHA and the Health Insurers to compile their lists based on either drug price increases of 50 percent or more over the past five years or 15 percent or more during the previous calendar year. For its WAC list, DVHA selected 4 drugs based on five-year increases and 6 drugs based on one-year increases. (Ex. C., p.1). Its net cost list also included a mix of drugs selected for their one-year and five-year increases. (Ex. C., pp.1-2).

BCBS selected drugs with net price increases of 50 percent or more over the past five years, and MVP selected drugs with net price increases of 15 percent or more during the previous calendar year.

B. Generic and Brand Name Drug Price Increases

The statute requires that DVHA and the Health Insures list at least one generic and one branded drug. DVHA listed one generic drug on its net list. That drug had the lowest percentage increase of the drugs listed, but had the highest total WAC spend. The branded drug increases ranged from a low of 20% for one year to a high of 730% for 5 years. Of the 5 generic drugs on its WAC list, there was a wide percentage increase, in both the one-year and five-year categories. One generic drug, for example, had a 94.99% one-year increase and a 250.41% five-year increase, with the total $29,374 WAC price paid in 2018 being among the lowest DVHA spends listed. While the WAC list showed the highest percentage price increases among the generic drugs, there were also substantial increases of 51.68% to 86.59% among the brand name drugs. The DVHA net price increase list and WAC price increase lists had no drugs in common.

BCBS and MVP each selected one generic drug, the price increases for which were 98.2% over five years and 44.6% over one year, respectively. MVP's brand name drug increases ranged from 21.4% to 67% over one year and BCBSVT's brand name drug increases ranged from 57.9% to 103.3% over 5 years.

Neither Health Insurer listed a generic or brand name drug that was common to either the DVHA WAC or net list.

C. Specialty Drugs

The statute requires that DVHA and the Health Insurers identify any "specialty drugs" that appear on their lists. "Specialty drugs" are used to treat chronic, serious, or life-threatening conditions and are often far more costly than traditional drugs.[6]

[6] They can cost thousands of dollars per month and may exceed $100,000 per year. There are few or no low-cost generics. "Although there is no accepted definition of *specialty pharmaceuticals*, they generally are drugs and biologics (medicines derived from living cells cultured in a laboratory) that are complex to manufacture, can be difficult to administer, may require special patient monitoring, and sometimes have Food and Drug Administration (FDA)-mandated strategies to control and monitor their use." https://www.healthaffairs.org/do/10.1377/hpb20131125.510855/full/. They may require specialized and temperature-controlled shipping, storage and handling.

DVHA identified one specialty drug on its WAC list for which the one and five-year increases were 19.9% and 68.09%, respectively, and one on its net list, for which the one and five-year increases were 21% and 52%, respectively.

All the drugs on the BCBS list were specialty drugs except for one.[7] As noted above, the five-year percentage increase for those drugs ranged from 57.7% to 119.5%. MVP included two specialty drugs whose prices increased 22.1% and 67% over a one-year period. The single drug common to both Health Insurers' lists is a specialty drug.

Conclusion

Pharmaceutical drug pricing is extraordinarily complicated. Each party in the drug distribution chain (which includes manufacturers, wholesalers, pharmacy benefit managers, pharmacies, health/plans/payers) is governed by myriad requirements, and they also have a variety of interests. While it is clear there are ongoing sizeable drug price increases, the process of preparing this report - including communications with DVHA and the Health Insurers over many months - has demonstrated the challenges to providing the public with useable information about pharmaceutical pricing.

[7] The single non-specialty drug was the generic that fulfilled the statutory requirement to include at least one generic. It had a five-year percentage increase of 98.2%, but the actual net spend was significantly lower than any other drug on the BCBSVT list.

Exhibit A

TOP 10 GROSS AMOUNT PAID (Chart 1)										
Therapeutic Category	PRODUCT_NAME	GENERIC NAME	LABELER_NAME	Brand or Generic (B/G)	LIST ID (1=1yr 5=5yr)	Rank by Gross Amount Paid of Drugs that Met Threshold 1= Highest Spend	PERCENT_INCREASE (Over One Year or Five Years)	GROSS AMOUNT PAID in CY2018	Specialty (Yes/No)	Appeared on previous list (Year)
Epilepsy	ONFI	clobazam	LUNDBECK, LLC	B	5	6	86.59%	$872,066.06	N	N
Diabetes	JARDIANCE	empagliflozin	BOEHRINGER INGELHEIM PHARMACEUTICALS	B	5	7	54.53%	$680,926.39	N	N
Antibiotic	XIFAXAN	rifaxamin	SALIX PHARMACEUTICAL	B	5	12	55.22%	$498,376.47	N	N
Antineoplastic (Cancer)	AFINITOR	everolimus	NOVARTIS	B	5	16	51.68%	$352,653.29	N	N
Psychotherapeutic	CLONIDINE HCL	clonidine HCl	UNICHEM PHARMACEUTICALS, INC.	G	1	4	20.00%	$63,948.55	N	N
Musculoskletal	METHOCARBAMOL	methocarbamol	CAMBER PHARMACEUTICALS, INC.	G	5	116	53.75%	$32,716.92	N	N
					1	6	47.27%		N	N
Antidepressant	FLUOXETINE HCL	fluoxetine HCl	ALEMBIC PHARMACEUTICALS INC.	G	1	8	250.16%	$28,240.46	N	N
					5	94	250.16%		N	N
Analgesic	IBUPROFEN	Ibuprofen	TIME-CAP LABS, INC.	G	5	107	61.14%	$22,783.26	N	N
					1	10	58.98%		N	N
Opioid Analgesic	MORPHINE SULFATE	morphine sulfate	WEST-WARD PHARMACEUTICALS CORP.	G	1	7	94.99%	$29,374.07	N	N
					5	91	250.41%		N	N
Multiple Sclerosis	AMPYRA	dalfampridine	ACORDA THERAPEUTICS, INC.	B	5	57	68.09%	$65,735.13	Y	N
					1	3	19.90%		Y	N

Exhibit B

TOP 10 NET AMOUNT PAID (Chart 2)											
Therapeutic Category	PRODUCT_NAME	GENERIC NAME	LABELER_NAME	Brand or Generic (B/G)	LIST ID (1=1yr 5=5yr)	Rank by Net Amount Paid of Drugs that Met Threshold 1= Highest Net Spend	PERCENT_INCREASE (Over One Year or Five Years)	GROSS AMOUNT PAID in CY2018	Specialty (Yes/No)	Appeared on previous list (Year)	Appeared on this year's GROSS (WAC) COST LIST
Immune Modulator	STELARA	ustekinumab	JANSSEN BIOTECH, INC	B	5	6	52%	$ 2,127,932.77	Y	N	N
					1	2	21%				
ADHD	METHYLPHENIDATE HYDROCHLO	methylphenidate	WATSON PHARMA, INC.	G	1	1	17%	$ 1,461,928.15	N	N	N
COPD	COMBIVENT RESPIMAT		BOEHRINGER INGELHEIM PHARMACEUTICALS	B	1	6	50%	$ 589,079.93	N	N	N
Gastrointestinal	NEXIUM	esomeprazole	ASTRAZENECA PHARMACEUTICALS LP	B	5	1	440%	$ 498,765.15	N	N	N
					1	3	201%				
Antidepressant	PRISTIQ	desvenlafaxine	WYETH LABORATORIES	B	5	2	730%	$ 421,231.63	N	Y	N
					1	4	67%				
HIV	GENVOYA		GILEAD SCIENCES, INC.	B	1	5	44%	$ 390,000.94	N	N	N
Antipsychotic	INVEGA		JANSSEN PHARMACEUTICALS, INC	B	5	5	131%	$ 316,988.97	N	N	N
					1	9	27%				
Diabetes	CONTOUR NEXT BLOOD GLUCOSE TEST STRIPS	BG Test Strips	ASCENSIA DIABETES CARE	B	5	3	65%	$ 250,205.15	N	N	N
					1	7	24%				
Pain (Neuropathic)	LIDODERM	lidocaine	ENDO PHARMACEUTICALS, INC.	B	5	4	213%	$ 195,698.61	N	Y	N
					1	8	20%				
antiarrhythmic	TIKOSYN	dofetilide	PFIZER LABORATORIES DIV PFIZER INC	B	5	9	422%	$ 125,610.99	N	N	N
					1	10	45%				

Exhibit C

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18 V.S.A. § 4635- Pricing Transparency Drug List-DVHA Methodology

Date: 09/06/2019

Vermont law 18 V.S.A. § 4635, entitled "Prescription Drug Cost Transparency" requires the Department of Vermont Health Access ("DVHA") to create two lists of 10 prescription drugs each for which the gross and net costs have increased by 50 percent or more over the past five years or 15 percent or more over the past calendar year. DVHA's Pharmacy Unit prepared data on drugs that meet the criteria per the following methodology.

Methodology used for selection of drug list for 18 V.S.A. § 4635:

The data was supplied by DVHA's Pharmacy Benefits Manager (PBM) Change Healthcare, based on criteria supplied by DVHA and produced a detailed listing of all drugs that exceeded the threshold as defined in statute. The final list of the top 10 drugs in each category was derived by reviewing these lists in detail, taking into consideration the previous year's lists, and brand, generic and specialty status. Net spend was also considered when generating the ranking of the drugs in the "net cost" list.

TOP 10 GROSS AMOUNT PAID (Chart 1)

This list contains drugs for which the wholesale acquisition cost (WAC) increased by 50 percent or more over the five-year period from 2014-2018 or by 15 percent or more in calendar year 2018. The WAC unit price for all years was pulled as of December 31st of each calendar year. The data was then averaged and grouped at the product name level. The data was initially sorted based on the highest total gross cost to DVHA according to the list from which it was derived (1-year or 5-year). An additional list was sorted for largest percent increase in WAC according to the list from which it was derived (1-year or 5-year).

DVHA included four of drugs that were in the top 20 of all drugs on the five-year list, and six drugs that were in the top 20 on the one-year list. Our focus was on drugs that experienced more recent and significant price increases in CY2018.

TOP 10-NET AMOUNT PAID (Chart 2)

This list contains drugs for which the net cost to DVHA increased by 50 percent or more over the five-year period from 2014-2018 or by 15 percent or more in calendar year 2018. DVHA net cost was calculated as pharmacy reimbursement minus any and all rebates. The total net cost for each NDC was divided by the total quantity (ex. tablets or capsules) of the drug reimbursed by DVHA for that NDC to obtain the Net Unit Cost for each drug. The data was pulled by Calendar Year, then averaged and grouped at the product name level. The data was initially sorted based on the highest net paid amounts according to the list it from which it was derived (1-year or 5-year). Another sort generated a list looking at the highest average percent increase according to the list from which it was derived (1-year or 5-year).

The drug lists were further refined to assure that at least one generic and one brand appeared on each list, and specialty drugs were identified. Specialty drugs were defined as per DVHA's posted list of specialty drugs on the DVHA website at: http://dvha.vermont.gov/for-providers/specialtydrugweblist.pdf.

Since DVHA is prohibited from publishing drug-specific net cost information, the gross cost to DVHA for each drug listed was provided as a benchmark. This will not align in rank order with the net cost of the drug to the State.

A summary of the drug NDC's analyzed appears below:

CY 2018									
Category	Total # NDC's Evaluated	# of NDCs Exceeded Threshold	% of Total	Number of generic NDCs exceeding threshold	Generic % of total NDCs exceeding threshold	Avg % Increase Generic	Avg % Increase Brand	Avg $ Inc Generic	Avg $ Increase Brand
WAC >= 50% last 5 Yr	81,116	3,934	4.85%	2,019	51.32%	328.74%	135.11%	$68.65	$79.11
WAC>= 15% last 1Yr	87,343	1,149	1.32%	775	67.45%	144.82%	69.86%	$40.46	$24.16

Exhibit D

BCBSVT List of Drugs with Largest Net Price Increase Impact

Pursuant to 18 V.S.A. § 4635 (b)(C)(i)

2018

RANKING	NATIONAL_DRUG_CODE	DRUG_NAME	MANUFACTURER	Brand/Generic	Specialty?	5-yr % Increase
1	00074433902	HUMIRA 40 MG/0.8 ML PEN	AbbVie	Brand	Yes	99.1%
2	58406044504	ENBREL 50 MG/ML SURECLICK	Amgen	Brand	Yes	103.3%
3	00074379902	HUMIRA 40 MG/0.8 ML SYRIN	AbbVie	Brand	Yes	93.3%
4	59572041028	REVLIMID 10 MG CAPSULE	Celgene	Brand	Yes	66.8%
5	68546031730	COPAXONE 20 MG/ML SYRINGE	Novartis	Brand	Yes	57.7%
6	58406043504	ENBREL 50 MG/ML SYRINGE	Amgen	Brand	Yes	119.5%
7	57894007002	SIMPONI 50 MG/0.5 ML PEN	Janssen	Brand	Yes	96.6%
8	50242010040	PULMOZYME 1 MG/ML AMPUL	Genentech	Brand	Yes	57.9%
9	00078056751	AFINITOR 10 MG TABLET	Novartis	Brand	Yes	77.8%
10	68682035710	DIHYDROERGOTAMINE 4 MG/ML	Oceanside Pharmaceuticals	Generic	No	98.2%

Note: Price increases were calculated after applying any manufacturer rebates and administrative fees.

Exhibit E

MVP List of Drugs with Largest Net Price Increase Impact
Pursuant to 18 V.S.A. § 4635(b)(1)(C)(i)
2018

Ranking	National Drug Code(s) (NDC)	Drug Name	Manufacturer	Brand/ Generic	Specialty?	1 Year % Increase
1	50242010040	PULMOZYME SOL 1MG/ML	Genentech	Brand	Yes	67.0%
2	00169255013	TRESIBA FLEX PEN 200U/ML	Novo Nordisk	Brand	No	62.7%
3	00591315901	URSODIOL CAP 300MG	Actavis	Generic	No	44.6%
4	00169266015	TRESIBA FLEX PEN 100U/ML	Novo Nordisk	Brand	No	37.4%
5	00169643810	LEVEMIR FLEX PEN 100U/ML	Novo Nordisk	Brand	No	33.6%
6	00071101568	LYRICA CAP 100MG	Pfizer	Brand	No	30.4%
7	00310620530	FARXIGA TAB 5MG	Astrazeneca	Brand	No	23.4%
8	00071101368	LYRICA CAP 50MG	Pfizer	Brand	No	23.2%
9	50419017103	STIVARGA TAB 40MG	Bayer	Brand	Yes	22.1%
10	63402030830	LATUDA TAB 80MG	Sunovion	Brand	No	21.4%

Note: Price increases were calculated after applying any manufacturer rebates and administrative fees.