Attorney General's Report on Prescription Drug Cost Transparency
Pursuant to 18 V.S.A. § 4635
December 1, 2022

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 regarding prescription drug costs. This report focuses on information provided to the AGO by the Department of Vermont Health Access ("DVHA"), Blue Cross and Blue Shield Vermont ("BCBSVT") and MVP Health Care ("MVP") for calendar year 2021.[1]

I. Statutory Reporting Requirements

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 also 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.[2]

[1] The AGO's 2019 report was prepared after discussing with Legislative leaders the challenges of complying with the reporting requirements of the statute. The same report format has been used by the AGO since that time. 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] Specialty drugs 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.

A. Statutory Requirements of DVHA

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") [3] 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 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[4] 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)).

DVHA's WAC list, net cost list, and an explanation of the drug selection criteria it used for each are attached as Exhibit A.

[3] WAC is defined under federal law as a manufacturer's "list price" for a drug to wholesalers or other direct purchasers but does not reflect any prompt pay or other discounts, rebates, or reductions in price. 42 U.S.C. § 1395w-3a (c) (6).

[4] "Net cost" is defined in 18 V.S. A. § 4635 (b)(1)(B) as the cost to DVHA net of rebates and other price concessions.

B. Statutory Requirements of Vermont Health Insurers

Pursuant to 18 V.S.A. § 4635 (b)(1)(C), the 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[5] 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 versions of the 2021 net cost lists provided by BCBSVT and MVP are attached hereto as Exhibits B and C, respectively. 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).

II. Factors That Influence Manufacturers' Drug Pricing

As observed by the AGO in previous Prescription Drug Cost Transparency reports, 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 specific order:

- 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,

[5] "Net cost" is defined in 18 V.S. A. § 4635 (b)(1)(C) as the cost to the insurance plans net of rebates and other price concessions.

- 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.

III. Analysis of Cost Information Submitted by DVHA and the Health Insurers

As mentioned above, the Health Insurers provide the AGO with their net dollar 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 or other price concessions it receives. As a result, it is not possible to compare DVHA's net drug costs to the Health Insurers' net drug costs.

A. How DVHA and the Health Insurers Selected the Drugs on the 2021 Lists

Under 18 V.S.A. § 4635, DVHA and the Health Insurers may 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. To be consistent and to maximize comparison of the lists, DVHA and the Health Insurers selected their 10 drugs based on an increase of 15 percent or more during calendar year 2021.

B. DVHA's 2021 Drug Selections

Since DVHA is prohibited from revealing drug-specific net cost information, its net amount list ranks the drugs from 1 through 10 but reflects the gross amount paid for those drugs. As DVHA observed in its footnote to the net cost chart, the gross amount paid "may not align in rank order with the net cost of the drug to the State." Ex. A., p.3.

The drugs on DVHA's 2021 WAC list and net amount lists did not overlap. There were no specialty drugs listed on its WAC list. There are 4 specialty drugs on its net amount list. DVHA listed 8 generic drugs on its WAC list and 3 generic drugs on its net amount list. Two of the drugs on DVHA's WAC list also appeared on its 2020 calendar WAC year list. One is a generic drug and the other is a brand drug. Neither is a specialty drug. DHVA noted that 2 of the drugs on its net amount list have been considered as treatments for Covid 19.

DVHA made several notable observations about the drug price trends it experienced over the past 3 years:

> Compared to 2019, there has been a 50% decline in the total number of drugs reaching the 15% increase per year threshold. There seems to be a consistent trend that fewer manufacturers are excessively increasing their wholesale acquisition costs for drugs.
>
> Compared to 2019, the average increase in generic drugs has declined. In 2019 the average increase for a generic was 177% ($0.68) compared to 2021 the average increase for a generic was 111% ($0.20).
>
> Generic drug prices consistently rose at a higher rate than brand drugs. In 2021 the average increase for generic 110% vs average increase brands was 27%.

Ex. A., p.4.

C. Health Insurers' 2021 Drug Selections

The Health Insurers listed no drugs in common in 2021, but the same brand specialty drug (Stelara) appeared on both the BCBSVT and DVHA 2021 net increase lists. The Health Insurers each listed 4 specialty drugs on their 2021 lists.

BCBSVT listed one generic which with a 44% increase over the 2020 net amount. MVP listed two generics, one with a 19.37% increase over 2020 and the other with a 36.85% increase over 2020. BCBSVT's brand name drug increases ranged from 21% to 53%, a significant decrease from the 2020 range of 546.5 % to 2700%. MVP's 2021 brand name drug increases ranged from 17.09% to 92.89% and represented a decrease from its 2020 brand name drug increases of 19.62% to 431.99%. There were no drugs common to BCBSVT's 2020 and 2021 lists. There was one brand drug common to MVP's 2020 and 2021 lists.

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 in both brand and generic drugs, 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.

Respectfully Submitted,

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