# Drug Transparency Report

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#### Prepared by:

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## **Table of Contents**

Introduction	3
Obligations	3
The Lists	4
Analysis	5
Drug Manufacturer Financial Assistance and PBM Rebates	9
EDDs Manufacturer Price Increase Justifications	10
Drug Manufacturer Price Increase Justifications	11
Pharmacy Benefit Manager Reporting	12
Pharmaceutical Representative Reporting	15
Compensation Provided by Pharmaceutical Representatives	16
Wholesalers	19
Discussion	20
Report Methodology and Reporting Compliance	20
Essential Diabetic Drug Manufacturer Reporting	20
Price Increase Justification Analysis	20
PBM Rebates	21
Pharmaceutical Representative Compensation and Samples Data	21
DHHS Invites You to Learn More	21
Appendix	21

#### Introduction

This report is submitted pursuant to the requirements of Nevada Revised Statutes (NRS) 439B.650. This information will be presented in a public hearing posted after June 1, 2022.

#### **Obligations**

Pursuant to NRS 439B.630, the Nevada Department of Health and Human Services (DHHS or the Department) is required to compile a list of prescription drugs essential for treating diabetes (Essential Diabetic Drugs or EDDs), a list of those Essential Diabetic Drugs that had a significant price increase as well as other medication that had a significant price increase and cost more than \$40 per course of therapy in Nevada. The final versions of these lists were published March 26, 2022. These lists may be viewed here: Final Essential Lists 32622 (nv.gov)

All manufacturers that produce medication included in Nevada's Essential Diabetes Drug List are required to submit to DHHS a report with data outlining drug production costs, profits, financial aid, and other drug-specific information and pricing data (NRS 439B.635). For drugs that experienced a recent significant price increase, manufacturers are required to submit a report that provides a justification for these price increases (NRS 439B.640).

As of this writing, five manufacturers are out of compliance and were issued letters regarding their obligation and the possibility of a penalty if the required reports are not received by the Department.

Pharmacy Benefit Managers (PBMs) are required to submit reports regarding rebates negotiated with manufacturers for drugs on both the Diabetic Essential Drug List and the Over \$40 Drug List (NRS 439B.645).

This year, wholesalers also began reporting for drugs on these lists. Wholesalers report information regarding wholesale acquisition cost (WAC), volume shipped into the state, and details regarding rebates.

DHHS is also required to maintain a registry of pharmaceutical sales representatives that market prescription drugs in Nevada (NRS 439B.660). These representatives are required to annually submit a list of health care providers and other individuals to whom they provided drug samples and/or individual compensation events exceeding \$10 or total compensation exceeding \$100 during the previous calendar year. Instructions to drug representatives clarify they are only required to report if they have five or more days of activity in Nevada.

When DHHS creates the annual report on compensation and samples, this report includes aggregated information regarding what pharmaceutical representatives provided to eligible health professionals and staff.

State law requires that DHHS compile a report concerning the price of Essential Drugs: NRS 439B.650.

On or before June 1 of each year, the Department shall analyze the information submitted pursuant to NRS 439B.635, 439B.640 and 439B.645 and compile a report on the price of the prescription drugs that appear on the most current lists compiled by the Department pursuant to NRS 439B.630, the reasons for any increases in those prices and the effect of those prices on overall spending on prescription drugs in this State. The report may include, without limitation, opportunities for persons and entities in this State to lower the cost of drugs while maintaining access to such drugs. (Added to NRS by 2017, 4299)

#### The Lists

DHHS created four lists, utilizing a methodology that met the requirements of NRS 439B.630. To generate these lists, DHHS used packaging and pricing data from First Data Bank.

The first list is simplified and shows both brand and generic names of Essential Diabetic Drugs. This is intended for consumers and is named "List #1."

The second list is Essential Diabetic Drugs and includes each National Drug Code (NDC) available for that drug. To generate the list, DHHS compiled a list of diabetes drug NDCs that included varying drug packaging formulations based on First Data Bank information for these drugs. This was named "List #2."

This Essential Diabetic Drug List does not include any drugs used to treat co-morbidities often present in individuals with diabetes. The list does not contain every drug that may be an effective treatment or approved for the treatment of diabetes. This list attempts to refine the numerous treatments to those approved for the treatment of diabetes. For this reason, some brand names, generics, or alternative brands may not be included.

DHHS analyzed this Essential Diabetic Drug List to identify those that experienced a significant price increase during the preceding one- and two-year periods as defined by Nevada law. This process evaluated price increases occurring during the 2020 and 2021 calendar years. This is named "List #3."

For Essential Diabetic Drugs, NRS 439B.630 requires that the percentage price increase be compared against the Consumer Price Index (CPI), Medical Care Component to identify drugs that experienced a significant price increase.

The CPI is designed to measure inflation over time and is published by the United States Department of Labor. This measures the average percentage change over time in the prices paid by consumers for medical care goods and services. Positive values represent an inflation in the average costs for medical care goods and services. These values act as a benchmark with which diabetic drug price increases are compared to identify the drugs that had a significant price increase.

The criteria were: the price increase must exceed the previous year CPI Medical Component or double the previous two years. For this report, those numbers were 2.2% for one year and 8.0% for two years.

The final list is a presentation of all other prescription, out-patient medication that met these criteria: the medication had to cost over \$40 per course of therapy and had to have taken a 10% WAC increase in the previous year (2021) or a 20% WAC increase in the previous two years (2020 to 2021). This was named "List #4."

#### **Analysis**

Nevada Medicaid claims were evaluated to look at trends as they apply to the posted drug lists.

Medicaid managed care organization and fee-for-service claims data for Nevada were obtained from the DHHS Office of Analytics. This dataset included the total Medicaid expenditures per NDC. For a claim to qualify under a certain calendar year, the prescription must have been filled during that calendar year.

Medicaid represents about 26% of Nevadans and is not a complete picture, but does give the Department a point of reference.

Table 1 represents the change in an average Nevada Medicaid claim over the last five years.

**Table 1: Medications Billed to Medicaid** 

Year	<b>Total Spend</b>	Total # of Medicaid Prescriptions	Average Cost per Claim
2017	\$428,783,630	5,034,528	\$85.17
2018	\$738,580,755	8,321,139	\$88.76
2019	\$680,200,258	7,309,635	\$93.06
2020	\$792,020,553	7,766,456	\$101.98
2021	\$813,233,775	7,427,940	\$109.48

DHHS looked at the top three 2021 Medicaid claims by both spend and volume. This is depicted in the tables below (Table 2 and Table 3).

Table 2: Medications Billed to Medicaid by Spend

Drug	\$ Spend	Indication
Biktarvy	\$33,446,954	HIV
Humira	\$29,102,830.00	Auto-immune disorders
Advate	\$21,597,473.00	Hemophilia

The above three medications in Table 2 represent over 10% of the total expenditures for Medicaid claims.

Table 3: Medications Billed to Medicaid by Volume

Drug	# of Prescriptions	Indication
Albuterol inhaler	133,666	Asthma, COPD
Ibuprofen	92,940	Pain, inflammation
Fluticasone nasal	64,861	Seasonal allergies

This year, 1,029 diabetic drugs appeared on the Essential Diabetic Drug List. Of those, 151 had a significant price increase. That is 14.7% and approximately the same as last year as depicted in Table 4 below.

**Table 4: Percent of EDDs with Significant Increase by Year** 

Year	Percent of EDDs with Significant Price Increase	Percent of EDDs with Significant Price Increase (new methodology)
2018 data	22.4 %	
2019 data	18.5 %	
2020 data	18.6 %	14.6 % *
2021 data	23.0 %	14.7 % *

<sup>\*</sup> Methodology changed in 2020. In 2018 and 2019, review of EDDs was limited to medications billed to Medicaid. In 2020 and 2021, all medications were included, without determining if they appeared in Medicaid billing.

Table 5 represents the differences in claim cost broken down by type. This is separated by general claims, essential diabetic drugs (EDDs), EDDs with a significant price increase and the new grouping of "over \$40" drugs.

**Table 5: Average of Medicaid Claims** 

Type of Claim	Total # of Claims	Total Cost	Average
			Cost
Essential Diabetic	339,856	\$89,527,683	\$263.42
Essential Diabetic with Increase	63,614	\$47,931,753	\$753.48
Over \$40	4,544	\$4,308,592	\$948.19
Total Medicaid Claims	7,427,940	\$813,233,775	\$109.48

4.6% of the medications billed to Medicaid were essential diabetic medications (339,856 out of 7,427,940). These medications cost \$89,527,683, about 11% of total spend. This means the percent spent exceeds the percent of prescriptions, as seen in previous years. This is best explained by the very high cost of popular, newer diabetic medications that are still protected by patent.

Diabetic medications that had a significant price increase comprised just 0.86% of total Medicaid prescriptions (63,614), but 5.9% of total Medicaid spend.

The average diabetic claim was \$263.42 for 2021, an increase from \$231.77 in 2020 and \$238.38 in 2019.

This year, DHHS began to evaluate medications that cost over \$40 for a course of therapy and had a significant price increase. 178 medications appeared on this list.

These medications made up a very small percentage of Medicaid prescription claims. The spend was also a small percentage, however, it was disproportionate. These "over \$40" medications comprised less than 1% of total prescriptions, at only 4,544 prescriptions statewide. With a total cost of \$4,308,591.43, the cost per prescription was disproportionately high at \$948.19. Table 5 above shows the cost of an average Medicaid claim to be \$109.48 and an average diabetic claim to be \$263.42.

Figure 1 evaluates "over \$40" claims by what condition they treat. This is broken down by the number of drugs that showed up on the list (not number of claims). The most prevalent group was medication to either treat opiate dependence or was an opiate (at 25%). This is followed closely by mental health medication. The following figure, Figure 2 shows this "over \$40" group broken down by number of claims.

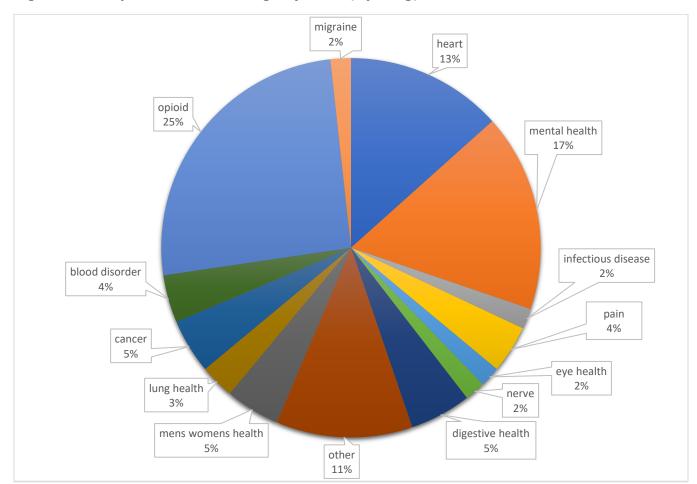


Figure 1. Compare Over \$40 Drugs by Class (by drug)

(Values of 1% or less were not included in the figure above.)

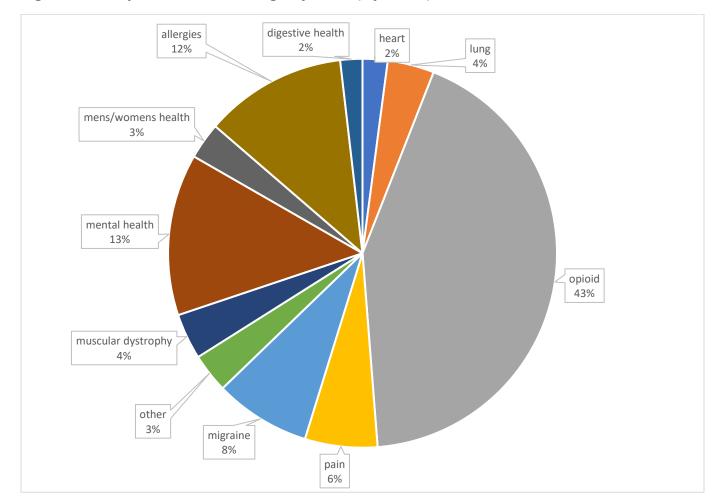


Figure 2. Compare Over \$40 Drugs by Class (by claim)

(Values of 1% or less were not included in the figure above.)

## **Drug Manufacturer Financial Assistance and PBM Rebates**

Manufacturers reported the financial assistance provided to consumers and rebates that were provided to PBMs (Figure 3). PBMs can negotiate prescription drug rebates with drug manufacturers. Some PBMs pass all these rebates on to insurers or consumers while others retain a portion of the rebates.

Most of the Essential Diabetic Drugs are generic and typically do not provide aid in the form of rebates, patient assistance or coupons. The total amount of financial assistance provided through patient prescription assistance programs was \$1,748,828,946.14.

The value of the aggregate rebates that manufacturers provided to PBMs for Nevada drug sales was \$245,134,537.06.

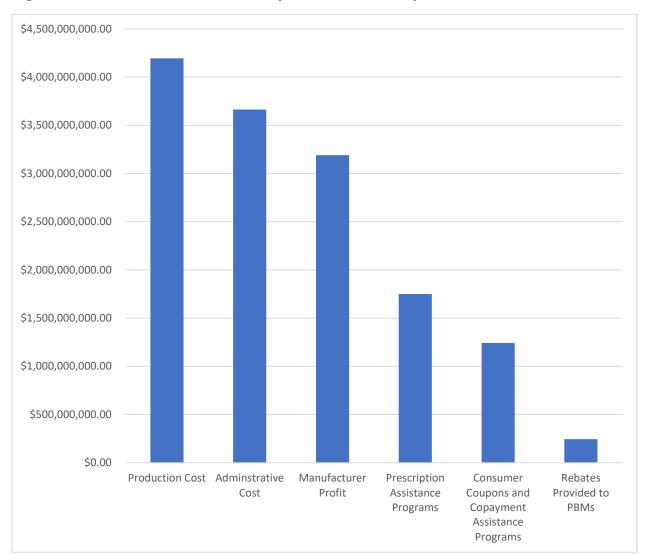


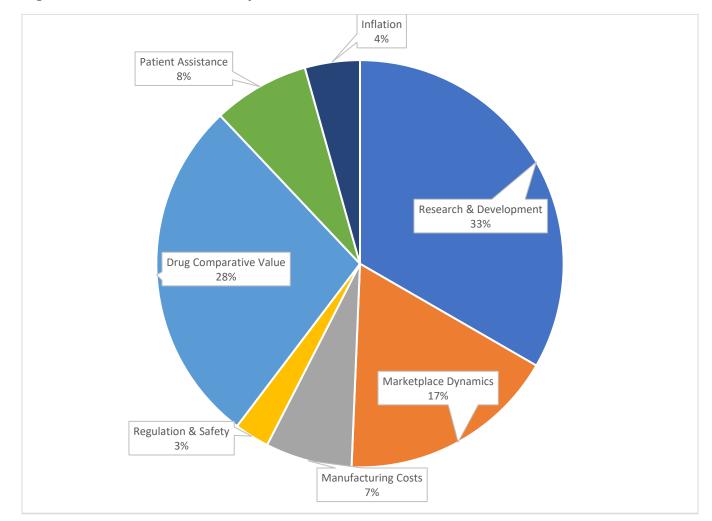
Figure 3. Manufacturer Profit Compared to other Expenses

#### **EDDs Manufacturer Price Increase Justifications**

Price increases were reported in two places. The first was all drugs on the EDD list (list #2) had to explain any increase in the last five years, even if not considered a "substantial increase." This information is depicted in Figure 4.

To assist with analysis, DHHS standardized responses into major categories. Responses were then quantified so that they could be compared for their relative prevalence. A single drug in some cases had more than one price increase justification.

Appendix 2 provides summarized examples of each category to further describe these justifications.



**Figure 4: Justifications for Any Price Increases for EDDs** 

(Values of 1% or less are not included in the above figure.)

## **Drug Manufacturer Price Increase Justification**

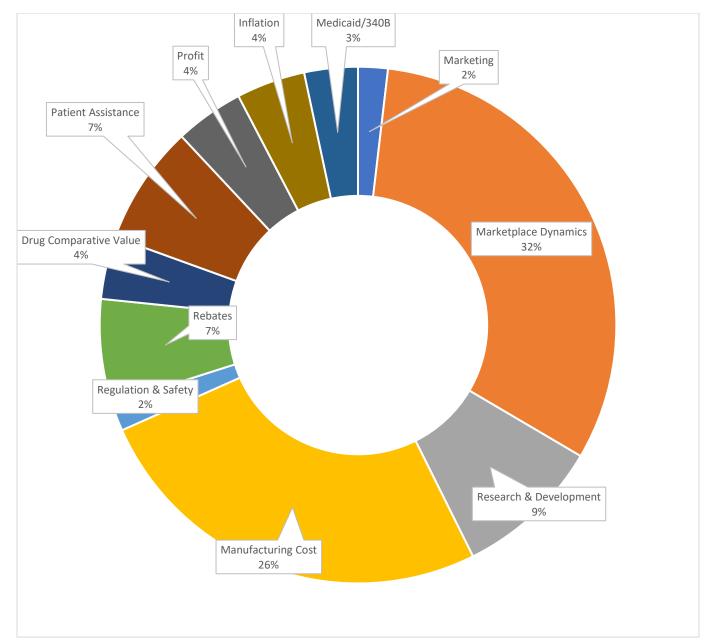
The second place that increases were reported was for drugs on list #3 or #4 that experienced a "substantial increase." This is very different than what is reported above as it only includes the reporting period of two years, and only substantial increases. That said, the responses were similar.

As reported, 151 drug NDCs in the 2021 Essential Diabetic Drug List had a significant price increase during the preceding one and/or two calendar years.

178 drug NDCs were reported on the Over \$40 list.

Drug manufacturers that appeared on either of these lists were required to submit a report outlining a justification for the price increases for each drug.

Some respondents instead reported a philosophy regarding how drugs should be priced, rather than drug specific information.



**Figure 5: Justifications for Significant Price Increases** 

In Figure 5, The most frequent justification for a price increase was Marketplace Dynamics, followed by Manufacturing Cost.

## **Pharmacy Benefit Manager Reporting**

PBMs reported the rebates negotiated with drug manufacturers during the immediately preceding calendar year for prescription drugs included on Nevada Drug Lists. PBMs reported the

rebates they retained, as well as the rebates that were negotiated for purchases of such drugs for use by:

- recipients of Medicaid,
- recipients of Medicare,
- persons covered by third party governmental entities that are not Medicare and Medicaid,
- persons covered by commercial insurance,
- other

Total reported rebates that PBMs negotiated with manufacturers for Essential Drugs for Nevadans were greater than \$88 million (Table 6). The total reported rebates are broken down into five categories:

- rebates for Medicaid recipients,
- rebates for Medicare recipients,
- persons covered by third parties that are government entities that are not Medicaid or Medicare,
- rebates for persons covered by commercial insurance,
- rebates for persons covered by all other third parties.

Some reports from PBMs could not be included in this final report as the data was not reported as requested and would distort an aggregated result. What is displayed in Table 6 below, is the compilation of the reports submitted with requested data.

This year, PBMs were required to break down by NDC and that may have caused some of the difficulty.

The issues seen by the Department include:

- 1. no data at all because a third party was utilized to negotiate rebates,
- 2. reporting on all NDCs rather than those on the lists,
- 3. reporting on all NDCs on part of the report, but only requested NDCs on other parts of report,
- 4. data did not correspond logically,
  - a. indicated more was retained than negotiated
  - b. individual groups negotiated exceed total

Templates will be edited to simplify future reporting.

**Table 6: Total Reported Rebates Negotiated by PBMs for Medications** 

Reported Value Description	Aggregate Value in United States Dollars	Percent of Total
	2021	
Total amount of all rebates that the PBM negotiated with manufacturers during the	\$88,612,533	100%
immediately preceding calendar year for Drugs on Nevada Lists		
Total amount of all rebates described in Row 1	\$4,732,910	5.3%
that were negotiated for purchases of such drugs		
for use by recipients of Medicaid		
Total amount of all rebates described in Row 1	\$39,099,138	44.1%
that were negotiated for purchases of such drugs		
for use by recipients of Medicare		
Total amount of all rebates described in Row 1	\$5,405,002	6.1%
that were negotiated for purchases of such drugs		
for use by persons covered by governmental		
entities that are not Medicaid or Medicare		
Total amount of all rebates described in Row 1	\$38,123,150	43.0%
that were negotiated for purchases of such drugs		
for use by persons covered by commercial		
insurers		
Total amount of all rebates described in Row 1	\$40,121	.05%
that were negotiated for purchases of such drugs		
for use by persons covered by all other third		
parties		
Total amount of all rebates described in Row 1	\$36,184,852	40.8%
that were retained by the PBM		

Figure 6 shows the percentage of reported rebates that PBMs negotiated with manufacturers for entity type.

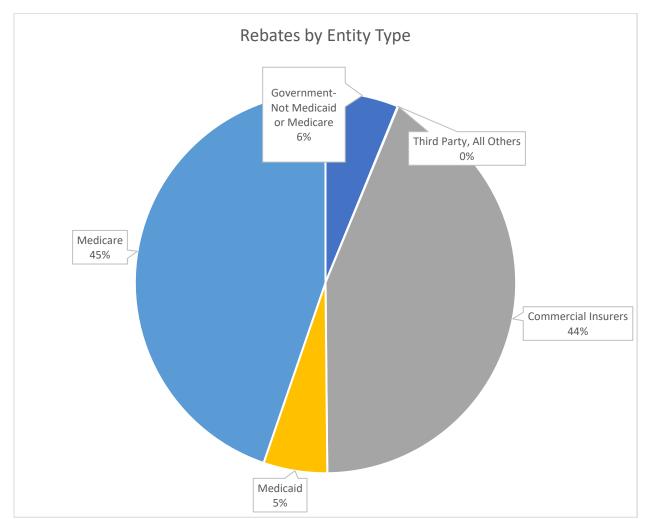


Figure 6: Reported PBM Rebates Negotiated by Insured Entity Type

## **Pharmaceutical Representative Reporting**

NRS 439B.660 requires that sales representatives registered with DHHS who engage in business in Nevada submit a report detailing their compensation and sample distributions in Nevada for the preceding calendar year. Sales representatives are required to report all licensed, certified, or registered health care providers, pharmacy employees, operators or employees of a medical facility, and individuals licensed or certified under the provisions of Title 57 of NRS to whom they provided eligible compensation or samples. Eligible compensation includes any type of compensation with a value of \$10 or total compensation with a value that is \$100 in aggregate. A total of 266,144 pharmaceutical representatives' events were reported for compensation and sample distribution to DHHS. This included 1,174 individuals with activity to report, and 229 different companies. Although only 1,174 had activity to report, 5,503 drug representatives were registered as "active" in Nevada.

#### **Compensation Provided by Pharmaceutical Representatives**

DHHS aggregated the reported compensation values from pharmaceutical representative reports (Table 7). Nevada healthcare providers and staff in their offices collectively received \$3,360,478.72 in compensation from pharmaceutical representatives and the average compensation amount was \$21.12, showing that the predominant pharmaceutical representative interactions with health providers, health support staff, and administration involved small value compensation transactions. Compensation values were categorized by two compensation types based on the reported data and the total reported values for each compensation type were aggregated. Most of the compensation was meal related and represented 90.7% of total compensation dollars with an average of \$19.42.

Since last year there was a significant increase in compensation events, a decrease in total number of manufacturers, and an increase in total dollars spent on these events, as depicted in Table 7.

Table 7: Compensation from Pharmaceutical Representatives by Compensation Type

Туре	Total Amount 2020	Average Amount 2020	Total Amount 2021	Average Amount 2021
Other	\$347,298.84	\$92.33	\$313,925.55	\$160.17
Food and/or	\$1,925,319.88	\$18.16	\$3,046,553.17	\$19.42
Beverage				
Total	\$2,272,618.67	\$20.62	\$3,360,478.72	\$21.12

DHHS aggregated reported compensation values from pharmaceutical representative reports. These values were categorized by recipient type in Table 8. Compensation is a blanket term for items of value transferred to a recipient and only rarely (less than 1% of events) refer to an actual transfer of money.

Because meals are allowed to be reported in aggregate, many chose to report this way. This limits the detail of the information provided in Table 8 as many fell into "office staff" category but may also fit into another category.

In addition, some activity was reported that was not specific to a Nevada representative. This included 3,604 more "events." Nearly 100% were sampling events although a few were meals, and a few cases of educational materials provided. This activity is not included in charts and figures that represent activity specific to Nevada registered representatives.

**Table 8: Compensation by Recipient Type** 

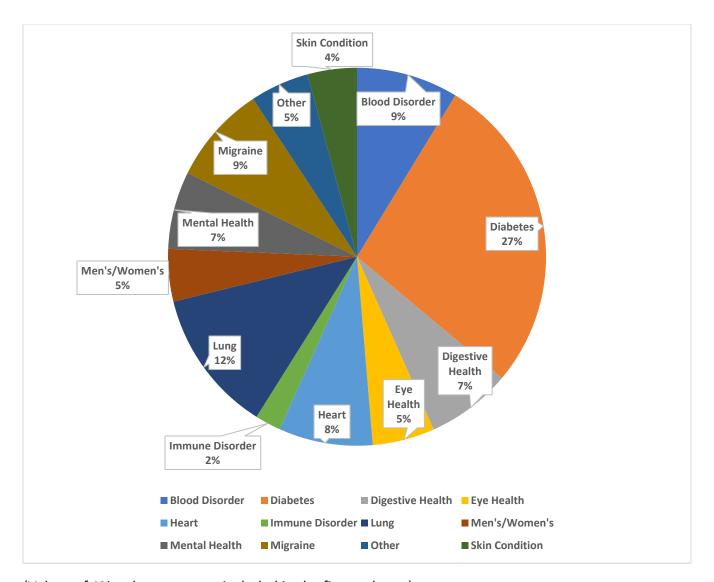
*Recipient Type	Total Compensation Amount	Average Compensation Amount
Pharmacist	\$79,178.73	\$25.72
Physician Assistant	\$65,442.71	\$20.03
RN/LPN (Not NP)	\$164,349.72	\$23.79
Nurse Practitioner (NP)	\$131,934.16	\$23.52
Office Staff	\$1,308,959.71	\$19.71
Other Health Care Provider	\$680,975.38	\$18.08
Other Non-Health Care Provider	\$375,325.43	\$18.51
Doctor (MD or DO)	\$552,719.50	\$35.14

<sup>\*</sup>The following are examples of professions grouped into selected recipient categories:

- Office Staff: receptionists, general office staff, scribe, scheduler
- Other Non-Health Care Provider: administration, technician, optical technician
- Other Health Care Provider: clinical social worker, therapist, psychologist, social worker, doctor of podiatric medicine, dentist

# Figure 7: Percentage Sample Distribution Events by Targeted Health Condition as Reported by Sales Representatives

This figure depicts sample distribution broken down by health condition. Those conditions are grouped and further explained below.



(Values of 1% or less were not included in the figure above.)

The following includes health conditions grouped into each major category:

- Blood Disorder: Anemia, Venous Thromboembolism, Kidney Conditions, Blood Clots
- Cancer: Cancer, Carcinoid Syndrome Diarrhea, Cancer-related Nausea and Vomiting
- Diabetes
- Digestive Health: Acid Reflux, Bowel Prep, Crohn's Disease, Ulcerative Colitis, Exocrine Pancreatic Insufficiency, Heartburn, Hemorrhoids, Irritable Bowel Syndrome, Overactive Bladder, Pancreatic Insufficiency, Ulcer
- Eye Health: Conjunctivitis, Dry Eye, Eye Pain and Swelling, Glaucoma, Macular Degeneration
- Heart Condition: Angina, Atrial Fibrillation, Cardiovascular Disease, Heart Attack, Stroke, Heart Disease, Heart Failure, High Cholesterol, Hypertension

- Infectious Disease: Hep C, Systemic Bacterial Infections, HIV
- Immune Disorder: Auto Immune Diseases, Osteoarthritis, Psoriatic Arthritis, Rheumatoid Arthritis
- Lung Health: Asthma, Chronic Obstructive Pulmonary Disease
- Men's & Women's Health: Birth Control, Endometriosis, Erectile Dysfunction, Fertility, Infection
- Women's Health, Menopause, Prostate, Low-Testosterone, Vaginal Dryness, Osteoporosis, Urinary Tract Infection
- Mental Health: Attention Deficit Hyperactivity Disorder, Binge Eating Disorder, Alzheimer's Disease, Bipolar Disorder, Depression, Schizophrenia, Pseudobulbar Affect
- Nerve Disorder: Multiple Sclerosis, Epilepsy, Parkinson's Disease, Neuropathy, Narcolepsy, Tardive Dyskinesia
- Opioid & Opioid Abuse Treatment: Drug Withdrawal, Opioid Managed Pain, Opioid-Induced Constipation
- Other: Weight Loss, Hyperthyroidism, Allergies, Botox and similar products (multiple indications), Oral or Injectable Steroids (multiple indications)
- Migraine
- Pain Relief: Treated with Topical NSAIDs, Topical Lidocaine and Oral NSAIDs
- Skin conditions: Acne, Actinic Keratosis, Angioedema, Fungal Skin Infections, Parasitic Skin Infections, Antipruritic, Athlete's Foot, Dermatitis, Eczema, Psoriasis, Rosacea/Severe Acne, Seborrheic Dermatitis, Itchy Skin

Figure 7 illustrates that samples most frequently provided were to treat diabetes (26%). Other frequently distributed drug samples included those that support lung health (12%), blood disorders (8%), and migraine (8%).

In the compensation and samples report released in 2018 by DHHS, diabetes followed by lung health were also reported as the top health conditions targeted by samples distributed in Nevada at 27% and 15%, respectively (Nevada DHHS, 2018a). These data points show that both diabetes and lung health are important markets for which pharmaceutical representatives are actively distributing samples.

#### Wholesalers

This year, wholesalers became part of Nevada transparency reporting. The information gathered in this first cycle did not contribute much information of value.

Although several wholesalers responded as requested, WAC information provided was already available and most wholesalers reported they had not negotiated any rebates with

manufacturers or any other party. One respondent indicated they negotiated rebates with manufacturers but expressed their result in percentage.

#### Discussion

This report represents the fifth annual compilation of drug transparency information received by DHHS from drug manufacturers, pharmaceutical representatives, PBMs, Nevada Medicaid, and other health-related entities. This year also included Wholesalers.

DHHS continues to strive to make sense of the reporting received. There are clarifying instructions that will be made going forward to streamline the data received.

In some cases, the Department has seen entities that seek to avoid reporting because a third party handles their rebate negotiation.

## **Report Methodology and Reporting Compliance**

This report was prepared in accordance with the requirements of NRS 439B.650. Only aggregated data that does not disclose the identity of any specific drug, manufacturer, or PBM was included in this report in accordance with Nevada Administrative Code 439.740. Unless otherwise indicated, information in this report is specific to the 2021 calendar year.

Manufacturer responses to increase justifications were weighted. Weighting allows for a dataset to be corrected so that results more accurately represent the information being studied. In this case manufacturer responses were counted for each NDC they represent, rather than each respondent. As an example, a manufacturer responding with one NDC would be counted once and a manufacturer with 10 NDCs would be counted 10 times. For the Essential Diabetic Drug report there were 13 manufacturer responses with increases. For the Significant Price Increase Report there were 33 manufacturer responses. In each case the number of responses indicates how many manufacturers had increases they were obligated to report.

## **Essential Diabetic Drug Manufacturer Reporting**

DHHS aggregated the manufacturer reported values for costs, profits, and rebates attributable to Essential Medications.

Manufacturers provided justifications for all price increases over the last five years. This contrasts with the price increase report as five year is included, and it includes all increases, even if it does not meet the criteria of "significant increase."

## **Price Increase Justification Analysis**

Drug manufacturers reported justifications for significant price increases of drugs on Nevada Lists #3 and #4. Responses were standardized into categories described in Appendix 2 so that they could be quantified and compared for their relative frequency. Manufacturers often reported

one or more justifications for the drug price increases. They provided a percentage of influence on price increase for each factor. Scoring was completed on a NDC level rather than a manufacturer level.

#### **PBM Rebates**

PBMs submitted rebate information for all drugs on List #2 and #4. Some PBMs reported 0 for rebates negotiated. DHHS added up all PBM reported rebates to create Table 5.

#### **Pharmaceutical Representative Compensation and Samples Data**

All pharmaceutical drug representative compensation and samples reports received by DHHS were standardized and merged into one dataset. DHHS received 266,144 pharmaceutical representative compensation and samples records.

#### **DHHS Invites You to Learn More**

DHHS invites you to view the Drug Transparency website at drugtransparency.nv.gov.

If you are interested in receiving email notifications for Nevada Drug Transparency information and updates, please subscribe to the LISTSERV online at drugtransparency.nv.gov.

Feedback and questions can be directed to the email: <a href="mailto:drugtransparency@dhhs.nv.gov">drugtransparency@dhhs.nv.gov</a>

### Appendix

1: Summary Descriptions of Price Increase Justifications

Note: the following are summary descriptions of price increase justifications provided by each major justification category. This appendix more clearly defines the justification categories and further clarifies the diverse responses received.

Research and Development: This category includes responses indicating that additional funds would support research and development of existing Essential Drugs and future medicines. It was indicated by manufacturers that drug research continues even after the FDA approves their drugs to verify safety and improve product formulations.

Rebates: Drug manufacturers enter contractual agreements to pay intermediaries like PBMs, insurers, labelers or distributors, group purchasing organizations, and other entities. Multiple responses indicated that PBMs and other entities are requiring larger discounts and rebates.

Generate Profit: Responses referenced that manufacturer had a responsibility to improve or maximize value for investors or shareholders. It was also indicated that manufacturers needed to increase prices to avoid not generating a profit at all.

Changes in Marketplace Dynamics: Responses indicated that market or commercial conditions induced in part the need for a price increase.

Supporting Regulatory and Safety Commitments: Responses in this category related to drug manufacturers' responsibility to fulfill governmental safety, licensing, and reporting responsibilities, including new or additional regulatory requirements.

Manufacturing Cost: This category related specifically to investments in manufacturing or improving or constructing new drug manufacturing facilities. This includes responses that outlined higher drug production costs and higher costs relating to commercial transportation.

Advertising and Marketing: Responses indicated a need to promote awareness of drugs through advertisements and further workforce training relating to sales.

Increased Rate of Inflation: Responses referenced general inflation that occurs in the medical market.

Medicaid and 340B Drug Discount Program: Responses outlined that state programs for Medicaid and the Federal 340B Drug Pricing Program require manufacturers to provide Medicaid and other eligible safety net providers with significant prescription drug rebates or discounts. Manufacturers offset the lost revenue from those rebates or discounts by raising prices and passing on costs to other consumers.

Operating Patient Assistance and Educational Programs: Responses specified that additional funds were needed to cover the costs of administering patient assistance and educational programs.

Drug Has More Competitive Value: Responses outlined that the drugs had more value to patients and the market. Drugs were also defined as innovative and effective and thus having more economic value to patients compared to other drugs on the market.