
Drug Transparency Report

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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 as required.

Data collected from the 2022 calendar year was utilized to create this report.

The process of manufacturing, distributing, and paying for pharmaceuticals involves numerous commercial entities, including drug manufacturers, wholesalers, pharmacies, pharmacy benefit managers (PBMs), and insurers. Real transaction prices, including rebates and discounts at each stage of this process, are needed to understand profits across the supply chain.

History of the Nevada Drug Transparency Program

This statute and program originated in the 2017 legislative session. This required the Department to compile a list of prescription drugs that the Department determined to be essential for treating diabetes in this State and the wholesale acquisition cost (WAC) of each drug on the list. The list was required to include, without limitation, all forms of insulin and biguanides marketed for sale in this State.

The 2019 legislative session built on Nevada's transparency law by including asthma drugs.

The 2021 session brought further changes. This removed asthma medications and added all other medication that cost over \$40 for a course of therapy and experienced a price increase that met criteria.

The above was codified into NRS 439B.630.

Obligations

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 were subject to a price increase that met criteria, as well as a list of any other medication subject to a price increase that met criteria and cost more than \$40 per course of therapy in Nevada (NRS 439B.630). The final versions of these lists were published February 1, 2023. These lists may be viewed here: [Nevada Drug Transparency Drug Lists 2023 \(nv.gov\)](#)

All manufacturers that produce medication included in Nevada's Essential Diabetic 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 price increase that met criteria, manufacturers are required to submit a report that provides a justification for these price increases (NRS 439B.640).

As of this writing, three 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).

Wholesalers report information regarding 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.

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 list includes the current WAC price.

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 price increase that met criteria during the preceding one- and two-year periods as defined by Nevada law. This process evaluated price increases occurring during the 2021 and 2022 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 price increase that met criteria.

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 met criteria for List #3.

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 4.0% for one year (2022) and 12.4% for two years (2021 to 2022).

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% or greater WAC increase in the previous year (2022) or a 20% WAC increase or greater in the previous two years (2021 to 2022) to meet criteria to appear on this list. This was named “**List #4.**”

Analysis

Nevada Medicaid claims were evaluated by looking at trends as they apply to the posted drug lists. This included both fee for service and managed care claims. It is estimated that Medicaid services about one third of Nevadans. Nevada does not yet have an all-claims data source available.

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.

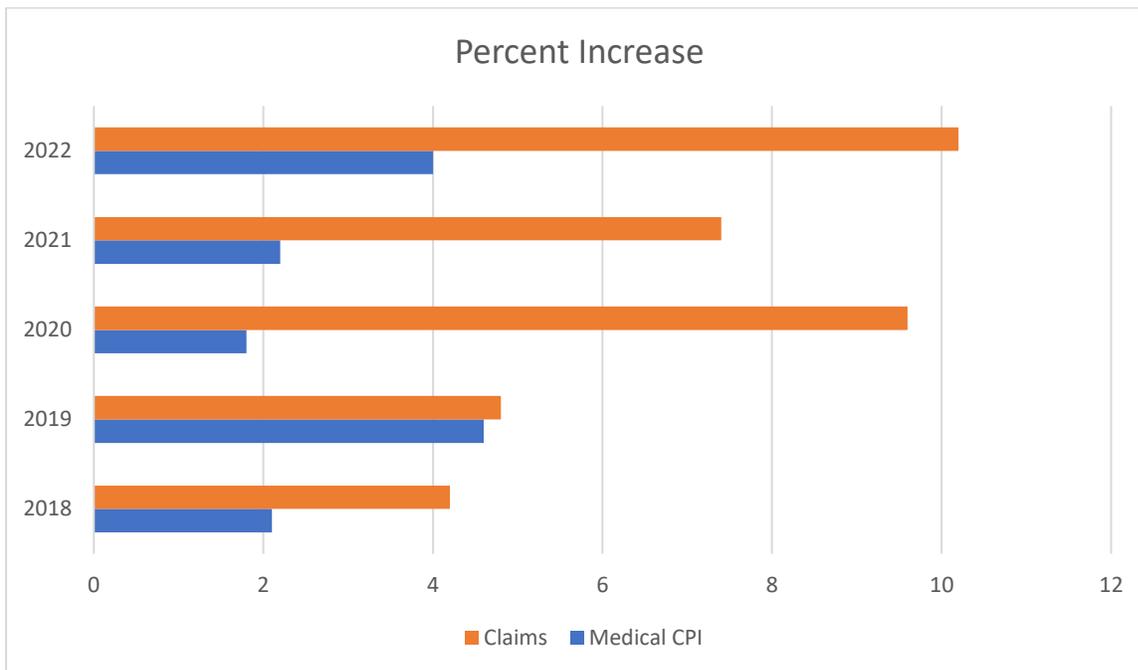
Table 1 represents the change in an average Nevada Medicaid claim over time.

Table 1: Medications Billed to Medicaid

Year	Total Spend	Total # of Medicaid Claims	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
2022	\$967,447,792	8,016,611	\$120.68

Since 2017, total spend has increased 125.6%, number of claims 59.2% and cost per claim 41.7%. This increase in cost per claim, (cost per prescription) eclipses the increase in Medical CPI for the same time period which stands at 14.7%. These increases are compared in Figure 1 below.

Figure 1. Comparison of Medical CPI with Medicaid Claim Cost Increase by Percent



DHHS looked at the top three 2022 Medicaid claims by both spend and volume. This is depicted in the tables below (Table 2 and Table 3).

Table 2: Top Three Medications Billed to Medicaid by Spend

Drug	Spend	Indication
Humira	\$15,511,414	Inflammatory diseases
Strensiq	\$12,166,219	Hypophosphatasia
Advate	\$11,782,665	Hemophilia

In the table above, these prescriptions only represent 879 patients (856 Humira, 10 Strensiq, 13 Advate) out of 519,303 total patients in 2022, or .17%.

Table 3: Top Three Medications Billed to Medicaid by Volume

Drug	Number of Claims	Indication
Albuterol inhaler	170,515	Asthma, COPD
Ibuprofen-multiple strengths	127,307	Pain, inflammation
Atorvastatin-multiple strengths	77,483	High cholesterol

This year, 1,073 diabetic drugs appeared on the Essential Diabetic Drug List. Of those, 144 had a price increase that met criteria. That is 13.4% and less than the previous two years as depicted in Table 4 below.

Table 4: Percent of EDDs with Increase by Year (That met criteria)

Year	Percent of EDDs with Price Increase	Percent of EDDs with Price Increase (new methodology)
2018 data	22.4 %	
2019 data	18.5 %	
2020 data	18.6 %	14.6 % *
2021 data	23.0 %	14.7 % *
2022 data		13.4% *

* Methodology changed in 2020. Before that, review of EDDs was limited to medications billed to Medicaid. Starting in 2020, all medications were included, without determining if they appeared in Medicaid billing. This was because Medicaid does not represent all the Nevada population. At this point, the Transparency Program does not have access to all payor data and a product not appearing in Medicaid billing does not mean it was not utilized in Nevada.

Figures 2 and 3 represent the differences in claims between 2021 and 2022. This is separated by total claims, Essential Diabetic drugs (EDDs), EDDs with a price increase that met criteria and “over \$40” drugs.

Figure 2. Total Spend by Claim Type 2021-2022

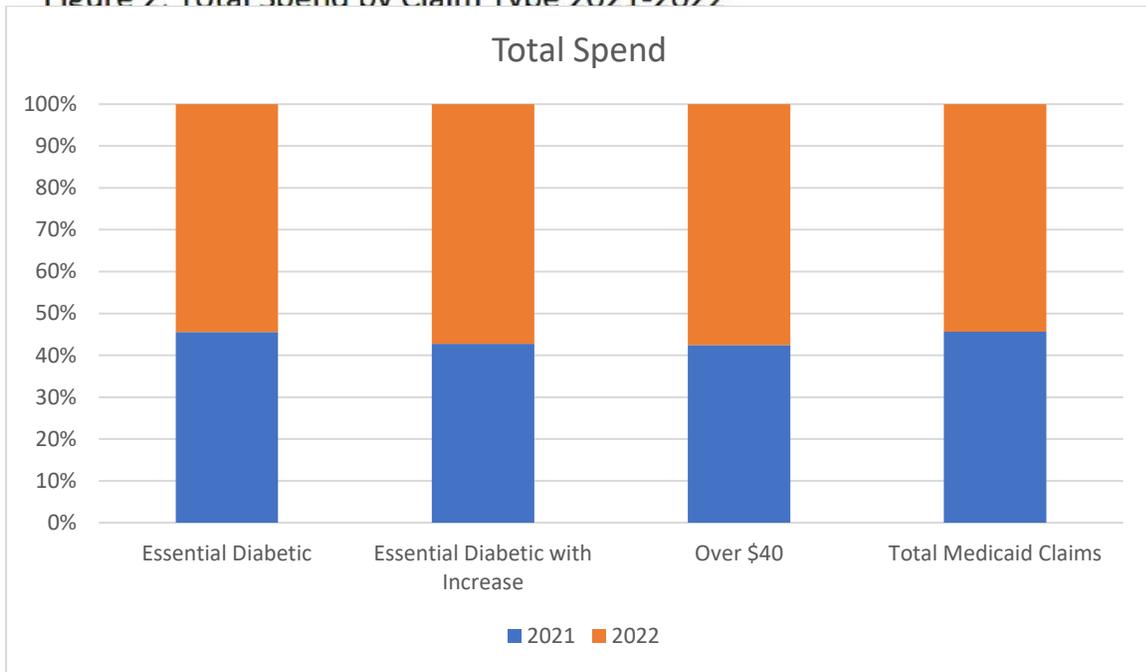
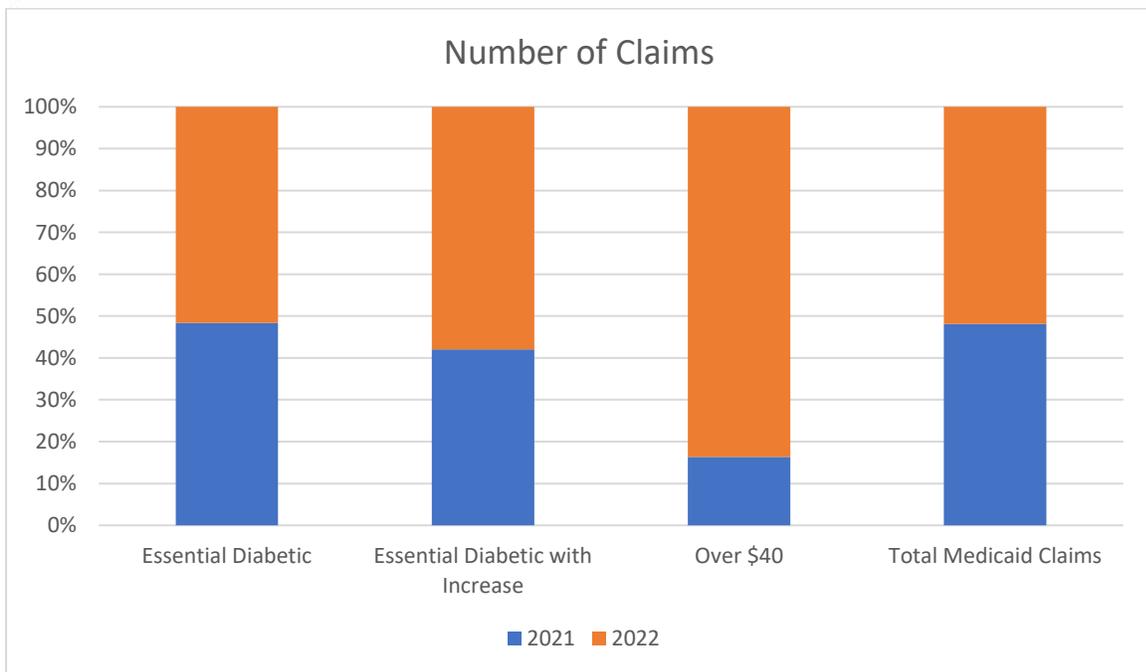


Figure 3. Number of Claims 2021-2022



In 2022, 4.5% of medication claims billed to Medicaid were Essential Diabetic medications but the cost was about 11.1% of total spend. As in previous years, the amount spent is disproportionate to the number of prescription claims. In general, diabetic medications cost more than other medications.

Diabetic medications that had a price increase that met criteria comprised just 1.1 % of total Medicaid prescriptions, but 6.6% of total Medicaid spend.

The average diabetic claim was \$295.26 in 2022, and this has increased each year.

DHHS also evaluated medications that cost over \$40 for a course of therapy and had a price increase that met criteria. 251 medications appeared on this list.

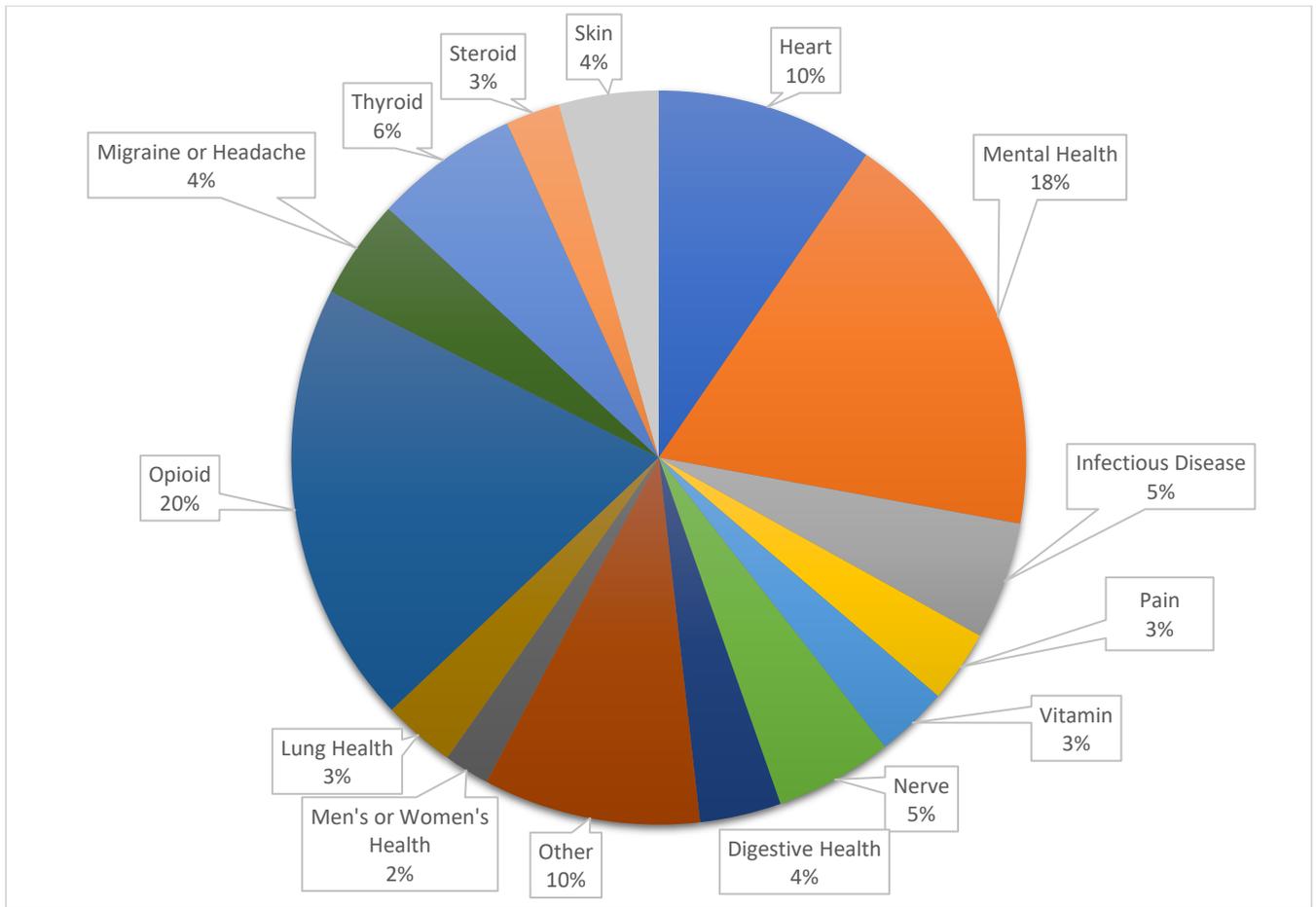
These medications made up a small percentage of Medicaid claims at under 1% of total prescriptions. The number of claims on this list quadrupled to 23,270 prescription claims statewide. The average cost of a prescription on this list dropped from \$948.19 to \$250.98.

Although the average cost of claims dropped 74%, not too much significance should be applied here. Because the list itself expanded, many more mainstream and less costly drugs were included. Last year was the first year this list was created. This year that list grew by about 30%. This was due to new price increases or because drugs that did not reach the 1-year 10% threshold were added this year due to reaching the 2-year 20 % threshold.

Figure 4 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 27%) followed by Mental Health (at 18%). This is very similar to data collected from the previous year. The 2022 transparency report showed 25% opiates and 17% mental health drugs.

Although opiates and drugs to treat opiate dependence are grouped together, the great majority were opiates themselves. Out of 251 medications on this list, 47 were actual opiates and two were drugs used to treat opiate dependency. This may be explained by the fact that there are more opiates on the market than drugs to treat dependence.

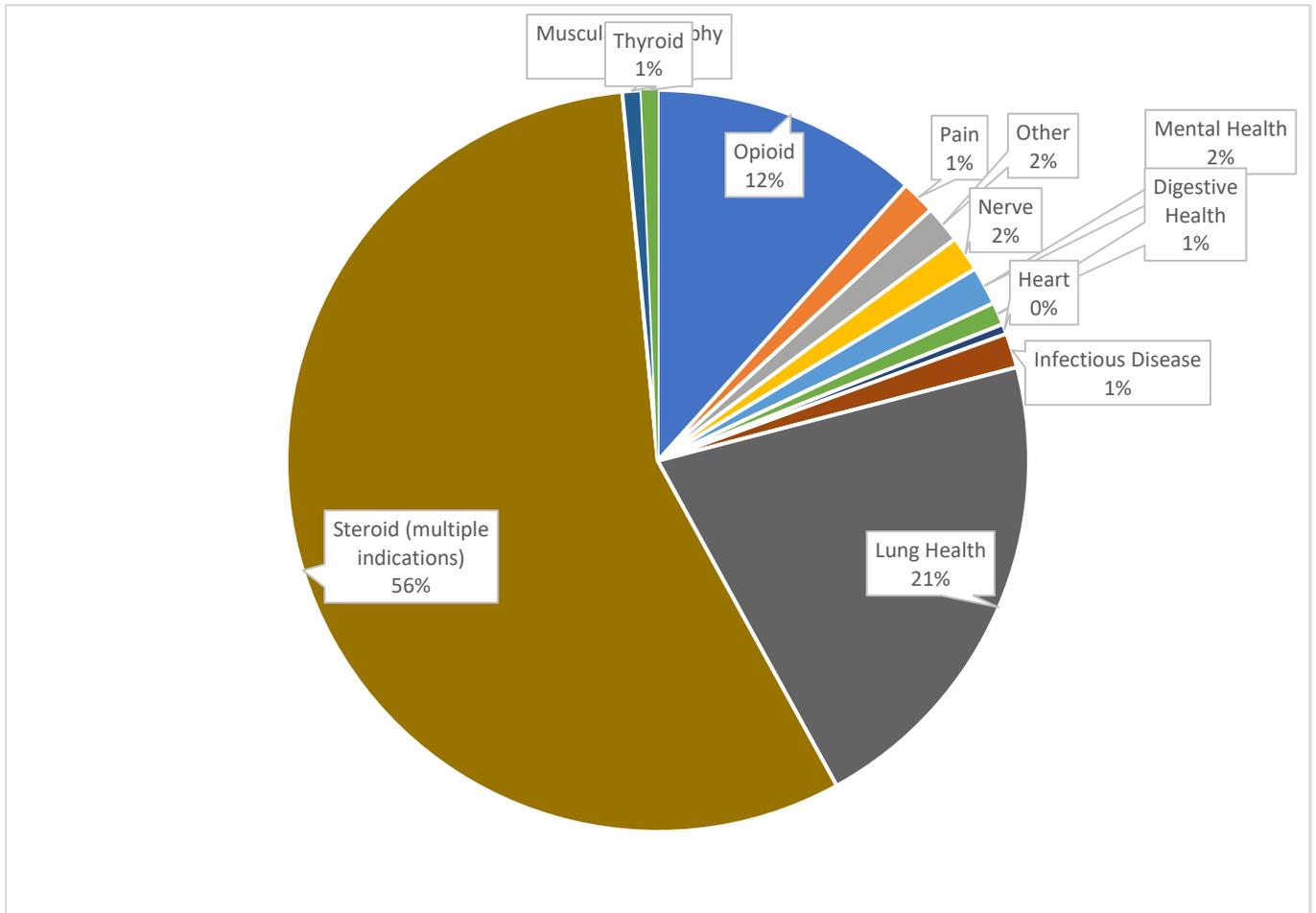
Figure 4. Compare Over \$40 Drugs by Class (by drug)



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

Figure 5. Compare Over \$40 Drugs by Class (by claim)

The following figure shows this “over \$40” group broken down by number of claims.



(Values of <100 claims were not included in the figure above.)

Drug Manufacturer Financial Assistance and PBM Rebates

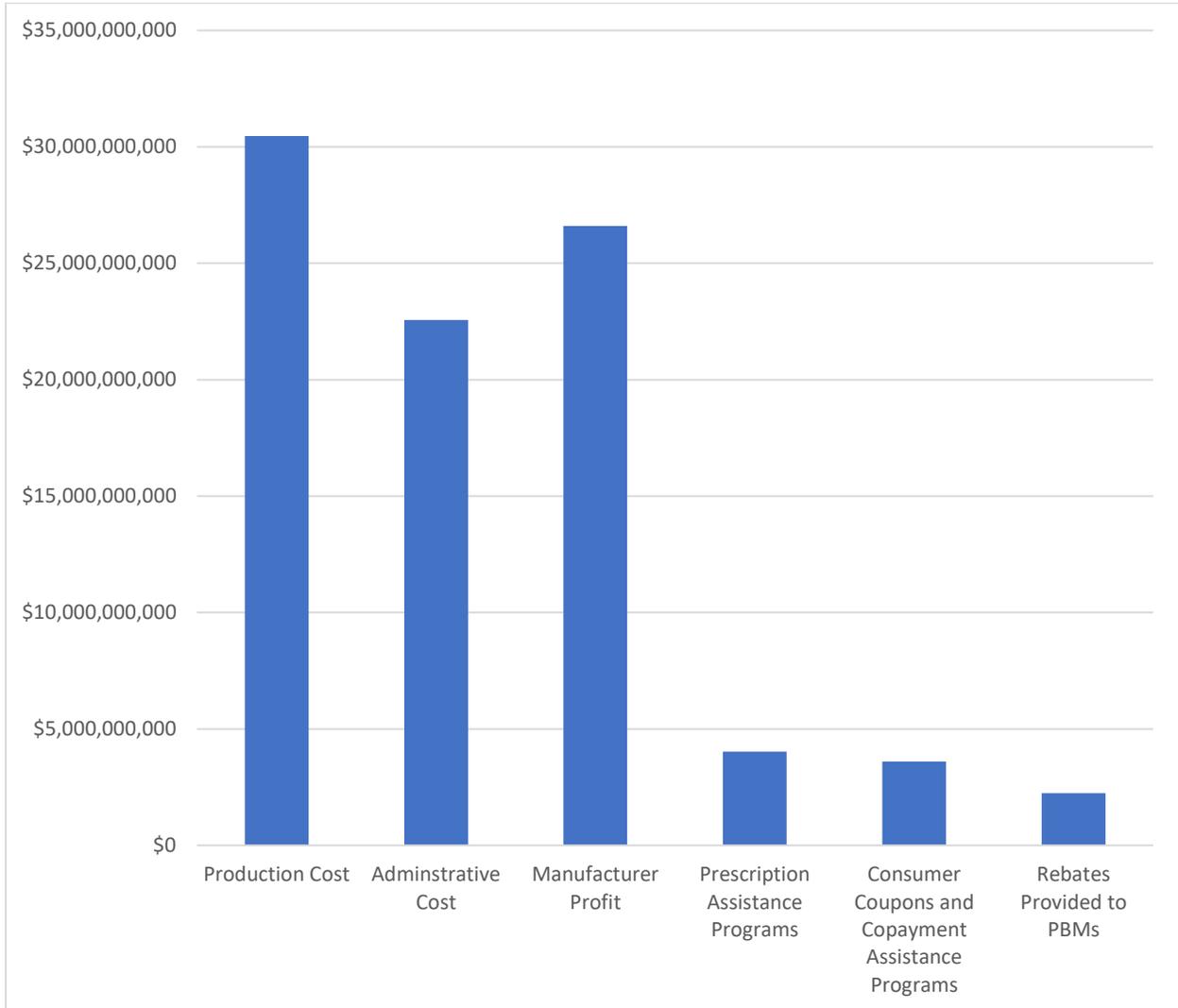
Manufacturers reported the financial assistance provided to consumers and rebates that were provided to PBMs (Figure 6). PBMs can negotiate prescription drug rebates with drug manufacturers. Some PBMs pass all these rebates on to insurers or consumers while others retain a portion of the rebates.

Most of the Essential Diabetic Drugs are generic and typically do not provide aid in the form of rebates, patient assistance, or coupons. The Over \$40 List also provided this information but is a much smaller list. The total amount of financial assistance provided through patient prescription assistance programs was \$4,025,487,647.

The value of the aggregate rebates that manufacturers provided to PBMs *that were reported to this program* for Nevada drug sales was \$2,248,336,358. This is not a complete number as some

manufacturers did not provide a number specific to Nevada but rather a number that applied to all 50 states (in the billions) or simply said they were unable to report specifically to Nevada.

Figure 6. Manufacturer Profit Compared to Other Expenses



Manufacturer Price Increase Justifications

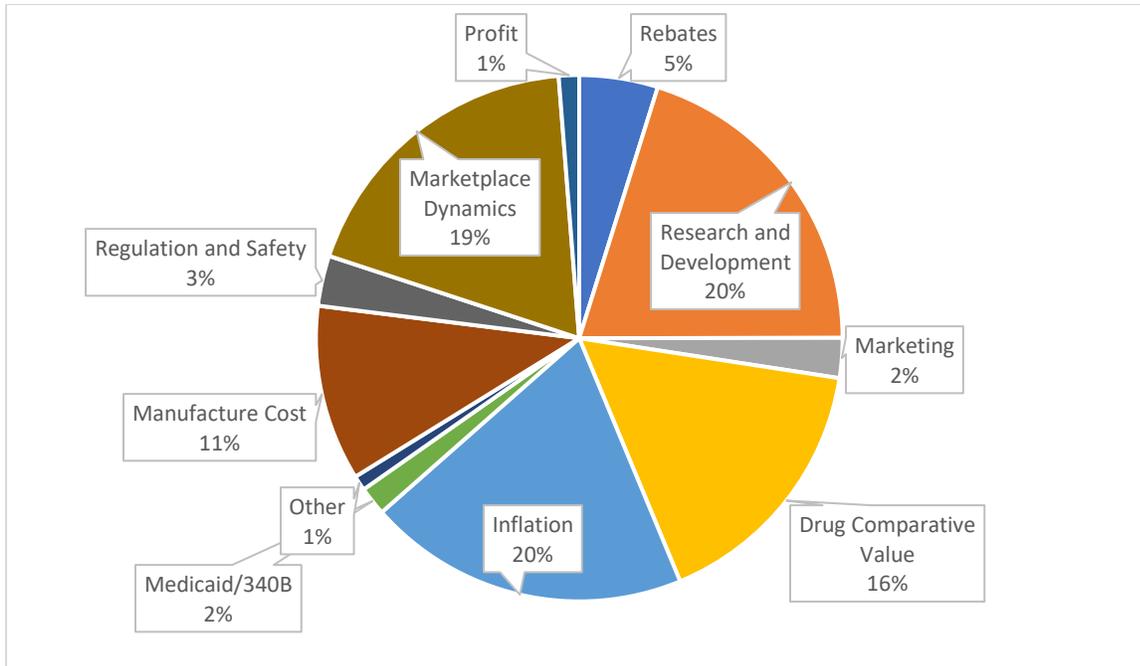
Price increases were reported in two places. The first place was all drugs on List #2 and List #4 had to explain *any* increase in the last five years, even if this increase did not meet criteria for “significant.” This information is depicted in Figure 7.

Increases that met the criteria described in NRS439B.640 were reported separately via the “increase” report. Those increases are depicted in Figure 8.

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 7: Justifications for Any Price Increases for EDDs or Over \$40 Drugs



Manufacturer Price Increase Justifications per NRS439B.640

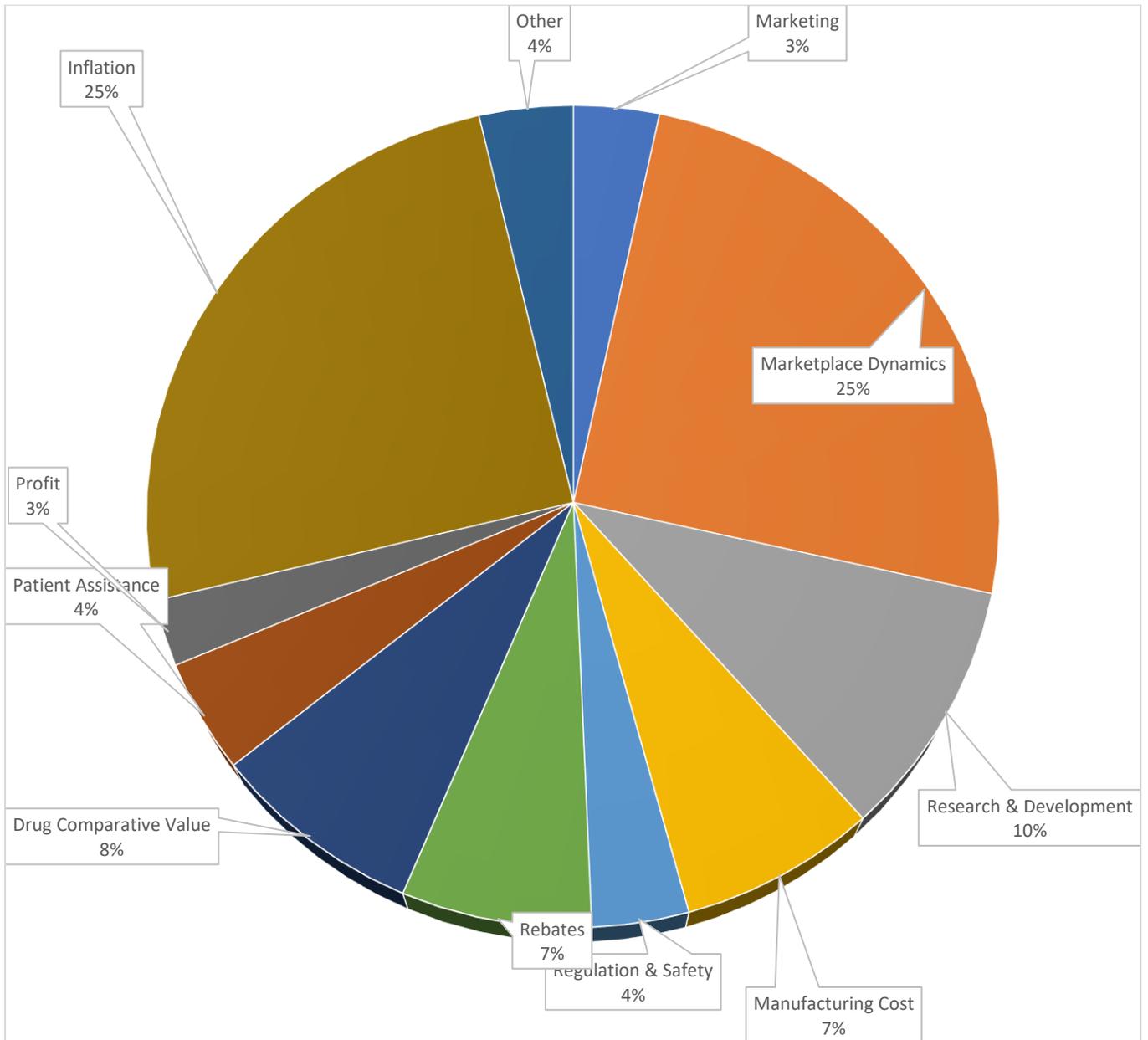
The second place that increases were reported was for drugs on list #3 or #4 that experienced an increase that met criteria. This is very different than what is reported above as it only includes the reporting period of two years, and only those that met criteria. That said, the responses were similar.

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

Figure 8: Justifications for Price Increases per NRS439B.640



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,
- persons covered by all other third parties.

Total reported rebates PBMs negotiated with manufacturers for drugs on Nevada lists were over \$110 million (Table 5). This is an increase from what was reported last year.

Table 5: Total Reported Rebates Negotiated by PBMs with Manufacturers

Reported Value Description	Value	%
Total amount of all rebates that the PBM negotiated with manufacturers	\$112,823,563	100%
Total amount of all rebates described in Row 1 that were negotiated for use by recipients of Medicaid	\$61,157,990	54.2%
Total amount of all rebates described in Row 1 that were negotiated for use by recipients of Medicare	\$13,890,266	12.3%
Total amount of all rebates described in Row 1 that were negotiated for use by persons covered by governmental entities that are not Medicaid or Medicare	\$9,377,974	8.3%
Total amount of all rebates described in Row 1 that were negotiated for use by persons covered by commercial insurers	\$27,083,937	24.0%
Total amount of all rebates described in Row 1 that were negotiated for use by persons covered by all other third parties	\$1,182,431	1.0%
Total amount of all rebates described in Row 1 that were retained by the PBM	\$2,479,660	2.2%

Table 6: Total Reported Rebates Negotiated by PBMs with Pharmacies

Reported Value Description	Value	%
Total amount of all discounts/fees negotiated with pharmacies	\$71,248,807	100%
Total amount of all discounts/fees described in Row 1 that were negotiated for use by recipients of Medicaid	\$530,012	0.7%
Total amount of all discounts/fees described in Row 1 that were negotiated for use by recipients of Medicare	\$31,661,558	44.4%
Total amount of all discounts/fees described in Row 1 that were negotiated for use by persons covered by governmental entities that are not Medicaid or Medicare	\$12,873,705	18.1%
Total amount of all discounts/fees described in Row 1 that were negotiated for use by persons covered by commercial insurers	\$26,083,840	36.6%
Total amount of all discounts/fees described in Row 1 that were negotiated for use by persons covered by all other third parties	\$3,158	<0.01%

Pharmaceutical Representative Reporting

NRS 439B.660 requires that sales representatives who engage in business in Nevada register with DHHS and 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 294,109 pharmaceutical representatives' events were reported for compensation and sample distribution to DHHS. This included 1,410 individuals with activity to report, and 240 different companies.

Compensation Provided by Pharmaceutical Representatives

DHHS aggregated the reported compensation values from pharmaceutical representative reports (Table 7). Nevada health care providers and staff in their offices collectively received \$5,032,398 in compensation from pharmaceutical representatives and the average compensation amount was \$21.05, 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 96 % of total compensation dollars with an average of \$20.04.

Since last year there has been an increase in compensation events, as well as an increase in total dollars spent on these events, as depicted in Table 7.

Table 7: Compensation from Pharmaceutical Representatives by Compensation Type

Type	Total Amount 2020	Average Amount 2020	Total Amount 2021	Average Amount 2021	Total Amount 2022	Average Amount 2022
Other	\$347,298.84	\$92.33	\$313,925.55	\$160.17	\$262,272	\$298.04
Food and/or Beverage	\$1,925,319.88	\$18.16	\$3,046,553.17	\$19.42	\$4,823,644	\$20.04
Total	\$2,272,619	\$20.62	\$3,360,479	\$21.12	\$5,032,398	\$21.05

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.

Some activity was reported that was not specific to a Nevada representative. This included 3,781 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

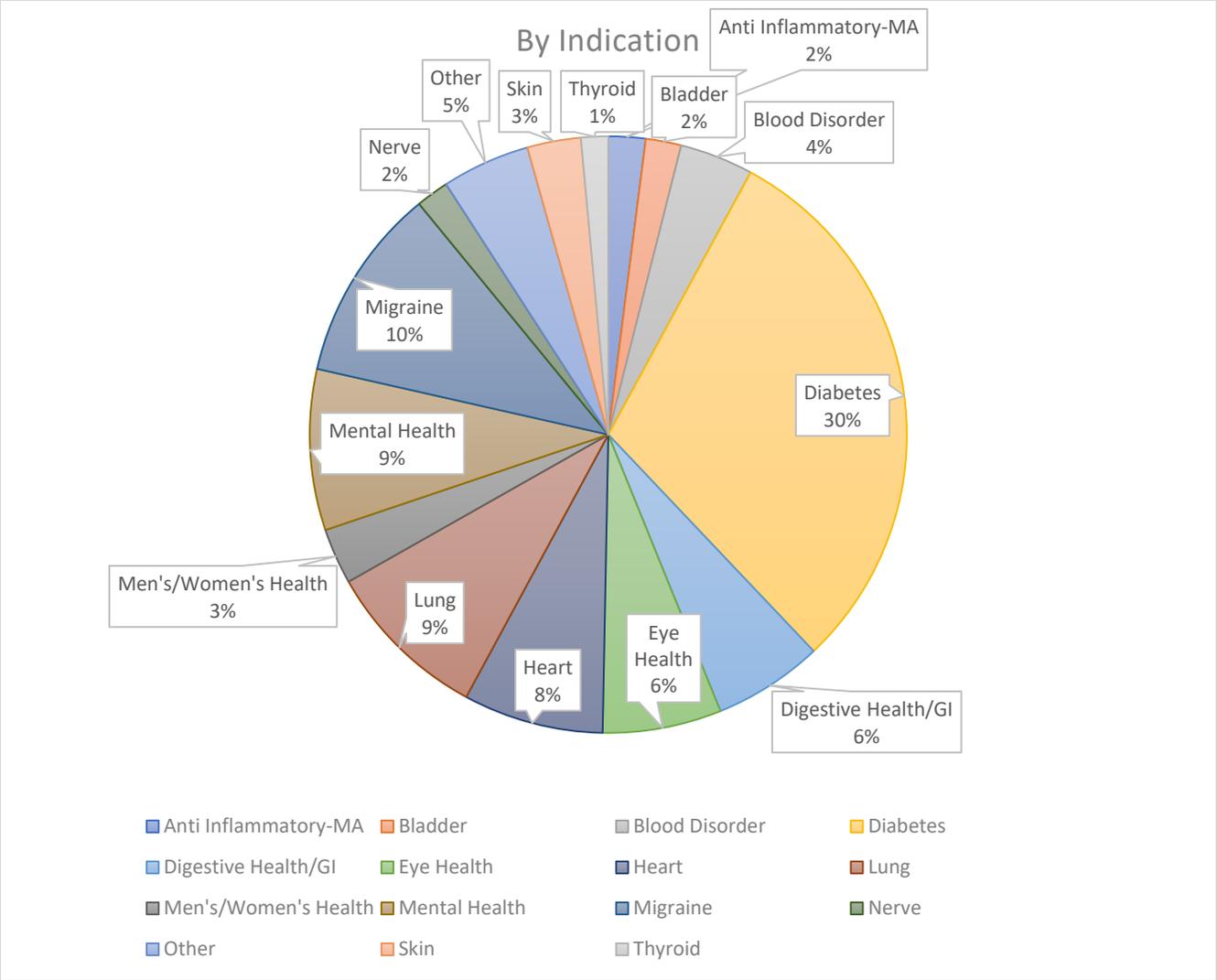
*Recipient Type	Total Comp Amount 2021	Total Comp Amount 2022	Average Comp Amount 2021	Average Comp Amount 2022
Pharmacist	\$79,178.73	\$110,206	\$25.72	\$27.06
Physician Assistant	\$65,442.71	\$80,636	\$20.03	\$21.67
RN/LPN	\$164,349.72	\$225,957	\$23.79	\$23.68
Nurse Practitioner (NP)	\$131,934.16	\$173,710	\$23.52	\$24.21
Office Staff	\$1,308,959.71	\$2,468,127	\$19.71	\$19.77
Other Health Care Provider	\$680,975.38	\$1,051,671	\$18.08	\$19.52
Other Non-Health Care Provider	\$375,325.43	\$418,752	\$18.51	\$18.61
Doctor (MD or DO)	\$552,719.50	\$556,495	\$35.14	\$33.78

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, pharmacy technician, medical assistant
- Other Health Care Provider: clinical social worker, therapist, psychologist, social worker, doctor of podiatric medicine, optometrist, dentist

Figure 9: 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 less than 1.0% were included in “other” category in the figure above.)

Figure 9 illustrates that samples most frequently provided were to treat diabetes (30%). This is consistent with years past although the percentage went up.

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

Wholesalers

Wholesalers became part of Nevada transparency reporting just one year ago. It is difficult for this program to determine if they are obligated to report as there is no source to determine if they handled drugs on Nevada lists within Nevada (unlike manufacturers where this is a source of such information).

To improve reporting from wholesalers the program has requested the Nevada Pharmacy Board post this reporting requirement on their site on the wholesaler tab. This is a place wholesalers are obligated to go for their state registration.

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 2022 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 and Over \$40 Report there were 96 manufacturer reports. 47 of these reported an increase in the past five years. For the Significant Price Increase Report there were 50 manufacturer reports. In each case the number of responses indicates how many manufacturers had increases they were obligated to report.

Essential Diabetic and Over \$40 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 NRS439B.640.

This reporting was required for drugs on Nevada Lists #2 and #4.

Price Increase Justification Analysis

Drug manufacturers reported justifications for 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 6.

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 294,108 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: drugtransparency@dhhs.nv.gov

Appendix

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.