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Drug Transparency Report

2019 Essential Diabetes Drugs

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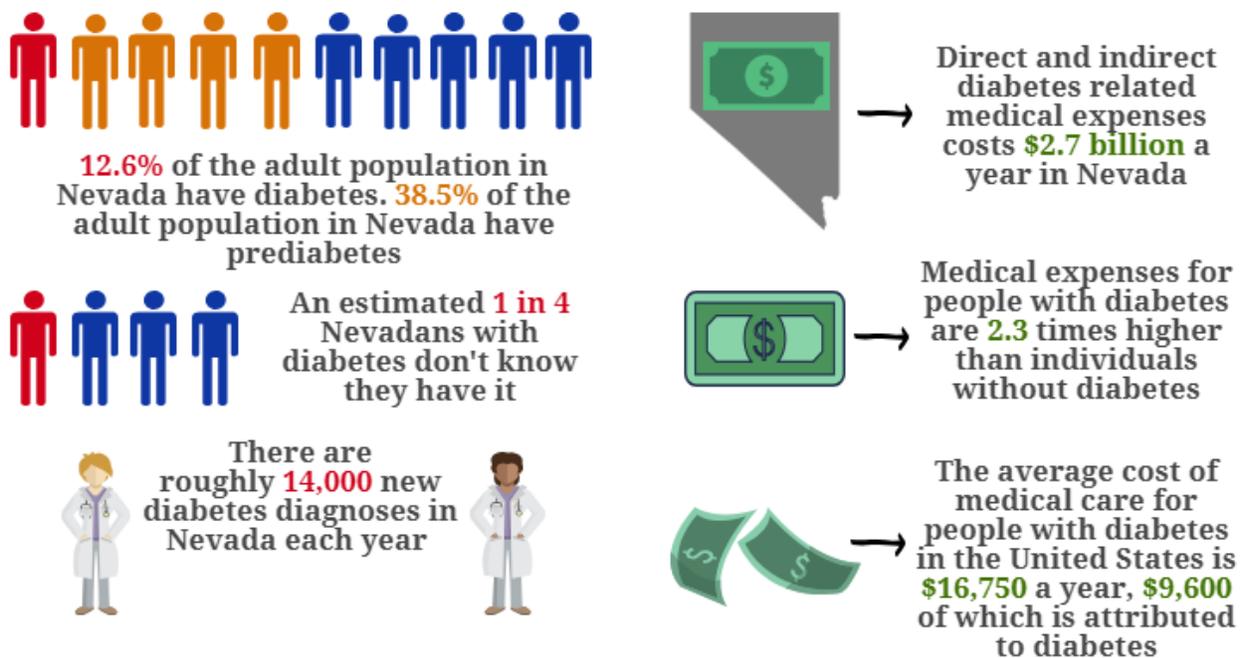


**Nevada Department of
Health and Human Services**

Introduction

Diabetes is an expensive chronic disease to treat. Its growing prevalence in Nevada induces a significant physical, mental, and financial burden on the state and its population. Within Nevada, approximately 12.6% of the adult population suffer from diabetes, with one in four of those residents not knowing that they have the disease (Figure 1). Rising costs of diabetes medications strain the overall health and finances of the state and its residents. It is estimated that diabetes-related medical expenses cost Nevada \$2.7 billion per year (Figure 1). Individuals with diabetes can expect to pay 2.3 times more in overall medical expenses than those without diabetes (Figure 1). The average cost per year for diabetes-related medical care is \$9,600 per patient, representing a significant financial challenge.

Figure 1: Prevalence and Financial Strain of Diabetes in Nevada*



*Sources: (American Diabetes Association, 2018a), (American Diabetes Association, 2018b)

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 in Nevada (Nevada Revised Statutes (NRS) 439B.630). The 2019 Essential Diabetes Drug (EDD) List was published on February 1, 2019 (Nevada DHHS, 2019a). All manufacturers that produce drugs included in Nevada's EDD List are required to submit to DHHS an EDD Report with data outlining drug production costs, profits, financial aid, and other drug-specific information and pricing data (NRS 439B.635). For those drugs that experienced a recent significant price increase, manufacturers are required to submit an EDD Price Increase Report that provides a justification for these price increases (NRS 439B.640). Pharmacy Benefit Managers (PBMs) are required to submit reports regarding rebates negotiated with manufacturers for Nevada's EDDs (NRS 439B.645). PBMs are entities that can fulfill a wide variety of functions, including assisting insurers and other health care organizations in developing a prescription drug formulary, negotiating pricing and discounts

for prescription drugs with drug manufacturers, contracting with pharmacies, and processing prescription drug insurance claims.

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. This report will include aggregated information regarding pharmaceutical representative compensation and samples provided to eligible health professionals and staff.

State law requires that DHHS compile a report concerning the price of EDDs:

NRS 439B.650: Department to compile report concerning price of essential diabetes drugs. 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 for the treatment of diabetes while maintaining access to such drugs.

(Added to NRS by [2017, 4299](#))

The overall goal of this report is to provide greater transparency about the process by which lifesaving prescription medications reach Nevadans. It will also outline opportunities for persons or entities in Nevada to lower the cost and maintain access to EDDs.

Results

General Analysis of 2019 EDDs

DHHS published the 2019 EDD List on February 1, 2019 that included 695 National Drug Codes (NDCs) (Nevada DHHS, 2019a). Each drug NDC represents a specific drug formulation, dosage, and packaging specification. This list contained a total of 52 distinct nonproprietary drugs. Over 25% of the drug NDCs represented biguanides, while less than 10% represented varying forms of insulins (Appendix 1). The clinically significant biguanide medication that treats diabetes is metformin (Blaslov, Naranda, Kruljac, & Pavlić Renar, 2018).

EDD Significant Price Increase Analysis

DHHS analyzed the 2019 EDDs to identify those that experienced a significant price increase during the preceding one- and two-year periods as defined by Nevada law. To identify the EDDs that experienced a significant price increase, EDDs were analyzed to identify any price increases occurring during the 2017 and 2018 calendar years. 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 (United State Department of Labor, 2019). A total of 155 or 22% of EDDs experienced a significant price increase during the periods analyzed (Table 1).

	Number of Drug NDCs	Percent
Significant Price Increase During the Previous One- and/or Two-Year Periods	155	22.4%
No Significant Price Increase	536	77.6%

DHHS analyzed the frequency of significant price increases over the time periods analyzed. As outlined in Table 2, 60% of the EDDs that experienced a significant price increase had a qualifying increase during both the one- and two-year periods.

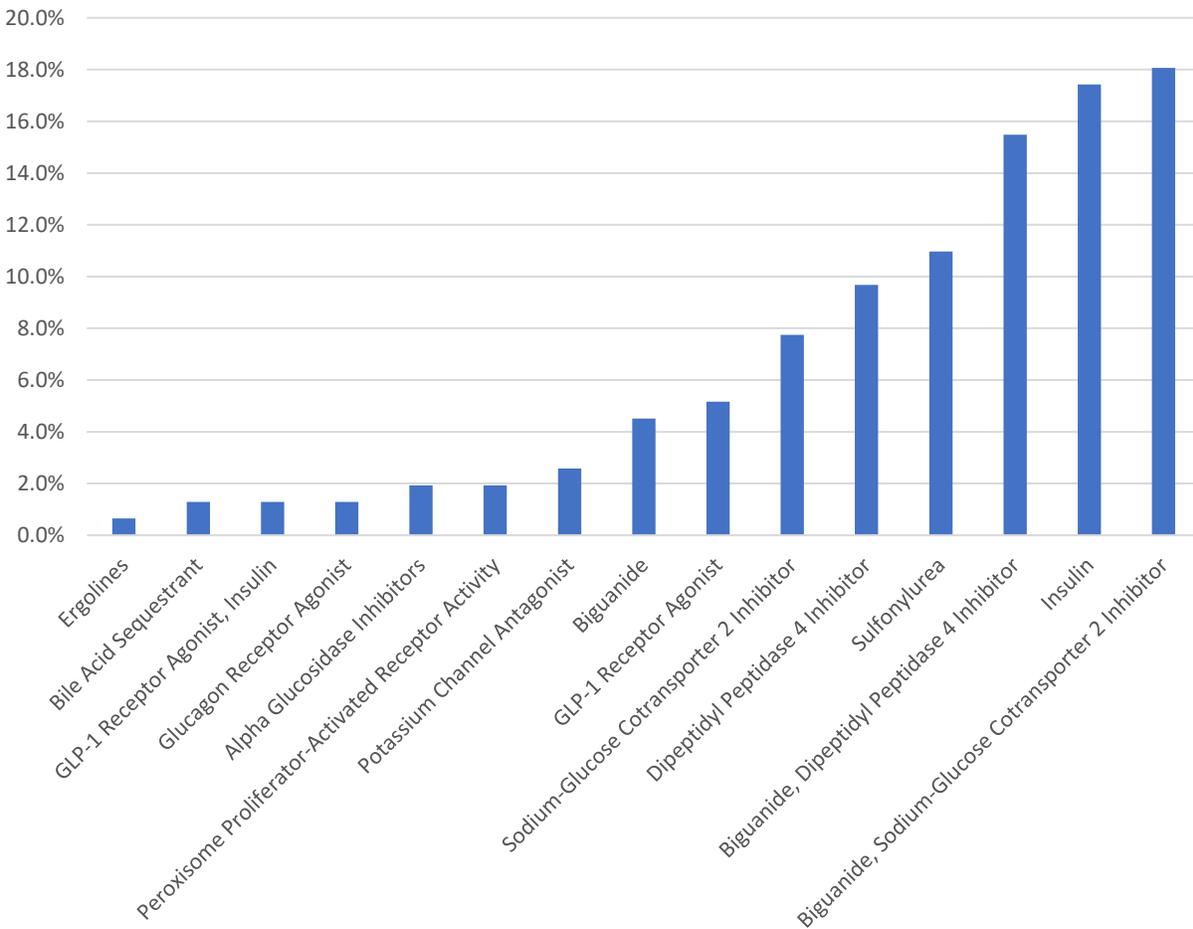
	Number of NDCs	Percent
Drug NDCs that Experienced Only a One-Year Significant Price Increase	29	18.7%
Drug NDCs that Experienced Only a Two-Year Significant Price Increase	33	21.3%
Drug NDCs that Experienced Both a One- and Two-Year Significant Price Increase	93	60.0%

The average increase in price for EDDs that experienced a significant price increase over the preceding calendar year was 6.4%, while the average increase over the preceding two-year period was 21.7% (Table 3). The one-year value was well above the annual CPI, Medical Care Component for 2017 or 2018, which were 2.5% and 2.0% respectively. Price increase percentages greater than these published values during each one-year period cannot be justified alone as maintaining pace with general medical inflation.

	Percent
Average One-Year EDD Price Increase	6.4%
Average Two-Year EDD Price Increase	21.7%

EDDs that experienced a significant price increase were analyzed by drug class in Figure 2. Insulin was the second most predominant class of drugs that experienced a significant price increase after a group that included combination drugs with a biguanide and a Sodium-Glucose Cotransporter 2 inhibitor.

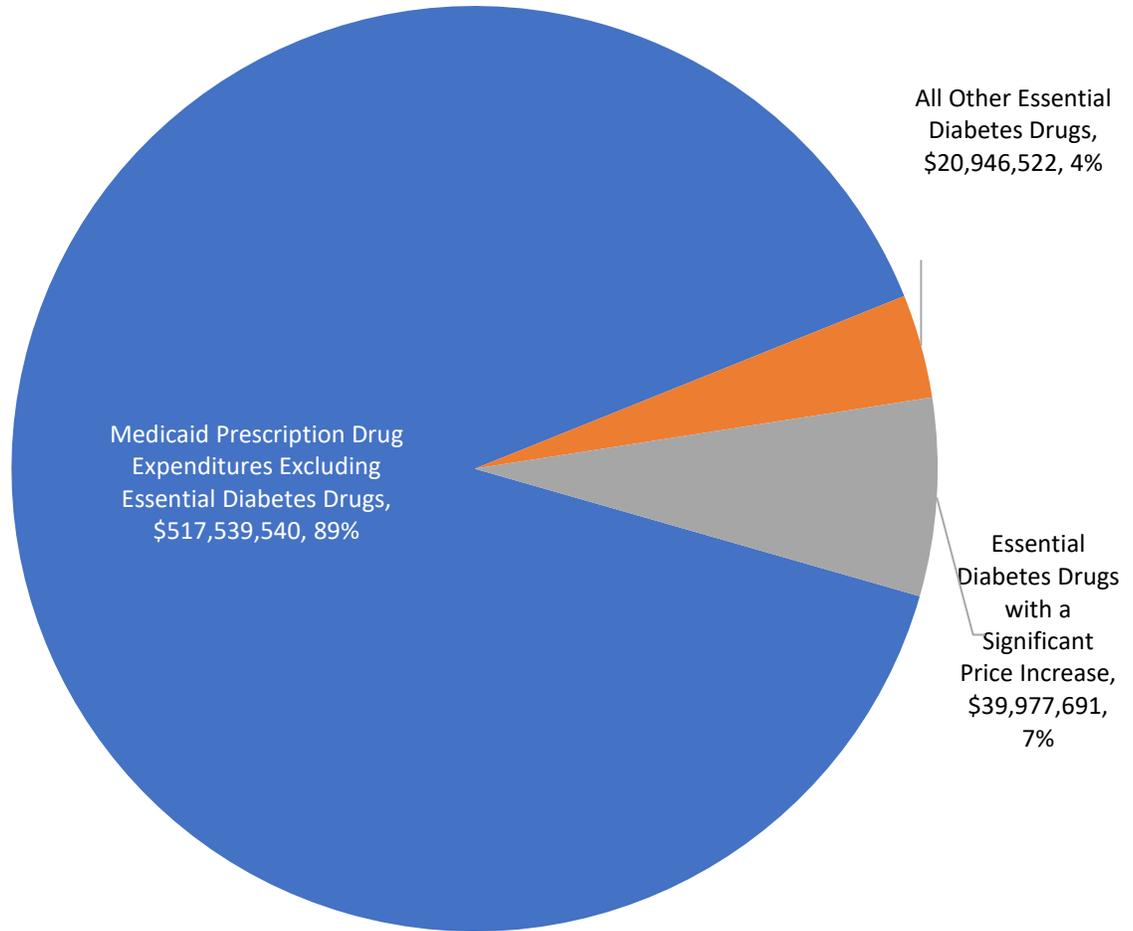
Figure 2: Percent Essential Diabetes Drug NDCs per Drug Classification that Experienced a Significant Price Increase



Medicaid Expenditures for Essential Diabetes Drugs

EDDs play a critical role in the health of Nevadans, including low-income and underserved populations covered by Medicaid. High EDD utilization is evidenced in the 2017 Medicaid expenditures for populations suffering from diabetes. Over 10% of total Medicaid expenditures on prescription drugs were specific to EDDs identified in 2019 by DHHS (Figure 3). Over 65% of the expenditures for EDDs were specific to drugs that experienced a significant price increase (Figure 3).

Figure 3: Medicaid Expenditures on Essential Diabetes Drugs Compared to All Other Drugs in 2017

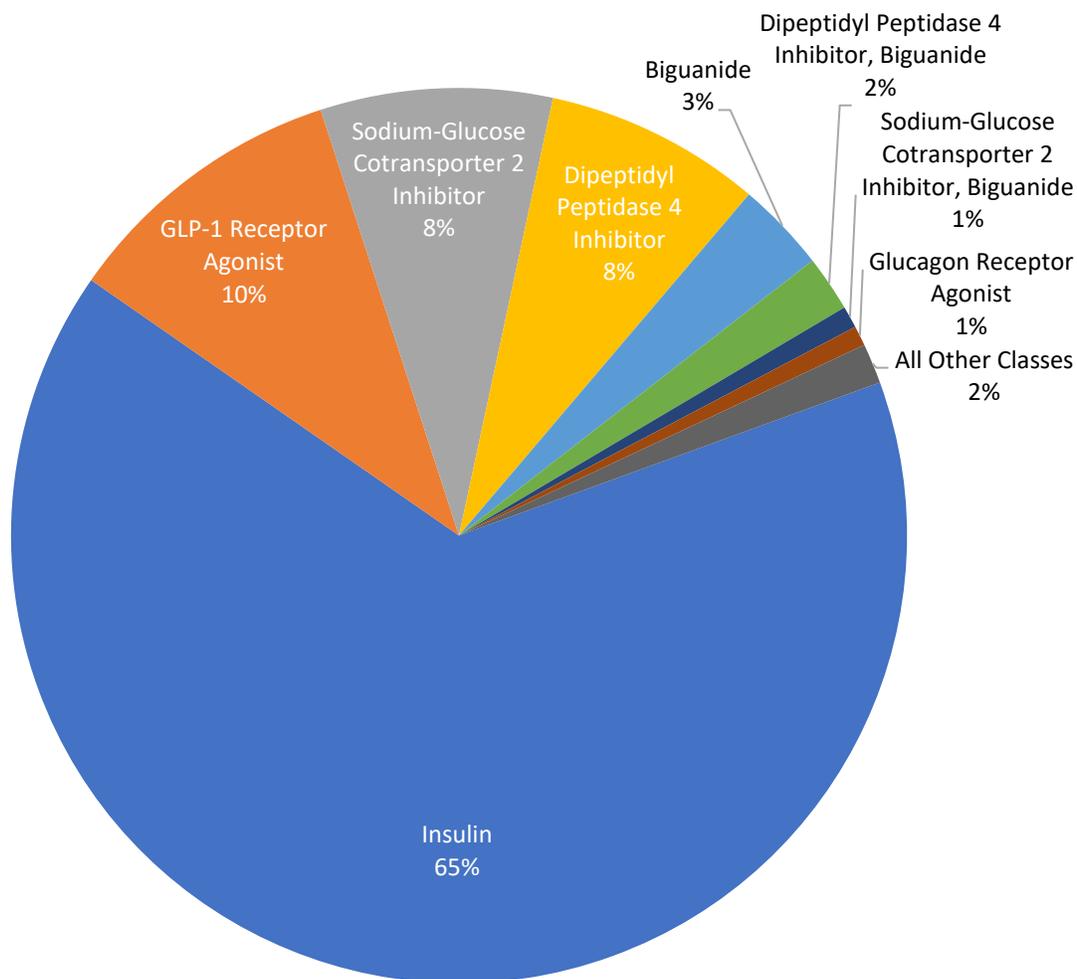


All Medicaid Expenditures in Nevada, 2017	\$578,463,752.72	100%
All Medicaid Expenditures for Essential Diabetes Drug, 2017*	\$60,924,212.93	10.5%
All Medicaid Expenditures for Essential Diabetes Drugs with a Significant Price Increase, 2017	\$39,977,691.16	6.9%

*Calculation includes EDDs that experienced a significant price increase

Medicaid expenditures for EDDs were compared by drug class, and insulins accounted for 65% of total 2017 spending for EDDs (Figure 4). Even though biguanides are the most prevalent class of drugs making up the EDD List (Appendix 1), they rank fifth in percentage of total Medicaid expenditures for EDDs in 2017 (Figure 4).

Figure 4: Percentage 2017 Medicaid Expenditures by Class of Essential Diabetes Drugs

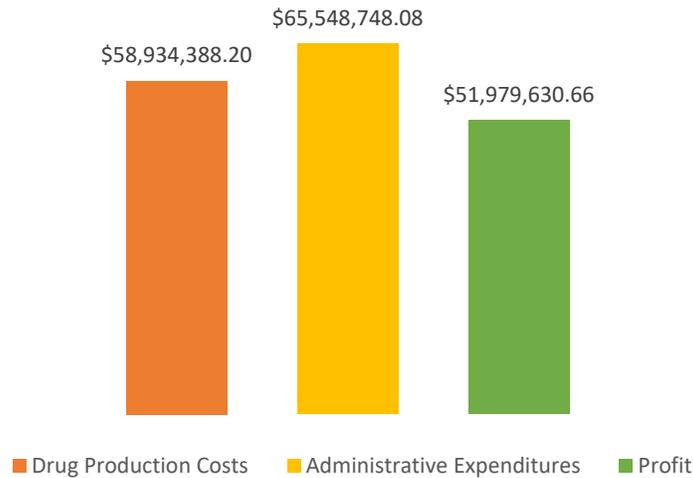


Drug Manufacturer Profits and Administrative and Production Costs for Essential Diabetes Drugs

Profits reported by drug manufacturers for EDDs ranged dramatically with reports indicating that 21% of drugs incurred either a loss or earned no profit. The average profit reported by manufacturers for EDDs was \$51,979,630, which was almost 48 times higher than the median (Figure 5, Table 4). The median profit was slightly higher than \$1,000,000.

The inflated average compared to the median was due to a subset of reports from large pharmaceutical companies that produced drugs with very high production and administrative costs and profits. The median value is used to describe the middle of a dataset that contains outliers. The advantage of using the median is that extreme values do not affect it as strongly as they do the average. Therefore, the median acts as a better indicator of the most commonly reported value.

Figure 5: Average Drug Production and Administrative Costs versus Average Profit



Overall, the average reported percentage of the manufacturer’s total profits that was attributable to an EDD for the period during which the manufacturer has marketed the drug for sale was 3.33% with a standard deviation of 12.53% (Table 4). Even considering the standard deviation, this data shows that the manufacturers’ profits were generally not dependent on a single drug. The standard deviation provides a calculation that shows the amount of variation in the dataset and indicates how measurements for a group are spread out from the average. A low standard deviation signifies that most of the values in the data set are close to the average and a higher deviation means that the data is more spread out. Because the standard deviation is close to four times the average, the data shows substantial variation between different drug reports.

Table 4: Essential Diabetes Drug Reported Profits and Production and Administrative Costs		
	Average	Standard Deviation
Percentage of the Manufacturer’s Total Profit Attributable to Essential Drug*	3.33%	12.53%
Profit	\$51,979,630	\$147,596,933
Total Cost of Producing the Drug	\$58,934,388	\$178,257,862
Total Administrative Expenditures Relating to the Drug†	\$65,548,748	\$143,251,749
Profit Divided by the Sum of Drug Production and Administrative Costs‡	1.52	5.19
*The percentage of the manufacturer’s total profit for the period during which the manufacturer has marketed the drug for sale that is attributable to the drug. †Multiple drug manufacturers reported \$0 for Total Administrative Expenditures, and likely included all their costs for manufacturing the drug in the Total Cost of Producing the Drug. ‡Values were calculated using the following formula: Profit/(Drug Production Cost + Total Administrative Expenditures). Ratios were then averaged.		

The average reported total drug production cost was \$58,934,388 with the average reported total administrative expenditures coming in higher at \$65,548,748 (Figure 5). Administrative expenditures included both the marketing and advertising costs. Lastly, the average values for both reported drug production and administrative expenditures were at least 18 times higher than the respective medians, showing the skewing effect of the large drug manufacturers' data. Figure 5 illustrates that based on the averages, profits are substantially less than either the drug production and the administrative costs.

DHHS sought to analyze profits compared to production and administrative costs in a way that would decrease the impact of large drug manufacturers' data on the overall averages. To do this for each drug, the profit was divided by the sum of the drug production and the administrative costs. This profit analysis helped to remove the sizable variation between large and small drug companies as each reported value was normalized to itself. Each of these individual values were then averaged. As an example of the ratio, if a product were produced for \$1 with administrative costs of \$1 and earned a profit of \$4, the above equation would identify two times the profit compared to the combined production and administration costs.

On average from reports received for EDDs, there was 1.52 times the profit earned compared to production and administrative costs (Table 4). In other words, EDDs on average earned \$1.52 in profit for every \$1.00 spent on combined production and administrative costs. A standard deviation of 5.19 helps to illustrate the large variation of data values which ranged from no profit to ratios with profits greater than 40 times the combined costs of production and product administration (Table 4). Of drugs included in this analysis, 76% earned profits greater than the combined cost of production and administrative expenditures. The averages presented in Figure 5 show a much lower ratio of profits to drug production and administrative costs compared to the average profit divided by the sum of drug production and administrative costs in Table 4 because of the effect of larger manufacturer reports skewing the data towards a lower profit ratio.

Drug Manufacturer Financial Assistance and PBM Rebates for Essential Diabetes Drugs

Drug manufacturers reported the financial assistance provided to consumers and rebates that were provided to PBMs (Table 5). PBMs can negotiate prescription drug rebates with drug manufacturers. Some PBMs pass all of these rebates onto insurers or consumers while others retain a portion of the rebates. Overall, 58% of reports for EDDs indicated that drug manufacturers provided no financial assistance through patient prescription assistance programs. The average reported total amount of financial assistance provided through patient prescription assistance programs was \$12,874,326. This value was inflated due to a subset of larger drug manufacturers providing high monetary values of financial assistance.

The median value for manufacturer financial assistance provided through patient prescription assistance programs was \$0 due to many manufacturers that did not expend funds on patient prescription assistance programs. The standard deviations for the values in Table 5 provide evidence of the large variations among the drug manufacturers for financial assistance to consumers and rebates provided to PBMs. The average reported value of the aggregate rebates that manufacturers provided to PBMs for Nevada drug sales was \$3,039,646. Of drug reports, 55%

reported no rebates provided by manufacturers to PBMs. Thus, there is substantial variation among drug manufacturers of EDDs in how they negotiate rebates with PBMs.

Table 5: Financial Assistance and PBM Rebates Provided to Drug Manufacturers for Essential Diabetes Drugs		
	Average	Standard Deviation
Total Amount of Financial Assistance Provided through Patient Prescription Assistance Programs	\$12,874,326	\$34,322,396
Cost Associated with Consumer Coupons and for Consumer Copayment Assistance Programs	\$14,036,828	\$34,095,434
Manufacturer Cost Attributable to Redemption of Consumer Coupons and Use of Consumer Copayment Assistance Programs	\$979,738	\$2,801,989
Aggregate Amount of All Rebates Manufacturers Provided to Pharmacy Benefit Managers for Drug Sales in Nevada	\$3,039,646	\$9,714,726

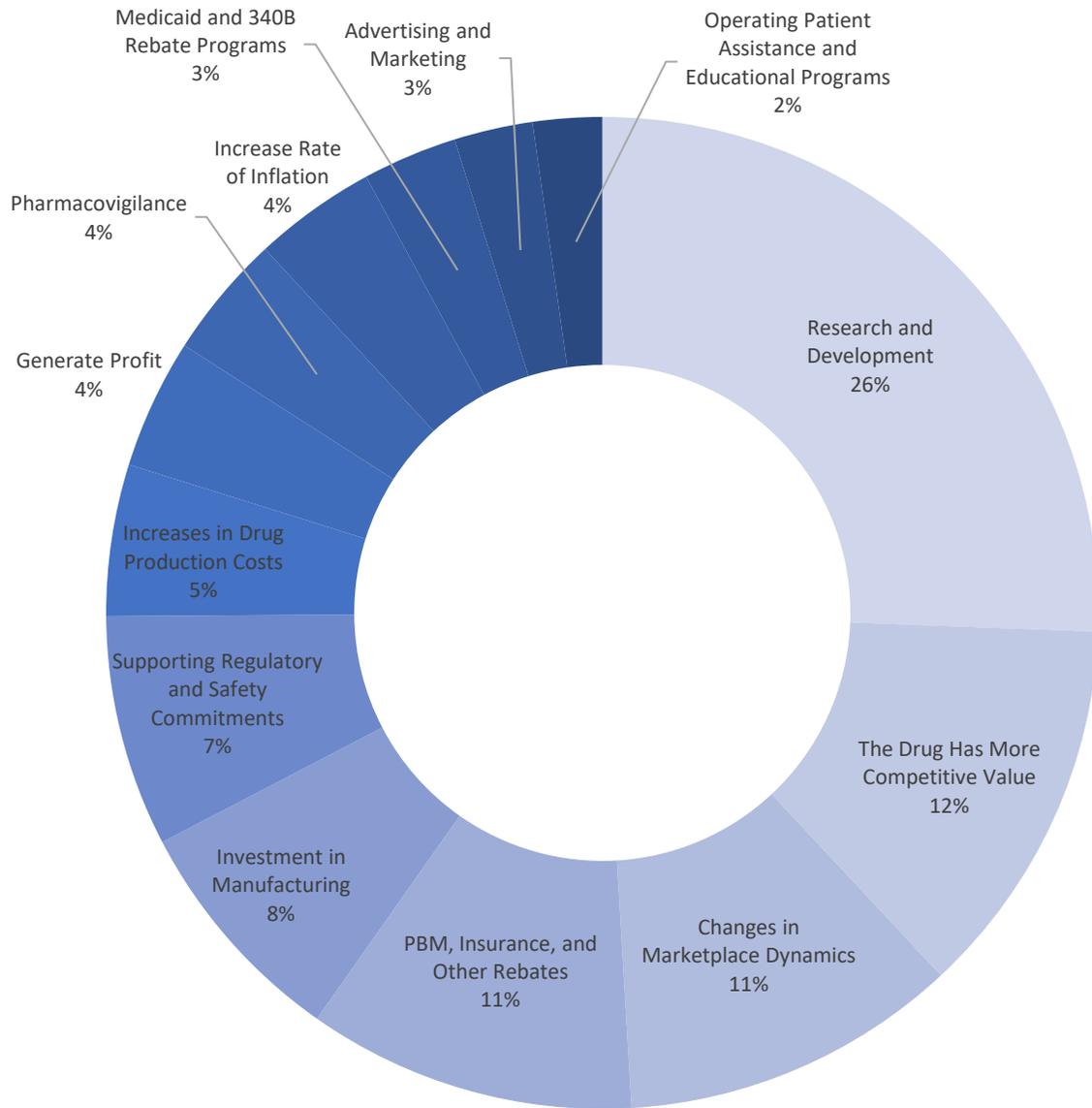
Drug Manufacturer Price Increase Justification

The CPI, Medical Care Component 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 drug price increases are compared in the law to identify the drugs that had a significant price increase over the immediately preceding one and two calendar years.

As previously reported, 155 drug NDCs in the 2019 EDD List had a significant price increase during the preceding one and/or two calendar years. Drug manufacturers that produced EDDs that experienced a significant price increase are required to submit a report outlining a justification for the price increases for each drug. DHHS standardized all the responses into major categories, showcased in Figure 6. Responses were then quantified so that they could be compared for their relative prevalence. A single drug in most cases had more than one price increase justification.

The most frequent justifications for price increases in order of prevalence were research and development investments (26%), the drug has more competitive value (12%), changes in marketplace dynamics (11%), rebates provided to PBMs, insurers, and others (11%), and investment in manufacturing (8%). Appendix 2 provides summarized examples of each category to further describe these justifications. Similar to the preceding report, research and development was most frequently reported as a justification for price increases of EDDs (Nevada DHHS, 2019b).

Figure 6: Justifications for Price Increases of Essential Diabetes Drugs



PBM Rebate Data

PBMs reported the rebates negotiated with drug manufacturers during the immediately preceding calendar year for prescription drugs included on the EDD List for Nevada. PBMs reported the rebates they retained, as well as the rebates that were negotiated for purchases of such drugs for the use by (1) recipients of Medicaid, (2) persons covered by third party governmental entities that are not Medicare and Medicaid, (3) third parties that are not governmental entities, and (4) persons covered by Employee Retirement Income Security Act (ERISA) plans in which by contract the PBMs are required to report drug transparency data to DHHS. DHHS received no monetary

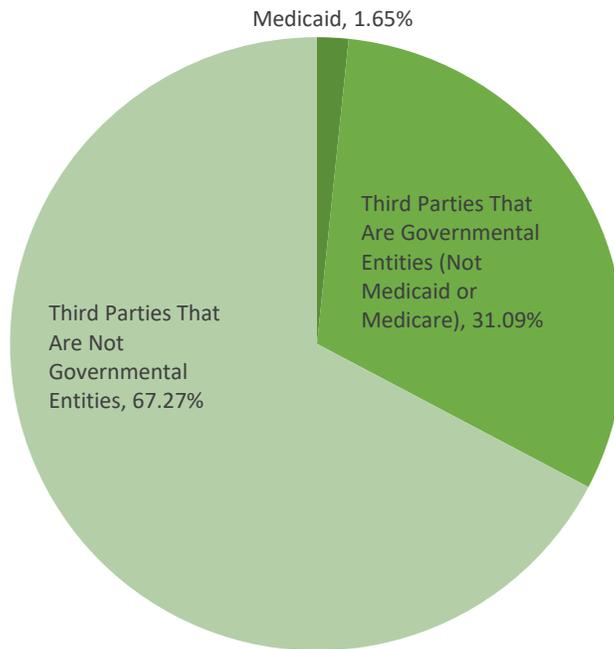
reporting for category four outlined above. Because some drug transparency data is already reported to the federal government by PBMs, DHHS did not require PBMs to report rebates that they already are required to submit to the federal government such as rebates for Medicare and for certain ERISA plans.

Total reported rebates that PBMs negotiated with manufacturers for EDDs for Nevadans were greater than \$1.9 billion (Table 6). The total reported rebates are broken down into three categories: 1) rebates for Medicaid recipients, 2) rebates for persons covered by third parties that are government entities that are not Medicaid or Medicare, and (3) rebates for persons covered by non-governmental third parties. Of all reported rebates negotiated by PBMs with manufacturers, 6.59% were retained by PBMs. This percentage might appear small, but it represents \$126,754,864 in rebates (Table 6). A subset of PBMs did not report retention of any rebates in contrast to some of the PBMs that reported retention of rebates ranging from below 4% to greater than 10%.

Table 6: Total Reported Rebates Negotiated by PBMs for Essential Diabetes Drugs	
Reported Value Description	Aggregate Value in United States Dollars
Row 1: Total amount of all rebates that the PBM negotiated with manufacturers during the immediately preceding calendar year for EDDs	\$1,922,857,158
Row 2: Total amount of all rebates described in Row 1 that were negotiated for purchases of such drugs for use by recipients of Medicaid	\$31,648,939
Row 3: Total amount of all rebates described in Row 1 that were negotiated for purchases of such drugs for use by persons covered by third parties that are governmental entities but are not Medicaid or Medicare	\$597,759,023
Row 4: Total amount of all rebates described in Row 1 that were negotiated for purchases of such drugs for use by persons covered by third parties that are not governmental entities	\$1,293,449,196
Row 5: Total amount of all rebates described in Row 1 that were retained by the PBM	\$126,754,864
*The total rebates reported in Row 1 are equal to the sum of the individual rebates reported in Rows 2 through 4. Row 5 represents rebates retained from the total rebates reported in Row 1.	

Figure 7 shows the percentage of reported rebates that PBMs negotiated with manufacturers for purchase of EDDs by entity type. Because of substantial rebates already provided to Medicaid and other governmentally insured individuals, additional rebates supporting Medicaid recipients composed a small percentage (1.65%) of the total reported rebates negotiated by PBMs (Figure 7). Over 67% of total reported rebates negotiated by PBMs with manufacturers were for third parties that are not governmental entities (Figure 7).

Figure 7: Percentage of Reported PBM Rebates Negotiated for Essential Diabetes Drugs by Insured Entity Type



Pharmaceutical Representative Compensation and Samples Data

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 the names of 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 that exceeds \$10 or total compensation with a value that exceeds \$100 in aggregate.

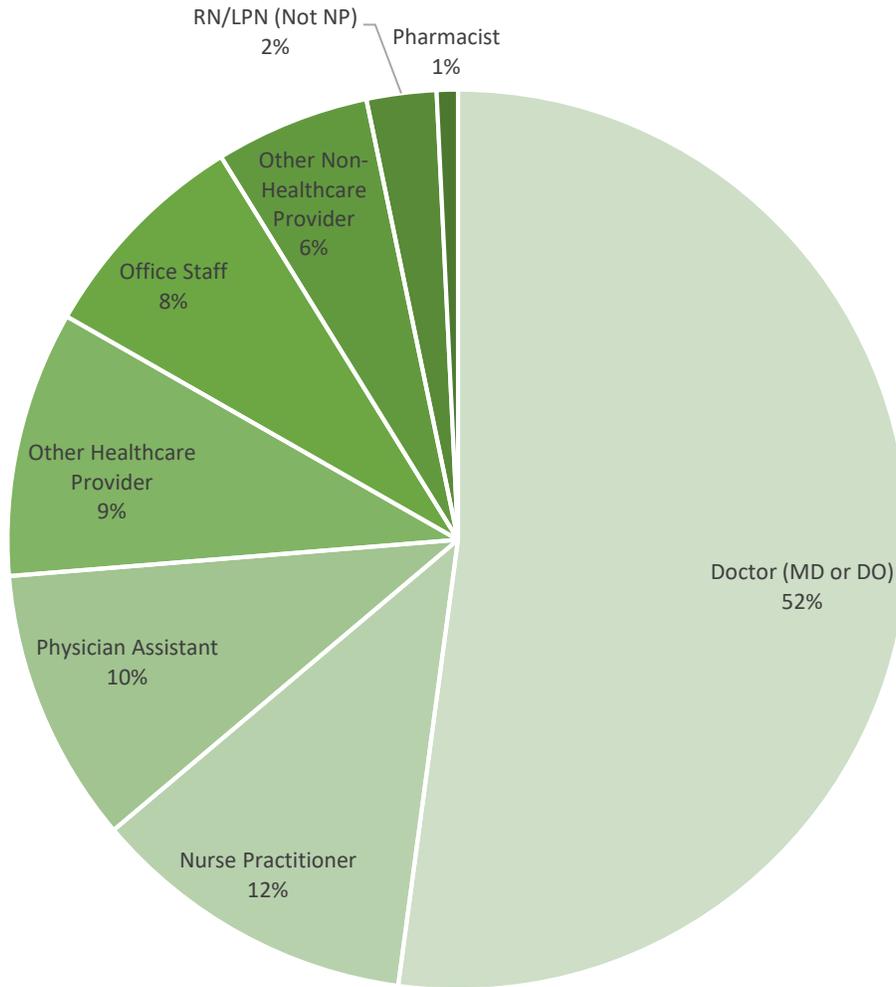
A total of 1783 pharmaceutical representatives reported compensation and samples distribution events to DHHS. These individuals represented 182 drug manufacturers. Pharmaceutical representatives reported substantially more events in which only samples were distributed (59%) than events in which they provided only compensation to recipients (Table 7).

Table 7: Total Reported Compensation and Sample Distribution Events	
Compensation Only Distribution Event	36.63%
Samples Only Distribution Event	59.15%
Combined Compensation and Samples Distribution Event	4.22%

The majority (52%) of reported sample distribution and compensation events were provided to medical or osteopathic doctors followed by nurse practitioners (12%), and subsequently physician

assistants (10%) (Figure 8). The most prevalent health professionals receiving sample or compensation events in Figure 8 are very similar to the values reported in the 2018 publication outlining compensation and samples distribution by pharmaceutical sales representatives (Nevada DHHS, 2018a).

Figure 8: Percent Professional Designation Group Receiving Sample or Compensation Distribution Events



Compensation Provided by Pharmaceutical Representatives

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 (Figure 9). A more specific categorization of compensation type is included in Table 9. Based on aggregation of reported data, doctors in Nevada collectively received \$597,023 in compensation from pharmaceutical representatives, although the average compensation event to doctors reported to DHHS was only \$24.41 (Table 8). Among all recipients, the average

compensation amount was \$20.28, showing that the predominant pharmaceutical representative interactions with health providers, health support staff, and administration involved small value compensation transactions (Table 8). Total reported compensation values provided to recipients in Nevada by pharmaceutical representatives was \$2,437,939 (Table 8).

Table 8: Average and Total Compensation by Recipient Type		
Recipient Type*	Total Compensation Amount	Average Compensation Amount
Pharmacist	\$71,079.08	\$32.02
Physician Assistant	\$149,806.82	\$17.83
RN/LPN (Not NP)	\$179,800.96	\$25.37
Nurse Practitioner (NP)	\$245,353.77	\$21.52
Other Non-Healthcare Provider	\$299,815.95	\$18.51
Office Staff	\$421,209.94	\$18.21
Other Healthcare Provider	\$473,850.02	\$17.34
Doctor (MD or DO)	\$597,023.21	\$24.41
Grand Total	\$2,437,939.75	\$20.28
*The following are examples of professions grouped into selected recipient categories:		
<ul style="list-style-type: none"> • Office Staff: receptionists, general office staff, scribe, scheduler • Other Non-Healthcare Provider: administration, technician, optical technician • Other Healthcare Provider: clinical social worker, therapist, psychologist, social worker, doctor of podiatric medicine, dentist 		

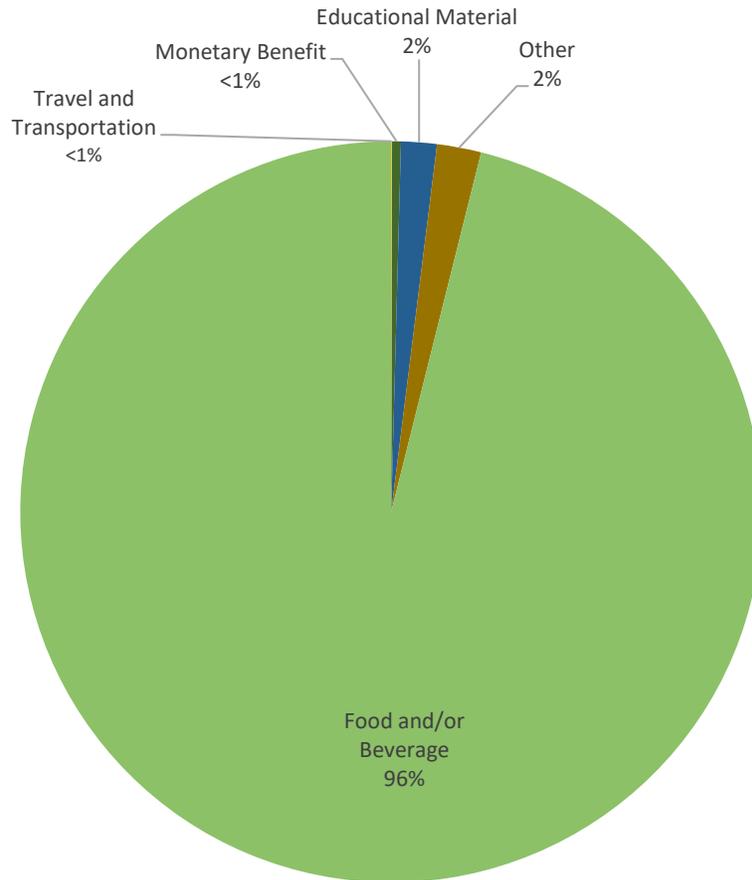
Compensation values were categorized by compensation type, and the total reported values for each compensation type were aggregated (Table 9). By far, food and/or beverage compensation carried the highest value of total compensation at \$2,176,514 (Table 9). This single category accounted for almost 90% of reported compensation value (Table 9). The highest average compensation amount per event was for the monetary benefit category with an average value of \$411 followed by travel and transportation at \$179 (Table 9).

Table 9: Reported Total and Average Compensation Values from Pharmaceutical Representatives in United States Dollars by Compensation Type		
Compensation Type	Total Compensation Amount	Average Compensation Amount
Travel and Transportation	\$7,894.97	\$179.43
Educational Material	\$25,434.63	\$13.59
Other	\$38,205.94	\$17.01
Monetary Benefit	\$189,890.01	\$411.91
Food and/or Beverage	\$2,176,514.20	\$18.83
Grand Total	\$2,437,939.75	\$20.28

When compensation events were categorized by compensation type, *Food and/or Beverage* compensation events accounted for 96% of all compensation events, followed by *Other* and

Educational Material (Figure 9). The *Other* category was specifically inputted by many reporting entities but was not clearly defined in the majority of events. *Monetary benefit* and *travel and transportation* represented less than 1% of total compensation events. Figure 9 differs from Table 9 in that Figure 9 displays the percentage of events that fall under specific compensation types while Table 9 displays the aggregate monetary expenditures by compensation type.

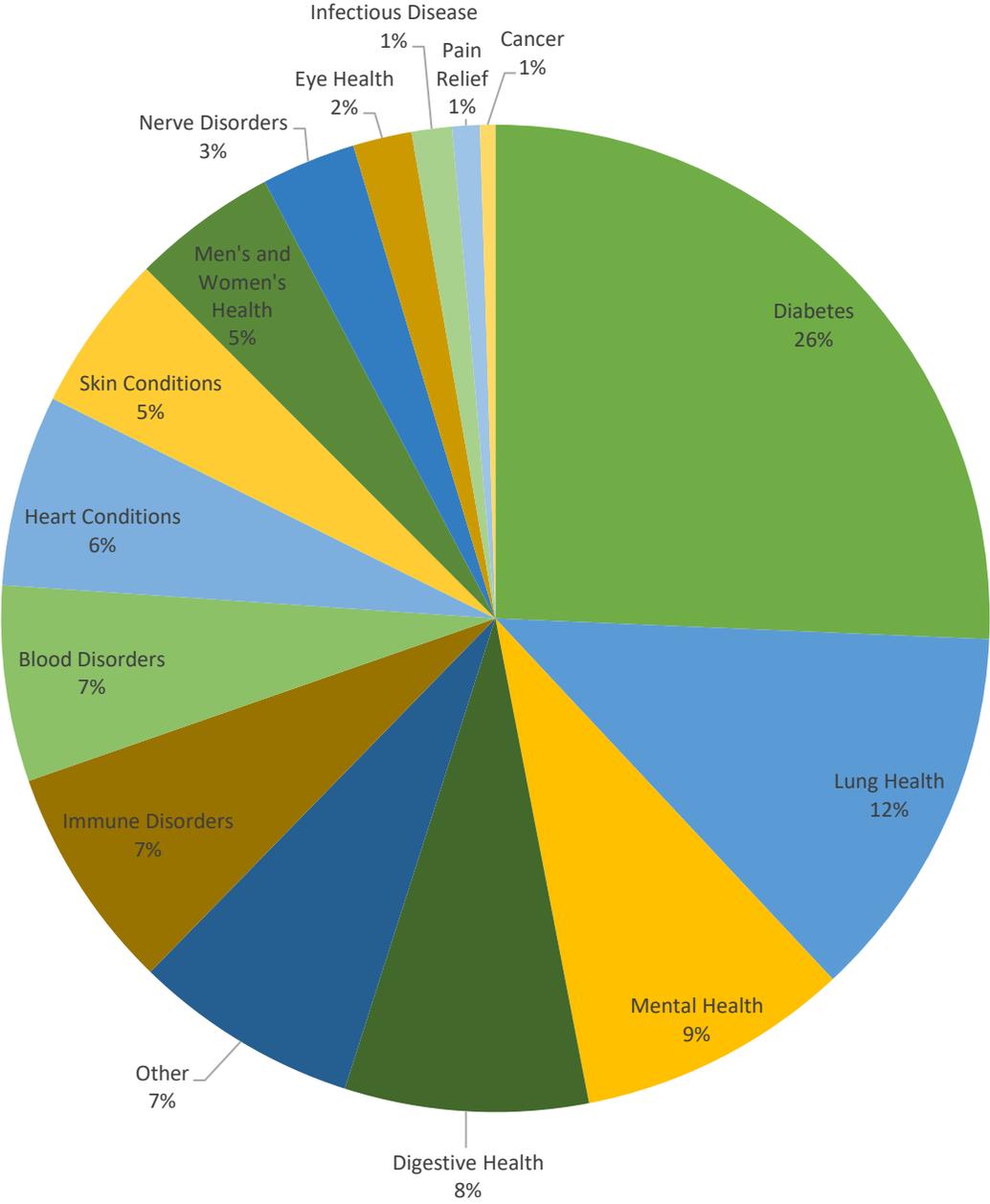
Figure 9: Compensation Events Categorized by Compensation Type



Events in which samples were distributed were categorized by the targeted health condition treated by each corresponding drug sample. The targeted health conditions were grouped by major health issue treated or organ system targeted. A listing of example health issues and medication types included in each grouping in Figure 10 is included in Appendix 3.

Figure 10 illustrates that samples most frequently provided were to treat diabetes (26%). Other frequently distributed drug samples included those that support lung health (12%), mental health (9%), and digestive health (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 are highly reproducible and show that both diabetes and lung health are important markets for which pharmaceutical representatives are actively distributing samples.

Figure 10: Percentage Sample Distribution Events by Targeted Health Condition as Reported by Sales Representatives



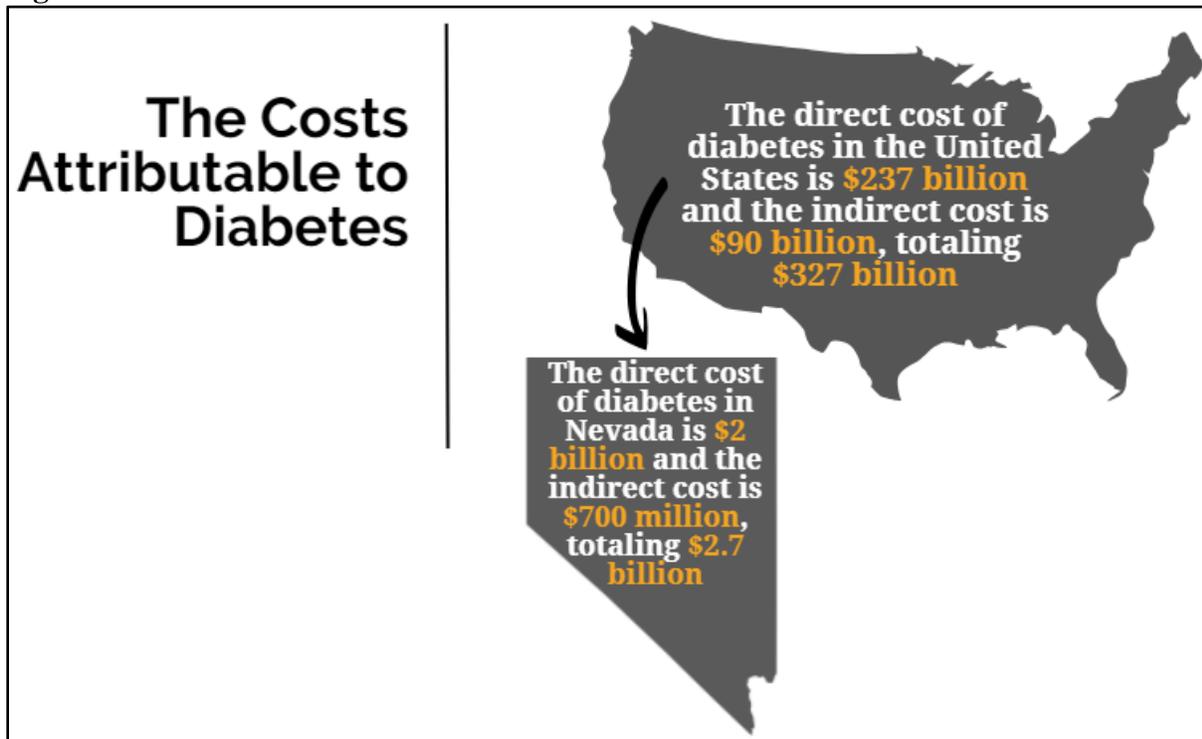
Discussion:

This report represents the second compilation of drug transparency information received by DHHS from drug manufacturers, pharmaceutical representatives, PBMs, Nevada Medicaid, and other health-related entities. This discussion will attempt to identify the effect of rising drug prices on consumers and the government. It will also outline opportunities for persons or entities in Nevada to lower the cost of EDDs and maintain access to EDDs.

Effect of Rising Essential Diabetes Drug Prices on General Diabetes Spending in Nevada

The cost of diabetes to Nevada is estimated to be \$2.7 billion per year, while the total annual United States spending is \$327 billion (Figure 11). The United States' value has increased from \$245 billion in 2012 when the cost was last examined, a 26% increase (American Diabetes Association, 2018b). Just two years earlier, the estimated yearly cost for diabetes in Nevada was \$2.4 billion dollar, showcasing a substantial increase in recent years (American Diabetes Association, 2016). This increase in spending for diabetes is in part due to the fact that many costly diabetes drugs are undergoing consecutive price increases year after year by many drug manufacturers. Of EDDs that experienced a significant price increase, 60% had significant one- and two-year price increases during 2017 and 2018 (Table 2). Additionally, the average two-year price increase was over 21% (Table 3). For many expensive medications like insulin, these price increases represent a substantial amount of money for health systems and consumers.

Figure 11: The Cost Attributable of Diabetes to the United States and Nevada*

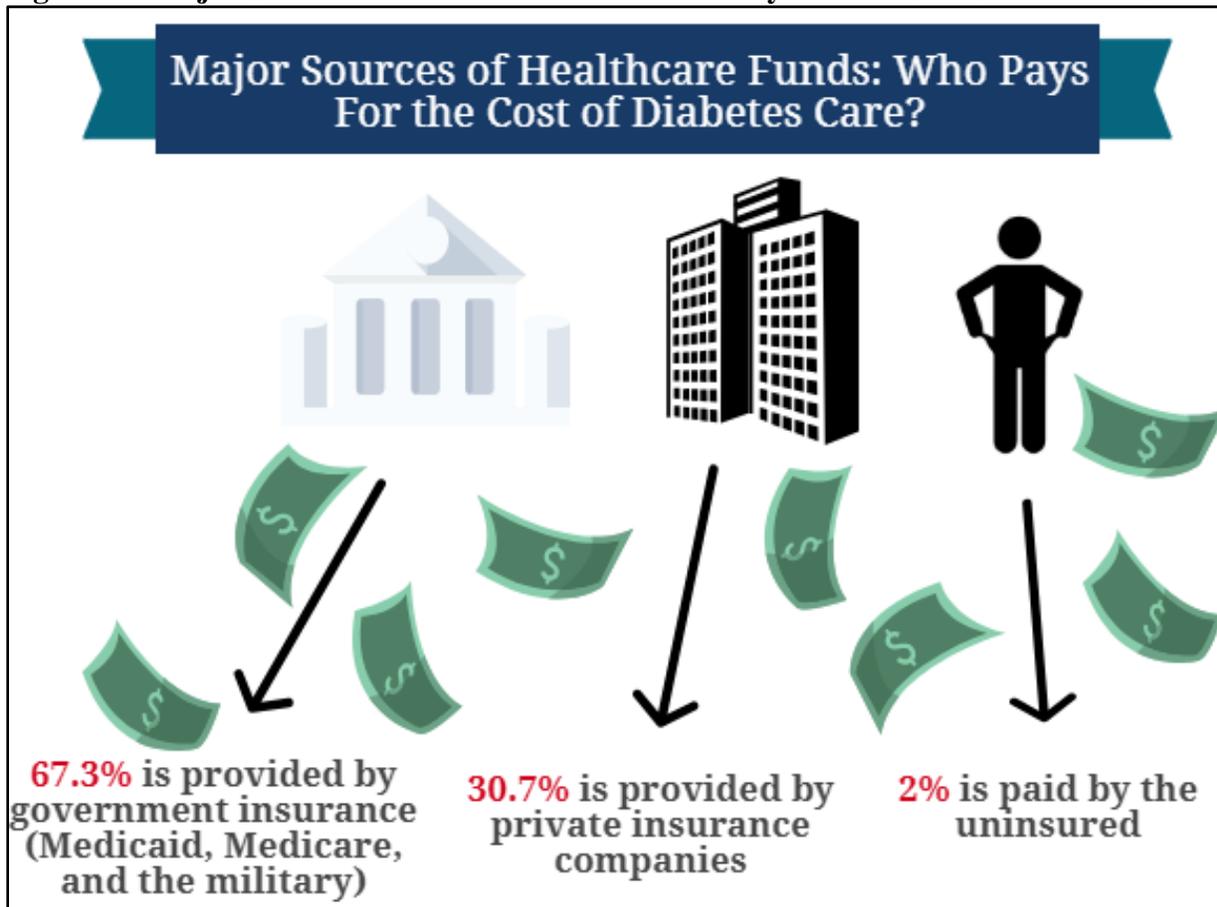


*Sources: (American Diabetes Association, 2018a), (American Diabetes Association, 2018b)

Effect of Rising Essential Diabetes Drug Prices on Governmental Prescription Drug Spending in Nevada

Nevada Medicaid spent \$60,924,212 in 2017 on drugs included on the 2019 EDD List (Figure 3). These total expenditures were higher than the reported value for the 2017 EDDs (Nevada DHHS, 2018b). Over 65% of this spending for 2019 EDDs was for drugs that experienced a significant increase in the previous one- and/or two-year periods (Figure 3). Overall in the United States, it is estimated that government insurance pays greater than 67% of costs for diabetes care, showcasing the strain that is placed on states and the federal government when diabetes drugs are consistently increasing in price (Figure 12).

Figure 12: Major Sources of Healthcare Funds: Who Pays for the Cost of Diabetes Care?*



*Source: (American Diabetes Association, 2018b)

Impact of Price Increases on Patient Health

Nevada Medicaid and the State's population experienced the financial burden of these price increases. There is growing evidence that prescription drug prices are inducing negative health and financial burdens on the population. Nationally, one in four people taking prescription drugs have a difficult time affording their prescribed medications (Kaiser Family Foundation, 2019a). When looking at populations most affected by prescription drug costs, it is those that are in fair to poor

health, those that take at least four medications per month, and low-income populations (Kaiser Family Foundation, 2019b). Nationally, more than one in four uninsured adults (28%) reported that they delayed or went without healthcare because of cost reasons (Kaiser Family Foundation, 2019c). From the same report, 7% of insured individuals reported cost barriers to accessing care.

With high deductible health plans that require major initial investment by those covered, these price increases could have caused a major strain on the financial health of Nevada residents covered by these plans. For those who are uninsured, these price increases could have prevented them from accessing adequate medical care to treat their diabetes. Nationally, among adults aged 45-64, almost 19% that were prescribed diabetic medications reduced or delayed taking medications to save money (Centers for Disease Control and Prevention, 2017). These significant price increases add to the burden imposed upon Nevada's diabetic patients.

Opportunities to Decrease Drug Spending while Maintaining Access to Essential Diabetes Drugs

Decreasing Overall Expenditures for EDDs

There have been significant efforts by state, private, and federal entities to decrease drug spending through drug transparency efforts while maintaining access to critical prescription drugs. Early in May 2019, the Federal Department of Health and Human Services (HHS) announced that it will require direct-to-consumer television advertisements for prescription drugs covered by Medicare or Medicaid to include the drug list price if that price is equal to or greater than \$35 for a month's supply or the usual course of therapy (US HHS, 2019). The HHS Secretary, Alex Azar stated:

Requiring the inclusion of drugs' list prices in TV ads is the single most significant step any administration has taken toward a simple commitment: American patients deserve to know the prices of the healthcare they receive...Patients who are struggling with high drug costs are in that position because of the high list prices that drug companies set. Making those prices more transparent is a significant step in President Trump's efforts to reform our prescription drug markets and put patients in charge of their own healthcare (US HHS, 2019).

Nevada health consumers should pay careful attention to the list price published in direct-to-consumer advertisements after this rule is implemented to become better informed and to help identify medications that are highly efficacious in treating patients while also being cost effective.

Many states are implementing drug transparency legislation. The National Academy for State Health Policy (NASHP) recently profiled drug transparency initiatives of seven states, highlighting Nevada's recent efforts (National Academy for State Health Policy, 2018a). NASHP also produced a detailed comparative summary chart of these initiatives (National Academy for State Health Policy, 2018b). Six out of seven states, including Nevada, required drug manufacturers to report or provide data if drug prices were increased above thresholds established in law. Five states, including Nevada, required drug manufacturers to report factors that caused the price increase. Of interest, four states required price reporting for new drugs entering the market, which could

provide useful public information and notification for new high-cost drugs entering the market. Monitoring prices of new drugs could allow for states to proactively identify drugs to include or exclude from preferred prescription lists or formularies based on drug efficacy and cost considerations.

Private entities are also actively involved in providing pricing transparency resources to consumers to decrease drug spending. There are online resources that allow consumers to visualize comparisons of drug prices among different pharmacies and retailers. Health consumers should be aware that prescription drugs are not equivalently priced at all pharmacies in their local areas. In 2015, the American Stroke Association published an article highlighting resources to help manage prescription drug costs (American Stroke Association, 2015). In this article, they highlight online services that display specific prescription drug prices and discounts at pharmacies with the option to search based on a specific geographic location. Consumers should carefully review retail options for pharmaceuticals and make informed, healthy choices. Health care consumers need to understand that carefully reviewing options for medication brand, type, and retail location can save them significant money while maintaining access to lifesaving medical interventions.

Decreasing Medicaid Expenditures for EDDs

A major challenge to containing Nevada Medicaid expenditures on EDDs is that Medicaid prescription drug benefits cover diverse options of prescription drugs that the Food and Drug Administration (FDA) approves. For this reason, Medicaid does not prohibit doctors from prescribing or patients obtaining many EDDs that experienced a significant increase. Nevada Medicaid and Nevada Check Up try to curb costs within constraints of federal law by publishing a list of preferred versus non-preferred drugs (Nevada Medicaid, 2019). This list provides guidance to health care providers and patients regarding drugs that are both clinically and cost effective. To further decrease drug spending by Medicaid, it is recommended that providers and patients carefully review available choices among medications to choose an effective treatment that when possible provides therapeutic equivalency at a lower cost to Nevada Medicaid or Nevada Check Up. Further, it is recommended that health providers and consumers review drug transparency reports carefully to understand changes in EDD prices.

As a high priority for cost savings, health providers that prescribe or recommend insulin therapy to diabetic patients should be aware of and carefully analyze the cost of medications that they prescribe to patients. Multiple forms of insulin deemed as EDDs accounted for 65% of Nevada Medicaid expenditures on EDDs (Figure 4). Health providers that treat diabetic patients with private insurance and the patients themselves should carefully review DHHS reports that identify drugs with significant price increases. These reports can help them to identify drugs that might be costing patients or health systems more without providing any therapeutic advantages over lower priced alternatives. With this knowledge, health providers and consumers can make more informed choices for essential diabetes medications that best treat diabetes while reducing overall drug spending.

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 2018 calendar year.

EDD Medicaid Expenditures Data

2017 Medicaid managed care organization and fee-for-service claims data for Nevada was obtained from the DHHS Office of Analytics. This dataset includes the total Medicaid expenditures per NDC.

EDD List and Price Increase Analyses

To compile the 2019 DHHS EDD List, DHHS utilized a methodology that met the requirements of NRS 439B.630. To generate the final list, DHHS compiled an initial list of diabetes drug NDCs that included varying drug packaging formulations based on prior and current stakeholder input. These NDCs were filtered down to include the drugs for which Nevada Medicaid expended funds in 2017 and/or 2018. Additional NDCs that were of interest to the public and stakeholders were added to this list.

This EDD 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 for diabetes or approved for the treatment of diabetes. This list attempts to refine the numerous treatments to those approved for the treatment of diabetes, identified by prescribers as essential and most frequently prescribed in Nevada as determined by publicly available data sources. For this reason, some brand names, generics, or alternative brands are included while others are excluded.

Out of the 695 EDDs published by DHHS in 2019, four of the drug NDCs did not have available wholesale acquisition cost (WAC) price history. These drugs could not be analyzed for a significant price increase as outlined in NRS 439B.630 because the law specifically requires the use of WAC data for the analysis. For this reason, Table 1 only reports 691 total EDDs analyzed for a significant price increase. NRS 439B.630 specifies that the price increase analysis should identify EDDs that have been subject to an increase in the WAC of a percentage equal to or greater than: (a) The percentage increase in the Consumer Price Index, Medical Care Component during the immediately preceding calendar year; or (b) twice the percentage increase in the Consumer Price Index, Medical Care Component during the immediately preceding two calendar years

The minimum prices active during 2017 and 2018 and the maximum active price for 2018 were compared to identify the one-year and two-year price increase percentages. The one-year price increases were compared against the 2018 annual CPI Medical Care Component, while the two-year price increases were compared against twice the combined annual CPI Medical Care Component values of 2017 and 2018. For the 2019 EDDs, the one-year percentage increase threshold value was 2%, and the two-year threshold value was 9%.

EDD Manufacturer Reporting

DHHS received EDD Reports from drug manufacturers for over 65% of all EDD NDCs published in the 2019 EDD List. DHHS received Price Increase Reports for over 44% of the drugs identified as having a significant price increase. DHHS will be contacting non-compliant organizations to obtain the required reports. DHHS was able to obtain explanations for price increases for an additional 47% of the drugs with a significant price increase. In the case of these drugs, manufacturers failed to submit Price Increase Reports but did submit EDD Reports. The EDD Report required manufacturers to provide explanations for price increases. In total, DHHS obtained justifications or explanations for price increases for over 91% of the EDD NDCs with significant price increases.

DHHS compiled and aggregated the drug manufacturer reported data so that each major drug included only one entry for each reporting criteria. Some manufacturers reported financial information at the individual NDC level. Other manufacturers aggregated financial information for a given drug by combining all NDC data. To account for this reporting variation, DHHS aggregated all reported values based on drug name by manufacturer to standardize the dataset.

DHHS standardized the manufacturer reported values for *Profit* and the *Percentage of Manufacturer's Total Profit Attributable to Essential Drug*. If a manufacturer reported a negative value for profit, DHHS standardized the data by converting these values to zero. DHHS defined profit as denoting financial gains earned from a reporting entity.

Unless otherwise indicated, drug manufacturer data was reported at the national level. Averages and other aggregated statistical data were calculated by analysis of a combined dataset. The *Profit Divided by the Sum of Drug Production and Administrative Costs* results reported in Table 4 was calculated by taking the profit for each individual drug and dividing it by the sum of the drug production and the administrative costs. These individual values were then averaged and reported in Table 4.

Price Increase Justification Analysis

Drug manufacturers reported narrative justifications for significant price increases of EDDs. Responses were standardized into categories described in Appendix 2 so that they could be quantified and compared for their relative frequencies. Manufacturers reported one or more justifications for the drug price increases. Regardless of the number of price increase justifications per drug reported by manufacturers, each individual drug was allotted an equal weight in the analysis used to create Figure 6. For the drugs that had more than one justification, each additional justification was assigned a proportionally smaller weight in the overall analysis.

PBM Aggregated Rebates

In contrast to the drug manufacturer data, PBMs submitted aggregated pricing rebates for all EDDs and did not report rebates for individual drugs. Unless otherwise indicated, data regarding PBMs is specific to Nevada. DHHS added up all PBM-reported rebates to create Table 6.

Pharmaceutical Representative Compensation and Samples Data

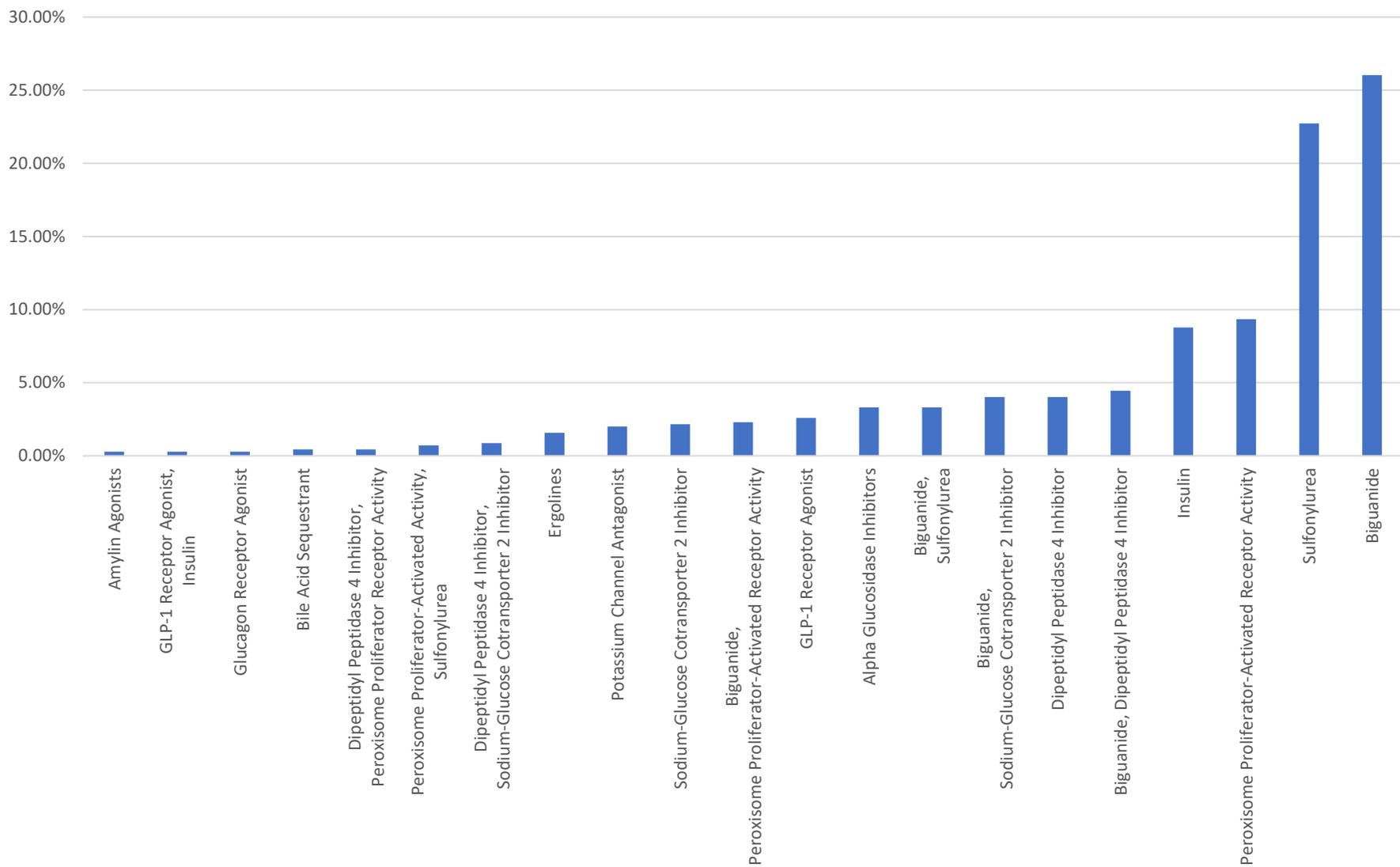
All pharmaceutical drug representative compensation and samples reports received by DHHS were standardized and merged into one dataset. DHHS received 295,149 pharmaceutical representative compensation and samples records. Of these records, 648 reported no compensation or sample distribution events by the registered pharmaceutical representative for 2018. Over 98% of the reports included the professional designation of the compensation and/or samples recipient.

Representative reporting completeness was greatly improved compared to the 2018 Compensation and Samples Report (Nevada DHHS, 2018a) because a new template and instructions were released that clarified reporting requirements. In 2019, 44% of active representatives submitted reports outlining compensation and samples distribution during the 2018 calendar year. The remaining 56% of active representatives were either not active in distributing samples or compensation at the thresholds established in law in Nevada or failed to report eligible events. To verify compliance with state law, DHHS will follow up with drug manufacturers and representatives. DHHS will update the reporting template and instructions and require all representatives to report even if they were not active in distributing compensation or samples.

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 1: Percent Drug Classification of Essential Diabetes Drugs NDCs



Appendix 2: 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 clarify the diverse responses received.

Research and Development: This category includes responses indicating that additional funds would support research and development of existing EDDs 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.

PBM, Insurance, and Other 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.

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.

Investment in Manufacturing: This category related specifically to investments in manufacturing or improving or constructing new drug manufacturing facilities.

Generate Profit: Responses referenced that manufacturers 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.

Pharmacovigilance: Scientific and other activities used to detect, characterize, identify, and prevent drug-related adverse effects.

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.

Increases in Drug Production Costs: Responses outlined higher drug production costs and higher costs relating to commercial transportation.

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.

Appendix 3: Examples of Sample Medication Targeted Health Conditions and Medication Types Reported in Figure 10

The following are examples of health conditions and medication types grouped into each major category:

- **Blood Disorders:** Anemia, Venous Thromboembolism, Kidney Conditions, Anticoagulants
- **Cancer:** Cancer, Chemotherapy, Carcinoid Syndrome Diarrhea, Cancer-Related Nausea and Vomiting
- **Diabetes:** Diabetes Mellitus, Diabetic Nerve Pain, Hyperglycemia, Type 1 and 2 Diabetes
- **Digestive Health:** Acid Reflux, Bowel Prep Kit, Crohn's Disease, Ulcerative Colitis, Exocrine Pancreatic Insufficiency, Heartburn, Hemorrhoids, Irritable Bowel Syndrome, Overactive Bladder, Pancreatic Enzymes, Ulcer
- **Eye Health:** Conjunctivitis, Dry Eye, Eye Drops, Eye Pain and Swelling, Glaucoma, Macular Degeneration
- **Heart Conditions:** Angina, Atrial Fibrillation, Cardiovascular Disease, Heart Attack, Stroke, Heart Disease, Heart Failure, High Cholesterol, Hypertension
- **Immune Disorder:** Autoimmune Diseases, Gout, Immunosuppressive Drug, Nonsteroidal Anti-Inflammatory Drug, 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, Morning Sickness, Prostate, Testosterone, Vaginal Dryness, Osteoporosis
- **Mental Health:** Attention Deficit Hyperactivity Disorder, Binge Eating Disorder, Parkinson's Disease, Alzheimer's Disease, Antidepressant, Bipolar Disorder, Depression, Schizophrenia
- **Nerve Disorders:** Multiple Sclerosis, Epilepsy, Parkinson's Disease, Neuropathy, Restless Leg Syndrome
- **Other:** Vitamin Supplement, Weight Loss, Hyperthyroidism, Allergies, Ear Drops, Non-24-hour Sleep-Wake Disorder, Transfusional Iron Overload, Nasal Polyps, Seizures,
- **Pain Relief:** Migraine, Muscle Relaxer
- **Infectious Disease:** Anti-fungal, Anti-parasite, Antibiotic, Cold Sores, Tonsillitis, Toxoplasmosis, Antibacterial, Vaccine, Shingles, HIV, Fungus, Ear Infection, Rotavirus, Hepatitis C Virus, Urinary Tract Infection, Herpes
- **Skin conditions:** Acne, Actinic Keratosis, Angioedema, Anti-Inflammatory Steroid, Antipruritics, Athlete's Foot, Botox, Dermatitis, Eczema, Psoriasis, Rosacea, Severe Acne, Seborrheic Dermatitis

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