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Supplemental Report

2017 Essential Diabetes Drugs

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**Nevada Department of
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DHHS compiled and aggregated the drug manufacturer reported data so that each major drug included only one entry for each reporting criteria. This prevented duplication as one drug can have many National Drug Codes (NDCs) that represent different dosage strengths and packaging specifications. Additionally per their submissions, most drug manufacturers do not track manufacturing and fiscal data at the individual drug NDC level. DHHS standardized and deduplicated the data for the downstream analysis. Drug manufacturer data was reported at the national level. Averages and other aggregated statistical data were calculated by analysis of the combined drug data. The *Profit Divided by the Sum of Drug Production and Administrative Costs* results reported in Table 1 were created 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 1. In contrast to the drug manufacturer data, PBMs submitted aggregated pricing rebates for all essential diabetes drugs and did not report rebates for individual drugs. DHHS added up all PBM-reported rebates to create Table 3.

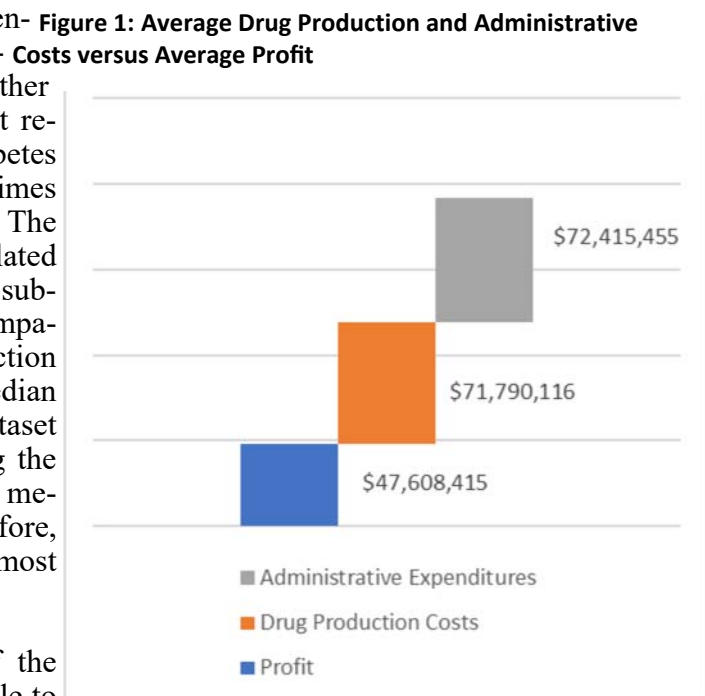
Results

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

Profits reported by drug manufacturers for essential diabetes drugs ranged dramatically with reports indicating that 28% of drugs incurred either a loss or earned no profit. The average profit reported by manufacturers for essential diabetes drugs was \$47,608,415, which was over 165 times higher than the median (Figure 1, Table 1). The median profit was below \$300,000. 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 the median as strongly as they do the average. Therefore, the median acts as a better indicator of the most common reported value.

Overall, the average reported percentage of the manufacturer's total profits that was attributable to each essential diabetes drug for the period during which the manufacturer has marketed the drug for sale was 2.38% with a standard deviation of 8.75% (Table 1). Even taking into account 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. The standard deviation indicates how measurements for a group are spread out from the average. A low standard deviation means 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.

The average reported total drug production cost was \$71,790,116 with the average reported total administrative expenditures coming in higher at \$72,415,455 (Figure 1). Administrative expenditures



included both the marketing and advertising costs. Lastly, the average values for both reported drug production and administrative expenditures were at least 50 times higher than the respective medians, showing the skewing effect of the large drug manufacturers' data. Figure 1 illustrates that based on the averages, profits are substantially less than either the drug production and the administrative costs.

Table 1: Essential Diabetes Drug Reported Profits and Production and Administrative Costs

	Average	Standard Deviation
Percentage of the Manufacturer's Total Profit Attributable to Essential Drug*	2.38%	8.75%
Profit	\$47,608,415	\$153,453,575
Total Cost of Producing the Drug	\$71,790,116	\$252,565,952
Total Administrative Expenditures Relating to the Drug†	\$72,415,455	\$158,331,919
Profit Divided by the Sum of Drug Production and Administrative Costs‡	1.58	5.44

*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. Some values were reported as negative due to the fact that manufacturers reported losing money on certain drugs.

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 production and administration costs. On average from reports received for essential diabetes drugs, there was 1.58 times the profit earned compared to production and administrative costs (Table 1). In other words, essential diabetes drugs on average earned \$1.58 in profit for every \$1.00 spent on combined production and administrative costs. A standard deviation of 5.44 helps to illustrate the large variation of data values which ranged from losses to ratios with profits greater than 20 times the combined costs of production and product administration (Table 1). Of drugs included in this analysis, 69% earned profits greater than the combined cost of production and administrative expenditures. The averages presented in Figure 1 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 1 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 that they provided to consumers and rebates that were provided to PBMs (Table 2). PBMs can negotiate prescription drug rebates with drug manufacturers. Some PBMs pass all these rebates onto insurers or consumers while others retain a portion of

the rebates. Overall, 60% of reports for essential diabetes drugs indicated that drug manufacturers provided \$0 of financial assistance through patient prescription assistance programs. The average reported total amount of financial assistance provided through patient prescription assistance programs was \$10,063,507. This value was inflated due to a subset of larger drug manufacturers providing high monetary values of financial assistance. The median value for total 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 2 provide evidence of the large variations among the drug manufacturers for financial assistance to consumers and rebates provided to PBMs.

Table 2: Financial Assistance and PBM Rebates Provided by Drug Manufacturers for Essential Diabetes Drugs

	Average	Standard Deviation
Total Amount of Financial Assistance Provided through Patient Prescription Assistance Programs	\$10,063,507	\$29,658,364
Cost Associated with Consumer Coupons and for Consumer Copayment Assistance Programs	\$15,551,568	\$45,781,212
Manufacturer Cost Attributable to Redemption of Consumer Coupons and Use of Consumer Copayment Assistance Programs	\$1,883,713	\$8,357,752
Aggregate Amount of All Rebates Manufacturer Provided to Pharmacy Benefit Managers for Drug Sales in Nevada	\$5,131,180	\$28,957,893

The average reported value of the aggregate rebates that manufacturers provided to PBMs for Nevada drug sales was \$5,131,180. Of drug reports, 59% reported no rebates provided by manufacturers to PBMs. Thus, there is substantial variation among drug manufacturers of essential diabetes drugs in how they negotiate rebates with PBMs.

Drug Manufacturers Price Increase Data

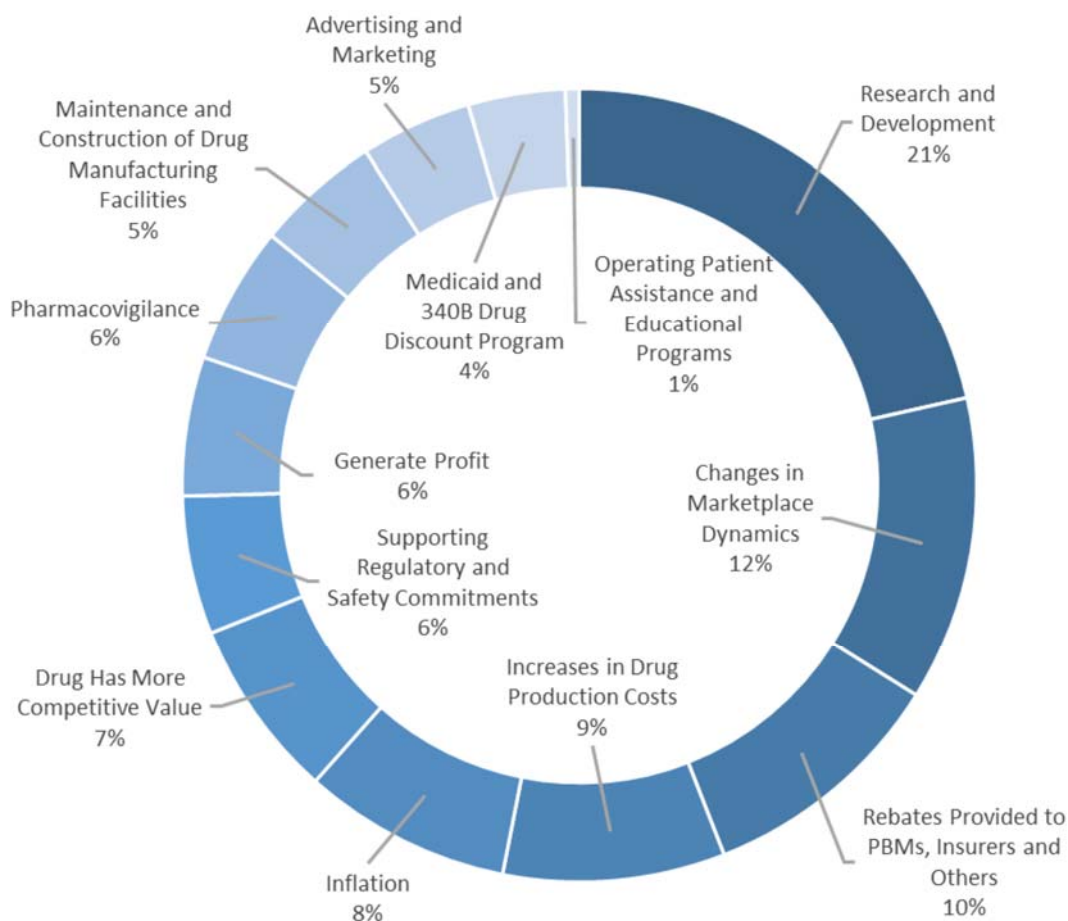
DHHS is required to identify the Essential Diabetes Drugs that had a significant price increase equal to or greater than (a) the percentage increase in the Consumer Price Index (CPI), Medical Care Component during the immediately preceding calendar year; or (b) twice the percentage increase in the CPI, Medical Care Component during the immediately preceding two calendar years. 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, 175 drug NDCs in the 2017 Essential Diabetes Drug List showed a price increase above the thresholds established in law³. The *Analysis of Essential Diabetes Drugs that had a*

Price Increase published by DHHS in September 2018 provides an analysis of the overall spending by Medicaid for the essential diabetes drugs and specifically for those that experienced a significant price increase². Drug manufacturers that produced an essential diabetes drug that experienced a significant price increase are required to provide a report outlining a justification for the price increases for each drug. DHHS standardized all the responses into major categories, showcased in Figure 2. Figure 2 also displays the percent of responses for drugs from manufacturers that utilized each price increase justification category. 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 (21%), changes in marketplace dynamics (12%), rebates provided to PBMs, insurers, and others (10%), increases in drug production costs (9%), and inflation (8%). An appendix at the end of this report provides summarized examples of each category to further describe these justifications. One of the most unexpected response categories reported by drug manufacturers was that price increases were specifically required to increase or generate profits.

Figure 2: Justifications for Price Increase of Essential Diabetes Drugs



PBM Rebate Data

PBMs reported the rebates negotiated with manufacturers during the immediately preceding calendar year for prescription drugs included in the essential diabetes drug list. PBMs also 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. For this reason, DHHS did not require PBMs to report rebates for Medicare and for certain ERISA plans.

Total reported rebates that PBMs negotiated with manufacturers for essential diabetes drugs equaled almost 1.7 billion dollars (Table 3). The total reported rebates are broken down into three categories: 1) rebates to Medicaid recipients, 2) rebates for government entities that are not Medicaid or Medicare, and (3) rebates to non-governmental third parties. Of all reported rebates negotiated by PBMs with manufacturers, 4.6% were retained by PBMs. This percentage might appear small, but it represents \$77,884,588 (Table 3). 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 1% to greater than 15%.

Table 3: Total Reported Rebates Negotiated by PBMs for Essential Diabetes Drugs

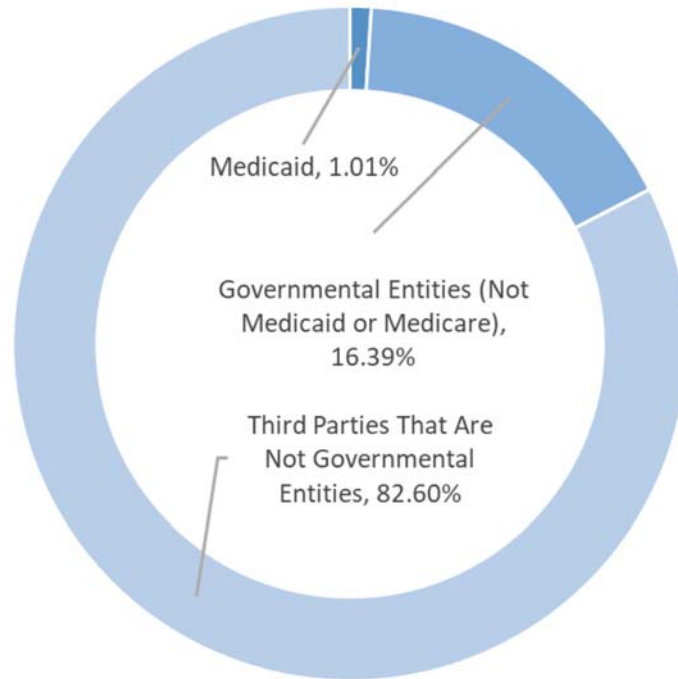
Reported Value Description	Aggregate Value in United States Dollars
Row 1: Total amount of all rebates that PBMs negotiated with manufacturers during 2017 for essential diabetes drugs*	\$1,697,669,441
Row 2: Total amount of all rebates described in Row 1 that were negotiated for purchases of such drugs for use by recipients of Medicaid	\$17,121,081
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	\$278,288,127
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	\$1,402,260,233
Row 5: Total amount of all rebates described in Row 1 that were retained by PBMs	\$77,884,588

*The total rebates reported in Row 1 are equal to the sum of the individuals rebates reported in Rows 2 through 4. Row 5 represents rebates retained from the total rebates reported in Row 1.

Figure 3 shows the percentage of reported rebates that PBMs negotiated with manufacturers for purchase of essential diabetes drugs 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%) of the total reported rebates negotiated by PBMs (Figure 3).

Over 82% of total reported rebates negotiated by PBMs with manufacturers were for third parties that are not governmental entities (Figure 3).

Figure 3: Percentage of Reported PBM Rebates Negotiated for Essential Diabetes Drugs by Insured Entity Type



Discussion

Impact of Essential Diabetes Drugs on Nevada Residents

Many Nevada residents suffer immensely from the effects of diabetes. In Nevada, approximately 12.6% of adults have diabetes⁴. Of these, 75,000 Nevada residents have diabetes but are undiagnosed. There are an estimated 787,000 Nevadans are prediabetic, with blood glucose levels higher than normal but not yet high enough to be diagnosed as diabetic⁴. An estimated additional 14,000 Nevadans are diagnosed each year as diabetic⁴. Drugs reported on the 2017 Essential Diabetes Drug List are critically important in helping to treat and manage the symptoms of chronic diabetes. Both health providers and their patients rely on these drugs as lifesaving medical interventions. Significant price increases to these medications can substantially strain Nevada residents' financial and physical health and Nevada's health system.

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

As reported previously⁵, Nevada Medicaid spent \$57,156,533 on drugs included on the 2017 Essential

⁴The Burden of Diabetes in Nevada (2018). American Diabetes Association. Data aggregated from 2015 data retrieved from [cdc.gov/diabetes/data](http://main.diabetes.org/dorg/assets/pdfs/advocacy/state-fact-sheets/Nevada2018.pdf). Retrieved on 2/12/2019 from <http://main.diabetes.org/dorg/assets/pdfs/advocacy/state-fact-sheets/Nevada2018.pdf>

⁵Analysis of Essential Diabetes Drugs that Had a Price Increase (2018). Nevada DHHS. Retrieved on 2/12/2019 from http://dhhs.nv.gov/HCPWD/Drug_Transparency_Essential_Lists_Reports_Resources/

Diabetes Drug List⁵. In an analysis of the 175 drug NDCs that experienced a price increase between 2016 and 2018, the following was previously reported⁵ and is highlighted to show the substantial impact of these price increases on Nevada Medicaid (*italics added for emphasis*):

Of the 175 NDCs DHHS identified as having a price increase above the thresholds established in law, *138 or 78.9% of those NDCs were drugs prescribed in 2017 by providers to Medicaid patients. The net payment by Medicaid, for the 138 NDCs experiencing a price increase was \$55,278,705, around 97% of the total Medicaid funds expended on essential diabetes drugs.* [...] The Medicaid data indicates that an estimated 67% of expenditures on those drugs that experienced a significant price increase established in law were dedicated to the cost of short-acting, long-acting, rapid-acting, and intermediate-acting insulin.

Nevada Medicaid and the state's population experienced the financial burden of these price increases. More than the majority of the expenditures were for insulin. 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 medications⁶. When looking at the populations that are the 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 populations⁷. Nationally, more than one in four uninsured adults (28%) reported that they delayed or went without healthcare because of cost reasons⁸. From the same report, 7% of insured individuals reported cost barriers to accessing care⁸. 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 that 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 money⁹. 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

A major challenge to containing Nevada Medicaid expenditures on essential diabetes drugs 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 essential diabetes drugs 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 drugs¹⁰. 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

⁶What are the recent and forecasted trends in prescription drug spending?, (2019) Kaiser Family Foundation. Retrieved on 3/01/2019 from https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/#item-people-taking-rx-drugs-say-can-afford-treatment-1-4-difficult-time-affording-medicine_2017

⁷KFF Health Tracking Poll (Conducted February 14-24, 2019), (2019) Kaiser Family Foundation. Retrieved on 3/4/2019 from <https://www.kff.org/health-reform/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/>

⁸How does cost affect access to care? (2019) Kaiser Family Foundation. Retrieved on 3/01/2019 from <https://www.healthsystemtracker.org/chart-collection/cost-affect-access-care/#item-start>

⁹QuickStats: Percentage of Adults Aged ≥45 Years Who Reduced or Delayed Medication to Save Money in the Past 12 Months Among Those Who Were Prescribed Medication, by Diagnosed Diabetes Status and Age — National Health Interview Survey, 2015. MMWR Morb Mortal Wkly Rep (2017);66:679. DOI: <http://dx.doi.org/10.15585/mmwr.mm6625a5>

¹⁰Nevada Medicaid and Nevada Check Up Preferred Drug List (PDL), (2019). Nevada Medicaid an Nevada Check Up. Retrieved on 3/07/2019 from https://www.medicaid.nv.gov/Downloads/provider/NV_PDL_20190201.pdf

Medicaid, DHHS recommends that providers and patients carefully review available choices among medications to choose an effective treatment that when possible provides sufficient or equal therapeutic equivalency at a lower cost to Nevada Medicaid or Nevada Check Up. DHHS also recommends that health providers and consumers review drug transparency reports carefully to understand changes in essential diabetes drug 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 are prescribing to patients. Multiple forms of insulin deemed as essential diabetes drugs accounted for 67% of Medicaid expenditures on essential diabetes drugs. 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.

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 <http://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 define the justification categories and further clarify the diverse responses received.

Research and Development: This category includes responses that indicated that additional funds would support research and development of existing essential diabetes drugs and future medicines. It was indicated by manufacturers that drug research continues even after the United States Food and Drug Administration approves their drugs to verify safety and improve product formulations.

Rebates Provided to PBMs, Insurers and Others: 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: Overall, responses indicated that market 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.

Maintenance and Construction of Drug Manufacturing Facilities: This category related specifically to improving or constructing new drug manufacturing facilities.

Generate Profit: Overall, 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: Overall, responses indicated a need to promote awareness of drugs through advertisements and further workforce training relating to sales.

Inflation: Overall, responses referenced general inflation that occurs in the medical market.

Medicaid and 340B Drug Discount Program: Overall, 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: Overall, responses specified that additional funds were needed to cover the costs of administering patient assistance and educational programs.

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

Drug Has More Competitive Value: Overall, 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.