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Drug Transparency Report 2020 Essential Drugs

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Nevada Department of Health and Human Services

Introduction

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 and asthma in Nevada (Nevada Revised Statutes (NRS) 439B.630). The 2020 Essential Drugs (ED) List was published on February 1, 2020 (Nevada DHHS, 2020a). All manufacturers that produce medication included in Nevada's ED List are required to submit to DHHS an ED 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 ED 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 EDs (NRS 439B.645).

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 EDs:

NRS 439B.650: Department to compile report concerning price of essential diabetes and asthma 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 <u>2017, 4299</u>)

The pricing of prescription medications is multifaceted, especially with regards to asthma and diabetes where there are many treatment options. In order to better understand pricing of prescription medications in the outpatient setting, the basic flow of money must be understood. There are several sectors that provide goods or services to customers in exchange for payment. Below is a conceptual model that demonstrates the general flow of medications, services, contracts, and funds for traditional medications.

Figure 1. Conceptual visualization of the flow of money and products between sectors and their contractual agreements.



In Figure 1, each relationship provides a service for an exchange of funds. This figure includes three main components for outpatient pharmacy: the flow of funds, the flow of prescription medications, and the contractual relationship between each entity, as indicated by the different colored arrows. Here we will provide an overview of those three components with respect to the manufacturer, the wholesaler, the pharmacy benefit manager (PBM), and the pharmacy.

Manufactures are the entities that produce a medication for sale. The wholesaler is responsible for distribution of medications to the pharmacy. The PBM is the intermediary between the health plan, the pharmacy, and the manufacturer. The PBM manages the pharmacy benefits for the health plan and is responsible for contracting between the health plan and the manufacturer. The PBM also creates a preferred medication list (i.e. formulary) and a preferred network of pharmacies for the health plan participants. Both the formulary and the preferred pharmacy network drive utilization. For example, if a pharmacy is not in the preferred network, health plan participants may not utilize that pharmacy. Similarly, if there are two competing prescription medications, and one is not on the formulary, the other will have increased utilization.

The PBM uses a rebate aggregator to negotiate rebates on prescription medications with the manufacturer. Agreements between the rebate aggregator and the manufacturer can incentivize formulary placement and increase potential utilization and thus sales for the manufacturer in exchange for a rebate payment back to the PBM. This in turn lowers the net cost of the medication, and that savings can be passed on to the payor (i.e. health plan). The PBM may operate their own rebate aggregator or outsource this service. Smaller PBMs have less negotiation power due to having a smaller number of participants than larger PBMs; therefore, smaller PBMs will often pay a fee to use the rebate aggregator of a larger PBM, which can then leverage more overall participants for more favorable negotiations. In other words, if a PBM has 1 million participants, it will have a lot more negotiating power to get favorable rebates than a PBM with 100,000 participants. By contracting with the rebate aggregator of the larger PBM, the smaller PBM can benefit from more favorable rebates, but they will pay a fee to do this. These negotiations can obviously have a large effect on the total cost of prescription medications. While giving a rebate to gain a favorable position on a preferred medication list means that the manufacturer will receive a lower overall price for medication, they simultaneously gain the opportunity for increased utilization and profit.

The PBM will also negotiate a discounted price for medications with different pharmacies to determine which pharmacies health plan participants can utilize. Pharmacies may be willing to offer a discount to gain favorable positioning in the network. Generic medications discounts are aggressively negotiated at the pharmacy level. Brand name medications do not have much negotiation in price at the pharmacy level; instead they are discounted via rebates as discussed above. The agreement between the pharmacy and the PBM allows health plan participants to obtain medications only from the preferred network of pharmacies, but at the negotiated discounted rate. The pharmacy will also have a vendor agreement with the wholesaler to obtain medications at a negotiated price.

As illustrated in Figure 1, the process of providing a prescription medication from the manufacturer to an individual is complex and multifaceted. There are several different levels of negotiations and rebates that ultimately affect the cost of the medication. The overall goal of this report is to provide greater transparency about these costs.

Results

General Analysis of 2020 Essential Drugs (ED)

DHHS published the 2020 ED List on February 1, 2020 that included 631 Anti-Diabetic and 281 Anti-Asthmatic National Drug Codes (NDCs) (Nevada DHHS, 2020a). Each NDC represents a specific drug formulation, dosage, and packaging specification. This list contained 99 distinct nonproprietary drugs.

ED Significant Price Increase Analysis

DHHS analyzed the 2020 EDs 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 EDs that experienced a significant price increase, EDs were analyzed to identify any price increases

occurring during the 2018 and 2019 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 States Department of Labor, 2019). A total of 130 or 16.6% of EDs experienced a significant price increase during the periods analyzed (Table 1).

Table 1: 2019 Essential Drugs that Experienced a Significant Price Increase		
	Number of Drug	
	NDCs	Percentage
Diabetes medications with a Significant Price Increase		
During the Previous One- and/or Two-Year Periods	117	18.5%
Diabetes Medications with no Significant Price		
Increase	514	81.5%
Asthma medications with a Significant Price Increase		
During the Previous One- and/or Two-Year Periods	13	4.6%
Asthma medications with no Significant Price		
Increase	268	95.4%

DHHS analyzed the frequency of significant price increases over the time periods analyzed. As outlined in Table 2, EDs that experienced a price increase were categorized by brand and generic medications.

Table 2: Number and Percent of Essential Drugs that Experienced a Significant Price		
Increase Per Time Period Analyzed		
	Number of Brand	Number of Generic
	NDCs (%)	NDCs (%)
Diabetic NDCs that Experienced Only a One-Year	96 (75%)	31 (25%)
Significant Price Increase		
Diabetic NDCs that Experienced Only a Two-Year	102 (80%)	26 (20%)
Significant Price Increase		
Asthma NDCs that Experienced Only a One-Year	5 (36%)	9 (64%)
Significant Price Increase		
Asthma NDCs that Experienced Only a Two-Year	8 (53%)	7 (47%)
Significant Price Increase		

The average increase in price for diabetes and asthma medications that experienced a significant price increase over the preceding calendar year was 11.2% and 19.3%, respectively, while the average increase over the preceding two-year period was 19.4% and 20.6%, respectively (Table 3). The one-year value was well above the annual CPI, Medical Care Component for 2018 or 2019, which were 2.0% and 2.8% 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.

Table 3: Average One- and Two-Year Price Increase for Essential		
Drugs that Experienced a Significant Price Increase		
	Percentage	
Average One-Year Essential Diabetic Medications	11.2%	
Price Increase		
Average Two-Year Essential Diabetic Medication	19.4%	
Price Increase		
Average One-Year Essential Asthma Medications	19.3	
Price Increase		
Average Two-Year Essential Asthma Medication Price	20.6%	
Increase		

EDs that experienced a significant price increase were analyzed by drug class in Figure 2. Once more, like the 2019 Drug Transparency Report brand name medications with no generic equivalent were the most predominant group of drugs that experienced a significant price increase.





*Combination medication with medication such as a DDP-4 inhibitor and a biguanide or thiazolidinedione, SGLT-2 with a biguanide were reported under DDP-4 or the SGLT-2 component since the biguanide/thiazolidinedione component has a minimal if any effect, of the overall pricing of the medication.

Medicaid Expenditures for Essential Drug

EDs play a critical role in the health of Nevadans, including low-income and underserved populations covered by Medicaid. ED utilization accounts for 11.29% of all claims in 2019 which represents a slight increase from 11.06% in 2018. EDs in 2019 account for 17.67% of overall Medicaid expenditures on prescription drugs, down from 19.59% in 2018 (Figure 3). EDs year after year are trending similarly in both utilization and expenditure (Figure 3 and Figure 4). Diabetes accounts for <5% of the utilization but accounts for over 10% of the spend. Asthma on the other hand more closely represents a 1 to 1 utilization to spend ratio (Figure 3, Figure 4, Table 4 and Table 5).

Figure 3: Medicaid Utilization on Essential Diabetes and Asthma Drugs Compared to All Other Drugs



Table 4. Medicaid Utilization				
Medicaid Pharmacy Utilization	2018 Claims	2019 Claims		
All Medicaid Pharmacy Claims	8,321,139	7,309,635		
All Medicaid Pharmacy Claims for Essential Diabetes	347,170	319,098		
Drugs				
Brand Medicaid Pharmacy Claims for Brand Diabetic	160,335	150,878		
Drugs				
Generic Medicaid Pharmacy Claims for Generic Diabetic	186,835	168,220		
Drugs				

Table 4. Medicaid Utilization		
All Medicaid Pharmacy Claims for Essential Asthma	573,146	825,582
Drugs		
All Medicaid Pharmacy Claims for Brand Asthma Drugs	117,9113	101,909
All Medicaid Pharmacy Claims for Generic Asthma	455,233	404,575
Drugs		





Overall, expenditures per claim for EDs have decreased for both asthma and diabetes compared to the increase of all pharmacy expenditures from 2018 to 2019 (Table 5). Average claim cost per brand or generic diabetic and generic asthma medications have declined in cost whereas asthma brand medications had a slight increase (Table 5).

Table 5. Medicaid Expenditure				
Medicaid Pharmacy	2018 Medicaid	2019 Medicaid	2018	2019
Expenditures	Pharmacy	Pharmacy	Average	Average
	Expenditures	Expenditures	Cost per	Cost per
			Claim	Claim
All Medicaid Pharmacy	\$738,580,755.11	\$680,200,257.77	\$88.76	\$93.06
Claims				
Medicaid Pharmacy Spend	\$80,464,506.51	\$71,320,652.75	\$231.77	\$223.51
for Essential Diabetes Drugs				
Medicaid Pharmacy Spend	\$64,208,874.39	\$48,883,432.40	\$112.03	\$96.52
for Essential Asthma Drugs				

Table 5. Medicaid Expendit	ure			
Medicaid Pharmacy Spend for Brand Diabetes Drugs	\$ 77,836,461.02	\$ 69,458,442.31	\$485.46	\$460.36
Medicaid Pharmacy Spend for Generic Diabetes Drugs	\$2,628,045.49	\$1,862,210.44	\$14.07	\$11.07
Medicaid Pharmacy Spend for Brand Asthma Drugs	\$32,733,175.03	\$28,314,351.78	\$277.60	\$277.84
Medicaid Pharmacy Spend for Generic Asthma Drugs	\$31,475,699.36	\$20,569,080.62	\$69.14	\$50.84

~ 90% of all the drug spend in the diabetic categories reside in the brand only classes (GLP-1, SGLT-2, DDP-4 and insulin) and represent a majority of the drugs that have experienced a significant price increase (Figure 5).



Figure 5: Percentage Medicaid Expenditures by Class of Essential Diabetes Drugs

Asthma expenditures were predominately incurred from inhaled beta-adrenergic agents and inhaled glucocorticoids both of which are majority brand name medications with limited generic availability. Biologics, specifically the Interleukin-5 Antagonists, are relatively new and growing in popularity in patients with severe asthma. These biologics would be typically classified as specialty medications by most payors due to their high cost.



Figure 6: Percentage Medicaid Expenditures by Class of Essential Asthma Drugs

Drug Manufacturer Profits and Administrative and Production Costs for Essential Drugs

The average profit reported by manufacturers for diabetes and asthma medications was \$16,380.387.88 and \$29,230,891.34, respectively (Figure 7, Table 6). Administrative expenditures included both the marketing and advertising costs. 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 or smaller pharmaceutical companies that are reporting zero for these costs. This also inflated the standard deviation.



Figure 7: Average Drug Production and Administrative Costs versus Average Profit

Administrative Costs		
	Average	Standard Deviation
Diabetes Profit	\$16,380,387.88	\$83,439,461.10
Diabetes Total Cost of Producing the Drug	\$15,213,129.01	\$77,998,069.69
Diabetes Total Administrative Expenditures	\$20,191,226.75	\$91,774,488.54
Relating to the Drug [†]		
Asthma Profit	\$29,230,891.34	\$107,741,820.53
Asthma Total Cost of Producing the Drug	\$10,617,455.24	\$44,413,924.75
Asthma Total Administrative Expenditures	\$20,368,572.70	\$118,882,430.04
Relating 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.		

 Table 6: Essential Diabetes and Asthma Drug Reported Profits and Production and

 Administrative Costs

Drug Manufacturer Financial Assistance and PBM Rebates for Essential Drugs

Drug manufacturers reported the financial assistance provided to consumers and rebates that were provided to PBMs (Table 7). PBMs can negotiate prescription drug rebates with drug manufacturers. Some PBMs pass all of these rebates on to insurers or consumers while others retain a portion of the rebates. The majority of the EDs are generic manufacturers and typically do not provide aid in the form of rebates, patient assistance or coupons. The average reported total amount of financial assistance provided through patient prescription assistance programs was \$22,612,970.06. This value was inflated due to a subset of larger drug manufacturers providing high monetary values of financial assistance.

The standard deviations for the values in Table 7 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 \$6,381,918.81.

Table 7: Financial Assistance and PBM Rebates Provided to Drug Manufacturers for			
Essential Diabetes and Asthma Drugs			
	Average	Standard Deviation	
Total Amount of Financial Assistance Provided through	\$22,612,970.06	\$43,982,392.84	
Patient Prescription Assistance Programs			
Cost Associated with Consumer Coupons and for	\$31,119,685.48	\$45,579,016.52	
Consumer Copayment Assistance Programs			
Manufacturer Cost Attributable to Redemption of	\$5,055,195.46	\$12,637,498.43	
Consumer Coupons and Use of Consumer Copayment			
Assistance Programs			
Aggregate Amount of All Rebates Manufacturers	\$6,381,918.81	\$10,030,995.75	
Provided to Pharmacy Benefit Managers for Drug Sales			
in Nevada			

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 reported, 155 drug NDCs in the 2019 ED List had a significant price increase during the preceding one and/or two calendar years. Drug manufacturers that produced EDs 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 (22%), changes in marketplace dynamics (22%), manufacturing cost (13%), and regulatory cost (9%). 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 EDs (Nevada DHHS, 2019b).



Figure 8: Justifications for Price Increases of Essential Diabetes and Asthma Drugs

PBMs reported the rebates negotiated with drug manufacturers during the immediately preceding calendar year for prescription drugs included on the ED 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 EDs for Nevadans were greater than \$138 million (Table 8). 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. Based on all the reported rebates negotiated by PBMs with manufacturers, 5.8% were retained by PBMs. 20% of the PBMs did not report any rebate amounts negotiated with a manufacturer, which indicates the PBM may not directly contract their own rebates. Half of the PBMs reported no retention of rebates.

Table 9. Table Devended Dabeder Name Cable DDMs for Example 1 Dabeder and Asthma

Table 8: Total Reported Rebates Negotiated by PBMs for Essential Diabetes and Asthma		
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 EDs	\$138,255,129.13	
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	\$1,664,572.38	
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	\$9,433,693.62	
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	\$119,175,359.07	
Row 5: Total amount of all rebates described in Row 1 that were retained by the PBM	\$7,981,504.06	
*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 EDs by entity type. Because of substantial rebates already provided to Medicaid and other government insured individuals, additional rebates supporting Medicaid recipients composed a small percentage (1.0%) of the total reported rebates negotiated by PBMs (Figure 7). Over 92%

of total reported rebates negotiated by PBMs with manufacturers were for third parties that are not governmental entities (Figure 7).





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 121,631 pharmaceutical representatives' events were reported for compensation and sample distribution to DHHS. These individuals represented 243 individual companies.

Compensation Provided by Pharmaceutical Representatives

DHHS aggregated the reported compensation values from pharmaceutical representative reports (Table 9). Nevada collectively received \$1,026,646.70 in compensation from pharmaceutical

representatives and the average compensation amount was \$14.61, showing that the predominant pharmaceutical representative interactions with health providers, health support staff, and administration involved small value compensation transactions (Table 9).

Compensation values were categorized by two compensation types based on the reported data and the total reported values for each compensation type were aggregated (Table 9). Majority of compensation was meal related and represented 82.5% of total compensation dollars with an average of \$16.68 (Table 9).

Table 9: Reported Total and Average Compensation Values from Pharmaceutical Representatives in United States Dollars by Compensation Type			
Total Compensation Average Compensation			
Compensation Type	Amount	Amount	
Other	\$102,984.90	\$4.84	
Food and/or Beverage	\$923,479.80	\$16.68	
Total	\$1,026,464.70	\$14.61	

Discussion:

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

Nevada Medicaid spent \$120,204,085.15 in 2019 on drugs included on the EDs list (Figure 3). Overall, the total expenditures were lower than the previous year (2018). From 2018 to 2019, the trend of utilization and cost of EDs is relatively flat. The majority of the expenditures for EDs fell within the brand name category. Although several manufacturers have been identified as having had significant price increases in their medications, both asthma and diabetes spend on a per claim basis has decreased over the past year.

Insulins continue to have the highest expenditure of the EDs for diabetes, which is to be expected. Two other diabetes medication classes that are growing and are likely to continue to grow in utilization are the SGLT-2 and GLP-1 medications. This is due to the drug efficacy, safety profile, reduction in cardiovascular events, and current American Diabetes Association guideline recommendations. These medications are generally more expensive but will be replacing less efficacious generically available oral treatment options. Also, of note, many payors are starting to experience an increase in SGLT-2 utilization for indications outside of diabetes as the Food and Drug Administration recently expanded their approved use to include a cardiovascular indication.

Overall there was a decrease in expenditures on a per claims basis for the asthma EDs. Inhaled long acting beta agonist and inhaled glucocorticoid medications had the highest utilization. Recently some of the inhaled medications for asthma have become available in a generic form, offering a significant reduction in cost compared to the brand name equivalents. This provides a more affordable option for patients with asthma and lowers overall costs associated with treatment.

One strategy to reduce costs while providing clinically appropriate medications is to optimize utilization management of preferred drugs and the contractual relationships between the entities discussed previously in order to obtain the lowest possible net cost. As mentioned, based on the findings of this report, the most recent price increases have not impacted Nevada Medicaid spending for asthma or diabetes on a per claim basis. The price increase could have been offset by the contractual relationships (as shown in Figure 1) which likely resulted in minimal impacts on Nevada Medicaid outpatient medications. Medicaid expenditures presented in this report are gross cost minus discounts; rebates have not been factored into the expenditures. Referring to Figures 5 and 6, the drug classes which incurred the highest expenditures for both asthma and diabetes are also the most widely rebated drug classes. Further insight into the various levels of prescription medication supply chain is needed to more accurately understand the net cost of a medication.

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.

Essential Drug Medicaid Expenditures Data

2018 and 2019 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. For a claim to qualify under a certain calendar year must have been filled during that calendar year.

Essential Drug List and Price Increase Analyses

To compile the 2020 DHHS ED 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 and asthma drug NDCs that included varying drug packaging formulations based First Data Bank information for these drug classes. These NDCs were filtered down to include the drugs for which Nevada Medicaid expended funds in 2019.

This ED 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 or asthma. This list attempts to refine the numerous treatments to those approved for the treatment of diabetes or asthma, 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.

Table 1 reported 912 total EDs that were analyzed for a significant price increase where a Wholesale acquisition Cost price was available. NRS 439B.630 specifies that the price increase analysis should identify EDs 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 2018 and 2019 and the maximum active price for 2019 were compared to identify the one-year and two-year price increase percentages. The one-year price increases were compared against the 2019 annual CPI Medical Care Component, while the two-year price increases were compared against twice the combined annual CPI Medical Care Component values of 2018 and 2019. For the 2020 EDs, the one-year percentage increase threshold value was 2.8%, and the two-year threshold value was 9.6%.

Essential Drug Manufacturer Reporting

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. In addition, some reported what is to be assumed at a non-aggregated level. DHHS did its best to account for this reporting variation and attempted to aggregate all reported values based on drug name by manufacturer to standardize the dataset. During the next reporting period a more standardized report will be generate to account for the variability.

DHHS standardized the manufacturer reported values for *Profit* and the *Percentage of Manufacturer's Total Profit Attributable to Essential Drugs*. DHHS defined profit as denoting financial gains earned from a reporting entity.

Price Increase Justification Analysis

Drug manufacturers reported narrative justifications for significant price increases of EDs. Responses were standardized into categories subjective to this author 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. Scoring was completed on a manufacturer level rather than an individual drug level. For each manufacturer that had more than one justification, each additional justification was assigned the same weight in the overall analysis. In future reporting a list of justifications based on previous reports will be created to better categorize the data.

PBM Aggregated Rebates

In contrast to the drug manufacturer data, PBMs submitted aggregated pricing rebates for all EDs and did not report rebates for individual drugs. Several PBMs reports zero for rebates negotiated. In future legislation the PBMs rebate aggregator should be required to report if the PBM does not directly contract rebates with manufactures. 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 121,631 pharmaceutical representative compensation and samples records.

DHHS Invites You to Learn More

DHHS invites you to view the Drug Transparency website at <u>drugtransparency.nv.gov</u>. If you are interested in receiving email notifications for Nevada Drug Transparency information and updates, please subscribe to the LISTSERV online at <u>drugtransparency.nv.gov</u>. Feedback and questions can be directed to the email: <u>drugtransparency@dhhs.nv.gov</u>

Appendix 1: Summary Descriptions of Price Increase Justifications

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

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