Steve Sisolak
Governor

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State of Nevada

Department of Health and Human Services

Drug Pricing Transparency in Nevada

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2017 SB 539
Drug Pricing Transparency for Essential Diabetes Drugs

- Signed into law in June of 2017
- First-in-the-nation pricing transparency law
- Requires the Department of Health and Human Services to create a list of essential diabetes drugs.
- Drug manufacturers, PBMs, drug representatives, and non-profits are required to submit reports with different data requirements.
- The Department of Health and Human Services compiles the data and produces a report annually.

Why Diabetes?

- Between 2002 and 2013, the average price of insulin nearly tripled.
- For more than 7.4 million Americans, insulin is a life-sustaining medication for which there is no substitute.
- In the last decade, the top three insulin manufacturers have increased the price of insulin by 700 percent.

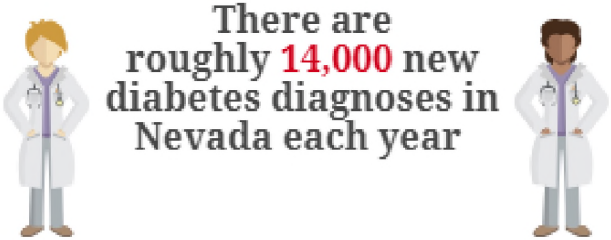
Prevalence and Financial Strain of Diabetes in Nevada



12.6% of the adult population in Nevada have diabetes. 38.5% of the adult population in Nevada have prediabetes



An estimated 1 in 4 Nevadans with diabetes don't know they have it



There are roughly 14,000 new diabetes diagnoses in Nevada each year



Direct and indirect diabetes related medical expenses costs $2.7 billion a year in Nevada



Medical expenses for people with diabetes are 2.3 times higher than individuals without diabetes



The average cost of medical care for people with diabetes in the United States is $16,750 a year, $9,600 of which is attributed to diabetes

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

2017 Senate Bill 539

- Nevada DHHS publishes an Essential Diabetes Drug list each year, on or before February 1st, indicating drugs with a significant price increase. The list must include the Wholesale Acquisition Cost (WAC) and all forms of insulin and biguanides marketed for sale in Nevada.
- **Essential Diabetes Drug manufacturers** submit a report on or before **April 1st** to DHHS with drug production costs, profits, financial aid, price increase justifications, and other drug-specific information.
- **Pharmacy benefit managers (PBM),** on or before **April 1st**, report rebates negotiated for Essential Diabetes Drugs.
- DHHS maintains a **pharmaceutical representative** registry and reports yearly on the compensation and samples distributed in Nevada. The report is done in aggregate and posted on or before **June 1st** of each year.
- Any **non-profit organization** that advocates on behalf of patients or funds medical research in Nevada and has received compensation or anything of value from a manufacturer, third party, or PBM, shall report on or before **February 1st** of each year, on those contributions.

2017 Senate Bill 539

- Nevada DHHS publishes an annual report by June 1st of each year, based on data received published online at http://drugtransparency.nv.gov.
- Nevada DHHS has published five reports based on drug manufacturer, PBM, and pharmaceutical representative data.
- Entities can be fined up to $5,000 each day for noncompliance.

Developing the Essential Diabetes Drug List for 2018 Report

- SB 539 required the Department of Health and Human Services (DHHS) pursuant to section 3.6 of the bill and Nevada Revised Statute (NRS) 439B.630 to compile a list of certain prescription drugs essential for treating diabetes. This was published on **October 31, 2017**. Below describes the process for creation of the list:

  - An initial list of frequently prescribed drugs used for the treatment of diabetes was created by pharmacists employed by the Department.
  - The list was then sent to prescribers in the state as a survey to solicit public comment and determine if any drugs needed to be removed/added. DHHS received over 300 responses.
  - That list was compared to the Medicaid pharmacy data reported to the Centers for Medicare and Medicaid Services (CMS) and information from the Public Employees Benefit Program on prescribed drugs. This prescriber data accounted for approximately 700,000 Nevadans insured under these public plans and was used to whittle down the list to just those drugs prescribed in Nevada.
  - The remaining drugs were checked against the Food and Drug Administration (FDA) database to ensure that only drugs approved by the FDA for the treatment of diabetes were included on the list. No drugs were included if their treatment of diabetes was considered an “off-label” use.

- Additionally, the Department was required to identify and report on drugs that had a significant increase in price. This report was published on **September 11, 2018**.

What Constitutes a "Significant Price Increase"?

- Price Increase in the Wholesale Acquisition Cost
  - Greater than or equal to the Consumer Price Index, Medical Care Component during the immediately preceding calendar year; or
  - Twice the percentage increase in the Consumer Price Index, Medical Care Component during the immediately preceding two calendar years.

Reports to Date

- **6-1-2018** Compensation and Samples Distributed by Pharmaceutical Sales Representative in Nevada
- **9-11-2018** Essential diabetes Drugs Price Increase Report (first list of essential drugs)
- **9-30-2018** Analysis of Essential Diabetes Drugs that had a Price Increase (first report/analysis of data collected)
- **3-8-2019** Supplemental Report – 2017 Essential Diabetes Drugs: DHHS received drug manufacturer and PBM reports specific to the 2017 Essential Diabetes Drugs and prepared the report as a supplement to the reports published in 2018.
- **5-31-2019** DHHS 2019 Drug Transparency Report

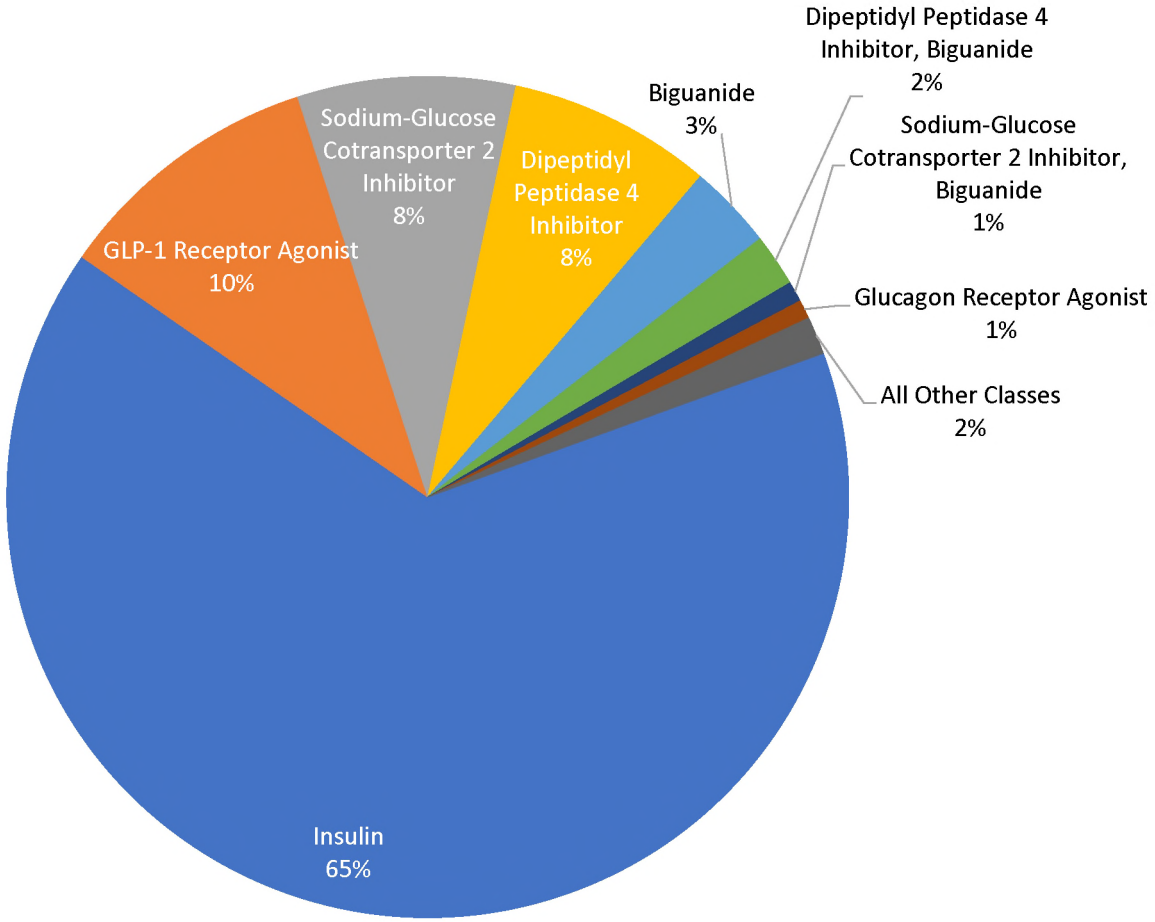
2019
Drug Transparency Report

2019 Essential Diabetes Drug List and Significant Price Increases

- DHHS created an Essential Diabetes Drug (EDD) List with 52 distinct nonproprietary drugs with 695 NDCs.
- 22.4% experienced a significant price increase.
- 60% of EDDs that experienced a significant price increase had a qualifying increase during both the previous one- and two-year periods.

Table 3: Average one- and two-year price increase for essential diabetes drugs that experienced a significant price increase	
Average one-year EDD Price Increase	6.4%
Average two-year EDD Price Increase	21.7%

Percentage by Class of Essential Diabetes Drugs of 2017 Medicaid Expenditures



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.

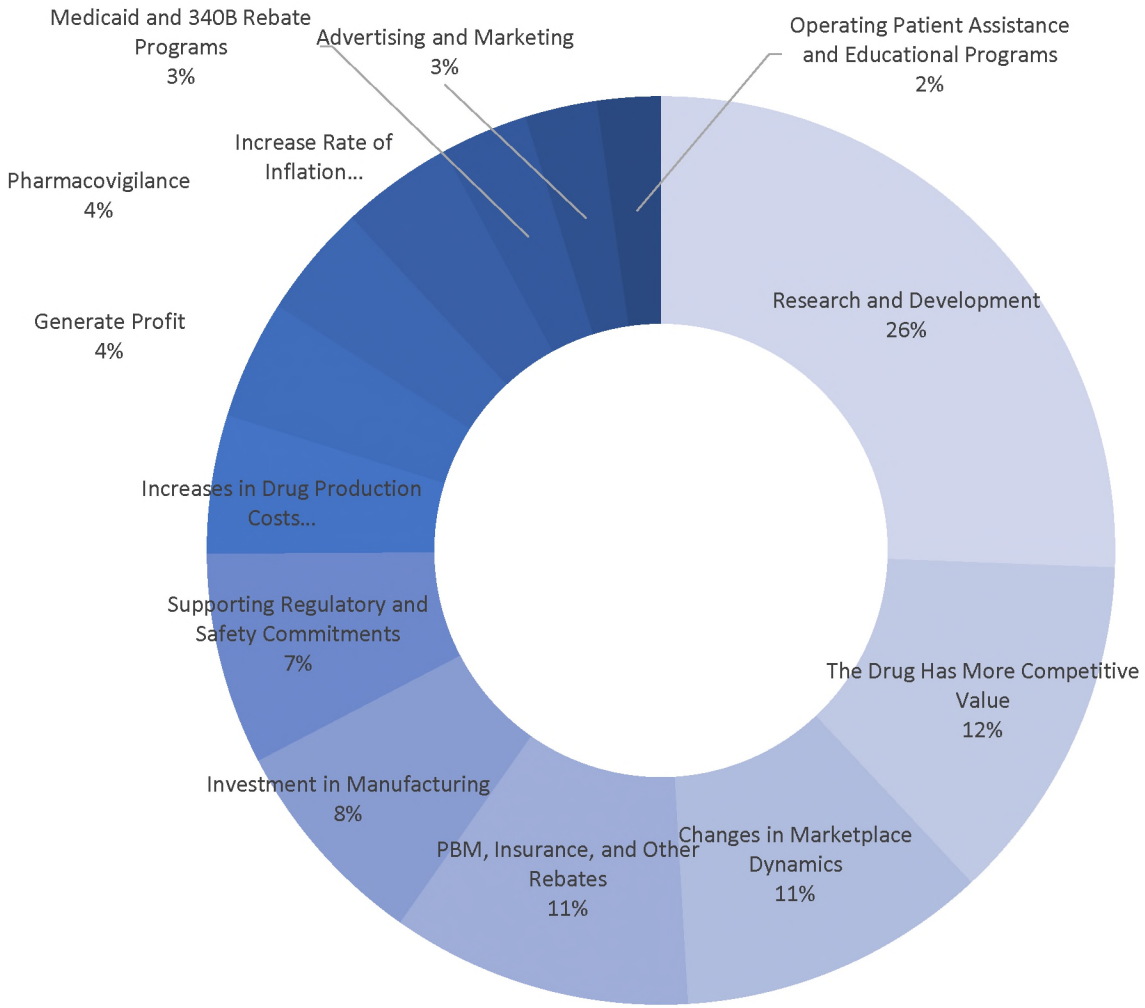
†Multiple drug manufacturers reported $0 for Total Administrative Expenditures, and likely included all their costs for manufacturing the drug in the Total Cost of Producing the Drug.

‡Values were calculated using the following formula: Profit/(Drug Production Cost + Total Administrative Expenditures). Ratios were then averaged.

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-Reported Justifications for Price Increases of Essential Diabetes Drugs

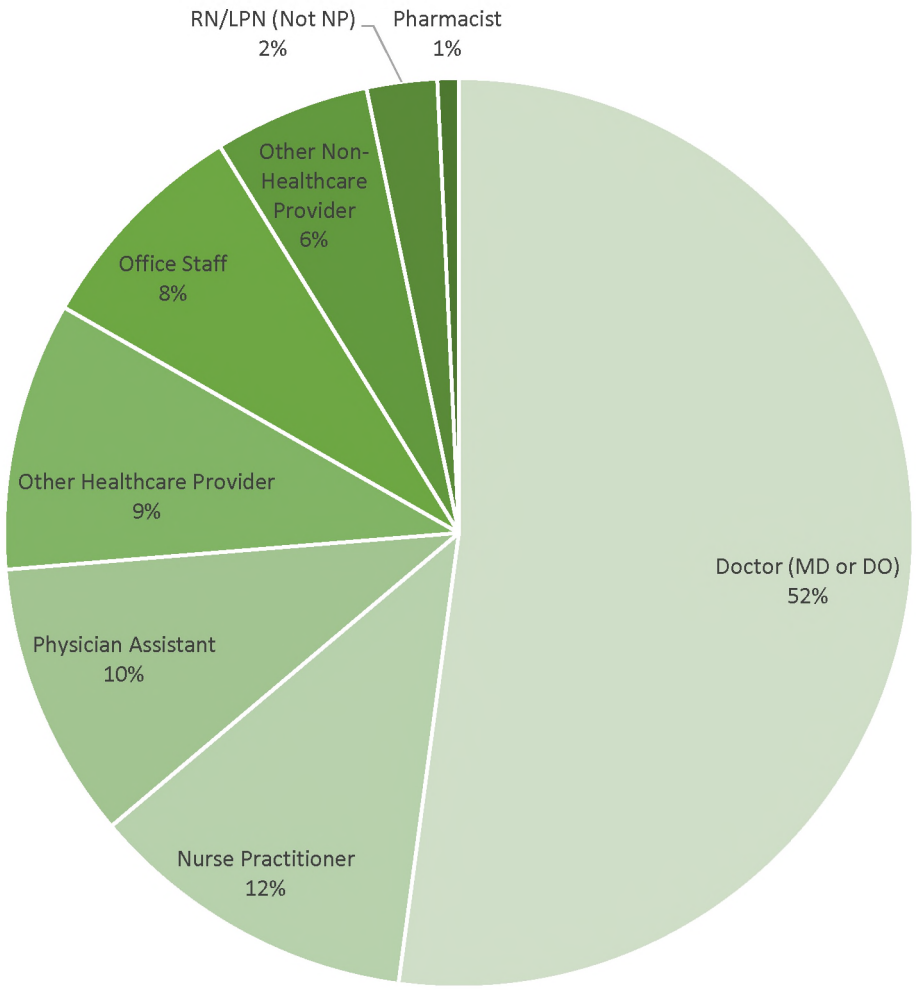


Total Reported Rebates Negotiated by PBMs for Essential Diabetes Drugs in Nevada

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 prescription drugs included on the list compiled by DHHS pursuant to subsection 1 of section 3.6 of Senate Bill 539	$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.

Percent Professional Designation Group Receiving Sample or Compensation Distribution Event by a Pharmaceutical Representative

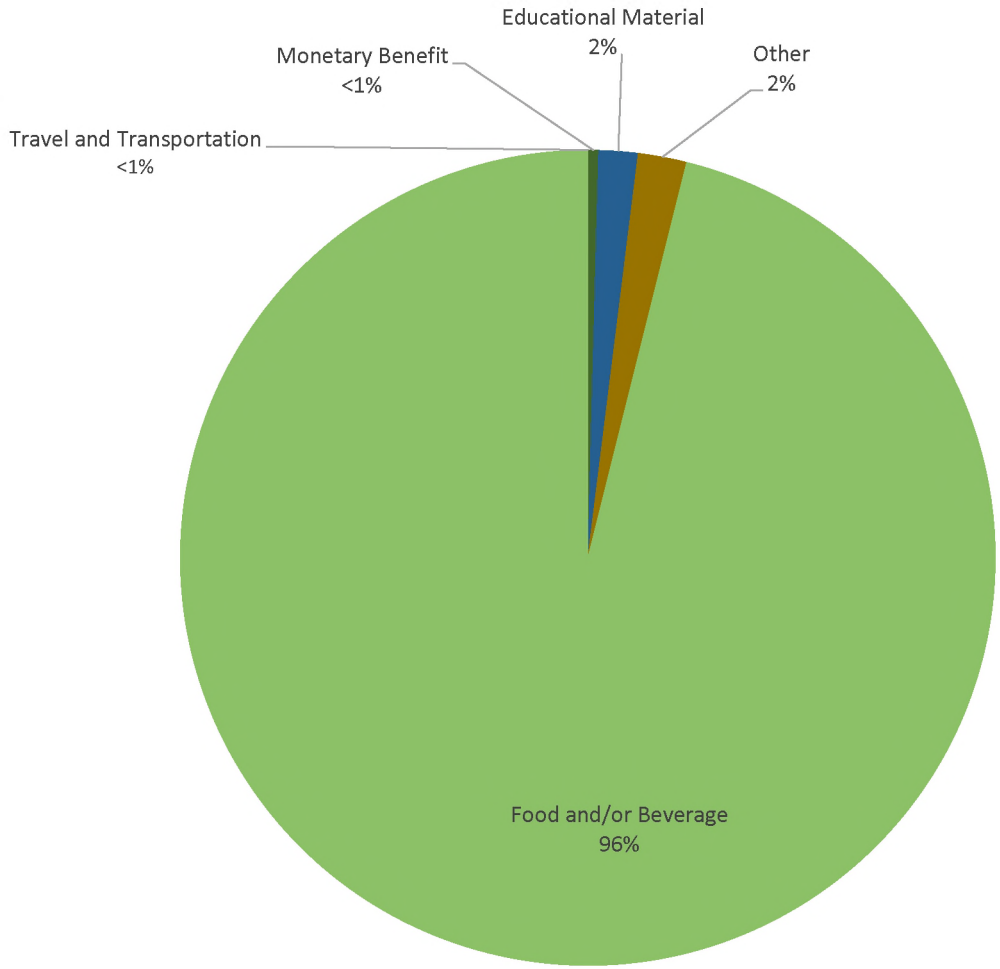


Average and Total Compensation from Pharmaceutical Representative by Recipient Type

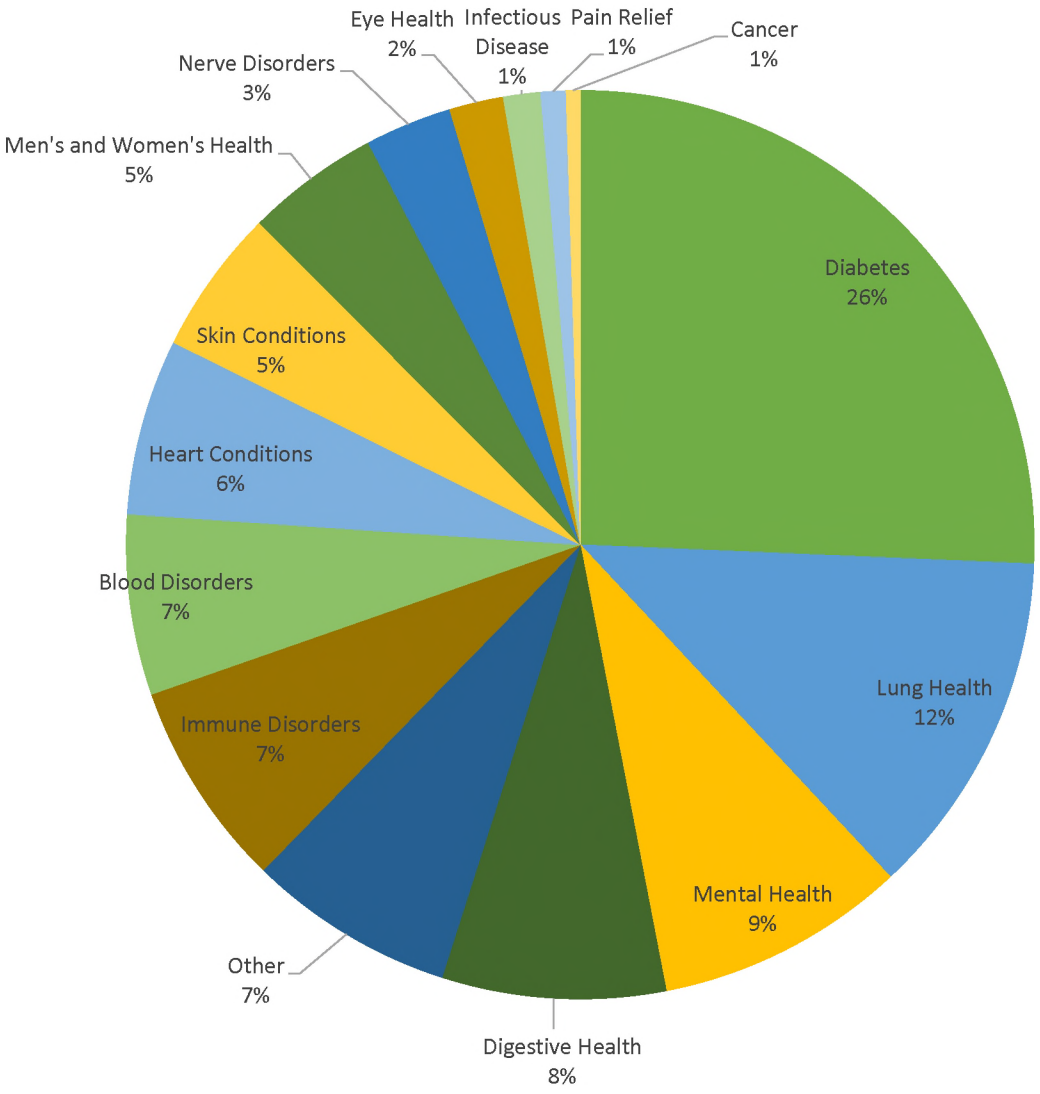
Recipient Type*	Total Compensation Amount	Average Compensation Amount
Pharmacist	$71,079.08	$32.02
Physician Assistant	$149,806.82	$17.83
Registered Nurse (RN)/Licensed Practical Nurse (LPN) (NOT Nurse Practitioner)	$179,800.96	$25.37
Nurse Practitioner (NP)	$245,353.77	$21.52
Other Non-Healthcare Provider	$299,815.95	$18.51
Office Staff	$421,209.94	$18.21
Other Healthcare Provider	$473,850.02	$17.34
Doctor (Doctor of Medicine (MD) or Doctor of Osteopathic Medicine (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:
•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 Events Categorized by Compensation Type



Percentage Sample Distribution Events by Targeted Health Condition as Reported by Sales Representative



Challenges and Road Blocks

- The major challenge to the law was the lawsuit outlined in these two articles:
  - https://thenevadaindependent.com/article/in-lawsuit-big-pharma-argues-nevada-law-creates-effective-cap-on-insulin-prices
  - https://thenevadaindependent.com/article/big-pharma-abandons-lawsuit-over-nevadas-insulin-pricing-transparency-law-after-state-approves-trade-secret-protection-regulations
- In 2017, two drug lobbying groups, the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Innovation Organization (BIO), filed a lawsuit.
- The two groups alleged that SB 539 violated federal patent and trade secret rules.
- According to the lawsuit, the bill removed economic incentives protected under patent law for pharmaceutical companies and it eliminated competition within the industry by removing protection of trade secrets.

SB 539 Regulations and the Defend Trade Secrets Act

- In June of 2018, the United States District Court for the District of Nevada dismissed without prejudice the litigation brought by PhRMA and the Biotechnology Innovation Organization (BIO).
- All parties agreed to voluntary dismissal after regulatory changes became effective (NAC 439.735) that included procedures to safeguard manufacturers' and PBMs' sensitive business information.
- Specific guidance related to the Defend Trade Secrets Act (DTSA) of 2016 were included.
- If a manufacturer or PBM believes that a data element included in their required reporting meets the standard of the Defend Trade Secrets Act (DTSA), a request to have the element declared confidential may be submitted.
- DHHS will notify the manufacturer or PBM if a public request for the data elements marked as confidential are requested and provide a copy of the written request.
- The manufacturer or PBM has 30 days to take legal action under the DTSA prior to releasing the information.

SB 539 Regulations and the Defend Trade Secrets Act

"The regulations are essential to protecting the proprietary information that forms the foundation of the competitive environment in which we operate and determines our ability to innovate and get patients the treatments they need," said James C. Stansel, PhRMA Executive Vice President and General Counsel. "Without these regulations and the Joint Status Report, Nevada's law would have conflicted with the federal patent laws as well as laws protecting trade secrets."

Challenges, Road Blocks and Lessons Learned

- Developing a methodology to obtain the required WAC data and analyze it to identify the price increases. We have had to develop automation tools to simplify the analysis.
- Developing a methodology to create the Essential List so that it could include general information about the drugs, while providing the NDC data for the reporting entities.
- Creating a system to collect, process, and report on the data. We received diverse data before we standardized data reporting.
- Developing a publication that is accessible to the public and policy makers. We want to improve the report so that people can more easily understand the data.
- A general challenge in the data is that it is self-reported and we do not audit the reporting entities.
- Dealing with public information requests so that we properly protect the data and support the public's right to know. The regulation (NAC 439.735) assists with that.

Manufacturer Compliance with SB539

Manufacturer	Penalty Letter Sent	Report Received	Report Complete	Informal Dispute Meeting Requested
Accord Healthcare	Yes	9/5/2019	Yes	Yes
Alkem Laboratories	Yes		No	No
Amneal Pharmaceuticals	Yes	8/28/2019	Yes	Yes
Apotex Corp	Yes	10/8/2019	Yes	Yes
Carlsbad Tech	Yes		No	Yes
Citron Pharma	Yes	9/4/2019	Yes	Yes
Daiichi Sankyo	Yes	8/26/2019	Yes	Yes
Epic Pharma LLC	Yes	10/18/2019	Yes	Yes
Glenmark Pharma	Yes	8/30/2019	Yes	Yes
Granules India	Yes	10/27/2019	Yes	Yes
Ingenus Pharmaceuticals	Yes	2/27/2019	Yes	Yes
Intas Pharmaceuticals	Yes		No	No
Inventia Healthcare	Yes	10/30/2019	Yes	No
Macleods Pharma	Yes	10/7/2019	Yes	Yes
Method Pharmaceuticals	Yes		No	No
Microlabs USA	Yes	9/18/2019	Yes	Yes
Nostrum Laboratories	Yes	10/10/2019	Yes	Yes
Par Pharmaceuticals	Yes	9/14/2019	Yes	Yes
Pharmadax Inc.	Yes	10/7/2019	Yes	Yes
Rising Pharmaceuticals	Yes	9/4/2019	Yes	Yes
Solco Healthcare	Yes	9/13/2019	Yes	No
Strides Pharma	Yes	10/14/2019	Yes	Yes
Time-Cap Labs	Yes	11/18/2019	Yes	Yes
Torrent Pharmaceuticals	Yes	9/10/2019	Yes	Yes
Virtus Pharmaceuticals	Yes	8/28/2019	Yes	Yes

Recent Updates

2019 Legislative Session

Senate Bill 262: The Department of Health and Human Services must also establish and report on Essential Asthma Prescription Medications

"The hundreds of thousands of Nevadans living with asthma deserve to know that the price they're paying for their medication they need to breathe is fair, and this bill will help shed some light on factors affecting these drug prices."

Governor Sisolak

NGA Pharmaceuticals Learning Collaborative: Targeted Technical Assistance on Strategy Development and Implementation

- Nevada applied to participate in the NGA Pharmaceuticals Learning Collaborative Project and was notified in July of 2019 that it was selected.
- The collaborative has assisted in the creation of a statewide workgroup to discuss and plan how to reduce pharmaceutical cost across state entities.
- The effort brings together DHHS, the Nevada Public Employees Benefit Program, Department of Corrections, the Nevada Silver State Scripts Board, and other collaborative partners.
- The kick off call took place in August 2019 with an in person meeting in October 2019.
- Monthly check-in calls will occur through June 2020.

NGA Pharmaceuticals Learning Collaborative: Targeted Technical Assistance on Strategy Development and Implementation

The primary goals for the project include:

1. Develop needed relationships, assess existing contracts, and develop a plan to establish a group purchasing agreement among Medicaid, Department of Corrections, and the Public Employees Benefit Program.
2. Engage the Silver State Scripts Board and assist with strategic planning under expanded authority.
3. Obtain and review existing DHHS pharmacy benefit contracts.
4. Review existing transparency reports and make recommendations to DHHS to make its reports more accessible and effective for the public and policy makers.
5. Collaborate with the Patient Protection Commission.

What's Next?

- States are continuing to take action on prescription drug prices. Rising drug costs continue to put financial strains on states and consumers.
- Insulin prices have increased dramatically in the past decade.
- Specialty drugs enter the market with unsustainably high launch prices
  - **Zolgensma**, a gene therapy drug that treats spinal muscular atrophy, launched at $2.1 million for a one-time treatment
  - **Luxturna**, which can cure rare blindness, costs $850,000 for a one-time treatment

Every state since 2017 has introduced legislation to address rising prescription drug prices.

Prescription Drug Transparency Legislation

- Eight states have passed transparency laws.
  - CA, CT, ME, NV, OR, TX, VT, and WA
- CA, ME, NV, OR, and VT have collected data and developed public lists of drugs that account for high total cost or high growth.
  - 17 drugs were reported in common across at least three states.
  - The most commonly reported high-cost drugs across states were diabetes medications.

Highest Total Cost or Highest Cost-Growth Drugs Reported by at Least Three States

Drug Class	Drug Name
Diabetes	Humalog, Januvia, Lantus Solar, Novolog, Metformin HCL, Metformin HCL ER, Victoza
Asthma	Symbicort
Hepatitis C	Harvoni, Epclusa
Multiple Sclerosis	Copaxone, Tecfidera
Cardiovascular	Xarelto
Human immunodeficiency virus (HIV)	Descovy
Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis	Stelara, Cosentyx, Enbrel, Humira Syringe, Humira Pen

Prescription Drug Transparency Legislation

- Reporting needs to be required from across the supply chain.
  - Manufacturers
  - Pharmacy Benefit Managers
  - Wholesalers
  - Health Plans
- We need to get to a common data set to align reporting across states and minimize the reporting burden.

Questions?

Contact Information

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Acronyms

- CMS – Center for Medicare and Medicaid Services
- DHHS – Department of Health and Human Services
- DO - Doctor of Osteopathic Medicine
- DTSA – Defend Trade Secrets Act
- HIV - Human Immunodeficiency Virus
- LPN – Licensed Practical Nurse
- MD – Doctor of Medicine
- NGA – National Governors Association
- NDC – National Drug Code
- NRS – Nevada Revised Statute
- NP – Nurse Practitioner
- PBM – Pharmacy Benefit Manager
- PhRMA – Pharmaceutical Research and Manufacturers of America
- RN – Registered Nurse
- WAC – Wholesale Acquisition Cost