Revised: February 21, 2018

Pharmaceutical Representatives:

- Reporting for Pharmaceutical Representatives, is it the individual's responsibility or the manufacturer's?
  - Both, please see below for specific requirements.

    - Manufacturers are required to submit a list of names of all pharmaceutical representatives who market prescription drugs in Nevada.

      - Section 4.6(1) of the law states "A **manufacturer** of a prescription drug shall provide to the Department a list of each pharmaceutical sales representative who markets prescription drugs on behalf of the manufacturer to providers of health care licensed, certified or registered in this State, pharmacies or employees thereof, operators or employees of medical facilities or persons licensed or certified under the provisions of title 57 of NRS and update the list at least annually."

    - Each pharmaceutical representative is required to submit a report of all compensation or prescription drug that was provided to a provider of health care licensed, certified or registered in this State, pharmacies and employees thereof, operators and employees of medical facilities and persons licensed or certified under the provisions of title 57 of NRS.

      - Section 4.6(4) of the law states "On or before March 1 of each year, **each person** who was included on a list of pharmaceutical sales representatives submitted pursuant to subsection 1 at any time during the immediately preceding calendar year shall submit to the Department a report, which must include, for the immediately preceding calendar year: (a) A list of providers of health care licensed, certified or registered in this State, pharmacies and employees thereof, operators and employees of medical facilities and persons licensed or certified under the provisions of title 57 of NRS to whom the pharmaceutical sales representative provided: (1) Any type of compensation with a value that exceeds $10; or (2) Total compensation with a value that exceeds $100 in aggregate; and (b) The name and manufacturer of each prescription drug for which the pharmaceutical sales representative provided a free sample to a provider of health care licensed, certified or registered in this State, pharmacy or employee thereof, operator or employee of a medical facility or person licensed or certified under the provisions of title 57 of NRS and the name of each such person to whom a free sample was provided."
        - While the law requires the individual to submit the yearly report, manufacturers may submit these yearly reports on behalf of pharmaceutical representatives in their employment.
        - Report formatting and specifics may be found at the end of this document.

- Does this law apply to any/all pharmaceutical representatives and not just those engaging in the sales and marketing of diabetes-related treatments?
  - Yes, this law applies to all pharmaceutical representatives.

- When we provide the list of the company's pharmaceutical sales representatives working in Nevada, is there a format that should be used?
    - An excel file is preferable listing the first name, last name and company that the individual represents. An example is provided below. This information can be e-mailed to drugtransparency@dhhs.nv.gov and should be updated as changes occur within your organization.

Company	Pharmaceutical Representative First Name	Pharmaceutical Representative Last Name

- When are the first reports due?
    - 2017 will be the first reporting period. The reportable period for this first report will be October 1, 2017-December 31, 2017. For all future reporting, the period will be based on the calendar year.

- What format should the reports be in?
    - At this time the Department is not requiring a specific format, however Excel is preferred.
        - The State of Nevada will accept the federal report to fulfill this requirement.

- Are veterinary pharmaceutical representatives required to register in the State of Nevada or provide a yearly report?
    - Only pharmaceutical representatives for human medications are required to register or report under SB 539.

- Are medical device representatives required to register with the State of Nevada and to submit the yearly report?
    - At this time, no medical device representative information is required to be submitted.

Prescriptions Drug Manufacturers:

- Sections 3.8 and 4 of the law require some drug manufacturers to submit certain reports on diabetes drug price increases to DHHS by April 1, 2018. When do you anticipate that DHHS will issue the format and other requirements for these reports?
    - Regulations have been drafted and are available for review on the website http://dhhs.nv.gov/HCPWD/Drug_Transparency/
    - Report formatting and specifics may be found at the end of this document.

- Section 26.9 of SB 539 makes the manufacturers' initial report due on July 1. Under Section 3.8 it states that the report is due on April 1. On which date is the initial report due?
    - The initial report for the Essential Diabetes Drugs posted for 2017 is July 1, 2018. In subsequent years, April 1st will be the due date beginning in 2019.

- Will Nevada implement the preemption clause for the reporting requirements in respect to Title 11 of the Social Security Act?
    - Based on the advice of the Department's Deputy Attorney General, the federal preemption clause will be implemented.
    - For detail on this preemption, you can read more here: https://www.ssa.gov/OP_Home/ssact/title11/1128G.htm

Pharmacy Benefit Managers:

- Report formatting and specifics may be found at the end of this document.

Consumers:

- Will this new law limit my access to drugs?
    - Senate Bill 539 does not in any way limit your access to medication. The law is intended to assist DHHS with research and analysis related to increasing costs for various medications required to treat diabetes.

Revised: February 28, 2018

Prescription Drug Manufacturers

Drug manufacturers must submit a report to the Nevada Department of Health and Human Services (DHHS) containing information described in the table below for Essential Diabetes Drugs posted on the DHHS website. Reports must be submitted to drugtransparency@dhhs.nv.gov annually by April 1st for the previous calendar year. DHHS will compile a report, submit and post it in accordance with NRS 439.

Reporting Information	Text or Number
Cost of producing the drug	Number
Total administrative expenditures relating to the drug, including marketing and advertising costs	Number
Profit earned from the drug	Number
Percentage of total profit for the previous calendar year that is attributable to each drug on the list published by the department	Number
Total amount of financial assistance provided through patient prescription assistance programs	Number
Cost associated with coupons provided directly to consumers and for programs to assist consumers in paying copayments, and the cost to the manufacturer attributable to the redemption of those coupons and the use of those programs	Number
Wholesale acquisition cost of the drug	Number
History of any increases in the wholesale acquisition cost of the drug over the five years immediately preceding the date on which the report is submitted, including: • the amount of each such increase expressed as a percentage of the total wholesale acquisition cost of the drug, • the month and year in which each increase became effective. • and any explanation for the increase.	Text Number Date Text
Aggregate amount of all rebates provided to pharmacy benefit managers for sales of the drug within Nevada.	Number
Reasons why the wholesale acquisition cost of the drug increased, if it did in the last year. For each drug, list factors contributing to the increase, and: • Percentage of total increase attributable to each factor, and • Explanation of role each factor played in the increase.	Text

Pharmacy Benefit Managers

Pharmacy benefit managers (PBM) must submit a report to the Nevada DHHS containing information described in the table below for prescription drugs posted to the department website. Reports must be submitted to drugtransparency@dhhs.nv.gov annually by April 1st for the previous calendar year. DHHS will compile a report, submit and post it in accordance with NRS 439.

Reporting Information	Text or Number
Total amount of rebates negotiated with manufacturers	Number
Total amount of all rebates described above that were retained by the PBM	Number
Total amount of all rebates negotiated for purchase of such drugs for use by: 1. Recipients of Medicare; 2. Recipients of Medicaid; 3. Persons covered by 3rd parties which are governmental agencies 4. Persons covered by 3rd parties which are NOT governmental agencies; and 5. Plans subject to the Employee Retirement Income Security Act (ERISA) that require compliance with the state reporting requirement.	Numbers and Text

Pharmaceutical Sales Representatives

Pharmaceutical sales representatives on a list submitted to DHHS by drug manufacturers during anytime in the previous calendar year must report to DHHS by March 1st for the previous calendar year, and must include items in the table below. DHHS will compile a report, submit to drugtransparency@dhhs.nv.gov and post it in accordance with NRS 439.

Reporting Information	Text or Number
List of health care providers or facilities to whom: 1. Any type of Compensation with a value that exceeds $10; or 2. Total compensation exceeding $100 in aggregate.	Text
The name and manufacturer of each prescription drug for which the pharmaceutical sales representative provided a free sample to a provider of health care licensed, certified or registered in this State, pharmacy or employee thereof, operator or employee of a medical facility or person licensed or certified under the provisions of title 57 of	Text

NRS and the name of each such person to whom a free sample was provided.	