NV Department of Health and Human Services
Drug Transparency Reporting Instructions

Diabetes Drug Manufacturer Reporting Instructions
Version (v): 07/13/2018; **Supersedes:** n/a
SB539 – Sec 3.8

Reporting Date:	On or before April 1; Exception July 1, 2018
Reporting Frequency:	Annually on or before April 1
Form Template Name:	"Diabetes Drug Manufacturer & 5YR WAC Additional Reporting_template vmm.dd.yy"
Worksheet Tabs:	First Tab: "Manufacturer Pg1 vmm.dd.yy" Second Tab: "Manufacturer Pg2 vmm.dd.yy" Third Tab (additional reporting template): "5Yr WAC Increase Temp vmm.dd.yy"

Purpose: SB539 created the requirement for manufacturers of a prescription drug that appears on the most current list compiled by the Nevada Department of Health and Human Services to report the costs of producing the drug; the total administrative expenditures; total amount of financial assistance provided through patient assistance; cost associated with coupons; the wholesale acquisition cost; history of any increase over the 5 years including percentage increase, date of increase, and explanation; aggregate amount of all rebates provided to Pharmacy Benefit Managers (PBMs); and any additional information as prescribed.

Reporting Requirements Detailed in Senate Bill 539, Sec. 3.8, found at the following link:
https://www.leg.state.nv.us/App/NELIS/REL/79th2017/Bill/5822/Text

Instructions:

1. The department's excel templates provide manufacturers with a standardized form to use for reporting that incorporates all the fields required by law in a classic format (Manufacturer Pg1_vmm.dd.yy & Manufacturer Pg2_vmm.dd.yy). Manufacturers may use alternate reporting formats if all the information required by law is supplied and clearly identified.
2. If using the department-provided template, all fields listed in the template document are required fields, unless otherwise noted. Please note that there are two tabs within the worksheet template that need to be completed if applicable (worksheet tab names: "Manufacturer Pg1_vmm.dd.yy" and "Manufacturer Pg2_vmm.dd.yy").
3. If using the department-provided template, please do not rearrange or change the departmental template headers in any way.
4. All values should be reported at the National level unless otherwise noted.
5. Unless otherwise indicated, all values should be specific to the calendar year immediately preceding the year of report submission.
6. For technical assistance, send your questions to: drugtransparency@dhhs.nv.gov

Selected Detailed Field Descriptions:

- **"Proprietary Prescription Drug Name":**
  The proprietary prescription drug name should be entered unless the drug does not have a proprietary drug name. If there is no proprietary name, the nonproprietary drug name should be repeated for this value.

- **"Total Cost of Producing the Drug":**
  A few examples of applicable expenditures include direct materials, production labor, and direct expenses. A drug manufacturer should include additional expenses as deemed necessary. Data should be aggregated so that one value is presented for each drug name listed in the most current list compiled by the Department pursuant to Senate Bill 539, Sec 3.6, subsection 1. This value does not need to be repeated for every separate NDC code of each drug (see example report tab).

- **"Total Administrative Expenditures Related to the Drug":**
  A few examples of administrative expenditures include executive compensation, accounting and legal fees, marketing, and advertising. A drug manufacturer should include additional expenses as deemed necessary. Data should be aggregated so that one value is presented for each drug name listed in the most current list compiled by the Department pursuant to Senate Bill 539, Sec 3.6, subsection 1. This value does not need to be repeated for every separate NDC of each drug (see example report tab).

- **"Percentage of Manufacturer's Total Profit Attributed to Drug During Marketing Period for Drug":**
  The percentage of the manufacturer's total profit for the period during which the manufacturer has marketed the drug for sale during the prior calendar year that is attributable to the drug should be reported here. Data should be aggregated so that one value is presented for drug name listed in the most current list compiled by the Department pursuant to Senate Bill 539, Sec 3.6, subsection 1. This value does not need to be repeated for every separate NDC of each drug (see example report tab).

WHOLESALE ACQUISITION COST DATA:

- **Special Note for Wholesale Acquisition Cost Data:**
  The wholesale acquisition cost (WAC) can vary between different dosage forms of a single prescription drug from the most current list compiled by the Department pursuant to Senate Bill 539, Sec 3.6, subsection 1. The wholesale acquisition cost data must be specific to each unique NDC code. Thus, one drug could have multiple rows of wholesale acquisition cost data to account for each separate NDC code (see example report tab).

- **"Complete NDC Code (format XXXX-XXXX-XX)":**

Provide the complete NDC code with hyphens (-) separating the labeler, product, and packaging codes. Example: 0123-1234-01. Include any leading zeros.

- **"Current Wholesale Acquisition Cost Unit Price of the Drug":**
  The wholesale acquisition cost of the drug should represent the most recent value available to the drug manufacturer for each individual NDC code for each reported drug.

- **"Wholesale Acquisition Cost Unit Price Five Years Immediately Preceding Date of Report Submission":**
  The wholesale acquisition cost should be the value for the date five years preceding the date of the "Current Wholesale Acquisition Cost Unit Price of the Drug".

- **"Increase in Wholesale Acquisition Cost (WAC) Unit Price in Previous Five Years in Dollars":**
  This value should only include the increase in WAC unit price from the previous value, and should not be the total WAC unit price. For example, if a drug increased from $20.00 to $25.00 per unit, the reported value in this section would be $5.00. Increases in drug price should be reported sequentially from the earliest increase during the five-year reporting period to the most recent price increase. The "Manufacturer Pg1_vmm.dd.yy" and "Manufacturer Pg2_vmmdd.yy" worksheet tabs may be utilized for reporting when there have been five or less price increases in the previous five years. *If there have been more than five increases, the "5YR WAC Increase Temp vmm.dd.yy" worksheet tab may be utilized to document all corresponding increases for each individual drug. Duplicate the "5Yr WAC Additional Reporting_template vmm.dd.yy" on another tab within the same worksheet for each drug that has had more than five prices increases in the previous five years and label each tab with the drug name.*

- **"Explanation for Increase":**
  This section should be used to provide a detailed explanation for the price increase for each drug.