Essential Drug Manufacturer Reporting Instructions
Version (v): 11/30/2021; **Supersedes:** 01/09/2019
NRS 439B.635

Reporting Date:	On or before April 1
Reporting Frequency:	Annually
Form Template Name:	"Essential Drug Manufacturer Reporting_template vmm.dd.yy"
Worksheet Tabs:	First Tab: "Manufacturer Pg1" Second Tab: "Manufacturer Pg2" Third Tab (additional reporting template): "5Yr WAC Increase Temp"

Purpose: NRS 439B.635 requires that manufacturers submit a report regarding the prescription drugs that appear on the most current list compiled by the Nevada Department of Health and Human Services (DHHS) pursuant to NRS 439B.630.

Reporting Requirements Detailed in NRS 439B.635 can be found at the following link:
https://www.leg.state.nv.us/NRS/NRS-439B.html#NRS439BSec635

Instructions:

1. DHHS's excel templates provide manufacturers with a standardized form to use for reporting that incorporates all the fields required by law.
2. 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 must be completed (worksheet tab names: "Manufacturer Pg1" and "Manufacturer Pg2").
3. Do not rearrange or change the 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. If a company produces essential diabetes and asthma drugs, both drug categories should be included in a single report.
7. For reports or technical assistance, send your questions or submissions 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":**
  This value should be in United States Dollars. The total cost should not be for an individual packaged unit, but the total national drug production costs. For example, it might cost $10 to produce one packaged unit, but to produce all units sold in one year is $1,000,000. The drug company should report the $1,000,000 value in this example. A few examples of applicable expenditures include, required infrastructure and equipment, direct materials, production labor, consumable manufacturing supplies, and direct expenses. A drug manufacturer should include additional expenses as deemed necessary. Production costs should be less rebates and applicable discounts. Data should be aggregated so that one value is presented for each drug name listed in the most current list compiled by DHHS pursuant to NRS 439B.630. This value does not need to be repeated for every separate National Drug Code (NDC) of each drug.

- **"Total Administrative Expenditures Related to the Drug":**
- This value should be in United States Dollars. The total expenditures should not be for an individual packaged unit, but the total drug administrative expenditures as explained above. A few examples of administrative expenditures include the costs of paying wages and salaries and providing benefits, accounting and legal fees, information technology, marketing, and advertising. Administrative expenses are categorized as indirect expenses on a company's income statement because they do not contribute directly to the making of a product. Research and development costs should be excluded. 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 DHHS pursuant to NRS 439B.630. This value does not need to be repeated for every separate NDC of each drug.

- **"Profit Manufacturer Earned from the Drug":**

This value should be in United States Dollars. This value should represent the excess of the transfer value of goods manufactured over their actual production cost. The value should represent the savings the company makes by manufacturing the goods. Essentially, this number should represent the money made from a drug after the cost of producing it, but before company-wide costs such as marketing, taxes or executive bonuses.

- **"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. Expressed as a percentage, profit margin indicates how many cents of profit has been generated for each dollar of sale. Data should be aggregated so that one value is presented for drug name listed in the most current list compiled by DHHS pursuant to NRS 439B.630. This value does not need to be repeated for every separate NDC of each drug (see example report tab).

- **"Total Amount of Financial Assistance Provided through Patient Prescription Assistance Programs":**

1. This value should be in United States Dollars. The aggregate rebates are defined as all discounts and/or price concessions that affects the price of a prescription drug which is provided by the manufacturer of the drug to a pharmacy benefit manager (excluding bona fide service fees as defined in 42 C.F.R §447.502).

- **"Cost Associated with Consumer Coupons and for Consumer Copayment Assistance Programs":**
  This value should be in United States Dollars.

- **"Manufacturer Cost Attributable to Redemption of Consumer Coupons and Use of Consumer Copayment Assistance Program":**
  This value should be in United States Dollars.

- **"Aggregate Amount of All Rebates Manufacturer Provided to Pharmacy Benefit Managers for Drug Sales in Nevada in Dollars":**
  This value should be in United States Dollars.

WHOLESALE ACQUISITION COST (WAC) DATA:

Special Note for WAC Data:
The WAC can vary between different dosage forms of a single prescription drug from the most current list compiled by DHHS pursuant to NRS 439B.630. The WAC data must be specific to each unique NDC. Thus, one drug could have multiple rows of WAC data to account for each separate NDC.

- **"Complete NDC (format XXXXX-XXXX-XX)":**
  Provide the complete 11-digit NDC with hyphens (-) separating the labeler, product, and packaging codes. Example: 01234-1234-01.

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

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

- **"Percentage Increase in Wholesale Acquisition Cost (WAC) Unit Price in Previous Five Years":**
  Percentage 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

Pg2" worksheet tab may be utilized for reporting when there have been five or fewer 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 for each drug 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. Incomplete or overly vague responses and responses indicating that this information is not available will be deemed noncompliant. For example, a response indicating "market conditions" or "market dynamics" is not sufficiently detailed. If "market conditions" were responsible for a price increase, a manufacturer would need to specifically describe what market conditions were responsible for the price increase and outline in detail why these impacted the price. Longer explanations can be included on the "5Yr WAC Increase Temp" tab as needed. This explanation does not need to be repeated for each NDC unless there were different reasons for increasing each NDC's price.