NV Department of Health and Human Services Drug Transparency Technical Guidelines

Drug Manufacturer Reporting-Diabetes and Over $40 Instructions v.09.20.2022

Version (v): 9/20/2022; Supersedes: 11/30/2021

NRS 439B.635

Reporting Date: On or before April 1

Reporting Frequency: Annually

Form Template Name: "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"

Fourth Tab: "Acquisition"

Purpose: NRS 439B.635 requires that manufacturers submit a report regarding the prescription drugs that appear on the most current lists 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. **The person responsible for submitting the report must include an affirmation of the accuracy of the information included. The department has provided such a form for convenience. If this form is not utilized, the following statement will suffice: "I declare under penalty of perjury that the attached is true and correct. Executed on (date)."**
2. **This document is for reporting on drugs that appear on List #2 and List #4.**
3. **DHHS's excel templates provide manufacturers with a standardized form to use for reporting that incorporates all the fields required by law.**

4. **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"). Tabs 3 and 4 will only be used as needed.**
5. **Tab 3 is utilized if there have been more than five WAC increases in past five years.**
6. **Tab 4 is utilized if intellectual property was acquired in past five years.**
7. **Do not rearrange or change the template headers in any way.**
8. **All values should be reported at the National level unless otherwise noted.**
9. **All responses should be in U.S. dollars.**
10. **Unless otherwise indicated, all values should be specific to the calendar year immediately preceding the year of report submission.**
11. **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":**

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":**

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 may be included here. 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 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 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). The total of this column must not exceed 100%.

➢ "Manufacturer Cost Attributable to Redemption and Administration of Consumer Coupons and Consumer Copayment Assistance Program":

Please include here both administrative costs as well as actual value of redeeming coupon.

➢ "Aggregate Amount of All Rebates Manufacturer Provided to Pharmacy Benefit Managers for Drug Sales in Nevada in 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).

<u>WHOLESALE ACQUISITION COST (WAC) DATA:</u>

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 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 an explanation for the price increase for each drug. This explanation does not need to be repeated for each NDC unless there were different reasons for increasing each NDC's price.

Incomplete or responses indicating that this information is not available will be deemed noncompliant.

Example justifications:

1. **Research and development**
2. **Rebates**
3. **General profit**
4. **Changes in marketplace dynamics (provide detail)**
5. **Supporting regulatory and safety commitments**
6. **Advertising and marketing**
7. **Increased rate of inflation**

8. **Medicaid and 340B Drug Discount Program**
9. **Operating patient assistance and educational programs**
10. **Drug has more competitive value**
11. **Other (provide detail)**

“Marketplace dynamics” and “other” require further detail. These responses will require a manufacturer to specifically describe what was 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.