NV Department of Health and Human Services Drug Transparency Technical Guidelines

Drug Manufacturer Significant Price Increase Reporting Instructions (v)08.09.2022; Supersedes: (v)10.20.2021

Reporting Date: On or before April 1

Reporting Frequency: Annually

Form Template Name: "Drug Manufacturer Price Increase Reporting _template vmm.dd.yy"

Worksheet Tabs:

First Tab: "Diabetes"

Second Tab: "Over $40 per Course of Therapy"

Purpose: NRS 439B.640 requires that manufacturers of prescription drugs that appear on the most current lists compiled by the Nevada Department of Health and Human Services (DHHS) report on factors that contributed to a significant increase in price with an explanation of each factor's role in the price increase; and any other information as prescribed.

Reporting Requirements Detailed in NRS 439B.640 can be found at the following link: https://www.leg.state.nv.us/NRS/NRS-439B.html#NRS439BSec640

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, with signature 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 #3 and List #4.**
3. **DHHS's excel template provides manufacturers with a standardized form that incorporates all the fields required by law.**
4. **All fields listed in the template document are required fields, unless otherwise noted.**
5. **The departmental template headers should not be rearranged or changed in any way.**
6. **All values should be reported at the National level unless otherwise noted.**
7. **If prices increased for all formulations, dosages, and packaging variants of one drug due to identical factors, drug manufacturers can submit one report per drug. Each National Drug Code (NDC) for which price increase factors are described should be listed in the report under the "NDC(s) (format XXXXX-XXXX-XX)" field. If more than one NDC is included in a cell, each NDC should be separated by a semicolon.**

8. **For each drug reported, the manufacturer may report as many factors as required to justify the price increase. The total "% Influence of Factors" for each drug should equal 100%.**
9. **Incomplete or responses indicating that this information is not available will be deemed noncompliant.**
10. **Example justifications:**
    a. **Research and development**
    b. **Rebates**
    c. **General profit**
    d. **Changes in marketplace dynamics (provide detail)****
    e. **Supporting regulatory and safety commitments**
    f. **Advertising and marketing**
    g. **Increased rate of inflation**
    h. **Medicaid and 340B Drug Discount Program**
    i. **Operating patient assistance and educational programs**
    j. **Drug has more competitive value**
    k. **Other (provide detail)****
11. **For reports or technical assistance, send your questions or submissions to: drugtransparency@dhhs.nv.gov**

****"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.**