NV Department of Health and Human Services Drug Transparency Frequently Asked Questions (FAQs)

Contents

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****The purpose of this document is to help answer questions regarding Drug Transparency guidelines and reporting information. ****

General FAQs

- **Will this new law limit consumers access to drugs?**
  NRS 439B 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. .

- **Defend Trade Secret Act of 2016 definition?**
  Public Law 114-153

- **What Is Drug Transparency Reporting?**
  The Department will collect information from drug manufacturers, pharmacy benefit managers, wholesalers, non-profits and pharmacies regarding the costs, rebates and other details related to NRS 439B.

  The report will include aggregated information and will describe the trends related to drug pricing and how those costs may impact the health system within Nevada.

Manufacturer FAQs

- **Manufacturer definition?**
  Defined by NRS 639.009 (https://www.leg.state.nv.us/NRS/NRS-639.html#NRS639Sec009)

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- **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

- **Reporting for Pharmaceutical Representatives, is it the individual's responsibility or the manufacturer's?** Both: (see below)

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

    NRS 439B.660 (1) 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 439B660(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.

- **Does this law apply to any/all pharmaceutical representatives and not just those engaging in the sales and marketing of drugs that appear on the Essential Drug List(s)?**
  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?**
  To register representatives, the employing manufacturer should send an email to: drugtransparency@dhhs.nv.gov with the following information (the Department's preferable format is excel – template and guidelines are posted at the following website http://dhhs.nv.gov/HCPWD/Drug_Transparency_Reporting/Manufacturers/:

  Action: the current action of adding or inactivating a representative, or any changes that might need to be made (with notes to identify those specific changes i.e. name correction, email correction, etc.).

Company Name: the name of the company for which the representative is working under.

Pharmaceutical Representative's legal First, Middle and Last Names: as represented on valid government issued identification.
Pharmaceutical Representative's Contact Telephone Number: the representative's business contact telephone number.
Pharmaceutical Representative's Business Contact Email Address: the representative's business email (specific to each representative and not one generalized email) Pharmaceutical Representative's Business Mailing Address: the representative's home office or business mailing address including the city, state, and zip code.

Pharmaceutical Representative's Status: provide notification of the representative's status of "Active or Inactive" and the date active or inactive.

Manufacturers should submit the names of all representatives in a single report notating if there are any new to "add", or anyone that should be "inactive" and the date they became active or inactive.

Third-party agencies that manage pharmaceutical representatives or compliance functions on behalf of a manufacturer may submit the list of names with the name of the manufacturer so long as they attach a letter of authorization from the manufacturer.

When new staff are hired, or are terminated from the company, notification to add or inactivate a representative from the DHHS registry shall be provided either when the representative begins work in Nevada or promptly upon termination to drugtransparency@dhhs.nv.gov.

- **When are the Pharmaceutical Representative's Comp and Samples reports due?**
  The pharmaceutical representative's comp and samples report is due March 1st of each year. This report will include all activity for the previous calendar year.

- **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.

- **Are manufacturers required to report to the Department if they do not produce any of the drugs currently posted on the Essential Drug List(s) posted by the Department?**
  Only manufacturers that produce drugs found on the current Essential Drug List(s) are required to report/notify the Department. (Note: Prescription drug manufacturers are all required to provide a list of each pharmaceutical sales representative who market prescription drugs in Nevada. Additionally, these representatives or manufacturers on behalf of the representatives must report on any type of drug provided as a sample or compensation given to providers of health care or others)

- **If a manufacturer believes that a data element in the report meets the standard of the Defend Trade Secrets Act (DTSA) a request to have the element declared confidential may be submitted as follows:**
  The designation must include a description of why the public disclosure of the data element by the Department would constitute the misappropriation of a trade secret under the DTSA, 18 U.S.C. § 1836 *et seq.* sufficient to confer jurisdiction under 18 U.S.C. § 1836 (b). This description asserting trade secret protection will be available upon request to the public.

  The Department will notify the manufacturer of any request for data elements designated as confidential and will provide the manufacturer a copy of the written request for those records.

  The Department will allow the manufacturer 30 days to take legal action under DTSA prior to releasing the information. No information will be released during the 30-day waiting period.

  The requesting party will be notified of the 30-day period and the Department will provide the designation that was specified by the manufacturer to assert that the data element qualifies as a trade secret under the DTSA.

  No release of information will occur during the 30-day period. If the manufacturer chooses to file for protection under DTSA during the 30-day period, no information will

be released until a final decision is received by the Department from the court, including all appeals.

Nonprofit Organizations FAQs

- **How do I know if my nonprofit organization is required to report?**

Two qualifiers determine if the nonprofit is required to create the yearly report:

  - Funding of medical research in the State of Nevada which may include:
    - Biomedical research
    - Basic medical research
    - Preclinical research
    - Clinical research
  - Advocacy on behalf of patients which may include:
    - Providing direct patient services to patients with chronic, debilitating and life-threatening illnesses who are confronting critical access issues, including insurance denials, access to care, medical debt crisis.
    - Acting as a liaison between a patient and their insurer, employer and/or creditors to resolve insurance, job discrimination and/or debt crisis matters relative to their diagnosis.
    - Working to promote access to affordable, quality healthcare for people with chronic, debilitating or life-threatening illnesses.

- **What activities are excluded from reporting requirements?**

Scientific and clinical activities undertaken by public health agencies.

This may include public health practice and public health research to prevent disease or injury and to improve the health of communities through activities such as disease surveillance, program evaluation, and outbreak investigation.

- **What is the process for reporting?**
  The report shall be placed on a publicly available website maintained by the nonprofit each calendar year by February 1.

  Posting may be a part of an annual report that the nonprofit organization creates as long as all data requirements are met and clearly marked.

  If the nonprofit organization does not maintain a website available to the public, the report should be sent to drugtransparency@dhhs.nv.gov for posting on a website maintained by the State of Nevada.

Pharmaceutical Sales Representatives FAQs

- **Reporting for Pharmaceutical Representatives, is it the individual's responsibility or the manufacturer's?** Both: (see below)

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

  > NRS 439B (1) 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) 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.

- **Does this law apply to any/all pharmaceutical representatives and not just those engaging in the sales and marketing of drugs on the Essential Drugs List(s)?**
  Yes, this law applies to all pharmaceutical representatives.

- **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.

- **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.

- **Are pharmaceutical sales representatives who are or were registered with the Department during anytime in the previous year required to submit a report to the Department for the previous calendar year?**
  Yes, by March 1st for the previous calendar year.

Pharmacy Benefit Managers FAQs

- **Pharmacy Benefit Manager definition?**
  Means an entity that contracts with or is employed by a third party and manages the pharmacy benefits plan or prescription drug coverage provided by a third party.

- **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

- Will the PBM report require both the aggregate sum of the data, and also data broken out by each individual drug?

  Yes, the aggregate amount of the rebates that the pharmacy benefit manager negotiated with manufacturers during the immediately preceding calendar year for purchases of prescription drugs included on the most current lists compiled by the Department , in total for each of those lists and for each drug must be included on this report.

Pharmacy FAQs

- What are pharmacies required to report under NRS 439B.655?

  The name of the pharmacy;

  The physical address of the pharmacy;

  The phone number of the pharmacy;

If the pharmacy maintains an electronic mail address, the electronic mail address of the pharmacy;

If the pharmacy maintains an Internet website, the Internet address of that website;

If a pharmacy is part of a larger company or corporation or a chain of pharmacies or retail stores, the parent company or corporation may provide to the Department the above information.

Wholesaler FAQs

- What are wholesalers required to report?

On or before April 1 of each year, a wholesaler that sells a prescription drug that appears on the Essential Drug List(s) compiled by the Department, shall submit:

The current wholesale acquisition cost of the drug and the minimum and maximum wholesale acquisition cost of the drug during the immediately preceding calendar year;

The total volume in units of the drug shipped by the wholesaler into this State during the immediately preceding calendar year;

The aggregate amount of rebates negotiated directly with the manufacturer of the drug for sales of units of the drug shipped by the wholesaler into this State during the immediately preceding calendar year;

The aggregate amount of rebates negotiated with pharmacies, pharmacy benefit managers and other entities for
sales of units of the drug shipped by the wholesaler into this State during the immediately preceding calendar year;