

NV Department of Health and Human Services
SB539 Drug Transparency Frequently Asked Questions (FAQs)

Table of Contents

| | |
|--|---|
| <u>General FAQs</u> | 2 |
| <u>Manufacturer FAQs</u> | 3 |
| <u>Nonprofit Organizations FAQs</u> | 6 |
| <u>Pharmaceutical Sales Representatives FAQs</u> | 7 |
| <u>Pharmacy Benefit Managers FAQs</u> | 9 |

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NV Department of Health and Human Services

SB539 Drug Transparency Frequently Asked Questions (FAQs)

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

General FAQs

- **Will DHHS proceed with any enforcement action for reports made during the first six months?**
06/07/2018: DHHS will not proceed with any enforcement action for reports made during the first six months. DHHS expects that all entities will work in good faith during the six-month period, but wants to ensure that manufacturers, sales representatives, pharmacy benefit managers, and non-profit organizations have ample opportunity to come into compliance with the statutes and regulations by January 15, 2019 before any enforcement action will be taken. DHHS anticipates that information regarding the wholesale acquisition cost (WAC) should be available during the summer of 2018 but may further extend deferment of enforcement action if needed. Sections 3.8 and 4 of the law require some drug manufacturers to submit certain reports on diabetes drug price increases to DHHS by April 1, 2018.
- **Will this new law limit consumers access to drugs?**
Senate Bill 539 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 required to treat diabetes.
- **Defend Trade Secret Act of 2016 definition?**
Public Law 114-153
- **Drug Transparency Reporting?**
The Department will collect detailed information from drug manufacturers and pharmacy benefit managers regarding the costs and rebates related to drugs listed on the List of Essential Diabetes Drugs created and posted on the Department website.

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

NV Department of Health and Human Services

SB539 Drug Transparency Frequently Asked Questions (FAQs)

Manufacturer FAQs

- **Manufacturer definition?**
Defined by NRS 639.009 (<https://www.leg.state.nv.us/NRS/NRS-639.html#NRS639Sec009>)
- **Do sections 3.8 and 4 of the law require some drug manufacturers to submit certain reports on diabetes drug price increases to DHHS by April 1, 2018.**
Yes.
- **Section 26.9 of SB 539 makes the manufacturers' initial report due on July 1. Under Section 3.8 it states that the report is due on April 1. On which date is the initial report due?**
The initial report for the Essential Diabetes Drugs posted for 2017 is July 1, 2018. Please see first bullet point on the previous page under General FAQs for additional information. In subsequent years, April 1st will be the due date beginning in 2019.
- **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.
Section 4.6(1) of the law 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 4.6(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)

NV Department of Health and Human Services

SB539 Drug Transparency Frequently Asked Questions (FAQs)

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 diabetes-related treatments?**

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.

NV Department of Health and Human Services

SB539 Drug Transparency Frequently Asked Questions (FAQs)

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 first Pharmaceutical Sales reports due per Section 4.6?**
2017 will be the first reporting period. The reportable period for this first report will be October 1, 2017-December 31, 2017. For all future reporting, the period will be based on the previous calendar year, due January 15th annually.
- **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 (section 3.8 and 4) if they do not produce any of the drugs currently posted in the “List of Essential Drugs for Treating Diabetes” posted by the Department?**
Only manufacturers that produce drugs found on the current “List of Essential Drugs for Treating Diabetes” are required to report/notify the Department as outlined in SB539 Sec. 3.8 and 4. (Note: Prescription drug manufacturers are all required by SB539 Sec. 4.6 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 as outlined in SB539 Sec. 4.6.)
- **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.

NV Department of Health and Human Services

SB539 Drug Transparency Frequently Asked Questions (FAQs)

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 for SB 539:

- 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.

NV Department of Health and Human Services

SB539 Drug Transparency Frequently Asked Questions (FAQs)

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.

Section 4.6(1) of the law 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 4.6(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 diabetes-related treatments?**

Yes, this law applies to all pharmaceutical representatives.

NV Department of Health and Human Services SB539 Drug Transparency Frequently Asked Questions (FAQs)

- **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 under SB 539.
- **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.
- **Do 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.

NV Department of Health and Human Services

SB539 Drug Transparency Frequently Asked Questions (FAQs)

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