

SB539 Drug Transparency Draft Regulations

Definitions:

Defend Trade Secrets Act of 2016 defined as Public Law 114-153.

Department defined as the Department of Health and Human Services.

Manufacturer as defined by NRS 639.009

Pharmacy Benefit Manager 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.

Section 1: Drug Transparency Report

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.

Section 2: Prescription Drug Manufacturers

1. Drug manufacturers must submit a report in the format listed on the Department website by April 1st for the previous calendar year.
2. 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.
 - a. The request must include a detailed description of why the data element qualifies as a trade secret under the DTSA. This detailed description asserting trade secret protection will be available upon request to the public.
 - b. The Department will notify the manufacturer of any request for data elements marked as confidential and will provide the manufacturer a copy of the written request for those records.
 - c. The Department will allow the manufacturer thirty days to take legal action under DTSA prior to releasing the information.
 - d. The requestor will be notified of the 30-day period and will be provided the detailed description provided by the manufacturer to assert that the data elements qualify as a trade secret under the DTSA.

Section 3: Pharmacy Benefit Managers

1. Pharmacy benefit managers must submit a report in the format listed on the Department website by April 1st for the previous calendar year.
2. If a pharmacy benefit manager 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.

- a. The request must include a detailed description of why the data element qualifies as a trade secret under the DTSA. This detailed description asserting trade secret protection will be available upon request to the public.
- b. The Department will notify the pharmacy benefit manager of any request for data elements marked as confidential and will provide the manufacturer a copy of the written request for those records.
- c. If the pharmacy benefit manager does not consent to the release of the data elements marked confidential to the requestor, the Department will allow the pharmacy benefit manager thirty days to take legal action under DTSA prior to releasing the information.
- d. The requestor will be notified of the 30-day period and will be provided the detailed description provided by the pharmacy benefit manager to assert that the data elements qualify as a trade secret under the DTSA.

Section 4: Pharmaceutical Sales Representative

Pharmaceutical sales representatives who are or were registered with the Department during anytime in the previous year must submit a report to the Department by March 1st for the previous calendar year. The report must be submitted in the format listed on the Department website.