PROPOSED REGULATION OF THE

DIVISION OF PUBLIC AND BEHAVIORAL HEALTH OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

LCB FILE NO. R042-18I

The following document is the initial draft regulation proposed

by the agency submitted on 03/09/2018

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

1. 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.
2. 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.

Sec. 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), the manufacturer must submit a designation to have the element declared confidential.
    a. 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.
    b. 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.
    c. The Department will allow the manufacturer thirty days to take legal action under DTSA prior to releasing the information. No information will be released during the 30-day waiting period.
    d. The requesting party will be notified of the 30-day period and the Department will provide the designation specified by the manufacturer to assert that the data element qualifies as a trade secret under the DTSA.
    e. 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 release of information will be completed until a final decision is received by the Department from the court, including all appeals.

Sec. 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 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.
    b. The Department will notify the pharmacy benefit manager of any request for data elements designated as confidential and will provide the pharmacy benefit manager a copy of the written request for those records.
    c. The Department will allow the pharmacy benefit manager 30 days to take legal action under DTSA prior to releasing the information. No information will be released during the 30-day waiting period.
    d. The requesting party will be notified of the 30-day period and the Department will provide the designation that was specified by the pharmacy benefit manager to assert that the data element qualifies as a trade secret under the DTSA.
    e. No release of information will occur during the 30-day period. If the pharmacy benefit manager chooses to file for protection under DTSA during the 30-day period, no release of information will be completed until a final decision is received by the Department from the court, including all appeals.

Sec. 4: Pharmaceutical Sales Representative

1. 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.
2. The report must be submitted in the format listed on the Department website.