NOTICE OF PUBLIC WORKSHOP

NOTICE IS HEREBY GIVEN that the Department of Health and Human Services will hold a public workshop to consider amendments to Nevada Administrative Code (NAC) Chapter 439.

The workshop will be conducted via videoconference beginning at 9:00 AM on Thursday, February 15, 2018, at the following locations:

Nevada Legislative Counsel Bureau 401 S. Carson St. Room 3137 Carson City, NV 89701	Nevada Legislative Counsel Bureau 555 E. Washington Ave. #5100 Room 4412E Las Vegas, NV 89101
Great Basin College 1500 College Parkway Elko, NV 89801	

These workshops will be conducted in accordance with NRS 241.020, Nevada's Open Meeting Law.

AGENDA

1. Introduction of workshop process
2. Public comment on proposed amendments to Nevada Administrative Code Chapter 439
3. Public Comment

The proposed changes will revise Chapter 439 of the Nevada Administrative Code and are being proposed in accordance with NRS 439.905, NRS 439.915 and Senate Bill 539 of the 2017 Legislative Session.

The proposed regulations provide provisions for the following:

1) Drug transparency reporting.
2) Establishes guidelines for prescription drug manufacturer yearly reporting.
3) Establishes guidelines for pharmacy benefit managers yearly reporting.
4) Establishes guidelines for pharmaceutical sales representative yearly reporting.

Members of the public may make oral comments at this meeting. Persons wishing to submit written testimony or documentary evidence may submit the material to Veronica Sheldon, Management Analyst at the following address:

Department of Health and Human Services
4126 Technology Way, Suite 100
Carson City, NV 89706
drugtransparency@health.nv.gov

Members of the public who require special accommodations or assistance at the workshops are required to notify Veronica Sheldon, Management Analyst, in writing to the Department of Health and Human Services, 4126 Technology Way, Suite 100, Carson City, Nevada, 89706, or by calling (775) 684-4255 at least five (5) working days prior to the date of the public workshop.

You may contact Veronica Sheldon, Management Analyst by calling (775) 684-4255 for further information on the proposed regulations.

A copy of the notice and the proposed regulations are on file for inspection and/or may be copied at the following locations during normal business hours:

Department of Health and Human Services
4126 Technology Way
Carson City, NV

Division of Public and Behavioral Health
4220 S. Maryland Parkway, Suite 810, Bldg D
Las Vegas, NV

Nevada State Library and Archives
100 Stewart Street
Carson City, NV

A copy of the regulations and small business impact statement can be found on the Department of Health and Human Services web page:

http://dhhs.nv.gov/HCPWD/Drug_Transparency/

A copy of the public workshop notice can also be found at Nevada Legislature's web page:
https://www.leg.state.nv.us/App/Notice/A/

Copies may be obtained in person, by mail, or by calling the Department of Health and Human Services at (775) 684-4255 in Carson City.

A copy of this notice has been posted at the following locations:

1. Department of Health and Human Services, 4126 Technology Way, First Floor Lobby, Carson City
2. Nevada State Library and Archives, 100 Stewart Street, Carson City
3. Legislative Building, 401 S. Carson Street, Carson City
4. Grant Sawyer Building, 555 E. Washington Avenue, Las Vegas
5. Early Intervention Services, 1020 Ruby Vista Drive, Suite 102, Elko, NV 89801
6. Division of Child and Family Services, 2655 Enterprise Rd, Reno, NV 89512

On the Internet at:
https://notice.nv.gov or http://dhhs.nv.gov/HCPWD/Drug_Transparency/

Copies may also be obtained from any of the public libraries listed below:

Carson City Library
900 North Roop Street
Carson City, NV 89702

Churchill County Library
553 South Main Street
Fallon, NV 89406

Clark County District Library
833 Las Vegas Boulevard North
Las Vegas, NV 89101

Douglas County Library
1625 Library Lane
Minden, NV 89423

Elko County Library
720 Court Street
Elko, NV 89801

Esmeralda County Library
Corner of Crook and 4th Street
Goldfield, NV 89013-0484

Eureka Branch Library
210 South Monroe Street
Eureka, NV 89316-0283

Henderson District Public Library
280 South Water Street
Henderson, NV 89105

Humboldt County Library
85 East 5th Street
Winnemucca, NV 89445-3095

Lander County Library
625 South Broad Street
Battle Mountain, NV 89820-0141

Lincoln County Library
93 Maine Street
Pioche, NV 89043-0330

Lyon County Library
20 Nevin Way
Yerington, NV 89447-2399

Mineral County Library
110 1st Street
Hawthorne, NV 89415-1390

Pahrump Library District
701 East Street
Pahrump, NV 89041-0578

Pershing County Library
1125 Central Avenue
Lovelock, NV 89419-0781

Storey County Library
95 South R Street
Virginia City, NV 89440-0014

Tonopah Public Library
167 Central Street
Tonopah, NV 89049-0449

Washoe County Library
301 South Center Street
Reno, NV 89505-2151

White Pine County Library
950 Campton Street
Ely, NV 89301-1965

Per NRS 233B.064(2), upon adoption of any regulations, the agency, if requested to do so by an interested person, either prior to adoption or within 30 days thereafter, shall issue a concise statement of the principal reasons for and against its adoption, and incorporate therein its reason for overruling the consideration urged against its adoption.

SMALL BUSINESS IMPACT STATEMENT 2018

PROPOSED AMENDMENTS TO NAC 439

The Nevada Department of Health and Human Services (DHHS) has determined that the proposed amendments should not impose an economic burden upon a small business or have a negative impact on the formation, operation or expansion of a small business in Nevada.

A small business is defined in Nevada Revised Statutes NRS 233B as a "business conducted for profit which employs fewer than 150 full-time or part-time employees."

This small business impact statement is made pursuant to NRS 233B.0608 (3) and complies with the requirements of NRS 233B.0609. As required by NRS 233B.0608(3), this statement identifies the methods used by the agency in determining the impact of the proposed regulation on a small business in sections 1, 2, 3, and 4 below and provides the reasons for the conclusions of the agency in section 8 below followed by certification by the person responsible for the agency.

Background

Senate Bill 539 was recently passed in June 2017 to compile a list of essential diabetes medications and obtain information related to these medications from drug manufacturers, pharmaceutical benefit managers (PBM), and pharmaceutical sales representatives. DHHS drafted regulations that further detail drug manufacturer, PBM, and pharmaceutical sales representative reporting requirements. The draft regulations also outline the process for drug manufacturers and PBMs to request of DHHS that data elements be declared confidential under the Defend Trade Secrets Act (DTSA). Lastly, the draft regulations define the notification and consent process for confidential data requests received by DHHS.

1) **A description of the manner in which comment was solicited from affected small businesses, a summary of their response and an explanation of the manner in which other interested persons may obtain a copy of the summary.**

Pursuant to NRS 233B.0608 (2)(a), DHHS has requested input from all known stakeholders.

A Small Business Impact Questionnaire was distributed along with a copy of the proposed regulation changes, using the following organization websites, listservs and social media platforms:

- DHHS Drug Transparency webpage (January 4, 2018)
- Nevada Board of Pharmacy website (January 9, 2018)
- Bureau of Health Care Quality and Compliance Nevada health facilities listserv (January 8, 2018)
- Nevada Medical Association website (January 5, 2018)
- Indian Health Services, Nevada Service Units (January 4, 2018)
- Nevada Department of Health and Human Services Facebook page (January 5, 2018)
- Nevada Division of Public and Behavioral Health Facebook page (January 5, 2018)

- Nevada Primary Care Association newsletter (January 8, 2018)
- Nevada Department of Health and Human Services Twitter page (January 5, 2018)

The questions on the questionnaire were:

1) How many employees are currently employed by your business?
2) Will a specific regulation have an adverse economic effect upon your business?
3) Will the regulation(s) have any beneficial effect upon your business?
4) Do you anticipate any indirect adverse effects upon your business?
5) Do you anticipate any indirect beneficial effects upon your business?

Summary of Comments Received
(11 total responses were received)

Will a specific regulation have an adverse economic effect upon your business?	**Will the regulation (s) have any beneficial effect upon your business?**	**Do you anticipate any indirect adverse effects upon your business?**	**Do you anticipate any indirect beneficial effects upon your business?**
One respondent answered "yes", stating "It will cost an additional $5,000 in staff time to prepare this report. This is only adding to the mountain of paperwork involved in running this business and will not help my business, but only burden it with more redundant paperwork." Five answered "no", and five skipped the question. One respondent stated, "we do advocate for civil rights of individuals with disabilities but we do not do direct services for them nor provide medications nor receive funding from any manufacturer".	Six respondents answered "no" and five skipped the question.	Two respondents answered "yes". One stated "Higher costs of medication for my clients due to additional cost burden of preparing more paperwork for pharmacies and drug manufacturers." The other respondent stated "To subject our employees to having their medications allowed or picked by the State of Nevada will cause undue stress regarding their health care. While we realize the cost of healthcare is considerable, this bill does not allow employers, employees a choice of their own healthcare." Four answered "no", and five skipped the question. One respondent that stated "no" added the condition	Six respondents answered "no" and five skipped the question.

Will a specific regulation have an adverse economic effect upon your business?	Will the regulation (s) have any beneficial effect upon your business?	Do you anticipate any indirect adverse effects upon your business?	Do you anticipate any indirect beneficial effects upon your business?
		"Not unless the cost of the medication goes up for the person taking it."	

2) Describe the manner in which the analysis was conducted.

The Small Business Impact Questionnaire was embedded in an online survey with a link to the proposed amendments to regulation, and distributed to the stakeholders identified above. Responses were reviewed individually and collectively to determine potential impacts of the proposed amendments. Staff have reviewed the regulations to ensure there is not a negative impact on small business.

3) The estimated economic effect of the proposed regulation on the small business which it is to regulate including, without limitation both adverse and beneficial effects and both direct and indirect effects.

Based on a preliminary analysis, DHHS does not anticipate adverse or beneficial direct or indirect economic effects from the proposed regulation on small businesses. Direct or indirect adverse or beneficial economic effects will be better determined by DHHS after the workshop scheduled for February 15, 2018.

4) Provide a description of the methods that the agency considered to reduce the impact of the proposed regulation on small businesses and a statement regarding whether the agency actually used any of those methods.

DHHS designed the information requests to mirror reports already submitted federally by organizations impacted by the proposed regulation. This will significantly reduce the resources needed to prepare and submit these reports. DHHS will also be holding a workshop on February 15, 2018 allowing for further input by stakeholders regarding the proposed regulations and how they will impact small businesses. These comments will be taken into consideration if any potential negative impact is identified.

5) The estimated cost to the agency for enforcement of the proposed regulation.

No new costs are anticipated for enforcement of the proposed regulation.

6) If the proposed regulation provides a new fee or increases an existing fee, the total annual amount DPBH expects to collect and the manner in which the money will be used.

The proposed regulation does not provide a new fee or increase an existing fee.

7) **An explanation of why any duplicative or more stringent provisions than federal, state or local standards regulating the same activity are necessary.**

The proposed regulation does not include duplicative or more stringent provisions than the Nevada Revised Statutes.

8) Provide a summary of the reasons for the conclusions of the agency regarding the impact of a regulation on small businesses.

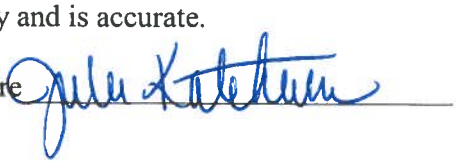
The response rate to the small business impact questionnaire was relatively low, which may be a reflection that stakeholders do not anticipate significant impacts from the proposed regulation. The majority of the respondents indicated no direct or indirect positive or negative impacts from the proposed regulation. Three of the responses reported anticipated negative impacts, with two referencing increased costs due to report preparation. DHHS designed the information requests to mirror reports already submitted federally by organizations impacted by the proposed regulation. This will significantly reduce the resources needed to prepare and submit these reports. The last anticipated negative impact reported by a respondent on the survey stated that the regulation would impose restrictions on the choice of health care and on the choice of available diabetic medications for Nevada residents. The proposed regulation in no way restricts the choice of health care or the choice of available diabetic medications for Nevada residents. Based on DHHS analysis of the proposed regulation and the responses received from the small business impact questionnaire, DHHS has determined that the proposed amendments should not impose an economic burden upon a small business or have a negative impact on the formation, operation or expansion of a small business in Nevada.

Any other persons interested in obtaining a copy of the summary may e-mail, call, or mail in a request to Veronica Sheldon at the Nevada Department of Health and Human Services at:

Department of Health and Human Services
4126 Technology Way, Suite 100
Carson City, NV 89701
Veronica Sheldon
Phone: (775) 684-4255
Email: drugtransparency@dhhs.nv.gov

Certification by Person Responsible for the Agency

I, Julie Kotchevar, Deputy Director of the Nevada Department of Health and Human Services certify to the best of my knowledge or belief, a concerted effort was made to determine the impact of the proposed regulation on small businesses and the information contained in this statement was prepared properly and is accurate.

Signature  Date: 1-29-18

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.

Revised: February 5, 2018

Frequently Asked Questions

Pharmaceutical Representatives:

- Reporting for Pharmaceutical Representatives, is it the individual's responsibility or the manufacturer's?
    - Both, please see below for specific requirements.

        - 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.
                - Report formatting and specifics may be found at the end of this document.

- 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?

    - An excel file is preferable listing the first name, last name and company that the individual represents. An example is provided below. This information can be e-mailed to drugtransparency@dhhs.nv.gov and should be updated as changes occur within your organization.

Company	Pharmaceutical Representative First Name	Pharmaceutical Representative Last Name

- When are the first reports due?
    - 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 calendar year.

- What format should the reports be in?
    - At this time the Department is not requiring a specific format, however Excel is preferred.
        - The State of Nevada will accept the federal report to fulfill this requirement.

- 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.

Prescriptions Drug Manufacturers:

- 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. When do you anticipate that DHHS will issue the format and other requirements for these reports?

    - Regulations have been drafted and are available for review on the website http://dhhs.nv.gov/HCPWD/Drug_Transparency/
    - Report formatting and specifics may be found at the end of this document.

Pharmacy Benefit Managers:

- Report formatting and specifics may be found at the end of this document.

Revised: February 5, 2018

Frequently Asked Questions

Consumers:

- Will this new law limit my 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.

Revised: January 18, 2018

Prescription Drug Manufacturers

Drug manufacturers must submit a report to the Nevada Department of Health and Human Services (DHHS) containing information described in the table below for prescription drugs posted on the DHHS website. Reports must be submitted to drugtransparency@dhhs.nv.gov annually by April 1st for the previous calendar year. DHHS will compile a report, submit and post it in accordance with NRS 439.

Reporting Information	Text or Number
Cost of producing the drug	Number
Total administrative expenditures relating to the drug, including marketing and advertising costs	Number
Profit earned from the drug	Number
Percentage of total profit for the previous calendar year that is attributable to each drug on the list published by the department	Number
Total amount of financial assistance provided through patient prescription assistance programs	Number
Cost associated with coupons provided directly to consumers and for programs to assist consumers in paying copayments, and the cost to the manufacturer attributable to the redemption of those coupons and the use of those programs	Number
Wholesale acquisition cost of the drug	Number
History of any increases in the wholesale acquisition cost of the drug over the five years immediately preceding the date on which the report is submitted, including: • the amount of each such increase expressed as a percentage of the total wholesale acquisition cost of the drug, • the month and year in which each increase became effective. • and any explanation for the increase.	Text Number Date Text
Aggregate amount of all rebates provided to pharmacy benefit managers for sales of the drug within Nevada.	Number
Reasons why the wholesale acquisition cost of the drug increased, if it did in the last year. For each drug, list factors contributing to the increase, and: • Percentage of total increase attributable to each factor, and • Explanation of role each factor played in the increase.	Text

Pharmacy Benefit Managers

Pharmacy benefit managers (PBM) must submit a report to the Nevada DHHS containing information described in the table below for prescription drugs posted to the department website. Reports must be submitted to drugtransparency@dhhs.nv.gov annually by April 1st for the previous calendar year. DHHS will compile a report, submit and post it in accordance with NRS 439.

Reporting Information	Text or Number
Total amount of rebates negotiated with manufacturers	Number
Total amount of all rebates described above that were retained by the PBM	Number
Total amount of all rebates negotiated for purchase of such drugs for use by: 1. Recipients of Medicare; 2. Recipients of Medicaid; 3. Persons covered by 3rd parties which are governmental agencies 4. Persons covered by 3rd parties which are NOT governmental agencies; and 5. Plans subject to the Employee Retirement Income Security Act (ERISA) that require compliance with the state reporting requirement.	Numbers and Text

Pharmaceutical Sales Representatives

Pharmaceutical sales representatives on a list submitted to DHHS by drug manufacturers during anytime in the previous calendar year must report to DHHS by March 1st for the previous calendar year, and must include items in the table below. DHHS will compile a report, submit to drugtransparency@dhhs.nv.gov and post it in accordance with NRS 439.

Reporting Information	Text or Number
List of health care providers or facilities to whom: 1. Any type of Compensation with a value that exceeds $10; or 2. Total compensation exceeding $100 in aggregate.	Text
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	Text

NRS and the name of each such person to whom a free sample was provided.	

STATE OF NEVADA

Department of Health and Human Services

Nevada Drug Transparency

For questions or to submit reports, you may contact staff by utilizing any of the following methods:

By Mail:
4126 Technology Way, Suite 100
Carson City, NV 89706

By Phone: (775) 684-4255

By E-Mail: drugtransparency@dhhs.nv.gov