

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?
<p>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.”</p> <p>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”.</p>	<p>Six respondents answered “no” and five skipped the question.</p>	<p>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.”</p> <p>Four answered “no”, and five skipped the question. One respondent that stated “no” added the condition</p>	<p>Six respondents answered “no” and five skipped the question.</p>

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