

SMALL BUSINESS IMPACT STATEMENT 2022

PROPOSED AMENDMENTS TO NAC 439

The Division of Public and Behavioral Health (DPBH) 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 the certification by the person responsible for the agency.

Background

Proposed amendments to Nevada Administrative Code (NAC) 439 update the following areas:

- Updated terms and definitions in Section 2 for Department, Director, Manufacturer, Pharmacy, Wholesaler and Pharmacy benefit manager
 - Added terminology to include the appointing of three (3) permanent employees to act as hearing officers. These hearing officers will perform this function in addition to their regular duties. Once a request for an appeal to be heard has been received, the Director will assign the appeal to the next hearing officer unless there is a conflict of interest, or they are otherwise disqualified from hearing the appeal
 - Included the requirement to notify the entity of the proposed penalty in writing, at least 15 days prior to the effective date of the imposition of the penalty. This notice will include statutory and regulatory authority for the penalty, the facts on which the penalty is based, circumstances the Department considered in taking the penalty, instructions for responding to the notice and the effective date of the penalty. This notice will be sent to the last known mailing address and email address of the entity
 - Section 5 now includes wording on the process when appealing a proposed fine
 - Section 6 includes wording for the hearing process
 - Section 7 includes wording for the decision after the hearing process
- 1) A description of the way comment was solicited from affected small business, a summary of their response and an explanation of the way other interested persons may obtain a copy of the summary.**

Pursuant to NRS 233B.0608 (2)(a), the Department of Health and Human Services has requested input from all known stakeholders.

A Small Business Impact Questionnaire was distributed to the Drug Transparency Listserv and all Wholesalers registered in the State of Nevada on January 14th, 2022. 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 Response

Summary of Comments Received

The comments submitted referred to the statute that imposes the reporting, and not the regulation that addresses the appeals process.

Nine completed surveys were received out of over 1000 contacts invited to complete the small business impact questionnaire.

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?
Yes-6 No -3	Yes-0 No-9	Yes-2 No-7	Yes-0 No-9

Question 2 had the following explanations:

Additional resource demands to respond to the unique questions presented by Nevada. Estimate the need for 0.1 FTE resource incrementally (\$20k).

Reporting data to states costs us a few thousand dollars per year per state. With the increasing number of states instituting reporting requirements, the time, effort and cost involved adversely impacts small businesses. The cost of compliance with additional regulations discourages small businesses from entering the pharma industry and/or reduces profitability, reducing competition and ultimately driving up prices for consumers as larger companies are at an advantage and can dictate prices.

Additional oversight and headcount workload to maintain unnecessary regulations that are readily available through secondary sources.

With the number of states that have recently proposed/enacted such regulations, we expect to require at least 1-2 additional headcount at \$100,000-\$150,000/year each. Every state expects

different levels of information, and they all use unique reporting procedures and various computer programs. Regulations can be up to 100+ pages in length. Third party reporting services are currently limited and fees exceed \$300,000/year and would still require additional inside personnel for support.

As a wholesaler, we track only certain information. We would be able to provide our purchase price from the manufacturer and our sale price to customers. However, we do not trace Wholesale Acquisition Cost, nor do we have any potential trends in pricing. Finally, we have only 2 persons in our Information Systems department. This would require considerable manpower time and resources to compile.

2) Describe the way the analysis was conducted.

The Small Business Impact Questionnaire was emailed to the stakeholders identified above. Responses were reviewed individually and collectively to determine potential impacts of the proposed amendments.

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.

The proposed amendments are not expected to have any economic effect - adverse or beneficial - on small businesses.

Result of review:

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 used any of those methods.

The agency is not seeking to make any changes to the application fee and doesn't expect for the proposed changes to impact small businesses.

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 way the money will be used.

There are no changes to a fee schedule.

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 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 impact from the proposed regulation.

Any other persons interested in obtaining a copy of the summary may e-mail, call, or mail in a request to Drug Transparency at:

Division of Public and Behavioral Health 4150
Technology Way, 3rd Floor
Carson City, NV 8970
1 Drug Transparency Phone: (775) 684-4255
Email: drugtransparency@dhhs.nv.gov

Certification by Person Responsible for the Agency

I, Richard Whitley, Director of the 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 business and the information contained in this statement was prepared properly and is accurate.

Signature:

Date:


2/9/2022