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DIVISION OF PUBLIC AND BEHAVIORAL HEALTH

OFFICE OF PUBLIC HEALTH INVESTIGATIONS AND EPIDEMIOLOGY (OPHIE)
LUPUS, SICKLE CELL, AND OTHER RARE DISEASES PROGRAM
LCB FILE NO. R108-22

INFORMATIONAL STATEMENT PER NRS 233B.066

1. **A clear and concise explanation of the need for the adopted regulation;**

   The proposed regulations will establish and sustain a system of report as it relates to lupus and its variants to report to the Chief Medical Officer. Additionally, requires the Chief Medical Officer to coordinate with the National Lupus Registry Program at the Centers for Disease Control and Prevention to establish and maintain a system of reporting. This will allow the Division to better understand the needs of patients living with lupus throughout the state, and this information will be imperative to development of programs and support systems for people living with sickle cell disease, and others impacted.

2. **A description of how public comment was solicited, a summary of public response, and an explanation how other interested persons may obtain a copy of the summary;**

   The Division of Public and Behavioral Health, Lupus, Sickle Cell, and Other Rare Diseases Program held a virtual Public Workshop on January 9, 2023, to consider proposed regulations LCB File No. R108-22. There was no comment on the proposed regulations.

   Any persons interested may obtain a copy of the meeting summary from the Public Workshop by visiting the Office of Public Health Investigations and Epidemiology website, https://dpbh.nv.gov/Programs/OPHIE/dta/Statutes/Public_Health_Informatics_and_Epidemiology_(OPHIE)_-_Statutes/ or by emailing atorrez@health.nv.gov.

3. **A statement indicating the number of persons who attended each hearing, testified at each hearing, and submitted written statements regarding the proposed regulation. This statement should include for each person identified pursuant to this section that testified and/or provided written statements at each hearing regarding the proposed regulation, the following information, if provided to the agency conducting the hearing:**

   A public workshop was held on January 9, 2023 and there were seven callers, and there was no public comment on the proposed regulations. There were no written statements that was submitted for the public workshop held on January 9, 2023. For a summary of the January 9, 2023 public workshop you may visit, https://dpbh.nv.gov/Programs/OPHIE/dta/Statutes/Public_Health_Informatics_and_Epidemiology_(OPHIE)_-_Statutes/ or by emailing atorrez@health.nv.gov.

A public hearing was held on June 2, 2023. There was no public written testimony or public comment for these regulations. For a summary of the June 2, 2023 public hearing, you may visit https://dpbh.nv.gov/Boards/BOH/Meetings/2023/2023_Nevada_State_Board_of_Health/ or by emailing StateBOH@health.nv.gov.

4. **A description of how comment was solicited (i.e., notices) from affected businesses, a summary of their response, and an explanation how other interested persons may obtain a copy of the summary.**

   The Division of Public and Behavioral Health prepared a distributed electronically was sent out on November 9, 2022 to four (4) listservs including Nevada Primary Care Association, the statewide UNR medical school listserv, the Nevada State Board of Medical Examiners, and the Nevada Hospital Association and a recipient from the Dreamsickle Kids Foundation. By November 30, 2022, no responses had been received, so the survey deadline was extended to December 9, 2022, and the survey was resent to these listservs and the recipient from the Dreamsickle Kids Foundation on November 30, 2022. Pursuant to NRS 233B.0608 (2)(a), DPBH also requested input from all Nevada-licensed health facilities listserv subscribers interested in information related to health facilities from Health Care Quality Compliance regulators. A Small Business Impact Questionnaire along with a copy of the proposed regulation changes were emailed on December 1, 2022, to these recipients which included all Nevada-licensed health facilities and listserv subscribers interested in information related to health facilities from Health Care Quality Compliance regulators.

SUMMARY OF RESPONSE

Summary of Comments Received **(There was 1 response received)**			
(Q#1) Will a specific regulation have an adverse economic effect upon your business?	**(Q#2) Will the regulation(s) have any beneficial effect upon your business?**	**(Q#3) Do you anticipate any indirect adverse effects upon your business?**	**(Q#4) Do you anticipate any indirect beneficial effects upon your business?**
0 – "Yes" Responses	0 – "Yes" Responses	0 – "Yes" Responses	0 – "Yes" Responses
1 – "No" Responses	1 – "No" Responses	1 – "No" Responses	1 – "No" Responses
Direct comments from small business impact survey issued November 9, 2023 There was no comments in the small business questionnaire.			

5. **If, after consideration of public comment, the regulation was adopted without changing any part of the proposed regulation, a summary of the reasons for adopting the regulation without change. The statement should also explain the reasons for making any changes to the regulation as proposed.**

   There were no changes to the regulations post public workshop and public hearing. No concerns were expressed during the public workshop or public hearing.

6. **The estimated economic effect of the regulation on the business which it is to regulate and on the public. These must be stated separately, and in each case must include:**

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(a) Both adverse and beneficial effects; and

The Division does not anticipate any direct adverse effects to small business or the general public. The direct beneficial effects of the regulations is that the state of Nevada will establish and maintain a system of reporting for lupus and its variants. Additionally, the Division does not anticipate any indirect adverse effects, and an indirect beneficial effects would be an increase in diagnosis and treatment of lupus.

(b) Both immediate and long-term effects.

As soon as the proposed regulations become effective, it would allow for increased opportunities for coordination and collaboration with other states and the Centers for Disease Control and Prevention to establish a system of reporting for lupus and its variants. The data collected through the lupus registry will allow the Division to better understand the needs of patients living with lupus throughout the state. This data is imperative to developing programs and support systems for people living with lupus and its variants, and other impacted by it.

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

There is no direct cost to the agency for enforcement of the proposed regulation.

8. A description of any regulations of other state or government agencies which the proposed regulation overlaps or duplicates and a statement explaining why the duplication or overlapping is necessary. If the regulation overlaps or duplicates a federal regulation, name the regulating federal agency.

LCB File No. R108-22 are not duplicative of existing regulations of other state, federal or other governmental agencies.

9. If the regulation includes provisions which are more stringent than a federal regulation which regulates the same activity, a summary of such provisions; and

The proposed regulations are not more stringent than the current federal regulations.

10. If the regulation establishes a new fee or increases an existing fee, a statement indicating the total annual amount the agency expects to collect and the manner in which the money will be used.

According to and section 3(2)(e)(2) of R108-22 require a researcher who wishes to obtain information from the sickle sell or lupus registry to pay a fee of $200 or the cost of providing the information. The Division expects approximately $9,000 annually to be used for Rare Disease Advisory Council (RDAC) support.

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