Steve Sisolak
Governor

Richard Whitley, MS
Director

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF PUBLIC AND BEHAVIORAL HEALTH
Helping people. It's who we are and what we do.

Lisa Sherych
Administrator

Ihsan Azzam,
Ph.D., M.D.
Chief Medical Officer

NOTICE OF PUBLIC WORKSHOP

NOTICE IS HEREBY GIVEN that the Division of Public and Behavioral Health (DPBH) will hold a public workshop to consider amendments to Nevada Administrative Code (NAC) 439.

The workshop will be conducted via videoconference beginning at 10:00 AM on Monday, January 9, 2023 at the following locations:

Physical Locations:
This meeting will be held virtually only. See information below.

Virtual Meeting Location:
Meeting Link: https://teams.microsoft.com/l/meetup-join/19%3ameeting_ZDA2MjJlMDgtMTExYy00MGVhLTlkODEtOTA0ODRmNzdlNTEy%40thread.v2/0?context=%7b%22Tid%22%3a%22e4a340e6-b89e-4e68-8eaa-1544d2703980%22%2c%22Oid%22%3a%22c6cbcd35-ecfc-41f0-8557-67e58ee3ad83%22%7d
Please Note: If you are having difficulties connecting online, please call into the meeting to participate by phone.

Join By Phone:
+1-775-321-6111
Phone Conference ID: 988 071 531#

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

AGENDA

1. Introduction of the workshop process
2. Public comment on errata to proposed regulation Legislative Council Bureau (LCB) file no. R107-22 amending Nevada Administrative Code (NAC) Chapter 439 in accordance with Assembly Bill (AB) 254 of the 2019 Legislative Session and Nevada Revised Statutes (NRS) Chapter 439.
3. Public comment on errata to proposed regulation LCB file no. R108-22 amending NAC Chapter 439 in accordance with Senate Bill (SB) 175 of the 81st Legislative Session of 2021 and NRS Chapter 439.
4. General Public Comment

LCB File No. 107-22 proposed regulation provide provisions for the following:
The proposed changes will revise NAC Chapter 439 in accordance with AB 254 from the 2019 Legislative session.

The proposed regulations stem from the passage of AB 254 (formally Bill Draft Request [BDR] 40-20), which

was introduced during the 80th Legislative Session and signed by Governor Steve Sisolak on June 3, 2019. The bill establishes and maintains a system for the reporting and analysis of certain information on sickle cell and its variants.

Current regulations do not outline the requirement of establishing and maintaining a system for reporting as it relates to sickle cell and its variants. The proposed regulations will update and require Nevada-licensed health facilities to report the Chief Medical Officer as it relates to sickle cell and its variants. Additionally, the Chief Medical Officer shall coordinate with the Sickle Cell Data Collection of the Centers for Disease Control and Prevention to establish and maintain the system for reporting.

LCB File No. 108-22 proposed regulation\ provides provisions for the following:
The proposed changes will revise NAC Chapter 439 in accordance with SB 175 from the 2021 Legislative session.

The proposed regulations stem from the passage of SB 175 (formally Bill Draft Request [BDR] 40-8), which was introduced during the 81st Legislative Session and signed by Governor Steve Sisolak in June 2021. The bill establishes and maintains a system for the reporting and analysis of certain information on lupus and its variants.

Current regulations do not outline the requirement of establishing and maintaining a system for reporting as it relates to lupus and its variants. The proposed regulations will update and require Nevada-licensed health facilities to report to the Chief Medical Officer as it relates to lupus and its variants. Additionally, the Chief Medical Officer shall coordinate with the National Lupus Patient Registry of the Centers for Disease Control and Prevention to establish and maintain the system for 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 Ashlyn Torrez, Health Program Specialist I at the following address:

Ashlyn Torrez
Division of Public and Behavioral Health
500 Damonte Ranch Parkway, STE 657
Reno, NV 89521
Email: atorrez@health.nv.gov

Members of the public who require special accommodations or assistance at the workshops are required to notify Ashlyn Torrez, Health Program Specialist I, in writing to the Division of Public and Behavioral Health, 500 Damonte Ranch Pkwy, STE 657 Reno, NV 89521 or by calling 775-447-0263 at least five (5) working days prior to the date of the public workshop.

You may contact Ashlyn Torrez by calling 775-447-0263 for further information on the proposed regulations or how to obtain copies of the supporting documents.

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:

Division of Public and Behavioral Health
4150 Technology Way, STE 300
Carson City, NV 89706

Division of Public and Behavioral Health
Office of Public Health Investigations & Epidemiology (OPHIE)
500 Damonte Ranch Pkwy, STE. 657
Reno, NV 89521

Nevada State Library and Archives
100 N. Stewart St.
Carson City, NV 89701

Southern Nevada Health District
280 S. Decatur Blvd.
Las Vegas, NV 89107

Washoe County Health District
1001 E. Ninth St.
Reno, NV 89512

A copy of the regulations and small business impact statement can be found on the Division of Public and Behavioral Health's web page:
https://dpbh.nv.gov/Programs/OPHIE/dta/Statutes/Public_Health_Informatics_and_Epidemiology_(OPHIE)_-_Statutes/

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

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

1. Division of Public and Behavioral Health, 4150 Technology Way, STE 300, Carson City
2. Division of Public and Behavioral Health, Attn: OPHIE, 500 Damonte Ranch Pkwy, STE 657 Reno, NV 89521
3. Nevada State Library and Archives, 100 N Stewart St. Carson City, NV 89706
4. Southern Nevada Health District, 280 S. Decatur Blvd. Las Vegas, NV 89107
5. Washoe County Health District, 1001 E. Ninth St. Reno, NV 89512

Copies may be obtained in person, by mail, or by calling the Division of Public and Behavioral Health at 775-447-0263.

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 2022

PROPOSED AMENDMENTS TO NAC 439 THROUGH LCB FILE NO. R107-22

The Division of Public and Behavioral Health (DPBH) has determined that the proposed amendments to the Nevada Administrative Code (NAC) Chapter 439, through Legislative Counsel Bureau (LCB) File No. R107-22 will have an adverse effect upon a small business, 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

The Nevada Department of Health and Human Services (DHHS) has drafted revisions to Nevada Administrative Code (NAC) Chapter 439 in accordance with Assembly Bill 254 (AB 254) from the 2019 Legislative Session.

AB254 revises provisions relating to rare disease and establishing a system for the reporting and analysis of certain information as it relates to Sickle Cell and its variants. This will allow DPBH to better understand the needs of patients living with sickle cell throughout the state. Additionally, this information will allow for developing programs and support systems for people living with sickle cell, and others who may be impacted by it.

Current regulations do not require Nevada-licensed health facilities to report on sickle cell and its variants to the Chief Medical Officer. The proposed regulation will update and require Nevada-licensed health facilities to report a case of diagnoses of sickle cell and its variants, and report sickle cell and its variants if it is the primary complaint of the patient. Additionally, any new treatment as indicated by the provider of health care.

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.**

The survey was posted as an online survey to the Office of Public Health Investigations and Epidemiology (OPHIE) website.

Individuals had the option to complete the survey online or mail, fax, or email your completed on or prior to Friday, December 9, 2022, to:

Ashlyn Torrez, Health Program Specialist I
Office of Public Health Investigations & Epidemiology
4150 Technology Way, STE 300
Carson City, NV 89706
Phone Number: (775) 447-0263
Email Address: atorrez@health.nv.gov
FAX: (775) 684-5999

The online survey was emailed 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 on November 8, 2022. As of 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.

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 (1 response was received)				
How many employees are currently employed by your business?	**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?**
1-149	Yes – 1 No – 0	Yes – 0 No – 1	Yes – 0 No – 1	Yes – 0 No – 1

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

An online small business impact survey was distributed via email and posted publicly to the DPBH OPHIE website, as described above. All questionnaire responses were conducted via the web, and none were received via email, fax, or mail. The proposed regulations, existing regulations, and the one (1) survey response were analyzed by the OPHIE Manager and the Health Program Specialist I to determine if the proposed regulations had an impact on small businesses or if it was existing regulations that had an impact on small businesses. This statement was prepared by the OPHIE Manager and the Health Program Specialist I.

A Public Workshop will be held January 9, 2023, to continue to obtain feedback on the proposed regulations.

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.

- Direct beneficial effects:
  - Will establish a system of reporting for sickle cell and its variants.

- Indirect beneficial effects:
  - Increase in diagnosis and treatment of sickle cell.

- Direct adverse effects:
  - The only respondent commented that their business currently would not be able to complete the reporting requirements in a timely manner due to the lack of staff. It was mentioned that funding needed for a dedicated medical records staff would require about 0.25 FTE, which would be around $9,000 to $9,360 annually.
- Indirect adverse effects:
  - None anticipated.

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.

DPBH has held several opportunities for businesses to provide input and comments regarding the proposed regulations, including the economic impact the proposed regulations may have on their business. Modifications to the proposed regulations have been made because of this input. These modifications included adding in a process to automate the reporting burden by utilizing hospital discharge data when available. Additionally, DPBH will work with medical providers and the Rare Disease Advisory Council to develop the data collection tool. This collaboration on the data collection tool will help DPBH create a tool that will limit the burden of reporting as much as possible but still meet the specifications set forth in AB254 and the regulations.

Additionally, a public workshop will be held on January 9, 2023, allowing for further input by businesses regarding the proposed regulations and how they will impact their business. These comments will be taken into consideration for possible further revisions to the regulations to reduce the economic impact on facilities.

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

These proposed regulations will not have any direct cost to the agency.

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 regulations will not add a new fee or increase any 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.

Sickle cell is not a nationally reportable condition, so this requirement could be considered more stringent than federal requirements. These regulations are a result of Assembly Bill 254 (AB 254) from the 2019 Legislative Session. These regulations were deemed necessary so Nevada could better understand the needs of patients living with sickle cell throughout the state. Additionally, this information will allow for developing programs and support systems for people living with sickle cell, and others who may be impacted by it.

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

In summary, the proposed regulations Legislative Counsel Bureau (LCB) file no. R107-22, in carrying out the provisions of AB 254 to update NAC 439, will have an adverse financial impact on the programs and/or small businesses. LCB file no. R107-22 will significantly benefit residents within the State of Nevada by:

1) Increase diagnosis and treatment for sickle cell and its variants.
2) Agency and state will have a better understanding of sickle cell.
3) Will establish a system for reporting of sickle cell and its variants.

Any other persons interested in obtaining a copy of the summary may e-mail, call, or mail in a request to Ashlyn Torrez at the Division of Public and Behavioral Health at:

Division of Public and Behavioral Health
500 Damonte Ranch Pkwy, Suite 657
Reno, NV 89521
Ashlyn Torrez
Phone: 775-447-0263
Email: atorrez@health.nv.gov

Certification by Person Responsible for the Agency

I, Lisa Sherych, Administrator of the Division of Public and Behavioral Health 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: 12/15/2022

PROPOSED REGULATION OF THE

STATE BOARD OF HEALTH

LCB File No. R107-22

July 15, 2022

EXPLANATION – Matter in ***italics*** is new; matter in brackets **[**~~omitted material~~**]** is material to be omitted.

AUTHORITY: § 1, NRS 439.200, 439.4931, 439.4933 and 439.4935; § 2, NRS 439.200 and 439.4931; § 3, NRS 439.150, 439.200 and 439.4933; § 4, NRS 439.150, 439.200, 439.4931 and 439.4935.

A REGULATION relating to public health; prescribing requirements concerning the reporting of information for inclusion in the system for the reporting of information on sickle cell disease and its variants; authorizing a facility or provider of health care to request that information be abstracted from its records for inclusion in the system; prescribing certain fees; authorizing certain persons and entities to obtain information from the system; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law requires the Chief Medical Officer to establish and maintain a system for the reporting of information on sickle cell disease and its variants. Existing law requires hospitals, medical laboratories and other facilities that provide screening, diagnostic or therapeutic services to patients with respect to sickle cell disease and its variants and providers of health care who diagnose or provide treatment for sickle cell disease and its variants to report to the system the information prescribed by regulation of the State Board of Health. (NRS 439.4929, 439.4931) **Section 2** of this regulation prescribes: (1) the form and manner of making such a report; (2) the information that must be included in a report; and (3) the time by which a facility or provider of health care is required to submit a report. **Section 2** also requires a facility or provider of health care that makes a report to provide any additional information requested by the Chief Medical Officer. **Section 2** also clarifies the cases for which a report must be submitted and establishes an administrative penalty for failure to submit a report when required. **Section 3** of this regulation authorizes a facility or provider of health care that would otherwise be required to make a report to instead request that the Division of Public and Behavioral Health of the Department of Health and Human Services abstract the required information from the records of the facility or provider for a fee.

Existing law requires the Board to adopt regulations establishing a protocol for allowing appropriate access to and preserving the confidentiality of the records of patients needed for research into sickle cell disease and its variants. (NRS 439.4931) Existing law also provides for the disclosure of data from the system to qualified scientific researchers who: (1) comply with appropriate conditions, as established under the regulations of the Board; and (2) pay a fee

established by regulation to cover the cost of providing the data. (NRS 439.4935) **Section 4** of this regulation prescribes the persons and entities to whom the Chief Medical Officer is authorized to disclose information in the system, including a qualified scientific researcher who: (1) enters into an agreement with the Chief Medical Officer concerning the use of the information that ensures the confidentiality of the information; and (2) pays a prescribed fee.

Section 1. Chapter 439 of NAC is hereby amended by adding thereto the provisions set forth as sections 2, 3 and 4 of this regulation.

Sec. 2. ***1. Except as otherwise provided in this section and section 3 of this regulation, each facility described in subsection 3 of NRS 439.4929 and each provider of health care described in subsection 4 of that section shall report the information prescribed by subsection 3 of this section to the Chief Medical Officer on a paper or electronic form prescribed by the Chief Medical Officer.***

2. A facility or provider of health care shall submit a report pursuant to subsection 1 for each patient for whom:

(a) The facility or provider of health care diagnoses a case of sickle cell disease and its variants; or

(b) Sickle cell disease and its variants is the primary complaint of the patient,

➥ as documented in the description of the diagnosis of the patient in the record of the patient by the use of a code established in the International Classification of Diseases, Tenth Revision, Clinical Modification, adopted by the National Center for Health Statistics and the Centers for Medicare and Medicaid Services, or the code used in any successor classification system adopted by the National Center for Health Statistics and the Centers for Medicare and Medicaid Services, for which "sickle cell" is listed in the description of the diagnosis.

3. Each report submitted pursuant to subsection 1 must include:

(a) The name, address, date of birth, sex at birth, gender identity or expression, race and ethnicity of the patient;

(b) The name, address and telephone number of the facility or provider of health care;

(c) The date on which the facility or provider of health care diagnosed or treated the patient;

(d) If the facility or provider of health care referred the patient to a hospital, medical laboratory or other facility for further diagnosis or treatment for sickle cell disease and its variants, the name, address and telephone number of that hospital, medical laboratory or other facility; and

(e) The information prescribed by paragraphs (b), (c), (d) and (f) of subsection 2 of NRS 439.4931.

4. If the Chief Medical Officer requests any additional information from a facility or provider of health care that submits a report pursuant to this section, the facility or provider of health care shall provide that information to the Chief Medical Officer.

5. A report pursuant to this section must be made:

(a) For a diagnosis made or an encounter with a patient for whom sickle cell disease and its variants was the primary complaint that occurs on or before June 30 of any calendar year, not later than September 30 of that calendar year.

(b) For a diagnosis made or an encounter with a patient for whom sickle cell disease and its variants was the primary complaint that occurs after June 30 of any calendar year, not later than March 31 of the immediately following calendar year.

6. A person or entity who owns and operates multiple facilities that are required to submit a report pursuant to this section may submit one report for all such facilities and is not required to segregate the information in the report by facility or provider of health care.

7. A case shall be deemed not to have been directly referred to a provider of health care or previously admitted to a hospital, medical laboratory or other facility for the purposes of subsection 4 of NRS 439.4929, and a provider of health care shall submit a report pursuant to subsection 1 for such a case, if:

(a) Sickle cell disease and its variants is the primary complaint that resulted in the visit to the provider of health care; or

(b) The provider of health care initiates a new treatment for sickle cell disease and its variants.

8. A hospital that reports information concerning the discharge of patients to the Department pursuant to NRS 449.485:

(a) Is not required to submit a report pursuant to this section; and

(b) Shall provide to the Chief Medical Officer upon request any records or other information related to a case of sickle cell disease and its variants.

9. The Division shall impose against each facility or provider of health care that fails to comply with the requirements of this section an administrative penalty of $200 for each calendar year in which such a failure occurs.

Sec. 3. *1. A facility described in subsection 3 of NRS 439.4929 or a provider of health care described in subsection 4 of that section may request that the Division abstract the information prescribed by section 2 of this regulation from the records of the facility or the*

provider. Such a request must be made before the date by which the facility or provider is required by subsection 5 of section 2 of this regulation to report the information.

2. The Division shall charge a facility or a provider of health care from whom information is abstracted pursuant to this section a fee of $50 for each hour of time spent by an employee of the Division to abstract the information.

Sec. 4. *1. Except as otherwise provided in subsection 2, a record of a patient in the system for the reporting of information on sickle cell disease and its variants established pursuant to NRS 439.4929 is confidential.*

2. The Chief Medical Officer may disclose information from the record of a patient in the system for the reporting of information on sickle cell disease and its variants established pursuant to NRS 439.4929 to:

(a) The patient to whom the record pertains and any legal representative of such a patient;

(b) The hospital, medical laboratory, other facility or provider of health care who reported the information or from whom the record was abstracted;

(c) Any other hospital, medical laboratory, other facility or provider of health care that participated in treating the patient or any registry associated with such a hospital, medical laboratory, other facility or provider of health care;

(d) A registry maintained by another governmental entity in the United States that enters into an agreement with the Chief Medical Officer concerning the use of the information that ensures the confidentiality of the information; or

(e) A qualified researcher whom the Division determines will conduct valid scientific research with the information and who:

(1) Enters into an agreement with the Chief Medical Officer concerning the use of the information that ensures the confidentiality of the information; and

(2) Pays a fee of $200 or the actual cost to the Division of providing the information to the researcher, whichever is greater.

SMALL BUSINESS IMPACT STATEMENT 2022

PROPOSED AMENDMENTS TO NAC 439 THROUGH LCB FILE NO. R108-22

The Division of Public and Behavioral Health (DPBH) has determined that the proposed amendments to the Nevada Administrative Code (NAC) Chapter439, through Legislative Counsel Bureau (LCB) File No. R108-22 will not have an adverse effect upon a small business, 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

The Nevada Department of Health and Human Services (DHHS) has drafted revisions to Nevada Administrative Code (NAC) Chapter 439 in accordance with Senate Bill 175 (SB 175) from the 2021 Legislative Session.

SB175 revises provisions relating to rare disease and establishing a system for the reporting and analysis of certain information as it relates to lupus and its variants. This will allow for DPBH to better understand the needs of patients living with lupus throughout the state. Additionally, this information will allow for developing programs and support systems for people living with lupus, and others who may be impacted by it.

Current regulations do not require Nevada-licensed health facilities to report on Lupus and its variants to the Chief Medical Officer. The proposed regulation will update and require Nevada-licensed health facilities to report a case of diagnoses of lupus and its variants, and report lupus and its variants if it is the primary complaint of the patient. Additionally, any new lupus treatment as indicated by the provider of health care.

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.**

The survey was posted as an online survey to the Office of Public Health Investigations and Epidemiology (OPHIE) website.

Individuals had the option to complete the survey online or mail, fax, or email your completed on or prior to Friday, December 9, 2022 to:

Ashlyn Torrez, Health Program Specialist I
Office of Public Health Investigations & Epidemiology
4150 Technology Way, STE 300
Carson City, NV 89706
Phone Number: (775) 447-0263
Email Address: atorrez@health.nv.gov
FAX: (775) 684-5999

The online survey was emailed 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 on November 8, 2022. As of 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.

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 (1 response were received)				
How many employees are currently employed by your business?	**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?**
1-149	Yes – 0 No – 1	Yes – 0 No – 1	Yes – 0 No – 1	Yes – 0 No – 1

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

An online small business impact survey was distributed via email and posted publicly to the DPBH OPHIE website, as described above. All questionnaire responses were conducted via the web, and none were received via email, fax, or mail. The proposed regulations, existing regulations, and the one (1) survey response were analyzed by the OPHIE Manager and the Health Program Specialist I to determine if the proposed regulations had an impact on small businesses or if it was existing regulations that had an impact on small businesses. This statement was prepared by the OPHIE Manager and the Health Program Specialist I.

A Public Workshop will be held January 9, 2023, to continue to obtain feedback on the proposed regulations.

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.

- Direct beneficial effects:
  - Will establish a system of reporting for lupus and its variants.

- Indirect beneficial effects:
  - Increase in diagnosis and treatment of lupus.

- Direct adverse effects:
  - No significant adverse economic effects are anticipated.
- Indirect adverse effects:
  - None anticipated.

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.

DPBH has held several opportunities for businesses to provide input and comments regarding the proposed SB 175 regulations, including the economic impact the proposed regulations may have on their business. Modifications to the proposed regulations have been made because of this input. A public workshop will be held on January 9, 2023, allowing for further input by businesses regarding the proposed regulations and how they will impact their businesses. These comments will be taken into consideration for possible further revisions to the regulations to reduce the economic impact on facilities.

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

These proposed regulations will not have any direct cost to the agency.

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 regulations will not add a new fee or increase any 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.

Lupus is not a nationally reportable condition, so this requirement could be considered more stringent than federal requirements. These regulations are a result of Senate Bill 175 (SB 175) from the 2021 Legislative Session. These regulations were deemed necessary so Nevada could better understand the needs of patients living with lupus throughout the state. Additionally, this information will allow for developing programs and support systems for people living with lupus, and others who may be impacted by it.

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

In summary, the proposed regulations Legislative Counsel Bureau (LCB) file no. R108-22, in carrying out the provisions of SB 175 to update NAC 439, will not have an adverse financial impact on the programs and/or small businesses. LCB file no. R108-22 will significantly benefit residents within the State of Nevada by:

1) Increase diagnosis and treatment for lupus and its variants.
2) Agency and state will have a better understanding of lupus.
3) Will establish a system for reporting of lupus and its variants.

Any other persons interested in obtaining a copy of the summary may e-mail, call, or mail in a request to Ashlyn Torrez at the Division of Public and Behavioral Health at:

Division of Public and Behavioral Health
500 Damonte Ranch Pkwy, Suite 657
Reno, NV 89521
Ashlyn Torrez
Phone: 775-447-0263
Email: atorrez@health.nv.gov

Certification by Person Responsible for the Agency

I, Lisa Sherych, Administrator of the Division of Public and Behavioral Health 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: 12/15/2022

PROPOSED REGULATION OF THE

STATE BOARD OF HEALTH

LCB File No. R108-22

July 15, 2022

EXPLANATION – Matter in ***italics*** is new; matter in brackets **[**~~omitted material~~**]** is material to be omitted.

AUTHORITY: § 1, NRS 439.200, 439.4978, 439.498 and 439.4982; § 2, NRS 439.200, 439.4978 and 439.498; § 3, NRS 439.150, 439.200, 439.4978 and 439.4982.

A REGULATION relating to public health; prescribing requirements concerning the reporting of information for inclusion in the system for the reporting of information on lupus and its variants; authorizing a facility or provider of health care to request that information be abstracted from its records for inclusion in the system; prescribing certain fees; authorizing certain persons and entities to obtain information from the system; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law requires the Chief Medical Officer to establish and maintain a system for the reporting of information on lupus and its variants. Existing law requires hospitals, medical laboratories and other facilities that provide screening, diagnostic or therapeutic services to patients with respect to lupus and its variants and providers of health care who diagnose or provide treatment for lupus and its variants to report to the system the information prescribed by regulation of the State Board of Health. (NRS 439.4976, 439.4978) **Section 2** of this regulation prescribes: (1) the form and manner of making such a report; (2) the information that must be included in a report; and (3) the time by which a facility or provider of health care is required to submit a report. **Section 2** also requires a facility or provider of health care that makes a report to provide any additional information requested by the Chief Medical Officer. **Section 2** authorizes a facility or provider of health care that would otherwise be required to make a report to instead request that the Division of Public and Behavioral Health of the Department of Health and Human Services abstract the required information from the records of the facility or provider, as applicable. **Section 2** also clarifies the cases for which a report must be submitted and establishes an administrative penalty for failure to submit a report when required.

Existing law requires the Board to adopt regulations establishing a protocol for allowing appropriate access to and preserving the confidentiality of the records of patients needed for research into lupus and its variants. (NRS 439.4978) Existing law also provides for the disclosure of data from the system to qualified scientific researchers who: (1) comply with appropriate conditions, as established under the regulations of the Board; and (2) pay a fee established by regulation to cover the cost of providing the data. (NRS 439.4982) **Section 3** of this regulation prescribes the persons and entities to whom the Chief Medical Officer is authorized to disclose

information in the system, including a qualified scientific researcher who: (1) enters into an agreement with the Chief Medical Officer concerning the use of the information that ensures the confidentiality of the information; and (2) pays a prescribed fee.

Section 1. Chapter 439 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 and 3 of this regulation.

Sec. 2. ***1. Except as otherwise provided in this section, each facility described in subsection 3 of NRS 439.4976 and each provider of health care described in subsection 4 of that section shall report the information prescribed by subsection 3 of this section to the Chief Medical Officer on a paper or electronic form prescribed by the Chief Medical Officer.***

2. A facility or provider of health care shall submit a report pursuant to subsection 1 for each patient for whom:

(a) The facility or provider of health care diagnoses a case of lupus and its variants; or

(b) Lupus and its variants is the primary complaint of the patient,

➥ as documented in the description of the diagnosis of the patient in the record of the patient by the use of a code established in the International Classification of Diseases, Tenth Revision, Clinical Modification, adopted by the National Center for Health Statistics and the Centers for Medicare and Medicaid Services, or the code used in any successor classification system adopted by the National Center for Health Statistics and the Centers for Medicare and Medicaid Services, for which "lupus" is listed in the description of the diagnosis.

3. Each report submitted pursuant to subsection 1 must include:

(a) The name, address, date of birth, sex at birth, gender identity or expression, race and ethnicity of the patient;

(b) The name, address and telephone number of the facility or provider of health care;

(c) The date on which the facility or provider of health care diagnosed or treated the patient;

(d) If the facility or provider of health care referred the patient to a hospital, medical laboratory or other facility for further diagnosis or treatment for lupus and its variants, the name, address and telephone number of that hospital, medical laboratory or other facility;

(e) Any other significant comorbidities with which the patient has been diagnosed, including, without limitation, kidney disease, cardiovascular disease, diabetes, fibromyalgia, any autoimmune disease other than lupus and its variants or severe skin infection; and

(f) The information prescribed by paragraphs (b), (c) and (f) of subsection 2 of NRS 439.4978.

4. If the Chief Medical Officer requests any additional information from a facility or provider of health care that submits a report pursuant to this section, the facility or provider of health care shall provide that information to the Chief Medical Officer.

5. A report pursuant to this section must be made:

(a) For a diagnosis made or an encounter with a patient for whom lupus and its variants was the primary complaint that occurs on or before June 30 of any calendar year, not later than September 30 of that calendar year.

(b) For a diagnosis made or an encounter with a patient for whom lupus and its variants was the primary complaint that occurs after June 30 of any calendar year, not later than March 31 of the immediately following calendar year.

6. A person or entity who owns and operates multiple facilities that are required to submit a report pursuant to this section may submit one report for all such facilities and is not required to segregate the information in the report by facility or provider of health care.

7. A case shall be deemed not to have been directly referred to a provider of health care or previously admitted to a hospital, medical laboratory or other facility for the purposes of subsection 4 of NRS 439.4976, and a provider of health care shall submit a report pursuant to subsection 1 for such a case, if:

(a) Lupus and its variants is the primary complaint that resulted in the visit to the provider of health care; or

(b) The provider of health care initiates a new treatment for lupus and its variants.

8. A hospital that reports information concerning the discharge of patients to the Department pursuant to NRS 449.485:

(a) Is not required to submit a report pursuant to this section; and

(b) Shall provide to the Chief Medical Officer upon request any records or other information related to a case of lupus and its variants.

9. A facility or provider of health care required to submit a report pursuant to this section may request that the Division abstract the information prescribed by subsection 3 from the records of the facility or the provider. Such a request must be made before the date by which the facility or provider is required by subsection 5 to report the information.

10. The Division shall impose against each facility or provider of health care that fails to comply with the requirements of this section an administrative penalty of $200 for each calendar year in which such a failure occurs.

Sec. 3. *1. Except as otherwise provided in subsection 2, a record of a patient in the system for the reporting of information on lupus and its variants established pursuant to NRS 439.4976 is confidential.*

2. The Chief Medical Officer may disclose information from the record of a patient in the system for the reporting of information on lupus and its variants established pursuant to NRS 439.4976 to:

(a) The patient to whom the record pertains and any legal representative of such a patient;

(b) The hospital, medical laboratory, other facility or provider of health care who reported the information or from whom the record was abstracted;

(c) Any other hospital, medical laboratory, other facility or provider of health care that participated in treating the patient or any registry associated with such a hospital, medical laboratory, other facility or provider of health care;

(d) A registry maintained by another governmental entity in the United States that enters into an agreement with the Chief Medical Officer concerning the use of the information that ensures the confidentiality of the information; or

(e) A qualified researcher whom the Division determines will conduct valid scientific research with the information and who:

(1) Enters into an agreement with the Chief Medical Officer concerning the use of the information that ensures the confidentiality of the information; and

(2) Pays a fee of $200 or the actual cost to the Division of providing the information to the researcher, whichever is greater.