## **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 mould 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 <u>International Classification of Diseases, Tenth</u> <u>Revision, Clinical Modification</u>, 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.