PROPOSED REGULATION OF THE STATE BOARD OF HEALTH

LCB FILE NO. R108-22I

The following document is the initial draft regulation proposed by the agency submitted on 06/24/2022

PROPOSED REGULATIONS OF THE STATE BOARD OF HEALTH

Italics, blue: New proposed language

[Red]: Removed language

AUTHORITY: Senate Bill 175 of the 81st Legislative Session (2021);

Section 1. Chapter 439 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 13, inclusive, of this regulation.

Sec. 2. As used in sections 2 to 12, inclusive, of this regulation, unless the context otherwise requires, the words and terms have the meanings ascribed to them in those sections of Senate Bill 175 of the 81st Legislative Session.

Sec. 5. "System" means the system established pursuant to section 5 of Senate Bill 175 of the 81st Legislative Session for the reporting of information on lupus and its variants.

Sec. 5. 1. Except as otherwise provided in section 7 of this regulation, any healthcare facility, medical laboratories and other provider of healthcare that diagnoses lupus and its variants or sees an individual where lupus is their primary complaint, per ICD-10 code that lists 'lupus' in the description shall report to the Chief Medical Officer using an electronic or paper form prescribed by the Chief Medical Officer:

- (a) The name, address, date of birth, gender, sex at birth, 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 patient was diagnosed or treated;
- (d) The name, address and telephone number of any hospital, medical laboratory or other facility to which the patient was referred for further diagnosis or treatment;
- (e) The variant of lupus with which the patient has been diagnosed;
- (f) The method of treatment, including, without limitation, any opioid prescribed;
- (g) Any other significant co-morbidities from which the patient has been diagnosed with, to include but not limited to: kidney disease, cardiovascular disease, diabetes, fibromyalgia,

other autoimmune disease, and severe skin infections;

- (h) If a patient diagnosed with lupus and its variants dies, his or her age at death; and
- (i) Any other information requested by the Chief Medical Officer.
- 3. A company that owns and operates multiple health care facilities may satisfy the requirements set forth in this section for all such health care facilities in one report without segregating by health care facility, or by provider of health care, the records subject to reporting.
- 4. Providers are exempt from reporting pursuant to subsection 1 for cases directly referred to the provider or cases that have been previously admitted to a hospital, medical laboratory or other facility, unless lupus is the primary complaint for the individuals medical visit or if the provider initiates a new course of treatment for lupus.
- 5. Hospitals that report discharge data to the division are exempt from reporting, but must provide additional medical records or patient details for specific individuals when requested by the Division.

Sec. 6.

A report required pursuant to section 5, subsection 1 must be made:

- (a) For a diagnosis made, medical visit where lupus was the primary complaint, and treatment initiated on or after January 1 and on or before June 30 of any calendar year, not later than September 30 of the same calendar year.
- (b) For a diagnosis made, medical visit where lupus was the primary complaint, and treatment initiated on or after July 1 and on or before December 31 of any calendar year, not later than March 31 of the immediately following calendar year.
- Sec. 7. 1. Any healthcare facility, medical laboratories and other provider of healthcare that provides screening, diagnostic or therapeutic services to patients with respect to lupus and its variants or provider of health care may request that the Division collect the information described in

section 5 or 6, as applicable, of this regulation, from the records of the facility or provider.

- 2. A request made pursuant to subsection 1 must be made before the date by which the provider is otherwise required to report the information pursuant to section 5 or 6, as applicable, of this regulation.
- 3. If the Division collects information from a facility or provider upon a request made pursuant to subsection 1, the provider must pay the fee prescribed by section 13 of this regulation. Any healthcare facility, medical laboratory and/or other provider of healthcare that diagnoses lupus and its variants and/or care for individuals where lupus is their primary complaint that do not fulfill this requirement will be subject to a \$200 fee annually, per calendar year.
- Sec. 8. 2. A qualified researcher in lupus and its variants who applies for access to the records shall be granted access, pursuant to Division data usage agreement policies that are in place to protect confidentiality, while promoting access to epidemiological data that could improve health care outcomes for individuals diagnosed with lupus and its variants. Data requests could be subject to the fees described in section 13.
- Sec 11. 1. Any record maintained in the system that contains the name of a patient or other information about a patient is confidential. The Chief Medical Officer or any employee of the Division shall not disclose the existence or nonexistence in the system of a record concerning any patient or disclose other information about the patient except to:
 - (a) The patient or a legal representative of the patient;
 - (b) The provider of health care who treated the patient;
- (c) The healthcare facility, medical laboratory and other provider of healthcare that provides screening, diagnostic or therapeutic services to patients with respect to lupus and its variants where the patient was treated;
 - (d) If the requirements of subsection 4 are met, a health care facility, medical laboratory or

other facility that provides screening, diagnostic or therapeutic services to patients with respect to lupus and its variants which participated in the treatment or diagnosis of the patient or a registry connected with one of those entities;

(e) A registry maintained by another state of the United States or a territory or insular possession subject to the jurisdiction of the United States that has entered into an agreement with the Chief Medical Officer to ensure the confidentiality of the record.

Sec. 12. The Division shall impose and collect the following fees:

- 1. For collecting information pursuant to section 7, subsection 3 of this regulation, a fee based on the actual costs incurred by the Division to collect the required information.
- 2. For collecting information pursuant to section 8 of this regulation, a fee of \$200 or the actual cost to the Division of providing the data, whichever is greater can be charged to a medical researcher to fulfill a significant data request.