PROPOSED REGULATION OF THE

STATE BOARD OF HEALTH

LCB File No. R107-20

August 20, 2021

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

AUTHORITY: §§ 1-4, 9 and 10, NRS 439.200 and 439.4931; §§ 5-7, NRS 439.200, 439.4929, 439.4931 and 439.4933; §§ 8 and 11, NRS 439.200, 439.4931 and 439.4935; § 12, NRS 439.200, 439.4931 and 439.4933; § 13, NRS 439.150, 439.200, 439.4931, 439.4933 and 439.4935.

A REGULATION relating to health care; requiring the reporting of certain information concerning cases of sickle cell disease and its variants for inclusion in the system for the reporting and maintenance of such information; providing for the confidentiality of certain information of the system; authorizing the disclosure of such information to certain persons; authorizing the imposition of an administrative penalty for failure to comply with requirements to report information for inclusion in the system; imposing fees for certain services relating to 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 and maintenance of information on sickle cell disease and its variants. (NRS 439.4929) Existing law requires the State Board of Health to adopt regulations: (1) prescribing the manner in which such information must be reported and the information that must be included in each report; and (2) 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) **Sections 2-4** of this regulation define necessary terms. **Sections 5 and 6** of this regulation prescribe: (1) the information that a facility which provides screening, diagnostic or therapeutic services with respect to sickle cell disease and its variants or a provider of health care is required to report to the Chief Medical Officer; (2) the manner in which such information must be reported; and (3) the dates by which the information must be reported. **Sections 7 and 13** of this regulation authorize a facility or provider to request that the Division of Public and Behavioral Health of the Department of Health and Human Services collect the required information from the records of the facility or provider for a fee. **Section 12** of this regulation provides for the imposition of an administrative penalty against a facility or provider that fails to: (1) report the required information; or (2) request that the Division collect the information in a timely manner.

Section 8 of this regulation: (1) provides that information of the system concerning a patient is, in general, confidential; (2) prescribes the persons and entities to whom the Chief Medical Officer is authorized to disclose such information; (3) requires a person with whom the Chief Medical Officer contracts to perform services using confidential information of the system to keep the information confidential; and (4) prescribes requirements governing the disclosure of confidential information to authorized persons by mail or via telephone. **Sections 9 and 10** of this regulation prescribe requirements for maintaining the confidentiality of information of the system. **Section 11** of this regulation requires a person who desires to use the confidential records of individual patients or the statistical data of the system for the purpose of scientific research into sickle cell disease and its variants to apply to the Chief Medical Officer. **Section 11** also prescribes the conditions for approving such an application. **Section 13** of this regulation prescribes the fee that the Chief Medical Officer will charge to such a person for access to that information.

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 13, inclusive, of this regulation, unless the context otherwise requires, the words and terms defined in sections 3 and 4 of this regulation have the meanings ascribed to them in those sections.***

Sec. 3. ***"Medical laboratory" has the meaning ascribed to it in NRS 652.060.***

Sec. 4. ***"System" means the system established pursuant to NRS 439.4929 for the reporting of information on sickle cell disease and its variants.***

Sec. 5. ***1. Except as otherwise provided in section 7 of this regulation, a health care facility, other facility that provides screening, diagnostic or therapeutic services to patients with respect to sickle cell disease and its variants, other than a medical laboratory, or provider of health care that diagnoses or treats a case of sickle cell disease or its variants 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, 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 sickle cell disease with which the patient has been diagnosed;

(f) The method of treatment, including, without limitation, any opioid prescribed for the patient and whether the patient has adequate access to that opioid;

(g) Any other diseases from which the patient suffers, including, without limitation, pneumonia, asthma or gall bladder disease;

(h) If a patient diagnosed with sickle cell disease and its variants dies, his or her age at death; and

(i) Any other information requested by the Chief Medical Officer.

2. A report required pursuant to subsection 1 must be made:

(a) For a diagnosis made or treatment initiated on or after January 1 but on or before March 31 of any calendar year, not later than June 30 of the same calendar year.

(b) For a diagnosis made or treatment initiated on or after April 1 but on or before June 30 of any calendar year, not later than September 30 of the same calendar year.

(c) For a diagnosis made or treatment initiated on or after July 1 but on or before September 30 of any calendar year, not later than December 31 of the same calendar year.

(d) For a diagnosis made or treatment initiated on or after October 1 of any calendar year but on or before December 31 of that calendar year, not later than March 31 of the immediately following calendar year.

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.

Sec. 6. *Except as otherwise provided in section 7 of this regulation, not later than 30 days after completing a pathology report concerning a specimen that shows evidence of sickle cell disease or its variants, a medical laboratory shall report to the Chief Medical Officer using an electronic or paper form prescribed by the Chief Medical Officer:*

1. The name, address, date of birth, gender, race and ethnicity of the patient from whom the specimen was obtained;

2. The name, address and telephone number of the provider of health care who ordered the examination of the specimen;

3. The name, address and telephone number of the medical laboratory;

4. The final diagnosis provided in the pathology report; and

5. Any other information requested by the Chief Medical Officer.

Sec. 7. *1. A health care facility, medical laboratory, other facility that provides screening, diagnostic or therapeutic services to patients with respect to sickle cell disease 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 facility or 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 facility or provider must pay the fee prescribed by section 13 of this regulation.

Sec. 8. *1. Except as otherwise provided in sections 2 to 13, inclusive, of this regulation, any record maintained in the system that contains the name of a patient or other information about a patient is confidential.*

2. 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 health care facility, medical laboratory or other facility that provides screening, diagnostic or therapeutic services to patients with respect to sickle cell disease 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 sickle cell disease 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, the District of Columbia, the Commonwealth of Puerto Rico 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; or

(f) A qualified researcher in sickle cell disease and its variants who applies for access to the records pursuant to section 11 of this regulation.

3. If the Chief Medical Officer contracts with another person to perform data processing or other services using the confidential information of the system, the other person shall maintain the confidentiality of the information to the same extent as is required by sections 2 to 13, inclusive, of this regulation and shall not disclose any of the information to a third person without the prior approval of the Chief Medical Officer.

4. The Chief Medical Officer or an employee of the Division may provide confidential medical information of the system concerning a patient's medical treatment for sickle cell disease and its variants with any health care facility, medical laboratory or other facility that provides screening, diagnostic or therapeutic services to patients with respect to sickle cell disease and its variants or a registry connected with one of those entities which has participated or is participating in treating the patient's illness if the person seeking the information:

(a) Has been identified in the manner described in subsection 6;

(b) Furnishes the employee of the system with specific information, other than the patient's name, which is sufficient to identify the patient without using his or her name; and

(c) Gives assurances to the employee of the system that the confidentiality of the information will be maintained to the same extent as is required by sections 2 to 13, inclusive, of this regulation.

5. If confidential information of the system is to be mailed to a provider of health care, health care facility or other facility that provides screening, diagnostic or therapeutic services to patients with respect to sickle cell disease and its variants, the envelope or container must be

addressed directly to the provider of health care or to the person designated by the applicable facility to receive such information.

6. If an employee of the Division receives a request to provide confidential information over the telephone pursuant to this section, and the employee does not personally know the requester, the employee shall verify the identity of the requester by making a telephone call to the telephone number, listed in a directory or given by an operator, for the purported person or facility.

Sec. 9. *Each employee of the Division who has access to confidential information of the system shall comply with the following procedures for maintaining the confidentiality of the information:*

1. All files containing confidential information, including, without limitation, the indexes for access to other files, must be locked when not in use.

2. All files on a computer containing confidential information, including, without limitation, the indexes for access to other files, must be closed and protected by password when not in use.

3. Passwords created pursuant to subsection 2 must be changed at least every 30 days.

4. All documents containing confidential information must be out of sight when an employee is away from his or her desk.

5. The doors to the system must be locked at all times when the office is vacant.

Sec. 10. *Each employee of the Division who takes confidential information of the system outside the offices of the Division shall comply with the following procedures:*

1. Any documents or files on a computer containing confidential information must be kept in the employee's briefcase when the documents or files on a computer are not in use.

2. If the employee takes any such document or file on a computer home or to a hotel or motel, the employee must:

(a) Safeguard it to the greatest extent possible; and

(b) Protect it from view by unauthorized persons.

3. The contents of such a document or file on a computer must not be discussed with any person except:

(a) An employee of the Division authorized to access confidential information of the system; or

(b) As otherwise authorized by the Chief Medical Officer.

4. If a briefcase or other container with such a document or computer file is to be:

(a) Left in the employee's car, the briefcase or other container must be locked in the trunk of the car.

(b) Taken as baggage on an airplane, train, bus or other carrier, the briefcase or other container must be kept in the employee's possession and must not be checked with the carrier unless the size or weight of the container precludes it from being retained in the employee's possession.

Sec. 11. *1. A person who desires to use the confidential records of individual patients or the statistical data of the system for the purpose of scientific research into sickle cell disease and its variants must apply in writing to the Chief Medical Officer. The applicant must:*

(a) Set forth in the application:

(1) His or her qualifications as an epidemiologist, provider of health care or employee of a bona fide program of research into sickle cell disease and its variants or other qualification for using confidential information and statistical data in the system; and

(2) A description of the research project in which that information will be used.

(b) Sign a statement, on a form furnished by the Chief Medical Officer or a designee thereof, in which the applicant agrees not to make any copies of the records, and to maintain the confidentiality of the information in the records in the manner required by sections 2 to 13, inclusive, of this regulation.

(c) Agree to:

(1) Pay the fee prescribed by section 13 of this regulation;

(2) Submit to the Chief Medical Officer or the designee for review and approval any proposed publication which is based on or contains information obtained from the system;

(3) Notify the Chief Medical Officer if, at any time during the research project or before publishing any results, the applicant finds evidence of an increased risk or a decreased survival rate for sickle cell disease and its variants as compared to other states in either:

(I) A geographical area of this State; or

(II) A particular group of persons in this State, including, without limitation, a group of persons identifiable by age, gender, race, ethnicity, occupation, lifestyle or place of residence; and

(4) Include in any publication which is based on or contains information obtained from the system the following disclosure in substantially the following form:

The views expressed herein are solely those of the author and do not necessarily reflect the views of the Division of Public and Behavioral Health of the Nevada Department of Health and Human Services.

2. The Chief Medical Officer or the designee shall:

(a) Before a researcher is allowed access to information of the system, make a written finding that the researcher is qualified as a researcher and has a need for the information; and

(b) Notify the Division as soon as practicable after the Chief Medical Officer receives notice of a finding described in subparagraph (3) of paragraph (c) of subsection 1. The Division shall independently assess the validity of the finding before the material may be published or released by the researcher.

Sec. 12. *1. Before imposing an administrative penalty pursuant to this section, the Division shall give notice in the manner set forth in NAC 439.345 which includes, without limitation, a time determined by the Chief Medical Officer within which the facility or provider must correct the violation of NRS 439.4933 or section 5 or 6 of this regulation, as applicable. The Division may, for good cause shown, extend the time within which the facility or provider must correct the violation.*

2. If a facility or provider fails to correct an alleged violation of NRS 439.4933 or section 5 or 6 of this regulation, as applicable, for which a notice of violation has been issued pursuant to subsection 1 within the time allowed for correction, the Division may:

(a) Collect the information from the records of the facility or provider. If the Division does so, the Division must collect from the facility or provider the fee prescribed by section 13 of this regulation.

(b) Impose an administrative penalty against the facility or provider. Such administrative penalties must not exceed $5,000 per calendar year.

3. If a facility or provider is aggrieved by a decision of the Division relating to the imposition of an administrative penalty pursuant to this section, the aggrieved facility or provider may appeal the decision pursuant to the procedures set forth in NAC 439.300 to 439.395, inclusive.

4. If a company chooses to make the records subject to reporting available to the Chief Medical Officer or the Chief Medical Officer's representative for multiple health care facilities owned or operated by the company in the manner described in subsection 3 of section 5 of this regulation, any administrative penalty imposed by the Board pursuant to this section for the failure of any health care facility owned or operated by the company to comply with the requirements of section 5 of this regulation will be imposed upon the company rather than the health care facility.

Sec. 13. *The Division shall impose and collect the following fees:*

1. For collecting information pursuant to section 7 of this regulation or subsection 2 of section 12 of this regulation, a fee based on the actual costs incurred by the Division to collect the required information.

2. For allowing a medical researcher to obtain data from the registry, a fee of $200 or the actual cost to the Division of providing the data, whichever is greater.