REPORTING AND ANALYZING INFORMATION ON SICKLE CELL DISEASE (NRS 439.4921 to 439.4943)

Section 1. NAC 439.### Definitions. *(NRS 439.4931) As used in NAC ###.010 TO ###.###, inclusive, unless the context otherwise requires:*

1. *"Sickle Cell Disease and its variants" has the meaning ascribed to it in NRS 439.4927.*
2. *"Division" means the Division of Public and Behavioral Health of the Department of Health and Human Services.*
3. *"Health care facility" has the meaning ascribed to it in NRS 457.020.*
4. *"Medical laboratory" has the meaning ascribed to it in NRS 652.060.*
5. *"Provider of health care" has the meaning ascribed to it in NRS 629.031.*

Section 2. NAC 439.### Reporting and submitting of information by provider of health care, health care facility and certain other facilities; deadlines for submission; standards for reporting information; waiver of electronic submission. *(NRS 439.4931)*

1. *Each health care facility, other facility that provides screening, diagnostic or therapeutic services, and providers of health care shall provide to the Chief Medical Officer a report on each case of Sickle Cell Disease and its variants diagnosed and or treated by the facility or provider.*
2. *Any reporting entity as described in subsection 1 shall report electronically all Sickle Cell Disease and its variants in conformance with the standards for reporting information concerning Sickle Cell Disease and its variants as described in section 3.*
   - (a) *Each provider of health care, health care facility and other facility described in subsection 1 shall provide the information to the Chief Medical Officer required pursuant to subsection 1:*
     - (1) *For any diagnosis made or treatment initiated for Sickle Cell Disease and its variants in the first quarter of a calendar year (January 1 – March 31), on or before June 30 of the same calendar year;*
     - (2) *For any diagnosis made or treatment initiated for Sickle Cell Disease and its variants in the second quarter of a calendar year (April 1 – June 30), on or before September 30 of the same calendar year;*
     - (3) *For any diagnosis made or treatment initiated for Sickle Cell Disease and its variants in the third quarter of a calendar year (July 1 – September 30), on or before December 31 of the same calendar year;*
     - (4) *For any diagnosis made or treatment initiated for Sickle Cell Disease and its variants in the fourth quarter of a calendar year (October 1 – December 31), on or before March 31 of the subsequent calendar year;*
   - ~~*(b) Health care facility and other facility that provides screening, diagnostic or therapeutic services to patients with respect to Sickle Cell Disease and its variants shall provide the information to the Chief Medical Officer required pursuant to subsection 1 within 6 months after a patient is admitted, and initially diagnosed with or treated for Sickle Cell Disease and its variants.*~~
   - (c) *If the information is not received within the required timeframe or if the Sickle Cell Disease or variant case is not reported, the reporting entity will be notified in writing. If no corrective action is taken to comply within 30 days of the original letter, the reporting entity is subject to a fee as provided in NAC 439.###. If no response is received, the Division will collect the required information from the reporting entity and a fee will be charged as set forth in NAC 439.###.*
3. *A health care facility as ascribed under NRS 457.020 who fails to report will be notified in*

writing. If no corrective action is taken to comply within 30 days of the original letter, the health care facility is subject to an administrative penalty as provided in NAC 439.###. If the Division collects the required information from the health care facility an abstract fee for each report will be charged as set forth in NAC 439.###.

4. *Information shall be reported and submitted in an electronic or paper format as approved by the Chief Medical Officer. A waiver can be filed with the Chief Medical Officer who determines that such a waiver is in the best interests of the general public. Any reports received in paper format are subject to [~~a fee as set forth in NAC 439.###~~] the same requirements as the electronic format.*

Section 3. NAC 439.### Reporting of information by medical laboratory. *(NRS 439.4931)*

1. *A medical laboratory that obtains a specimen which, upon examination, shows evidence of Sickle Cell Disease or its variants shall, within 30 working days after the date that the pathology report is completed, provide information concerning its findings to the Chief Medical Officer using electronic or paper means approved by the Chief Medical Officer or a designee thereof.*
2. *The information provided by a medical laboratory pursuant to subsection 1 must include, without limitation, for each specimen which shows evidence of Sickle Cell Disease or its variants which are subject to reporting pursuant to NAC 439.###.:*

   (a) *The name, address, date of birth, race and ethnicity, of the person from whom the specimen was obtained;*
   (b) *The name, address and telephone number of the provider of health care who ordered the examination of the specimen;*
   (c) *The name, address and telephone number of the medical laboratory that examined the specimen;*
   (d) *The final diagnosis from the pathology report; and*
   (e) *~~[Any other relevant information from the pathology report.]~~ Any additional information requested by the Division.*

Section 4. NAC 439.### Reporting of information by provider of health care*. (NRS 439.4931)*

1. *A provider of health care who diagnoses or provides treatment to a case of Sickle Cell Disease or its variants shall, [~~within 3 months after the date of that visit~~], in the timeframe pursuant to section 2, subsection 2, paragraph a, provide information concerning its findings to the Chief Medical Officer using electronic or paper means approved by the Chief Medical Officer or a designee thereof.*
2. *Information provided by a provider of health care pursuant to subsection 1 must include, without limitation:*

   (a) *The name, address, date of birth, gender, race and ethnicity of the patient;*
   (b) *The name, address and telephone number of the provider of health care making the report;*
   (c) *The date and final diagnosis and treatment of the patient; and*
   (d) *The name, address and telephone number of the hospital, medical laboratory and other facility that provides services to patients with respect to Sickle Cell Disease or its variants to which the patient was referred or admitted.*
   (e) *The variant of sickle cell disease with which the person 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; and,*
   (g) *Any other disease from which the patient suffers, including, without limitation, pneumonia, asthma and gall bladder disease.*
   (h) *Other information as requested by the Division.*

Section 5. NAC 439.### Confidentiality of information; Persons with whom Chief Medical Officer contracts; Disclosure of information: Authorized recipients; verification of identity. (NRS 439.4931) *All documents in the possession of the registry which contain names of patients with respect to Sickle Cell Disease or other or its variants are confidential.*

1. *If the Chief Medical Officer contracts with another person to perform data processing or other services using the confidential information of the registry, the other person shall maintain the confidentiality of the information to the same extent as is required in this section, and shall not disclose any of the information to a third person without the prior approval of the Chief Medical Officer.*

2. *The Chief Medical Officer or person employed in the registry shall not disclose the existence or nonexistence in the registry of a record concerning any patient or disclose other information about the patient except to:*
   (a) *The patient or a legal representative;*
   (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 or its variants where the patient was treated;*
   (d) *A health care facility, medical laboratory or other facility that provides services to patients with respect to Sickle Cell Disease or its variants or a registry connected with one of those entities which has participated or is participating in treating the patient;*
   (e) *Other states' Sickle Cell Disease registries who have entered into data sharing agreement which ensure confidentiality; or*
   (f) *A qualified researcher in Sickle Cell Disease.*

3. *If a request for information about a patient is made over the telephone by the provider of health care who treated the patient or by a representative of the health care facility, medical laboratory or other facility that provides services to patients with respect to Sickle Cell Disease or its variants in which the patient was treated, and the caller is not known to the employee who receives the call at the registry, the employee must verify the identity of the caller in the manner described in NAC 439.###.*

Section 6. NAC 439.### Procedures for maintaining confidentiality of information. (NRS 439.4931) *Each employee of the Division who has access to confidential information of the registry shall comply with the following procedures for maintaining the confidentiality of that 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 registry must be locked at all times when the office is vacant.*

Section 7. NAC 439.### Procedures for taking confidential information outside offices of Division. (NRS 439.4931) *Each employee of the Division who takes confidential information of the registry 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 anyone outside the registry, expect as approved 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 container must be locked in the trunk of the car.*
   (b) *Taken as baggage on an airplane, bus or other carrier, the 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 its being retained in the employee's possession.*

Section 8. NAC 439.### Mailing of confidential information; list of persons authorized to receive confidential information. (NRS 439.4931) *If confidential information of the registry is to be mailed to a provider of health care, health care facility or other facility with respect to Sickle Cell Disease or its variants, the envelope or container must be addressed directly to the provider of health care or to the person designated by the health care facility or other facility that provides screening, diagnostic or therapeutic services to patients with respect to Sickle Cell Disease or its variants, to receive such information.*

~~*Section 9. NAC 439.### Persons with whom Chief Medical Officer contracts.* (NRS 439.4931) *If the Chief Medical Officer contracts with another person to perform data processing or other services using the confidential information of the registry, the other person shall maintain the confidentiality of the information to the same extent as is required in this section, and shall not disclose any of the information to a third person without the prior approval of the Chief Medical Officer.*~~

~~*Section 10. NAC 439.### Disclosure of information: Authorized recipients; verification of identity.* (NRS 439.4931)~~

~~1. *The Chief Medical Officer or person employed in the registry shall not disclose the existence or nonexistence in the registry of a record concerning any patient or disclose other information about the patient except to:*
   ~~(g) *The patient or a legal representative;*~~
   ~~(h) *The provider of health care who treated the patient;*~~
   ~~(i) *The health care facility, medical laboratory or other facility that provides screening, diagnostic or therapeutic services to patients with respect to Sickle Cell Disease or its variants where the patient was treated;*~~
   ~~(j) *A health care facility, medical laboratory or other facility that provides services to patients with respect to Sickle Cell Disease or its variants or a registry connected with one of those entities which has participated or is participating in treating the patient;*~~
   ~~(k) *Other states' Sickle Cell Disease registries who have entered into data sharing agreement which ensure confidentiality; or*~~
   ~~(l) *A qualified researcher in Sickle Cell Disease.*~~~~
2. *If a request for information about a patient is made over the telephone by the provider of*~~

~~*health care who treated the patient or by a representative of the health care facility, medical laboratory or other facility that provides services to patients with respect to Sickle Cell Disease or its variants in which the patient was treated, and the caller is not known to the employee who receives the call at the registry, the employee must verify the identity of the caller in the manner described in NAC 439.###.*~~

Section 11. NAC 439.### Disclosure of information: Requirements of person seeking information. *(NRS 439.4931) The Chief Medical Officer or a person employed in the registry may provide confidential medical information in the registry concerning a patient's medical treatment for Sickle Cell Disease or its variants to the patient or a legal representative, any health care facility, medical laboratory or other facility that provides services to patients with respect to Sickle Cell Disease or its variants or registry connected with one of those entities which has participated or is participating in treating that patient's illness if the person seeking the information:*

1. *Has been identified in the manner described in NAC 439.###;*
2. *Furnishes the employee of the registry with specific information, other than the patient's name, which is sufficient to identify the patient without using his or her name; and*
3. *Gives assurances to the employee of the registry that the confidentiality of the information will be maintained to the same extent as is required in NAC 439.###, inclusive.*

Section 12. NAC 439.### Verification of identity of person making request by telephone. *(NRS 439.4931) If an employee in the registry receives a request to provide confidential information over the telephone pursuant to NAC 439.###, 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.*

Section 13. NAC 439.### Disclosure of information: Scientific research into Sickle Cell Disease and its variants. *(NRS 439.4931)*

1. *A person who desires to use the confidential records of individual patients or the statistical data of the registry for the purpose of scientific research into Sickle Cell Disease or 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 or its variants or other qualification for using confidential information and statistical data in the registry; 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 NAC 439.###, inclusive.*
   - *(c) Agree to:*
     - *(1) 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 registry;*
     - *(2) 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 or 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

(3) Include in any publication which is based on or contains information obtained from the registry 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 Department of Health and Human Services.

2. The Chief Medical Officer or the designee must:

(a) Before a researcher is allowed access to information in the registry, 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 (2) 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.

Section 14. NAC 439.### Administrative penalty for violation; appeal; single report authorized for company that operates multiple facilities; imposition of administrative penalty upon company rather than facility. (NRS 439.4931, 439.4933)

1. A "violation" means a failure of a health care provider or health care facility as defined in section 2, subsection 1, to provide the information pursuant to section 4, subsection 2, a - h.
2. 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 person must correct the violation of NRS 439.4933. The Division may, for good cause shown, extend the time within which the person must correct the violation.
3. If a person fails to correct an alleged violation of NRS 439.4933 for which a notice of violation has been issued pursuant to subsection 1 within the time allowed for correction, the Division may impose an administrative penalty of not more than $5,000 per calendar year against the person.
4. If a person is aggrieved by a decision of the Division relating to the imposition of an administrative penalty pursuant to this section, the aggrieved person may appeal the decision pursuant to the procedures set forth in NAC 439.300 to 439.395, inclusive.
5. A company that owns and operates multiple health care facilities may satisfy the requirement set forth in subsection 1 of NRS 439.4933 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.
6. 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 4, 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 subsection 1 of NRS 439.4933 will be imposed upon the company rather than the health care facility.

Section 15. NAC 439.### Fees. (NRS 439.150, 439.4931, 439.4933, 439.4935***)*** *The Chief Medical Officer shall charge and collect from:*

1. *A health care facility who is required to report information on cases of Sickle Cell Disease or its variants pursuant to NRS 439.4929 or a health care facility or other facility that provides services to patients with respect to Sickle Cell Disease or its variants, a fee for:*
   - (a) *Each report prepared by the Division from the records of the facility. This fee is based on the actual cost incurred if Division staff enters the provider office or facility to collect the required information and [may include salary and travel expenses].*
   - ~~(b) [Each report that does not conform to the standards as outlined in NAC 439.### and requires additional data collection and editing .....$15]~~
   - ~~(c) [Each paper report that requires data entry in the registry system .....$35]~~
   - (d) *Each report not submitted in the required time frame or was missed by the provider or facility shall be charged a fee of $50.*
2. *A medical researcher who obtains data from the registry, a fee of $200 or the actual cost of providing the data, whichever is more.*