ADOPTED REGULATION OF THE

STATE BOARD OF HEALTH

LCB File No. R041-08

Effective September 18, 2008

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

AUTHORITY: §§1-7 and 9, 10, 12 and 13, NRS 439.200 and 439.265; §§8 and 11, NRS 439.200.

A REGULATION relating to public health; prescribing the provisions for the Immunization Information System established by the Department of Health and Human Services; and providing other matters properly relating thereto.

- **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 to 6, inclusive, of this regulation have the meanings ascribed to them in those sections.
 - Sec. 3. "Department" means the Department of Health and Human Services.
 - Sec. 4. "Health Division" means the Health Division of the Department.
- Sec. 5. "Provider" means any person who is licensed, certified or otherwise authorized by the laws of this State, or the regulations adopted pursuant thereto, to administer immunizations.
- Sec. 6. "System" means the Immunization Information System established by the Department pursuant to NRS 439.265.

- Sec. 7. 1. A provider administering an immunization to a child shall provide notice about the System to the parent or guardian of the child on a form provided by the Health Division. The notice must include:
 - (a) A description of the System;
- (b) A description of the information concerning the child which will be reported by the provider for inclusion in the System, including, without limitation, the immunization record of the child and the information required by section 10 of this regulation; and
- (c) The procedure for a parent or guardian to decline inclusion of the information concerning his child in the System.
- 2. The notice required by subsection 1 must be provided upon the initial visit of a child to a provider for administration of an immunization.
- 3. If a parent or guardian declines inclusion of the information concerning his child in the System, the parent or guardian is responsible for notifying the provider of his decision to opt out of the System at each subsequent visit of the child to the provider for an immunization.
- Sec. 8. 1. An adult may voluntarily participate in the System pursuant to the provisions of this section. A provider administering an immunization to an adult shall provide notice about the System to the adult on a form provided by the Health Division. The notice must include:
 - (a) A description of the System;
- (b) A description of the information concerning the adult which will be reported by the provider for inclusion in the System if the adult voluntarily participates in the System, including, without limitation, the immunization record of the adult and the information set forth in section 11 of this regulation; and

- (c) The procedure for an adult to withdraw inclusion of his information in the System.
- 2. The notice required by subsection 1 must be provided upon the initial visit of an adult to a provider for administration of an immunization.
- 3. An adult may only be included in the System if he provides written consent for his inclusion. An adult who provides such consent may withdraw his participation in the System at any time in accordance with the procedure prescribed by the Health Division.
- Sec. 9. 1. Except as otherwise provided in subsection 3, the Health Division shall include in the System all immunization records in the possession of the Health Division for immunizations of children and adults administered before July 1, 2009.
- 2. Except as otherwise provided in this subsection and subsection 3, a provider may report for inclusion in the System, on a form developed by the Health Division, the records of the immunizations administered to any child or adult before July 1, 2009, if such information was not previously reported. A provider may report the information concerning an adult only if the adult provides voluntary written consent for his participation in the System.
- 3. The Health Division shall develop and make available to providers and the general public the form by which the parent or guardian of a child or an adult may request the removal of the immunization records included in the System pursuant to this section.
- Sec. 10. 1. In addition to the information required by NRS 439.265, a provider who administers an immunization to a child on or after July 1, 2009, shall report the following information, if available, to the Department for inclusion in the System:
 - (a) The address of the child;
 - (b) The county in which the child resides;
 - (c) The child's date of birth;

- (d) The state and country in which the child was born;
- (e) The full name of the child's mother;
- (f) The manufacturer and lot number of the vaccine administered to the child; and
- (g) The date on which the immunization was administered to the child.
- 2. The Health Division shall provide the form for reporting the information required by subsection 1. A provider may report the information directly to the System or may use the form provided by the Health Division.
- Sec. 11. 1. A provider who administers an immunization to an adult on or after July 1, 2009, shall, upon the voluntary written consent of the adult pursuant to section 8 of this regulation, report the following information, if available, to the Department:
 - (a) The name and address of the person who received the immunization;
 - (b) The county in which the person resides;
 - (c) The person's date of birth;
 - (d) The state and country in which the person was born;
 - (e) The person's gender;
 - (f) The person's race or ethnicity;
 - (g) The manufacturer and lot number of the vaccine administered to the person; and
 - (h) The date on which the immunization was administered to the person.
- 2. The Health Division shall provide the form for reporting the information required by subsection 1. A provider may report the information directly to the System or may use the form provided by the Health Division.
- Sec. 12. Except as otherwise provided in NRS 439.265 or other specific statute, the information included in the System is confidential and access must be limited to:

- 1. A provider of health care as defined in NRS 439.820;
- 2. The Nevada System of Higher Education or a private college or university authorized to operate in this State;
 - 3. A child care facility as defined in NRS 432A.024;
- 4. Public schools and private schools as defined in NRS 385.007 and 394.103, respectively;
 - 5. The Department;
- 6. An insurer as defined in NRS 679B.540, regardless of whether the insurer directly covered the immunization;
 - 7. An agency which provides child welfare services as defined in NRS 432B.030; and
 - 8. The Department of Corrections.
- Sec. 13. An immunization record provided by the System shall be deemed an official certificate of immunization, as required for enrollment in any school, college or university and child care facility in this State.

NOTICE OF ADOPTION OF PROPOSED REGULATION LCB File No. R041-08

The State Board of Health adopted regulations assigned LCB File No. R041-08 which pertain to chapter 439 of the Nevada Administrative Code.

INFORMATIONAL STATEMENT

1. A description of how public comment was solicited, a summary of public response, and an explanation how other interested persons may obtain a copy of the summary.

Letters were sent to all entities that the Bureau of Community Health (BCH) could identify as possibly being affected by the regulations as well as local health authorities advising them of proposed changes in immunization requirements. The entities that were identified were immunization providers (both public and private), childcare facilities throughout the state, all public and private schools and all universities. These entities were provided with a copy of the proposed regulations as well as the Notice of Public Workshop and Notice of Public Hearing.

Public workshops were held in Las Vegas on August 20, 2007, Elko on August 22, 2007, and in Reno on August 23, 2007. The Notice of Public Workshop was published in the Las Vegas Review Journal and Reno Gazette Journal on July 30, 31, 2007 and August 1, 2007. Copies of the proposed regulations were sent to state and county offices statewide and all county libraries. In addition, the workshop notice was mailed to immunization providers, public and private schools, and universities.

The Notice of Public Hearing was published in the Las Vegas Review Journal and the Reno Gazette-Journal on April 18, 19, and 20, 2008. A copy of the notice was mailed to immunization providers, public and private schools, and universities.

Public comments received at the workshops and in writing were minimal. A total of eight individuals attended and testified at the workshops. All comments received during the workshops were in support of the proposed regulation amendments. One immunization provider expressed concerns in writing regarding additional recordkeeping duties and potential costs for staff needed to input the vaccinations into the IIS.

Interested persons may obtain a list of the recipients and a summary of written responses to the solicited comments by contacting Tami Chartraw, Immunization Registry Manager, Immunization Program, BCH, 4150 Technology Way, Suite 150, Carson City, NV 89706 or by calling 775-684-4032.

- 2. The number of persons who:
 - (a) Attended the hearing;
 - (b) Testified at each hearing; and
 - (c) Submitted to the agency written statements.

On June 20, 2008, the State Board of Health meeting was held in Carson City and via videoconference to Carson City.

- a. A total of 58 members of the public attended the hearing.
- b. A total of one (1) members of the public testified at the hearing regarding the proposed regulations.
- c. A total of four (4) written comments were received and included in the board packet.
- 3. A description of how comment was solicited from affected businesses, a summary of their response, and an explanation how other interested persons may obtain a copy of the summary.

Comments were solicited from businesses and the general public as indicated in the response to Question 1, so the response to this requirement is the same.

4. If the regulation was adopted without changing any part of the proposed regulation, a summary of the reasons for adopting the regulation without change. The statement should also explain the reasons for making any changes to the regulation as proposed.

Based on input from representatives of Southern Nevada Health District an errata was included in the presentation to the Board of Health. The change was to the required data elements in regulations. The change added the words "if available" to those required elements because of the differences in where inventory information is stored by Southern Nevada Health District. The change also allows providers that do not have access to all of the data elements to still be in compliance with the law.

- 5. The estimated economic effect of the regulation on the business which it is to regulate and on the public. These must be stated separately, and in each case must Include:
 - (a) Both adverse and beneficial effects; and
 - (b) Both immediate and long term effects.

Anticipated effects on the business which NAC 439 regulates:

- A. Adverse: None. Beneficial: Less immunization record scattering; reduction in duplicate vaccinations
- B. Immediate and Long-Term: None

Anticipated effects on the public which NAC 439 regulates:

- A. Adverse: None. Beneficial: Protection against vaccine preventable disease through better record-keeping.
- B. Immediate and Long-Term: None
- 6. The estimated cost to the agency for enforcement of the proposed regulation.

The estimated cost to the agency for enforcement of the proposed regulation is dependent on the number of providers that choose manual data entry over input into the registry. Until the law is in effect (July 1, 2009) it is impossible to determine the projected cost of state staff time for this data entry. Costs will be handled through the existing administrative process.

7. A description of any regulations of other state or government agencies which the proposed regulation overlaps or duplicates and a statement explaining why the duplication or overlapping is necessary. If the regulation overlaps or duplicates a federal regulation, name the regulating federal agency.

The proposed regulations do not overlap or duplicate any other Nevada state regulations.

8. If the regulation includes provisions which are more stringent than a federal regulation which regulates the same activity, a summary of such provisions.

The proposed regulations do not duplicate federal regulations.

9. If the regulation provides a new fee or increases an existing fee, the total annual amount the agency expects to collect and the manner in which the money will be used.

The amendments do not establish any new fees or increase any existing fees.

10. If the proposed regulation is likely to impose a direct and significant economic burden upon a small business or directly restrict the formulation, operation or expansion of a small business. What methods did the agency use in determining the impact of the regulation on a small business?

The proposed regulation is not expected to impose a direct and significant economic burden upon a small business any greater than that imposed by the statute. The regulations specify in more detail what data is to be reported and who may access the system. The regulation should assist in reducing time and effort needed to comply with the legislation by providing clear direction as to the data to be collected and reported.