

**ADOPTED REGULATION OF THE
STATE BOARD OF HEALTH**

LCB File No. R094-09

Effective January 28, 2010

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

AUTHORITY: §§1 and 4, NRS 439.200; §§2 and 3, NRS 439.200 and 439.265.

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

Section 1. Section 8 of LCB File No. R041-08 is hereby amended to read as follows:

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 *LCB File No. R041-08*; and
 - (c) The procedure for an adult to ~~{withdraw inclusion of}~~ *decline inclusion of* his *or her* 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.

4. If an adult declines inclusion of his or her information in the System, the adult is responsible for notifying the provider of the decision to opt out of the System at each subsequent visit of the adult to the provider for an immunization.

Sec. 2. Section 9 of LCB File No. R041-08 is hereby amended to read as follows:

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]~~ *to* 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]~~ *unless the adult has declined inclusion of his or her information* in the System ~~[.]~~ *pursuant to section 8 of LCB File No. R041-08.*

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. 3. Section 10 of LCB File No. R041-08 is hereby amended to read as follows:

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 ~~and~~; *and*

(h) The information required pursuant to the Listing of Core Data Items prescribed by the Centers for Disease Control and Prevention of the United States Department of Health and Human Services. A copy of the Listing of Core Data Items may be obtained, free of charge, from:

(1) The Centers for Disease Control and Prevention at the Internet address

<http://www.cdc.gov/vaccines/programs/iis/stds/coredata.htm>; or

(2) The Department by mail at 4126 Technology Way, Room 100, Carson City, Nevada 89706, or by telephone at (775) 684-4000.

2. The Health Division shall provide the form for reporting the information required by subsection 1. A provider ~~may~~ *shall* report the information ~~directly~~ :

(a) Directly to the System ; or ~~may use~~

(b) If an undue hardship prevents the provider from reporting the information directly to the System, using the form provided by the Health Division.

Sec. 4. Section 11 of LCB File No. R041-08 is hereby amended to read as follows:

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]~~ *unless* the adult *has declined inclusion of his or her information in the System* pursuant to section 8 of *LCB File No. R041-08*, 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 *name*, manufacturer and lot number of the vaccine administered to the person;

~~[and]~~

- (h) The date on which the immunization was administered to the person ~~[]~~; *and*
- (i) *The information required pursuant to the Listing of Core Data Items prescribed by the Centers for Disease Control and Prevention of the United States Department of Health and Human Services. A copy of the Listing of Core Data Items may be obtained, free of charge, from:*

(1) The Centers for Disease Control and Prevention at the Internet address

<http://www.cdc.gov/vaccines/programs/iis/stds/coredata.htm>; or

(2) The Department by mail at 4126 Technology Way, Room 100, Carson City, Nevada 89706, or by telephone at (775) 684-4000.

2. The Health Division shall provide the form for reporting the information required by subsection 1. A provider ~~{may}~~ **shall** report the information ~~{directly}~~ :

(a) ***Directly*** to the System ; or ~~{may-use}~~

(b) ***If an undue hardship prevents the provider from reporting the information directly to the System, using*** the form provided by the Health Division.

HEALTH DIVISION
Bureau of Child, Family and Community Wellness
Immunization Program, 2
LCB File # R094-09

Information Statement per NRS 233B.066

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.

Public workshops were held in Carson City and Las Vegas on July 6, 2009. Public workshop notices appeared in the Reno Gazette-Journal and the Las Vegas Review-Journal on June 10, 11 and 12, 2009. Copies of the proposed regulation amendments and Notice of Public Workshop were sent to state and county offices statewide, including all main public libraries. The notice and proposed regulation amendments were also sent by fax and email to vaccine providers statewide.

The Notice of Public Hearing was published in the Reno Gazette-Journal on November 13, 14 and 15, 2009 and the Las Vegas Review-Journal on November 10, 11 and 12, 2009. Copies of the Notice of Public Hearing and proposed regulation amendments were faxed and emailed to vaccine providers statewide and mailed to all main public libraries and county health departments on November 6, 2009.

No public comment was received regarding the proposed amendments. There were no attendees at either workshop location.

Copies may be obtained by contacting the State of Nevada Immunization Program by calling, 775-684-5900

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

- (a) 44
- (b) 1 person testified at the hearing
- (c) 1 person submitted a written statement in support of the amendment

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 from immunization providers were solicited during the draft proposal process by the Bureau of Child Family & Community Wellness and each provider received a Small Business Impact Questionnaire. A total of 178 questionnaires were faxed to immunization providers in the State of Nevada. No questionnaires were returned.

Copies of the summary of these questionnaires are available from the office of the Bureau of Child Family & Community Wellness, 4150 Technology Way, Suite 101, Carson City, Nevada 89706. The office may be contacted at 775-684-5900.

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.

The regulation was adopted without any changes since factors such as the proposed regulation were clear, no public comment or objection from small businesses were expressed and positive outcome of the regulation.

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.
 - (a) The beneficial economic effect of these regulations would be to establish statewide reporting of administered immunizations for all age groups.
 - (b) The adverse economic effect of these regulations would be additional administrative time to report immunization data.

6. The estimated cost to the agency for enforcement of the proposed regulation,

There is no estimated cost to the agency for enforcement of the proposed regulations.

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.

This regulation does not represent duplication of local, state or federal levels.

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

There are no federal regulations for the same activity.

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.

There are no fees associated with this regulation.

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?

Economic impacts will be minimal for small business. However BCFCW has hired three dedicated trainers to facilitate regular and frequent free statewide training sessions on the use of the registry. As an incentive, continuing education credits are offered to nurses and pharmacists attending the sessions. BCFCW is also working towards developing and offering methods of electronic data exchange to lessen the amount of administrative time used to report immunization data. To assist the agency with this project, the Nevada State Immunization Program was accepted as a participant in the Centers for Disease Control and Prevention's (CDC) Enhanced Technical Assistance Project. Three additional contractual staff were brought on by the program to assist providers in entering provider-specific historical immunization data into the registry.

Questionnaires were sent to 178 immunization providers throughout the State of Nevada to assess adverse economic effects, beneficial effects, indirect adverse effects and indirect benefits of the proposed regulation.