NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES NOTICE OF PUBLIC HEARING

October 15, 2019 1:00 p.m. Central Time Gold's Building, Room 534 1033 O Street, Lincoln, Nebraska

The purpose of this hearing is to receive comments on proposed changes to Title 173, Chapter 8 of the Nebraska Administrative Code (NAC) – Concerning the Establishment and Operation of the Nebraska State Immunization Information System. The chapter regulates the input, access, and transfer of data in the Immunization Information System. The proposed changes remove duplicative statutory language from the regulation and update formatting.

Authority for these regulations is found in Neb. Rev. Stat. § 81-3117(7).

Interested persons may attend the hearing and provide verbal or written comments or mail, fax or email written comments, no later than the day of the hearing to: DHHS Legal Services, PO Box 95026, Lincoln, NE 68509-5026, (402) 742-2382 or dhhs.regulations@nebraska.gov, respectively.

A copy of the proposed changes is available online at http://www.sos.ne.gov, or by contacting DHHS at the mailing address or email above, or by phone at (402) 471-8417. The fiscal impact statement for these proposed changes may be obtained at the office of the Secretary of State, Regulations Division, 1201 N Street, Suite 120, Lincoln, NE 68508, or by calling (402) 471-2385.

Auxiliary aids or reasonable accommodations needed to participate in a hearing can be requested by calling (402) 471-8417. Individuals with hearing impairments may call DHHS at (402) 471-9570 (voice and TDD) or the Nebraska Relay System at 711 or (800) 833-7352 TDD at least 2 weeks prior to the hearing.

FISCAL IMPACT STATEMENT

Agency: Department of Health and Human Services			
Title:173 Communicable diseases Prepared by:Obed Tompieu			
Chapter:8 Immunization information	Date prepared:5/22/2019		
System			
Subject: Immunization Information System	Telephone:4024713727		

Type of Fiscal Impact:

	State Agency	Political Sub.	Regulated Public
No Fiscal Impact	(⊠)	(⊠)	(図)
Increased Costs	(🗆)	(🗆)	(🗆)
Decreased Costs	(🗆)	(🗆)	(🗆)
Increased Revenue	(🗆)	(🗆)	(🗆)
Decreased Revenue	(🗆)	(🗆)	(🗆)
Indeterminable	(🗆)	(🗆)	(🗆)

Provide an Estimated Cost & Description of Impact:

State Agency:

Political Subdivision:

Regulated Public:

If indeterminable, explain why:

EFFECTIVE 6/21/2014

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES

173 NAC 8

TITLE 173 COMMUNICABLE DISEASES

CHAPTER 8 CONCERNING THE ESTABLISHMENT AND OPERATION OF THE NEBRASKA STATE IMMUNIZATION INFORMATION SYSTEM

<u>8-001 SCOPE AND AUTHORITY</u>: The purpose of these rules is to implement <u>Neb. Rev. Stat.</u> §§ 71-541 to 71-541.01 which authorizes the Department of Health and Human Services to establish an immunization information system (IIS) for the purpose of providing a central database of immunization information which can be accessed and used pursuant to these rules and regulations.

8-002 DEFINITIONS: When terms are used in 173 NAC 8, the following definitions apply:

<u>Authorized user</u> means all health care professionals, health care facilities, health care services, schools, postsecondary educational institutions, electronic health-record systems, public health departments, health departments of other states, Indian health services, and tribes who are permitted access to immunization records in the State Immunization Information System.

<u>Data encryption</u> means the electronic obfuscation of data within an electronic message using industry standard practices for encryption.

Department means the Department of Health and Human Services.

<u>Electronic health record (EHR) system</u> means any computerized or electronic system used to capture and store patient identifying health information including immunization data.

<u>Health care facility</u> means any facility licensed or exempt from licensure under the Health Care Facility Licensure Act.

<u>Health care professional</u> means any person authorized by law to order or administer an immunization.

<u>Health care service</u> means any service licensed or exempt from licensure under the Health Care Facility Licensure Act.

EFFECTIVE 6/21/2014

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES

173 NAC 8

<u>Health department of other states</u> means any State Health Department established to promote the health and well-being of all residents within its jurisdiction.

<u>Immunization standard message</u> means a standard electronic message meeting specifications as identified by current versions of the Nebraska State Immunization Information System *Flat File Specifications* or *HL7 Specifications for Immunization*.

<u>Licensed child care facility</u> means any facility or program licensed under the Child Care Licensing Act.

<u>Postsecondary educational institution</u> means any organization or business enterprise which offers courses or subjects for which tuition is charged, and at the place of business of which a course of instruction is available through classroom instruction, home study, or both to a person for the purpose of training, preparing, or improving the person for an occupation even though the organization's or business enterprise principal efforts may not be exclusively educational in nature.

<u>Local public health department</u> has the same meaning as in <u>Neb. Rev. Stat.</u> § 71-1626.

<u>Public health authority</u> means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

Real-time message means the transmission of discrete standard electronic messages to the Department as they are generated by the EHR system.

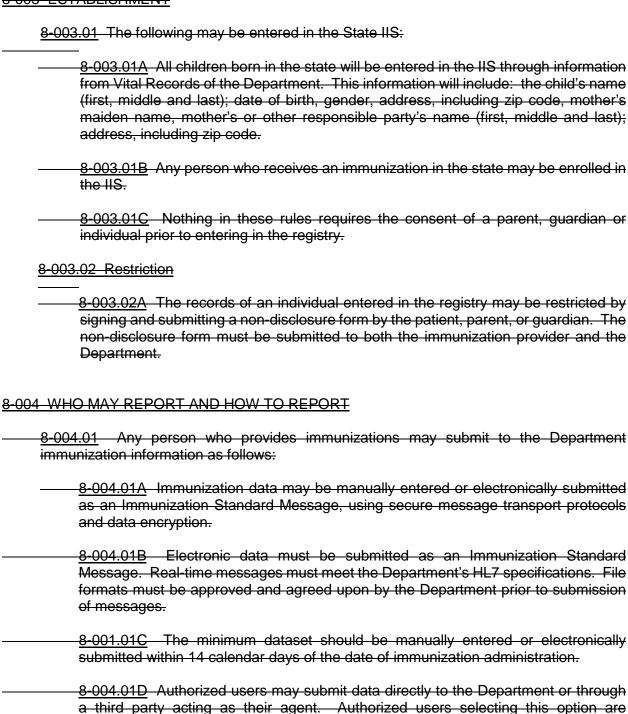
Restricted immunization information means all information contained within an immunization record in the IIS is restricted by the patient or, if the patient is a minor, the patient's parent or legal guardian, from access from everyone other than the professional or entity that provided the immunization(s).

<u>School</u> means any approved or accredited school under <u>Neb. Rev. Stat.</u> §§ 79-318 or 79-1601 offering courses of instruction to its students on the school's premises.

<u>Secure message transport protocol</u> means a method of sending electronic data to the department in a way that prevents unauthorized access to the data as specified by the Department.

8-003 ESTABLISHMENT

this rule.



responsible for ensuring that all data specifications conform to the requirements of

8-005 ACCESS TO IMMUNIZATION RECORDS

8-005.01 An authorized user may only access unrestricted information in the IIS as follows:

<u>8-005.01A</u> An authorized user will be given a unique user ID, password, and system role which will determine the level of access to unrestricted immunization information on an individual who is presently under that authorized user's care, or enrolled in the authorized user's facility, school, post-secondary educational institution, program or health plan, except as otherwise provided by law.

<u>8-005.01B</u> An authorized user that is a state or local public health authority may, in addition to accessing unrestricted information described in subsection 8-005.01A of this rule, access unrestricted information on an individual within the public health jurisdiction for authority's assessment, evaluation, surveillance and outreach related to immunization promotion and vaccine-preventable disease prevention.

<u>8-005.01C</u> The Department may require any authorized user who has accessed an individual's record to provide evidence that such individual was under the care of the authorized user or enrolled in the authorized user's facility, school, post-secondary educational institution, program or health plan at the time the individual's record was accessed.

<u>8-005.01D</u> The Department may report violations of these rules by any authorized user who has accessed an individual's record to the appropriate licensing or regulatory authority.

<u>8-005.02</u> Individuals, parents, and guardians are authorized access to their own or their child's immunization record. To ensure data confidentiality the Department shall:

<u>8-005.02A</u> Require that the first name, last name, date of birth, and social security number be populated in the IIS in order for the record to be accessed by the individual, parent, or guardian.

<u>8-005.02B</u> Require the individual, parent, or guardian to search for a record using the first name, last name, date of birth, and social security number of the Individual for whom they are searching.

<u>8-005.02C</u> Display, upon successful search, first name, middle name, last name, date of birth, gender, race, ethnicity, mother's maiden name (first and last), date of immunization, immunization type, and immunization recommendations, and shall not display social security numbers and address information.

<u>8-005.02D</u> A licensed child care facility may access the immunization record of a child under its care.

173 NAC 8

8-006 DATA CONFIDENTIALITY AND SECURITY

<u>8-006.01</u> Identifiable immunization information from the IIS shall only be disclosed to authorized users or as otherwise stated in these rules.

<u>8-006.02</u> An authorized user shall not disclose information from the IIS except to another authorized user or as otherwise stated in these rules.

<u>8-006.03</u> All authorized users shall abide by such security policies and procedures to safeguard information in the IIS deemed necessary by the Department. Such policies and procedures may include, but are not limited to, confidentiality agreements, the use of computer passwords, and user identification codes. The Department shall provide copies of the policies and procedures to all authorized users who participate in the IIS. Policies and procedures may be supplied electronically through the IIS.

<u>8-006.04</u> No authorized user shall be subjected to civil or criminal liability, or be deemed to have engaged in unprofessional conduct for reporting to, receiving from, or disclosing information relating to the IIS when made reasonably and in good faith and in accordance with the provisions of these rules or any regulation adopted thereto.

<u>8-006.05</u> The Department must secure the data within the IIS in a manner that will ensure the confidentiality and security of said data.

<u>8-006.06</u> The Department must maintain a secure message transport protocol which ensures the confidentiality and security of said data.

DRAFT NEBRASKA DEPARTMENT OF 08-15-2019 HEALTH AND HUMAN SERVICES

173 NAC 8

- TITLE 173 COMMUNICABLE DISEASES
- CHAPTER 8 CONCERNING THE ESTABLISHMENT AND OPERATION OF THE NEBRASKA STATE IMMUNIZATION INFORMATION SYSTEM
- 001. SCOPE AND AUTHORITY. The purpose of these regulations is to implement Nebraska Revised Statute (Neb. Rev. Stat.) §§ 71-539 to 71-544.
- <u>002.</u> <u>DEFINITIONS.</u> When terms are used in 173 Nebraska Administrative Code (NAC) 8, the following definitions apply:
 - <u>002.01 AUTHORIZED USER. Individuals and entities authorized to access immunization</u> records in the Immunization Information System.
 - 002.02 DATA ENCRYPTION. The electronic obfuscation of data within an electronic message using industry standard practices for encryption.
 - <u>002.03 ELECTRONIC HEALTH RECORD (EHR) SYSTEM. Any computerized or electronic system used to capture and store patient identifying health information including immunization data.</u>
 - <u>002.04 HEALTH CARE FACILITY. Any facility licensed or exempt from licensure under the Health Care Facility Licensure Act.</u>
 - 002.05 HEALTH CARE PROFESSIONAL. Any person authorized by law to order or administer an immunization.
 - <u>002.06 HEALTH DEPARTMENT OF OTHER STATES.</u> Any state health department established to promote the health and well-being of all residents within its jurisdiction.
 - <u>002.07 IMMUNIZATION INFORMATION SYSTEM. A central database of immunization information which can be accessed and used pursuant to these regulations.</u>

- 002.08 IMMUNIZATION STANDARD MESSAGE. A standard electronic message meeting specifications as identified by current versions of the Immunization Information System *Flat File Specifications* or *HL7 Specifications* for *Immunization* available from the Department upon request.
- 002.09 LICENSED CHILD CARE FACILITY. Any facility or program licensed under the Child Care Licensing Act.
- 002.10 POSTSECONDARY EDUCATIONAL INSTITUTION. Any organization or business enterprise which offers courses or subjects for which tuition is charged, and at the place of business of which a course of instruction is available through classroom instruction, home study, or both to a person for the purpose of training, preparing, or improving the person for an occupation even though the organization's or business enterprise principal efforts may not be exclusively educational in nature.
- 002.11 LOCAL PUBLIC HEALTH DEPARTMENT. Has the same meaning as in Neb. Rev. Stat. § 71-1626.
- 002.12 PUBLIC HEALTH AUTHORITY. An agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.
- <u>002.13 REAL-TIME MESSAGE. The transmission of discrete standard electronic messages to the Department as they are generated by the Electronic Health Record (EHR) system.</u>
- 002.14 RESTRICTED IMMUNIZATION INFORMATION. All information contained within an immunization record in the Immunization Information System is restricted by the patient or, if the patient is a minor, the patient's parent or legal guardian, from access from everyone other than the professional or entity that provided the immunization(s).
- <u>002.15 SCHOOL.</u> Any approved or accredited school under Neb. Rev. Stat. §§ 79-318 or 79-1601 offering courses of instruction to its students on the school's premises.
- 002.16 SECURE MESSAGE TRANSPORT PROTOCOL. A method of sending electronic data to the Department in a way that prevents unauthorized access to the data as specified by the Department.
- <u>003.</u> <u>WHO MAY REPORT AND HOW TO REPORT.</u> Any person who provides immunizations may submit immunization information to the Department as follows:
 - <u>003.01 DATA SUBMISSION. Immunization data may be manually entered or electronically submitted using secure message transport protocols and data encryption.</u>

- 003.02 ELECTRONIC DATA. Electronic data must be submitted as an Immunization Standard Message. Real-time messages must meet the Department's HL7 specifications. File formats must be approved and agreed upon by the Department prior to submission of messages.
- <u>003.03 MINIMUM DATASET. The minimum dataset should be manually entered or electronically submitted within 14 calendar days of the date of immunization administration.</u>
- 003.04 AUTHORIZED USERS. Authorized users may submit data directly to the Department or through a third party acting as their agent. Authorized users selecting this option are responsible for ensuring that all data specifications conform to the requirements of these regulations.
- <u>004.</u> <u>ACCESS TO IMMUNIZATION RECORDS.</u> An authorized user may only access unrestricted information in the Immunization Information System as follows:
 - 004.01 LEVEL OF ACCESS. An authorized user will be given a unique user identification, password, and system role which will determine the level of access to unrestricted immunization information on an individual who is presently under that authorized user's care, or enrolled in the authorized user's facility, school, post-secondary educational institution, program or health plan, except as otherwise provided by law.
 - 004.02 LOCAL PUBLIC HEALTH AUTHORITY. An authorized user that is a state or local public health authority may, in addition to accessing unrestricted information described in subsection 173 NAC 8-005.01, access unrestricted information on an individual within the public health jurisdiction for assessment, evaluation, surveillance and outreach related to immunization promotion and vaccine-preventable disease prevention.
 - 004.03 EVIDENCE OF CARE OR ENROLLMENT. The Department may require any authorized user who has accessed an individual's record to provide evidence that such individual was under the care of the authorized user or enrolled in the authorized user's facility, school, post-secondary educational institution, program or health plan at the time the individual's record was accessed.
 - 004.04 INDIVIDUALS, PARENTS, AND GUARDIANS ACCESS TO THEIR CHILD'S IMMUNIZATION RECORD. In order for individuals, parents, and guardians to access to their own or their child's immunization record, the following requirements must be met:
 - (A) The first name, last name, date of birth, and social security number must be populated in the Immunization Information System in order for the record to be accessed.
 - (B) The individual, parent, or guardian must search for a record using the first name, last name, date of birth, and social security number of the individual for whom they are searching.
- 005. DATA CONFIDENTIALITY AND SECURITY. An authorized user shall not disclose information from the Immunization Information System except to another authorized user or as otherwise stated in these regulations. All authorized users shall abide by such security policies and procedures to safeguard information in the Immunization Information System deemed

DRAFT 08-15-2019

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES

173 NAC 8

necessary by the Department. Such policies and procedures may include, but are not limited to, confidentiality agreements, the use of computer passwords, and user identification codes.