

**Department of State Health Services**  
**Council Agenda Memo for State Health Services Council**  
**August 17 – 18, 2016**

**Agenda Item Title:** Amendments to a rule and new rule concerning the immunization registry.

**Agenda Number:** 4.c.

**Recommended Council Action:**

For Discussion Only

For Discussion and Action by the Council

**Background:**

The Immunization Program, within the Infectious Disease Prevention Section within the Division for Disease Control and Prevention Services, promotes public health by providing services to prevent, control, reduce, and eliminate vaccine-preventable diseases in children and adults in Texas. Such services include:

- Managing the Texas Vaccines for Children program to distribute federal and state-funded vaccines to approximately 3,400 clinic sites across the state;
- Administering ImmTrac – the statewide immunization registry;
- Contracting with local health departments to enhance 11 population-based activities in their communities;
- Contracting with Federally Qualified Health Centers to deliver immunization services in the communities they serve;
- Providing public and provider education and promotion of immunizations; and
- Monitoring school and licensed child-care facilities for compliance of immunization requirements.

The program is funded through the Centers for Disease Control & Prevention (CDC) federal funds and by general revenue funds.

**Summary:**

The purpose of the amendments and the new rule is to comply with House Bill 2641, 84<sup>th</sup> Legislature, Regular Session, 2015, which directed the Department of State Health Services to allow the immunization registry to exchange data elements with a health information exchange (HIE) as defined in Health and Safety Code §182.151.

The rule amendments and new rule:

- Stipulate the definition of an HIE as defined in Health and Safety Code §182.151;
- Clarify procedures and requirements for the exchange of data between the immunization registry and HIEs; and
- Stipulate that data access and transmittal will be subject to provisions of the department's data usage agreement and that access and transmittal of immunization registry data by an HIE must be made for immunization registry purposes only.

The new rule and amendment will affect healthcare providers, practitioners, physicians, the staff of immunization providers, patients receiving immunizations, their families, immunization registry and HIE staff, immunization registry and HIE consumers, and immunization programs throughout the state. There is no anticipated fiscal impact to the state or local governments, nor possible adverse economic effect on small or micro-businesses as a result of the addition of this new rule.

**Key Health Measures:**

Health providers can increase their quality of care because HIEs provide another avenue through which they will be able to more readily access and transmit immunization data to and from the immunization registry. Adding

another method for providers to add to and access information in the immunization registry will help decrease duplication, cost, and incidents of unnecessary re-vaccination, and make it easier for doctors and patients to find more complete vaccination information.

Public health officials will have increased access to immunization data to quickly respond to vaccine preventable disease outbreaks.

Allowing the HIEs and the immunization registry to exchange immunization data facilitates consolidation of individual immunization records. The Centers for Disease Control and Prevention estimates that 20% of the children in the United States see more than one health care provider and have fragmented records. Allowing the HIE to exchange data with the immunization registry can help keep records accessible, up-to-date, and in a central location.

**Summary of Input from Stakeholder Groups:**

Input was solicited via email from the following internal and external stakeholders: Texas Academy of Family Physicians, Texas Association of Local Health Officials, Texas Immunization Stakeholder Working Group members, Texas Medical Association, Texas Nurses' Association, Texas Pediatric Society, The Immunization Partnership (TIP), Health IT Regional Extension Centers, Texas Hospital Association, Texas Medical Association Alliance, Texas Health Services Authority, Texas eHealth Alliance (TeHA), Texas Association of Health Information Organizations, Paso del Norte, RioOne, Rio Grande Valley HIE, Integrated Care Collaboration, Greater Houston Health Connect, Healthcare Access San Antonio, the Texas Department of State Health Services, and the Texas Health and Human Services Commission.

The Immunization Program received feedback from TIP and TeHA. TIP was in favor of the proposed amendment and new rule. TeHA expressed concerns regarding the clarity of rule language to permit HIEs to read and access data in ImmTrac. The Immunization Branch feels that the rule is clear that an HIE may access and transmit data so long as it is requested by an authorized healthcare provider, consented for by the patient, and requested in accordance with all other provision of state and federal law.

**Proposed Motion:**

Motion to recommend HHSC approval for publication of rules contained in agenda item # 4.c.

**Approved by Assistant Commissioner/Director:** Janna Zumbrun **Date:** 7-20-16

**Presenter:** Imelda Garcia **Program:** Infectious Disease Prevention **Phone No.:** 512-776-7679  
Section

**Approved by CPEA:** Carolyn Bivens **Date:** 7/21/16

Title 25. HEALTH SERVICES  
Part 1. DEPARTMENT OF STATE HEALTH SERVICES  
Chapter 100. Immunization Registry  
Amendment to §100.1 and new §100.11

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission, on behalf of the Department of State Health Services (department), proposes an amendment to §100.1 and new §100.11, concerning the requirement to allow health information exchanges (HIEs) access to the immunization registry.

BACKGROUND AND PURPOSE

The purpose of the amendment is to implement House Bill (HB) 2641, 84th Legislation, Regular Session, 2015, which amended Health and Safety Code, Chapter 161, Subchapter B, Immunizations, and directed the department to allow the immunization registry to exchange data elements with a health information exchange (HIE) as defined in Health and Safety Code, §182.151.

SECTION-BY-SECTION SUMMARY

The proposed amendment to §100.1 adds the definition of an HIE as defined in Health and Safety Code, §182.151.

The proposed new §100.11 will allow the immunization registry to exchange data elements with an HIE as defined in Health and Safety Code, §182.151. The proposed new rule will clarify procedures and requirements for the exchange of data between the immunization registry and HIEs. The new rule will stipulate that data access and transmittal will be subject to provisions of the department's data usage agreement and will state that access and transmittal of immunization registry data by an HIE must be made for immunization registry purposes only.

FISCAL NOTE

Imelda Garcia, Director, Infectious Disease Prevention Section, has determined that for each year of the first five years that the sections will be in effect, there will be no fiscal implications to state or local governments as a result of enforcing and administering the sections as proposed.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Ms. Garcia has also determined that there will be no adverse impact on small businesses or micro-businesses required to comply with the sections as proposed. This was determined by interpretation of the rules that small businesses and micro-businesses will not be required to alter their business practices in order to comply with the sections. Therefore, an economic impact statement and regulatory flexibility analysis for small and micro-businesses are not required.

ECONOMIC COSTS TO PERSONS AND IMPACT ON LOCAL EMPLOYMENT

There are no anticipated economic costs to persons who are required to comply with the sections as proposed. There is no anticipated negative impact on local employment.

## PUBLIC BENEFIT

In addition, Ms. Garcia has also determined that for each year of the first five years the sections are in effect, the public will benefit from adoption of the sections. The public benefit anticipated as a result of enforcing or administering the sections will be the following:

Health providers can increase their quality of care because HIEs provide another avenue through which they will be able to more readily access and transmit immunization data to and from the immunization registry. Adding another method for providers to add to and access information in the immunization registry will help decrease duplication, cost, and incidents of unnecessary re-vaccination, and makes it easier for doctors and patients to find more complete vaccination information.

Public Health officials will have increased access to immunization data to quickly respond to vaccine preventable disease outbreaks.

Allowing the HIEs and the immunization registry to exchange immunization data facilitates consolidation of individual immunization records; the Centers for Disease Control and Prevention estimates that 20% of the children in the United States see more than one health care provider and have fragmented records.

Allowing the HIEs to exchange data with the immunization registry can help keep records accessible, up to date, and in a central location.

## REGULATORY ANALYSIS

The department has determined that this proposal is not a "major environmental rule" as defined by Government Code, §2001.0225. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

## TAKINGS IMPACT ASSESSMENT

The department has determined that the proposal does not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Government Code, §2007.043.

## PUBLIC COMMENT

Comments on the proposal may be submitted to Imelda Garcia, Department of State Health Services, Infectious Disease Prevention Section, Immunization Program, Mail Code 1946, P.O. Box 149347, Austin, Texas, 78714-9347 or by email to [DSHSInfDisease@dshs.state.tx.us](mailto:DSHSInfDisease@dshs.state.tx.us). Comments will be accepted for 30 days following publication of the proposal in the *Texas Register*.

## LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the proposed rules have been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

## STATUTORY AUTHORITY

The amendment and new rule are authorized by Health and Safety Code, Chapter 161 which provides the department with the authority to allow Health Information Exchanges access to the immunization registry; and Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001.

The amendment and new rule affects Health and Safety Code, Chapter 161; Health and Safety Code, Chapter 1001; and Government Code, Chapter 531.

Title 25. HEALTH SERVICES  
Part 1. DEPARTMENT OF STATE HEALTH SERVICES  
Chapter 100. Immunization Registry  
Amendment to §100.1 and new §100.11

Legend: (Proposed Amendment and New Rule)

Single Underline = Proposed new language

**[Bold, Print, and Brackets]** = Current language proposed for deletion

Regular Print = Current language

(No change.) = No changes are being considered for the designated subdivision

§100.1. Definitions.

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) - (6) (No change.)

(7) Health information exchange--A health information exchange organization as defined by Health and Safety Code, §182.151.

(8) [(7)] Hostile Military or Paramilitary Act--An attack or other use of force by an armed force of a nation or an organized unofficial group, against forces, property and/or infrastructure of the United States, state or local government.

(9) [(8)] Immediate family member--The parent, spouse, child, or sibling of a person who resides in the same household as the person.

(10) [(9)] Immunization history--An accounting of all vaccines that a person has received, or evidence of immunity, and other identifying information.

(11) [(10)] Immunization record--A record containing the name and date of birth of the person to whom a vaccine was administered; dates of vaccine administration; types of vaccine administered; and name and address of the provider that administered the vaccines; or other evidence of immunity to a vaccine-preventable disease.

(12) [(11)] Immunization registry--The database or single repository that contains immunization histories, which include necessary personal data for identification. This database is confidential, and access to content is limited to authorized users.

(13) [(12)] Payor--An insurance company, a health maintenance organization, or another organization that pays a health care provider to provide health care benefits, including the administration of vaccines to a person younger than 18 years of age.

(14) [(13)] Potential disaster--An incident or event capable of causing widespread or severe damage, injury, or loss of life or property resulting from any natural or man-made cause,

including fire, flood, earthquake, wind, storm, wave action, oil spill or other water contamination, volcanic activity, epidemic, air contamination, blight, drought, infestation, explosion, riot, hostile military or paramilitary action, or other public calamity requiring emergency action, or energy emergency.

(15) [(14)] Provider--Any physician, health care professional, or facility personnel duly licensed or authorized to administer vaccines.

(16) [(15)] Public health emergency--An occurrence or imminent threat of an illness or health condition, caused by bioterrorism, epidemic or pandemic disease, or novel and highly fatal infectious agent or biological toxin, that poses a substantial risk of a significant number of human fatalities or incidents of permanent or long-term disability. Such illness or health condition includes, but is not limited to, an illness or health condition resulting from a natural disaster.

(17) [(16)] Terrorist attack--An activity that is dangerous to human life and/or potentially destructive of critical infrastructure or key resources and is intended to intimidate or coerce the civilian population, or influence or affect the conduct of a government by mass destruction, assassination, and/or kidnapping.

(18) [(17)] User--An entity or individual authorized by the department to access immunization registry data.

(19) [(18)] Vaccine--Includes toxoids and other immunologic agents which are administered to a person to elicit an immune response (immunization) and thus protect against infectious diseases.

#### §100.11. Authority of a Health Information Exchange.

(a) Notwithstanding Health and Safety Code, §161.0073 and §161.008, and subject to the provisions of the department's data usage agreement, a health information exchange, as defined in Health and Safety Code, Chapter 182, may access and transmit health-related information under Health and Safety Code, §161.007(d), §161.00705(a), §161.00706(b), and §161.008(i), if the access or transmittal is:

(1) made for the purpose of assisting in the reporting of immunization registry information to the appropriate agency;

(2) requested and authorized by the appropriate health care provider, practitioner, physician, facility, or other person who is required to report data elements regarding an immunization record as outlined in Health and Safety Code, Chapter 182;

(3) made in accordance with the applicable consent requirements for the immunization registry under Health and Safety Code, Chapter 182; and

(4) made in accordance with the requirements of Health and Safety Code, Chapter 182 and all other state and federal law.

(b) A health information exchange may only use and disclose the information that it accesses or transmits under subsection (a) of this section in compliance with this chapter and all applicable state and federal law, and may not exchange, sell, trade, or otherwise make any prohibited use or disclosure of the information.