

**Department of State Health Services  
Agenda Item for State Health Services Council  
January 30-31, 2008**

**Agenda Item Title:** Amend 25 TAC, Part 1, Chapter 100, §§100.1 – 100.6; New §§100.7-100.10; Repeal §§100.7 - 100.8, related to the Immunization Registry

**Agenda Number:** 4f

**Recommended Council Action:**

For Discussion Only

For Discussion and Action by the Council

**Background:**

The Immunization Registry is located within the Immunization Branch in the Disease Prevention and Intervention Section of the Division for Prevention and Preparedness Services. The Immunization Branch provides services to prevent, control, reduce, and eliminate vaccine-preventable diseases in children and adults, with emphasis on interventions to improve vaccine coverage of children under 36 months of age.

ImmTrac is the Texas immunization registry developed by the Texas Department of State Health Services. ImmTrac is a free, confidential registry designed to consolidate immunization records from multiple providers and store a child's immunization information electronically in one secure central system. ImmTrac offers physicians and other healthcare providers and authorized users easy online access to a child's immunization history. ImmTrac is part of a DSHS initiative to increase vaccination coverage for children across Texas.

**Summary:**

25 TAC, Part 1, Chapter 100 concerns the Immunization Registry, which is the database or single repository that contains immunization histories, which include necessary personal data for identification.

The proposed amendments, repeal, and new sections update the agency, division, section, and branch names, reorder text and sections to improve rule clarity and efficiency, and implement portions of SB 11, 80th Legislature, Regular Session, 2007, which include:

- Requires records of antivirals, vaccines or other medications administered to both adults and children during times of emergency be included in ImmTrac.
- Authorizes individuals to choose to maintain their immunization records in the registry; without a written request by an individual to maintain the individual's immunization records in the registry, the records will be removed upon expiration of the period determined by the Health and Human Services Commission after the end of the emergency.
- The law allows providers, birth registrars, and local registries to affirm that they have consent on file in their offices and removes the requirement that DSHS verify consent.

**Summary of Input from Stakeholder Groups:**

Preliminary internal DSHS stakeholder input was obtained from DSHS Commissioner, Government Affairs, and Community Preparedness Section. The Immunization Branch will share the proposed rule with external stakeholders, such as, Texas Medical Association and Texas Pediatric Association, by e-mail distribution in early January 2008, prior to the January 30-31, 2008, State Health Services Council meeting. Feedback will be considered and addressed with comments received during the 30-day public comment period.

**Proposed Motion:** Motion to recommend HHSC approval for publication of rules contained in agenda item #4f.

**Agenda Item Approved by Assistant Commissioner/Director:** Casey Blass **Date:** 12/21/07

**Person Presenting:** Jack Sims **Program:** Immunization Branch **Phone No:** 458-7111 ext. 6215

**Final CAM Approved by Consumer Affairs:** RMM **Date:** 12/21/07

Title 25. HEALTH SERVICES  
Part 1. DEPARTMENT OF STATE HEALTH SERVICES  
Chapter 100. Immunization Registry  
Amendment §§100.1-100.6  
New §§100.7-100.10  
Repeal §§100.7-100.8

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission on behalf of the Department of State Health Services (department) proposes amendments to §§100.1-100.6, repeal of §§100.7-100.8, and new §§100.7-100.10 concerning the Texas Immunization Registry (the Registry).

BACKGROUND AND PURPOSE

Government Code, §2001.039, requires that each state agency review and consider for readoption every 4 years each rule adopted by that agency pursuant to the Government Code, Chapter 2001. Sections 100.1-100.8 have been reviewed and the department has determined that reasons for adopting the sections continue to exist because rules on this subject are needed, although current language in §§100.7 and 100.8 is being renumbered as §§100.9 and 100.10 (respectively), with minor changes, so that entirely new language can be proposed as new §§100.7 and 100.8. This rulemaking also proposes amendments that would implement portions of Senate Bill (SB) 11, 80th Legislature, Regular Session (2007), which amended Health and Safety Code (the Code), Chapter 161. This rulemaking proposal would also make various clarifying amendments designed to improve the efficiency and readability of these rules sections.

The proposed amendments, repeal, and new sections update the agency, division, section, and branch names, reorder text and sections to improve rule clarity and efficiency, and implement SB 11 requirements.

SECTION-BY-SECTION SUMMARY

Section 100.1(2) is proposed to be amended to clarify that a managing conservator or legal guardian can also grant the requisite consent. Section 100.1(3) is proposed to be amended to reflect the language of the Code, §161.0001(1), including amendments made by SB 11. Section 100.1(4) is proposed to be amended to reflect the current name of the department. Existing §100.1(5) is proposed to be renumbered as §100.1(9) and to be amended by changing “child” to “person” to reflect SB 11 requirements. Existing §100.1(6) and (7) are proposed to be renumbered as §100.1(10) and (11), respectively. Existing §100.1(8) is proposed to be deleted as confusing and unnecessary language, and is proposed to be replaced with a new definition for “immediate family member” to reflect the requirements of SB 11. Existing paragraphs (9), (10), and (11) in §100.1 are proposed to be renumbered to §100.1(12), (14), and (17), respectively. Existing §100.1(12) is proposed to be renumbered to §100.1(18), with “a person” replacing “children” in order to reflect SB 11 requirements. New definitions are proposed to be numbered as paragraphs (5)-(8), (13), (15), and (16) to implement SB 11 requirements.

Section 100.2(a) is proposed to be amended to reflect amendments made to the Code, §161.0073(a) by SB 11, and is also proposed to be amended by adding language to reflect that a managing conservator or legal guardian may also offer the required consent. Section 100.2(b) is proposed to be amended by adding a statement which expressly states that Registry information may only be accessed by the persons listed in rule, for the purposes enumerated in the rule. Further amendments are proposed to reflect the new classes of persons brought into the regulatory scheme by SB 11. Amendments are also proposed at subsection (b) to reflect that a managing conservator or legal guardian may also offer the required consent.

Section 100.3 is proposed to be amended by changing the section title to reflect that “guardian” is a reference to a “legal guardian.” Section 100.3(a) is proposed to be amended to add managing conservators and legal guardians to the list of those to be informed under the requirement, along with a cross-reference to the method to be used. The subsection is also proposed to be amended by adding language that reflects changes to §161.007(a) of the Code made by SB 11. Section 100.3(b) is proposed to be amended to add managing conservators and legal guardians to the list of persons that will receive the referenced materials. Section 100.3(c) is proposed to be amended to add managing conservators and legal guardians to the list of persons that may receive the referenced notices. Section 100.3(d) is proposed to be amended to add managing conservators and legal guardians to the list of persons that will receive the referenced notices. Section 100.3(d)(6) is proposed to be amended to add managing conservators and legal guardians to the list of persons regarding reporting the referenced violation, and to insert “alleged” in front of “violation” to reflect that such a violation will not have been proven at that point of the process.

Section 100.4 is proposed to be amended by changing the section title, and subsection (a), to reflect that this rule section is only applicable to Registry consent and withdrawal relating to minors, since these same issues will be dealt with separately in new §§100.7 and 100.8 regarding SB 11 requirements as to certain adults. Section 100.4(a)(2) is proposed to be amended by updating the current name and contact information of the department. Existing subsection (b) is proposed to be renumbered as subsection (c), with a new subsection (b) proposed to be inserted which describes the consent process by which information on minors is included in the Registry. In the new subsection (b), the cross-reference to new §100.7 is necessary because SB 11 provides for inclusion of information regarding minors into the Registry without consent (and therefore without consent needing to be verified) in the limited situations described in the new rule section. New subsection (b) would also specify how the department will handle consent verifications in situations involving minors where such verification is required, which is authorized under the authority given to the department under changes to the Code, §161.007(a)(5) made by SB 11. This process is designed to maximize efficiency of Registry operations. Existing subsection (c) is proposed to be renumbered as new subsection (d), and is proposed to be amended to add managing conservators and legal guardians to the list of persons regarding withdrawal of consent, and is also proposed to be amended by adding a cross-reference to new §100.7 to reflect the exception to the ability to withdraw consent, per SB 11. Existing subsection (d) is proposed to be renumbered as new subsection (e), and is proposed to be amended to add managing conservators and legal guardians to the list of persons who may request exclusion of the information, while paragraph (2) updates the department’s current name

and contact information and also includes a cross-reference to new §100.7 to reflect the exception to the ability to request exclusion, per SB 11.

Section 100.5 is proposed to be amended by renumbering the existing subsection (a) as a new subsection (b), with changes that: reflect the new classes of persons brought into the Registry via SB 11; clarify that managing conservators and legal guardians are included in the list of persons who can submit the referenced information; improve readability; and expressly state that submissions of the referenced information must be according to department requirements. A new subsection (a) is proposed which would provide an updated comprehensive list of the classes of persons who will have information contained in the Registry, given SB 11 requirements. Existing subsection (b) is proposed to be renumbered as new subsection (c), with changes that reflect the new classes of persons brought into the Registry via SB 11, as well as changes to improve readability. Existing subsection (c) is proposed to be renumbered as new subsection (e), with changes that: effectively reflect the statutory scheme for release of immunization records; expressly states the limitations of use (if any) for each class of person listed, to prohibit parties allowed direct access to the Registry from viewing records beyond those they are authorized to see, given state and federal confidentiality laws; and expressing the limitation of direct electronic access to the Registry, which is necessary due to resource constraints of the department and is advisable to help preserve confidentiality. Existing subsection (d) is proposed to be renumbered as subsection (h), with changes that better express liability limitations by cross-referencing the applicable Code provision, rather than attempting to paraphrase statutory language. A new subsection (d) is proposed to concisely set out the methods the department has to choose from when verifying consent, under the authority granted the department under §161.007(a)(5) of the Code as amended by SB 11. Existing subsection (e) is proposed to be renumbered as new subsection (i), with changes to reflect the new classes of persons brought into the Registry via SB 11. New subsection (f) is proposed to provide a cross-reference to new §100.7 regarding release of information under the scenarios described in that rule. New subsection (g) is proposed to provide a cross-reference to new §100.8 relating to release of information regarding first responders and their immediate family under that rule.

Section 100.6 is proposed to be amended by adding language to the section title which states that the section covers medical verifications as well, and that the entire section is applicable only to minors (as opposed to adults added to the Registry scheme under SB 11, which will be covered elsewhere in the rules). Subsection (a) is proposed to be amended for readability and clarity. Subsection (b) is proposed to be amended by deleting confusing and outdated text and replacing it with a clear statement regarding the providers' obligation to submit the required data elements to the department within the stated 30 day deadline. Subsection (c) is proposed to be amended in a manner similar to subsection (b), except that (c) is applicable to applicable payors as opposed to providers. Subsection (d) is proposed to be amended by adding managing conservator and legal guardian to the list of persons who can provide a child's immunization history to the department. Existing subsection (e) is proposed to be deleted because its subject matter will be covered under other provisions under this section as reorganized. Existing subsection (f) is proposed to be renumbered as subsection (e), with changes to improve clarity. Existing subsection (g) is proposed to be renumbered as subsection (f).

The text in existing §§100.7-100.8 is proposed to be moved to §§100.9 and 100.10, respectively, with changes as part of the reorganization of this subchapter (see discussion of proposed changes below).

New §100.7 is being proposed to implement changes to the Code, Chapter 161, amended by SB 11 regarding the following scenarios: potential and declared disasters; public health emergencies; terrorist attacks; hostile military or paramilitary actions; and/or extraordinary law enforcement emergency events. SB 11 mandates a major expansion in the existing scope of the Registry. Under that legislation, the Registry must contain specified information regarding persons who receive an immunization, antiviral, and/or other medication administered to prepare for, and/or in response to, the listed scenarios--as stated in proposed new subsection (a) of the section. The provider deadline to submit data elements is set at 30 days in the new subsection (b). This will allow the Registry to reflect an accurate picture of the immunizations, etc. being administered in the emergency so that information will be available to those who need it. SB 11 amends §161.00705 of the Code to include requirements for the department to track adverse reactions in these situations, and proposed new rule subsection (c) implements this requirement. The rule language states that such tracking will be based on reports the department receives from health care providers, as opposed to being based on an impractical attempt by the department to proactively contact all providers who were active in any given disaster/emergency. The statute does not make such reporting mandatory for providers, and the agency does not have the resources to attempt to identify and contact all these providers who administered health care during the emergency. SB 11 provides that consent is not necessary for the health care information at issue to be included in the Registry, but goes on to charge the agency with determining the time period following the disaster/emergency event after which consent would be required for continued inclusion. Department Preparedness Program staff have analyzed this situation, using their long expertise in public health and emergency management in Texas, and have determined that the appropriate time period is five years after the end date of the emergency scenario. Reasons for choosing this time period are based on public health needs:

1) The five year period is commonly used as the interval for when boosters are recommended (e.g., tetanus, pneumonia if >64 years). To avoid over-immunizing individuals under proposed §100.7, and to avoid the costs of revaccinating persons who don't keep personal records, a five-year period in the Registry would be sufficient for record-checking purposes.

2) Adequate time is needed to track individuals with adverse reactions that are reported to the department by the providers at issue. It is currently unknown how many adverse reactions will result from use of antiviral drugs, antibiotics, vaccines, or emergency use authorization (EUA) drugs that may be used during a scenario described in proposed §100.7. The department tracking of adverse reactions following such a scenario may take years, especially if a large number of individuals are affected. Five years is a minimal time in which to examine trends.

New §100.7(d) specifies the details of how this post-emergency transition period will work. Since the Texas Legislature did not define the various emergency terms used in SB 11, and did not include an explicit method for determining their duration, the proposed new subsection (d) states that: for types of emergencies where existing statutes provide for the duration, that will be the controlling trigger date; for types of emergencies where the law does not so provide, the

department will determine the end date and post it on the department website. The department will use its expertise in public health and emergency management to make the latter determinations, and the website posting should be an effective method of getting this information disseminated. Once the time period referenced in subsection (d) has passed, consent is required under SB 11 and proposed new subsection (e) details the mechanics of that process. Proposed new subsection (f) pertains to department release of the information, and implements SB 11 changes to §161.00705(g) of the Code.

New §100.8 implements changes to the Code, Chapter 161, amended by SB 11 regarding immunization information of first responders and their immediate families. SB 11 contains a second major expansion in the existing scope of the Registry. Under that legislation, first responders (and immediate family members, as defined, over 18) may request that a provider who administers an immunization to the person provide information regarding that immunization to the department for inclusion in the Registry, as described in proposed new rule subsection (a). Unlike the scenarios described in proposed new §100.7, the new legislation does not make this requirement mandatory. Rather, it is an available option for the persons covered. Proposed new subsection (b) requires the provider to submit that information, upon receiving such a request, as mandated by SB 11 through amendments to §161.00706(b) of the Code. The language in this subsection goes on to articulate deadlines and mechanics for how this works, including the logistics and methodologies for verification of the request for inclusion in the Registry. Proposed new subsection (c) describes the logistics of making the request. Proposed subsection (d) covers the issue of medical verification regarding information submitted under this section, and lists documents that will be acceptable for that purpose. Proposed new subsection (e) details when the department can release such information, and this language tracks SB 11 amendments to §161.00706(d). Proposed new subsection (f) details the ability of the person to have their information removed from the Registry, and this language tracks SB 11 amendments to §161.00706(e).

New Section 100.9 provides the definition for an official immunization record, and is merely the language from existing §100.7 moved as part of the reorganization of this subchapter.

New §100.10 provides instructions for filing complaints about the Registry, and details the department's associated reporting requirements. This is the language from existing §100.8 moved as part of the reorganization of this subchapter, but with changes that: insert "alleged" in front of "failure to comply" to reflect that such a violation will not have been proven at that point of the process; improve readability; and include new reporting requirements associated with SB 11.

#### FISCAL NOTE

Casey S. Blass, Section Director, Disease Prevention and Intervention Section, has determined that for each year of the first five-year period the sections are in effect, there will be no fiscal implications to state or local governments. The department or state costs associated with the Immunization Registry rule amendments required by Senate Bill 11 for IT programming, operational changes, and first responder education will be absorbed within available resources and new funding will not be requested. Also, Mr. Blass has determined that there would be

some new burdens placed on certain health care providers by the regulations being proposed, given that SB 11 expands the scope of patients who will have health care information placed in the Registry and therefore inherently expands the types of providers who care for those patients. Some of these impacted providers may be small or micro-businesses (see the following small and micro-business impact analysis below).

## SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Once a provider is within the scope of proposed rules, then the rules provide for certain things that must be done such that the impacts are definite (e.g., provider must devote resources necessary to file reports). Since these impacts will happen, the department analysis under Economic Impact Statement of this preamble will also serve to satisfy the Small Business Impact Analysis required by Government Code, §2006.002(a).

The Economic Impact Statement of this preamble does not explicitly cover “micro-businesses,” but Government Code, §2006.002(a), requires an analysis of the impacts on such businesses. The department believes that many of the health care providers impacted by the proposed rules will be “micro-businesses” as well as “small businesses”, and thus the department’s analyses regarding the latter will also be applicable to the former. While it is true that a micro-business may be inherently somewhat less able to absorb new regulatory burdens than a small business, the department believes that the reporting, etc. requirements in the proposed rules would be minimal enough to not place an undue burden on these “micro-business” providers.

There is no anticipated negative impact on local employment.

Government Code, Chapter 2006, was amended by the 80th Legislative Regular Session (House Bill 3430) to require that, before adopting a rule that may have an adverse economic effect on small businesses, a state agency must first prepare an Economic Impact Statement and a Regulatory Flexibility Analysis.

The definition of a “small business” for purposes of this requirement was codified in §2006.001(2) of the Government Code. Under this definition, a “small business” is an entity that is: for profit, independently owned and operated; and has fewer than 100 employees or less than \$6 million in annual gross receipts. Independently owned and operated businesses are self-controlling entities that are not subsidiaries of other entities or otherwise subject to control by other entities (and are not publicly traded).

Mr. Blass has determined that there may be an adverse economic effect on those small businesses directly regulated by the proposed rules. Therefore, the following two analyses have been performed:

## ECONOMIC IMPACT STATEMENT

There are two major areas of possible impact regarding the proposed rules. The first area of impact is regarding the new system that would allow health care providers and birth registrars, if they chose, to affirm consent for persons online in the Registry. The second area of impact is

regarding new reporting requirements mandated by SB 11 and implemented by this rulemaking package. This second area can be subdivided into two subsets. The first subset is health care providers who already report immunization information regarding children in Texas, but who would now have to also report data regarding any patients they have covered by proposed new rules §100.7 and §100.8. The second subset is healthcare providers who currently do not give immunizations to children, and thus do not report under existing rules, but who may give immunizations to adults under proposed new rules §100.7 and §100.8 and would thus be required to do certain Registry reporting as to patients covered under those rule sections.

The proposed changes to §100.4, pursuant to SB 11, would allow the department to implement a process for the health care providers in question to affirm consent for their patient's Registry participation if that affirmation has not already been done by another allowable person under the rule (birth registrars are discussed separately below). Current law requires all providers to report to the Registry immunizations administered to children under 18 years of age. The department is required to verify consent prior to inclusion of the information in the Registry. Currently, a significant number of providers fax or mail the completed consent forms to the department, and they are verified via a manual evaluation of each form by department staff. The proposed rules would allow the department to verify consent by providing a process for providers to affirm consent for their patients, and then to indicate that this has been done electronically in the Registry. This standardized affirmation process would allow for significantly quicker creation of new client records in the Registry, with concurrent faster realization of all the benefits that come with data inclusions in the Registry.

If a provider elects to use it, the new affirmation process would require that a provider site, if not already registered and reporting to the Registry, submit a registration application for Registry participation (access to the Registry has always required registration). The registration application is free of charge and can be completed and submitted by a provider or provider staff in approximately 10 to 15 minutes. A provider site may include one or more physicians in that practice in its registration. A provider/provider site that is approved for Registry participation may access the Registry free of charge at any time. A computer with Internet access is required for access to the Registry, and basic computer skills are necessary. Actual economic cost will vary depending on the provider staff assigned to completion of the registration application (e.g., office manager, nurse, physician). However, the department believes that the current state of health care practice in Texas, given the complexities of various governmental and private insurance coverages, is such that the providers impacted by this proposed rule will already have the technological capability to facilitate Registry access and will possess (or have staff that possess) the requisite skills for registering for, and entering information into, the Registry (if they are not already doing so).

The new affirmation process would be necessary only for the addition of new clients who are not already enrolled in the Registry. The vast majority of newborns are currently enrolled in the Registry during the birth registration process. It is estimated that over 90% of Texas children under age 6 are currently enrolled in the Registry. The affirmation process, when necessary, will require approximately 7 to 12 minutes of provider staff time to perform a client search, print the Registry consent form for signature, get the form filled out and signed, and perform the online affirmation that a signed consent form has been obtained. Immediately after affirmation, the

provider may enter immunization data into the Registry for that patient. Actual economic cost will vary depending on the provider staff resources to obtain and affirm consent and enter data into the Registry (e.g., nurse, office manager, medical records or clerical staff), but the additional burden should be minimal. Those providers who are currently mailing or faxing consent forms to the department should actually experience improved efficiency, given that currently the provider must wait until the department verifies consent before the provider can enter information into the Registry for that patient. Under the proposed rules, the provider could log on to the Registry, affirm consent, and immediately begin entering information on the immunizations the provider just administered.

The approximate number of small businesses (health care providers and provider sites) potentially impacted by the changes to §100.4 is 9,000 to 14,000 (including pediatricians, general practice physicians, family practice physicians and family medicine physicians).

Proposed changes to §100.4 would also allow the department to implement a process (similar to the one described above) for a birth registrar to affirm consent for a newborn's Registry participation. Currently, a birth registrar in possession of a completed consent form for a newborn child faxes or mails the form to the department for verification of consent. The proposed rules would allow the department to verify consent by providing a process for a birth registrar to affirm electronically that consent has been obtained from the parent/managing conservator/legal guardian. The difference between this process and the one described previously for health care providers is that birth registrars would use the Texas Electronic Registrar system (an existing database which birth registrars use to enter vital statistic data) as a portal to affirm consent. This standardized affirmation process would allow for significantly quicker creation of new client records in the Registry, with concurrent faster realization of all the benefits that come with data inclusion in the Registry. Electronic integration of the Registry consent affirmation process with the Texas Electronic Registrar system would require a minor change in birthing center workflow but will not require additional time or staff resources, compared to the current process--birth registrars would be able to facilitate enrollment of a child into the Registry more quickly than is the case today with the registrar currently faxing or mailing consent forms to the department, given the inherent lag time for processing before the child is approved for Registry inclusion.

Changes to §100.7 require that health care providers report immunizations, antivirals, and other medications administered to individuals to prepare for, or in response to, a list of events related to disasters and emergencies. Because of the inherent time imperatives in the emergency/disaster-related scenarios covered in SB 11, the process for reporting to the Registry would require that a provider site, if not already registered and reporting to the Registry, submit a one-time registration application for Registry participation. The registration application is free of charge and can be completed and submitted by a provider or provider staff in approximately 10 to 15 minutes. Registration is required for each provider site (facility) that will report information to the Registry or access Registry data. A provider site may include one or more physicians in that practice in its registration. A provider/provider site that is approved for Registry participation may access the Registry free of charge at any time. A computer with Internet access is required for access to Registry data, and basic computer skills are necessary. Actual economic cost will vary depending on the provider staff assigned to completion of the

registration application (e.g., office manager, nurse, physician). The department realizes that the new reporting requirements will fall on some providers who do not treat children and therefore have had no experience with the Registry. There will unavoidably be a higher learning curve for these provider sites than for those sites already working with the Registry. As a general matter, the department also realizes that there will be a small impact on all providers who must comply with the new reporting requirements required by SB 11 and reflected in the proposed rule. However, the department believes that the current state of health care practice in Texas, given the complexities of various governmental and private insurance coverages, is such that the providers impacted by this proposed rule will already have the technological capability to facilitate Registry access and will possess (or have staff that possess) the requisite skills for registering for, and entering information into, the Registry (if they are not already doing so). The infrequency of the disaster/emergency scenarios referenced in the rule should minimize the frequency of reporting that has to be done under proposed §100.7.

In the event of a disaster or emergency, a health care provider administering immunizations, antivirals, and/or other medications to individuals to prepare for, or in response to, the disaster/emergency scenario will be required to report information to the Registry. Reporting will be performed using Internet Registry access, as prescribed by the department. It is estimated that reporting of a patient's data elements to the Registry can be performed in approximately 2 to 4 minutes, including performing a client search and data entry of required information. SB 11 (and thus the proposed rule) does not require that consent be granted for data inclusion in the Registry until a certain time period, described in proposed §100.7(d), has passed. However, SB 11 provides that consent must be granted and verified for the information to remain in the Registry after that date. In the event that a patient wishes to grant consent for retention of data in the Registry, beyond the period described above, the provider may print the Registry consent form for the patient's completion and signature and then perform the online affirmation that proper consent has been obtained. At this point, the affirmation process is similar to that described for proposed §100.4 in this preamble, and the potential impacts should also be similar.

SB 11 states that the health care providers at issue here may report adverse reactions to the immunizations, antivirals, and other medications to the department, and the proposed rules reflect this language. Because the provider has a choice in whether to make such reports, and thus is completely in control of whether any economic impact associated with such reporting is incurred, the department does not analyze those possible impacts here.

The approximate number of small businesses (health care providers and provider sites) potentially impacted by the changes to §100.7 is 10,000 to 16,000 (including pediatricians, general practice physicians, family practice physicians, family medicine physicians and emergency medicine physicians). Impacts will be lesser, as discussed above, for the subset of these providers who are already working with the Registry when one of these scenarios begins, as opposed to those who have no familiarity with it. Potential impact to these providers may vary depending on the nature, extent and duration of the disaster/emergency. Impacts to these providers may be minimized because the department expects that public health facilities (e.g., local health departments; department regional clinics) will play the initial and primary role in disaster/emergency response. A limited number of small business providers may become

involved in initial disaster response activities, although they will likely perform a larger role in response activities if the event increases in severity or duration.

Proposed changes to §100.8, pursuant to SB 11 requirements, would require that health care providers report data elements regarding immunizations to the Registry at the request of a first responder or an immediate family member of a first responder (the first responder or immediate family member may elect to submit immunization information directly to the department for inclusion in the Registry). The process for provider reporting to the Registry requires that a provider site, if not already registered and reporting to the Registry, submit a one-time registration application for Registry participation. The registration application is free of charge and can be completed and submitted by a provider or provider staff in approximately 10 to 15 minutes. Registration is required for each provider site (facility) that will report information to the Registry or access Registry data. A provider site may include one or more physicians in that practice in its registration. A provider/provider site that is approved for Registry participation may access the Registry free of charge at any time. A computer with Internet access is required for access to Registry data, and basic computer skills are necessary. Actual economic cost will vary depending on the provider staff assigned to completion of the registration application (e.g., office manager, nurse, physician), and whether the provider site is already working with the Registry.

The department is required to verify the request from a first responder or immediate family member prior to inclusion of the client's information in the Registry. The proposed rules allow the department to verify the request for inclusion by providing an online process for a provider to electronically affirm that such a request has been received. This standardized affirmation process would allow for immediate creation of new client records in the Registry and will facilitate immediate reporting of immunizations by providers. The affirmation process, when necessary, will require approximately 2 to 5 minutes of provider staff time to enter client information into the Registry and perform the online affirmation that a request for inclusion has been obtained. Immediately after affirmation of the request, the provider may enter immunizations relating to first responders or immediate family members into the new client's record. It is estimated that the actual reporting of a client's data elements into the Registry can be performed in approximately 2 to 4 minutes. Actual economic cost will vary depending on the provider staff assigned to affirm the request for inclusion and enter data into the Registry (e.g., nurse, office manager, medical records or clerical staff). Some minor resource impact will be felt by these providers who must follow the new reporting requirements, with lesser impacts on those providers who are already working with the Registry (similar to the situation with impacts regarding proposed new §100.7). Presumably the type of patients described in proposed new §100.8 will make up a small percentage of a provider's over-all practice, which should function to minimize this reporting burden.

The approximate number of small businesses (health care providers and provider sites) potentially impacted by the changes to §100.8 is 7,000 to 10,000 (including general practice physicians, family practice physicians, family medicine physicians and emergency medicine physicians). The impact to these providers may be minimized because the proposed rules allow a first responder or immediate family member to submit immunization information directly to the department for inclusion in the Registry. The department is also evaluating a process that

would allow a first responder or immediate family member to submit a request for Registry inclusion, as well as immunization information, through the department Health Service Region offices and through participating local health departments.

## REGULATORY FLEXIBILITY ANALYSIS

Government Code, Chapter 2006, was amended by the 80th Legislative Regular Session (House Bill 3430) 2007 to require, as part of the rulemaking process, state agencies to prepare a Regulatory Flexibility Analysis that considers alternative methods of achieving the purpose of the rule. There is an exception to this requirement, however. An agency is not required to consider alternatives that, while possibly minimizing adverse impacts on small businesses, would not be protective of the “health, safety and environmental and economic welfare of the state.” When the proposed rules are merely an implementation of legislative directives because of statutory changes, that proposed rule language becomes *per se* consistent with the health, safety, or environmental and economic welfare of the state, and therefore the department need not consider alternative methodologies as part of the preamble small business impact analysis. Of the two categories of potential impacts discussed herein, the first group (related to consent verification through an online system) only occur if the regulated party chooses to take upon himself the burden of helping the other person demonstrate consent to the agency. It is not a mandatory burden on the provider or birth registrar. Only the second major group of impacts is mandatory, and those are the reporting impacts. SB 11 mandates that providers report the listed data elements for those patients, and in those scenarios, described in proposed new rules §100.7 and §100.8.

## PUBLIC BENEFIT

Mr. Blass has determined that for each year of the first five years that 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 as proposed is to operate the program to ensure the safety of the public, and to clarify processes. Inclusion of medical information in the Registry is inherently good for both the health of the individual patient and for public health in general. Individual patients are benefited by their health care providers having compiled and concise health care information readily available concerning that patient, so that health care can be delivered in an informed and proactive manner which avoids the negative health outcomes possible when providers do not have a full knowledge of what care other providers have given the patient. The Registry also facilitates vaccination reminder notifications, which should increase the number of persons who are properly immunized. Public health is benefited because better health care to individual patients reduces the chance of disease outbreaks in the public. The public at large is also benefited by improvements in efficiency in the delivery of health care. Such efficiencies should help to contain health care costs. Because the proposed rules bring more people within the scope of the Registry, there should be a commensurate expansion in the health (and other) benefits that the Registry provides. These benefits should be particularly significant regarding health care administered before, during and after public emergencies (see proposed new rule at §100.7), given the public health challenges inherent in such events.

Proposed rule changes designed to clarify processes regarding the Registry should make the rules more efficient and easier to understand, which should in turn increase the number of persons agreeing to submit information into the Registry.

## 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 proposed rules do 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, do not constitute a taking under Government Code, §2007.043.

## PUBLIC COMMENT

Comments on the proposed rules may be submitted to Victoria Brice, Disease Prevention and Intervention Section, Division of Prevention and Preparedness, Department of State Health Services, 1100 West 49th Street, MC-1946, Austin, Texas 78756, 512-458-7111, extension 6658, or by email to Victoria.Brice@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

Most proposed rule amendments result from SB 11 changes to Chapter 161 of the Health and Safety Code. Sections 100.1-100.10 are authorized by Health and Safety Code, §81.021, which requires the department to protect the public from communicable disease; and §81.004 which allows the department to adopt rules for the effective administration of the Communicable Disease Act; 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. Review of the sections implements Government Code, §2001.039.

The rules affect Health and Safety Code, Chapters 81, 826 and 1001; and Government Code, Chapter 531.

Sections for repeal.

§100.7. Official Immunization Record.

§100.8. Complaints.

Legend: (Proposed Amendment(s))

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) Child--The person or individual younger than 18 years of age to whom a vaccine has been administered.

(2) Consent--A statement signed by a parent, managing conservator, or legal guardian agreeing that the child's immunization history can be included in the registry and that the child's immunization record may be released from the registry.

(3) Data elements--The information:

(A) consistent with 42 U.S.C. §300aa-25, as amended, defined as the information a provider who administers a vaccine is required to record in a medical record, including:

(i) the date the vaccine is administered;

(ii) the type of vaccine administered, vaccine manufacturer and lot number;

(iii) the name, address, and if appropriate, the title of the provider administering the vaccine; and

(iv) any adverse or unexpected events for a vaccine; and

(B) relating to an immunization, antiviral, and/or other medication administered to prepare for a potential disaster, public health emergency, terrorist attack, hostile military or paramilitary action, or extraordinary law enforcement emergency or in response to a declared disaster, public health emergency, terrorist attack, hostile military or paramilitary action, or extraordinary law enforcement emergency.

**[Consistent with 42 U.S.C. §300aa-25, as amended, data elements are defined as the information a provider who administers a vaccine is required to record in a medical record, including:]**

**[(A) the date the vaccine is administered;]**

**[(B) the type of vaccine administered, vaccine manufacturer and lot number; and]**

**[(C) the name, address, and, if appropriate, the title of the provider administering the vaccine.]**

(4) Department--The Department of State Health Services [**Texas Department of Health**].

(5) Extraordinary Law Enforcement Emergency--Within the context of a public health emergency, a situation which requires extra staffing, overtime and/or extra-jurisdictional law enforcement forces.

(6) First Responder--As defined by Government Code, §421.095.

(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.

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

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

(10) [(6)] 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.

(11) [(7)] 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.

**[(8) Parent--A parent, managing conservator, or legal guardian.]**

(12) [(9)] 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.

(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.

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

(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.

(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.

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

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

## §100.2. Confidentiality.

(a) Except as provided by Health and Safety Code, Chapter 161, Subchapter A, §161.00705, information [Information] that individually identifies a child or other individual, and is received by the department for the immunization registry, is confidential and may be used by the department for registry purposes only. Unless specifically authorized by Health and Safety Code, Chapter 161, Subchapter A, the department may not release registry information to any individual or entity without the written consent of the person or, if a minor, the parent, managing conservator, or legal guardian.

(b) A written confidentiality statement shall be signed by an authorized representative of the user. Any user of the registry shall protect the confidentiality of all immunization histories, records, and reports. Registry information may only be accessed by the limited persons, and used for the limited stated purposes, detailed at §100.5(e) of this title (relating to Receipt and Release of Registry Data). A person required to report information to the department for registry purposes or authorized to receive information from the registry may not disclose individually identifiable information of a child or other individual to any individual or entity without the written consent of the individual [person] or, if a child [minor], the parent, managing conservator or legal guardian, or except as provided by the Occupations Code, Chapter 159, or the Insurance Code, Article 28B.04.

(c) Registry information is not subject to discovery, subpoena, or other means of legal compulsion for release to any person or entity, except as provided by Health and Safety Code,

Chapter 161, Subchapter A. Registry information is not admissible in any civil, administrative, or criminal proceeding.

§100.3. Informing Parent, Managing Conservator, or Legal Guardian.

(a) A parent, managing conservator or legal guardian of a patient younger than 18 years of age shall be informed, via the methodology described at subsection (b) of this section, that the department has established and maintains an immunization registry for the primary purpose of establishing and maintaining a single repository of immunization records to be used in aiding, coordinating, and promoting efficient and cost-effective childhood vaccine-preventable disease prevention and control efforts.

(b) The department shall provide written materials and forms to providers for the purpose of informing a parent, managing conservator or legal guardian about the immunization registry and specific information collected in that registry.

(c) The department and providers may use the registry to provide notices by mail, telephone, personal contact, or other means to a parent, managing conservator or legal guardian regarding his or her child who may be due or overdue for a particular vaccine according to the department's immunization schedule.

(d) The first time the department receives registry data, from a person other than the child's parent, managing conservator or legal guardian, for a child for whom the department has received consent to be included in the registry, the department shall send a written notice to the parent, managing conservator or legal guardian disclosing:

(1) that providers and payors may be sending the child's immunization information to the department;

(2) the information that is included in the registry;

(3) the persons to whom the information may be released;

(4) the purpose of the registry;

(5) the procedure to exclude a child from the registry; and

(6) the procedure to report an alleged [a] violation if a parent, managing conservator or legal guardian discovers a child is included in the registry after exclusion has been requested.

§100.4. Registry Consent and Withdrawal Relating to a Minor.

(a) A parent, managing conservator or legal guardian of a patient younger than 18 years of age may consent to the inclusion of the child's immunization history in the immunization registry by doing one of the following:

(1) indicating consent at birth certificate registration, including by electronic signature;

(2) submitting written notification to the department in a format prescribed by the department or substantially similar and mailed to the Department of State Health Services [Texas Department of Health], Immunization Branch [Division], 1100 West 49th Street, MC-1946, Austin, Texas 78756, or by calling the Immunization Branch [Division] at (800) 252-9152 to request a consent form; **[or]**

(3) completing written consent to be submitted to a health care provider, birth registrar, regional health information exchange, or local immunization registry, who may review that consent and affirm that consent has been obtained via an affirmation process as directed by the department [by a provider or payor].

(b) Unless otherwise provided by §100.7 of this title (related to Potential and Declared Disasters, Public Health Emergency, Terrorist Attack, Hostile Military or Paramilitary Action, and Extraordinary Law Enforcement Emergency Event), the department shall verify consent before including the reported information regarding the child in the immunization registry. Under Health and Safety Code, §161.007(a)(5), the department may elect to verify consent by receiving affirmation from a health care provider, birth registrar, regional health information exchange, or local immunization registry that consent has been obtained. The department shall provide notice to a provider that submits data elements for a person for whom consent cannot be verified. The notice shall contain instructions for obtaining and affirming consent and resubmitting the data elements to the department.

(c)[(b)] Consent is required to be obtained only one time, and is valid until the child becomes 18 years of age, unless the consent is withdrawn in writing.

(d) [(c)] A parent, managing conservator or legal guardian of a patient younger than 18 years of age may withdraw consent for the child to be included in the registry at any time by submitting written notification to the department in a format prescribed by the department or substantially similar and mailed to the Department of State Health Services [Texas Department of Health], Immunization Branch [Division], 1100 West 49th Street, MC-1946, Austin, Texas 78756, or by calling the Immunization Branch [Division] at (800) 252-9152 to request a consent withdrawal form. Unless otherwise provided by §100.7 of this title, the [The] department shall remove information from the immunization registry for any person for whom consent has been withdrawn, and the department shall send the parent, managing conservator or legal guardian a written confirmation of the removal of the information. The department may not retain individually identifiable information about any person for whom consent has been withdrawn except as provided for by §100.7 of this title.

(e)[(d)] A parent, managing conservator or legal guardian may request exclusion of a **[the]** child's immunization history from the immunization registry by doing one of the following:

(1) indicating the request for exclusion at birth certificate registration, including by electronic signature; or

(2) submitting written notification to the department in a format prescribed by the department or substantially similar and mailed to the Department of State Health Services [Texas Department of Health], Immunization Branch [Division], 1100 West 49th Street, MC-1946, Austin, Texas 78756, or by calling the Immunization Branch [Division] at (800) 252-9152 to request an exclusion form. Unless otherwise provided by §100.7 of this title, on [On] receipt of a written request to exclude a child's immunization records from the registry, the department shall send the parent, managing conservator or legal guardian a written confirmation of receipt of the request, and shall exclude the child's records from the registry. The department may not retain individually identifiable information about any person for whom an exclusion has been requested, unless otherwise allowed under §100.7 of this title.

#### §100.5. Receipt and Release of Registry Data.

(a) The immunization registry must contain information on the immunization history obtained by the department under this chapter regarding:

(1) a person who is younger than 18 years of age and for whom consent has been obtained;

(2) persons immunized to prepare for or in response to an event under §100.7 of this title (relating to Potential and Declared Disasters, Public Health Emergency, Terrorist Attack, Hostile Military or Paramilitary Action, and Extraordinary Law Enforcement Emergency Event); and

(3) first responders and/or their immediate family members for whom a request has been submitted, as described at §100.8 of this title (relating to First Responder Immunization Information).

(b) [(a)] The department may obtain the data constituting an immunization record for a person [child] from a public health district, a local health department, the [child's] parent, managing conservator or legal guardian of a patient younger than 18 years of age, a physician [to the child], a payor, or from any health care provider licensed (or otherwise legally authorized) to administer vaccines. Submission of this information must be according to the procedures and in the format prescribed by the department.

(c) [(b)] Except as provided by §100.7 and §100.8 of this title [Effective January 1, 2005], the department shall verify consent before including information received under subsection (b) of this section [from a person other than the child's parent] in the immunization registry. The [Effective January 1, 2005, the] department may not retain individually identifiable information about a person for whom consent cannot be verified.

(d) When the department verifies consent under subsection (c) of this section, it may do so by any of the following, at its discretion:

(1) manual or electronic review of the consent form document signed (including by electronic signature) by a parent, managing conservator or legal guardian at birth certificate registration;

(2) manual or electronic review of a consent form signed by a parent, managing conservator or legal guardian and submitted to the department by mail to the Department of State Health Services, Immunization Branch, 1100 West 49th Street, MC-1946, Austin, Texas 78756 (consent forms may also be received by facsimile);

(3) affirmation by a health care provider, birth registrar, regional health information exchange, or local immunization registry that consent has been obtained, as described in Health and Safety Code, §161.007(a)(5), and in a manner prescribed by the department.

(e) [(c)] Except as limited by subsections (f) and (g) of this section, the [The] department may release the data constituting an immunization record: **[for a child to any entity that is described by subsection (a) of this section to a school or child care facility in which the child is enrolled, or to a state agency having legal custody of the child.]**

(1) to the parent, managing conservator, and/or legal guardian of a person younger than 18 years of age; and/or

(2) to the following entities, with those entities subject to the stated limitations:

(A) a Texas public health district or a Texas local health department, for public health purposes within their areas of jurisdiction;

(B) a physician or any health care provider licensed (or otherwise legally authorized) to administer vaccines in Texas, for treating the child as a patient;

(C) a Texas school or Texas child care facility, for a child enrolled in that school or child care facility;

(D) a payor currently authorized by the Texas Department of Insurance to operate in Texas, for immunization records related to the specific person in Texas covered under the payor's policy; and/or

(E) a state agency having legal custody of a child.

(3) Direct electronic access to the immunization registry information shall be limited to entities described in paragraph (2) of this subsection, for use under the stated limitations and subject to registration and access requirements as provided by the department.

(f) For persons immunized to prepare for, or in response to, an event covered by §100.7 of this title, the department may release information from the registry as provided in §100.7(f) of this title.

(g) For first responders and/or their immediate family members 18 years of age or older, the department may release information from the registry as provided in §100.8(e) of this title.

(h) [(d)] Health and Safety Code, §161.0105, provides limited liability protections, as described in those provisions. [A person, including a provider, a payor, or an employee of the department, that submits in good faith an immunization history or data to or obtains in good faith an immunization history or data from the department in compliance with this section is not liable for any civil damages.]

(i) [(e)] The department may release nonidentifying summary statistics related to the registry that do not individually identify an individual [a child].

§100.6. Reporting to the Registry, and Medical Verification, relating to a Minor.

(a) Data elements regarding an immunization record provided to the department under this section, whether electronically or by other means, shall be submitted in a format and manner prescribed by the department.

(b) Except as otherwise provided by §100.7 of this title (relating to Potential and Declared Disasters, Public Health Emergency, Terrorist Attack, Hostile Military or Paramilitary Action, and Extraordinary Law Enforcement Emergency Event), [Effective January 1, 2005,] a health care provider who administers an immunization to a person younger than 18 years of age shall provide data elements regarding an immunization to the department within 30 days of administration of the vaccine. **[Effective January 1, 2005, the department shall verify consent before including the reported information in the immunization registry, and the department may not retain individually identifiable information about a person for whom consent cannot be verified. For immunizations administered prior to January 1, 2005, providers shall provide an immunization history for persons for whom consent to participate in the registry has been obtained unless the immunization history is submitted to a payor.]**

(c) A [Effective January 1, 2005, a] payor that receives data elements from a provider who administers an immunization to a person younger than 18 years of age shall provide the data elements to the department within 30 days of receipt of the data elements from a provider. **[Effective January 1, 2005, the department shall verify consent before including the reported information in the immunization registry, and the department may not retain individually identifiable information about a person for whom consent cannot be verified. For immunizations administered prior to January 1, 2005, payors shall provide an immunization history for persons for whom consent to participate in the registry has been obtained.]**

(d) A parent, managing conservator or legal guardian may provide evidence of a child's immunization history [**, in a format provided by the department or one substantially similar,**] directly to the department for inclusion in the registry. The department shall ensure that the immunization history submitted by a parent, managing conservator or legal guardian is medically verified immunization information by requiring the parent, managing conservator or legal guardian to submit evidence that includes a copy of one or more of the following:

(1) the child's medical record indicating the immunization history and including a provider's signature and the name and address of the provider;

(2) A vaccine-specific invoice from a health care provider for the immunization;

(3) vaccine-specific documentation showing that a claim for the immunization was paid by a payor;

(4) an immunization record signed by a school official; or

(5) an immunization history provided by a local or state immunization registry.

**[(e) The department shall provide notice to a provider that submits an immunization history for a person for whom consent cannot be verified. The notice shall contain instructions for obtaining consent and resubmitting the immunization history to the department.]**

**(e) [(f)]** A provider shall, upon request of the department, provide additional information to clarify data elements [**an immunization history**] submitted to the department.

**(f) [(g)]** The department shall provide instruction and education to providers about the immunization registry provider application and enrollment process and expedite processing of provider applications.

Legend: (Proposed New Rule)

Regular Print = Proposed new language

§100.7. Potential and Declared Disasters, Public Health Emergency, Terrorist Attack, Hostile Military or Paramilitary Action, and Extraordinary Law Enforcement Emergency Event.

(a) The immunization registry shall contain information regarding persons who receive an immunization, antiviral, and/or other medication administered:

(1) to prepare for a potential disaster, public health emergency, terrorist attack, hostile military or paramilitary action, and/or an extraordinary law enforcement emergency event, as those terms are defined in §100.1 of this title (relating to Definitions);

(2) in response to a declared disaster, public health emergency, terrorist attack, hostile military or paramilitary action and/or extraordinary law enforcement emergency event, as those terms are defined in §100.1 of this title.

(b) A health care provider who administers an immunization, antiviral, and/or other medication as described in subsection (a) of this section shall provide the data elements to the department, within 30 days of that medical treatment, in a format and manner prescribed by the department.

(c) The department shall track, in the immunization registry, adverse reactions to an immunization, antiviral, and/or other medication administered as described in subsection (a) of this section. A health care provider who administers such an immunization, antiviral, and/or other medication may provide data related to adverse reactions to the department, in a format and manner prescribed by the department, for inclusion in the immunization registry. Department tracking will be based on the reports it receives under this subsection.

(d) Unless consent is obtained and verified, the individually identifiable information collected in the registry under this section shall only be retained in the registry for a period of 5 years following the end of the event as described in subsection (a) of this section. The end date of these occurrences shall be as specifically provided for by law. In the absence of law which specifically determines the end date, the department shall determine such an end date and post that date on its website.

(e) An individual or, if a child, the child's parent, managing conservator or legal guardian, may consent in writing to the continued inclusion of the person's information collected under this section in the registry past the retention time period specified in subsection (d) of this section by:

(1) mailing (or faxing) written notification to the department, in a format prescribed by the department, at: Department of State Health Services, Immunization Branch, 1100 West 49th Street, MC-1946, Austin, Texas 78756, (a consent form may be obtained by calling the Immunization Branch at (800) 252-9152, or online at [www.ImmTrac.com](http://www.ImmTrac.com)); or

(2) completing a consent form document, which must be verified by affirmation by a health care provider in a manner prescribed by the department.

(f) The department may release the information collected in the registry under this section with consent of the individual or, if a child, the child's parent, managing conservator or legal guardian, or to a state agency or health care provider for:

(1) the purposes outlined in Health and Safety Code, Chapter 161, Subsection A;  
and/or

(2) the purpose of aiding and coordinating communicable disease prevention and control efforts during an event as described in subsection (a) of this section.

§100.8. First Responder Immunization Information.

(a) A person 18 years of age or older who is a first responder or an immediate family member of a first responder may request that a health care provider who administers an immunization to the person provide the data elements regarding the immunization to the department for inclusion in the registry.

(b) A health care provider, on receipt of a request under subsection (a) of this section, shall submit the data elements to the department within 30 days of administration of the vaccine in a format and manner prescribed by the department. The department shall verify the request before including the information in the registry. The department may elect to verify the request for inclusion in the registry by obtaining an affirmation from the health care provider that a request has been received.

(c) A person 18 years of age or older who is a first responder or an immediate family member of a first responder may request inclusion of that person's immunization history in the registry by:

(1) mailing written notification to the department, in a format prescribed by the department, at: Department of State Health Services, Immunization Branch, 1100 West 49th Street, MC-1946, Austin, Texas 78756, (a request form may be obtained by calling the Immunization Branch at (800) 252-9152 , or online at [www.ImmTrac.com](http://www.ImmTrac.com)); or

(2) completing a written request to the person's health care provider, to be verified by affirmation (in a manner prescribed by the department) by the health care provider that such a request has been received.

(d) The department shall ensure that the immunization history submitted by the individual under subsection (c)(1) of this section is medically verified immunization information by requiring the individual to submit evidence that includes a true and accurate copy of one or more of the following:

(1) the individual's medical record indicating the immunization history and including a provider's signature and the name and address of the provider;

(2) a vaccine-specific invoice from a health care provider for the immunization;

(3) vaccine-specific documentation showing that a claim for the immunization was paid by a payor;

(4) an immunization record signed by a school official; or

(5) an immunization history provided by a local or state immunization registry.

(e) The department may release the information collected in the registry under this section with consent of the individual or to any health care provider licensed or otherwise authorized to administer vaccines.

(f) A person whose immunization records are included in the registry under this section may request in writing that the department remove the information from the registry. The department shall remove the person's immunization records from the registry not later than the 10th day after receiving a request.

§100.9. Official Immunization Record. An immunization record obtained from the immunization registry shall be accepted as an official immunization record of the individual.

§100.10. Complaints.

(a) A person may file a complaint with the department related to the department's alleged failure to comply with a request for exclusion of an individual from the registry by mailing such a complaint to: Manager, Immunization Branch, Department of State Health Services, 1100 West 49th Street, MC-1946, Austin, Texas 78756; or by e-mail to the attention of Manager, Immunization Branch at [feedback.ImmDirector@dshs.state.tx.us](mailto:feedback.ImmDirector@dshs.state.tx.us). The department shall respond to the written complaint within 30 days of that receipt of that complaint.

(b) A person may report an incident of discrimination for requesting exclusion of an individual from the registry, or for using an exemption for a required immunization, by mailing written notification to: Manager, Immunization Branch, Department of State Health Services, 1100 West 49th Street, MC-1946, Austin, Texas 78756; or by e-mail to the attention of Manager, Immunization Branch at [feedback.ImmDirector@dshs.state.tx.us](mailto:feedback.ImmDirector@dshs.state.tx.us). The department shall respond to the written notification within 30 days of receipt of that notification.

(c) The department shall report to the Legislative Budget Board, the governor, the lieutenant governor, the speaker of the House of Representatives, and appropriate committees of the legislature not later than September 30 of each even-numbered year. The report shall:

(1) include the number of complaints received by the department related to the department's alleged failure to comply with requests for exclusion of individuals from the registry;

(2) identify all reported incidents of discrimination for requesting exclusion of individuals from the registry or for using an exemption for a required immunization;

(3) include the number of complaints received by the department related to the department's alleged failure to remove information from the registry as required by §100.7 of this title (relating to Potential and Declared Disasters, Public Health Emergency, Terrorist Attack, Hostile Military or Paramilitary Action, and Extraordinary Law Enforcement Emergency Event) after an event described in that section; and

(4) include the number of complaints received by the department related to the department's alleged failure to comply with written requests for the removal of information relating to first responders and their immediate family under §100.8 of this title (relating to First Responder Immunization Information).

Sections for repeal.

#### ~~§100.7. Official Immunization Record~~

~~An immunization record obtained from the immunization registry shall be accepted as an official immunization record of the child.~~

#### ~~§100.8. Complaints.~~

~~(a) A person may file a complaint with the department related to the department's failure to comply with a request for exclusion of an individual from the registry by mailing written notification to: Director, Immunization Division, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756; or by e-mail to the attention of Director, Immunization Division at feedback.ImmDirector@tdh.state.tx.us. The department shall respond to the written complaint within 30 days of receipt of the complaint.~~

~~(b) A person may report an incident of discrimination for requesting exclusion of an individual from the registry, or for using an exemption for a required immunization, by mailing written notification to: Director, Immunization Division, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756; or by e-mail to the attention of Director, Immunization Division at feedback.ImmDirector@tdh.state.tx.us. The department shall respond to the written notification within 30 days of receipt of the notification.~~

~~(c) The department shall report to the Legislative Budget Board, the governor, the lieutenant governor, the speaker of the house of representatives, and appropriate committees of the legislature not later than September 30 of each even-numbered year. The report shall:~~

~~—(1) include the number of complaints received by the department related to the department's failure to comply with requests for exclusion of individuals from the registry; and~~

~~—(2) identify all reported incidents of discrimination for requesting exclusion of individuals from the registry or for using an exemption for a required immunization.~~