

**Department of State Health Services
Council Agenda Memo for State Health Services Council
November 19 – 20, 2014**

Agenda Item Title: Amendment to a rule concerning immunization requirements in Texas elementary and secondary schools

Agenda Number: 4.b

Recommended Council Action:

For Discussion Only

For Discussion and Action by the Council

Background:

The Immunization Branch, located in the Infectious Disease Control Unit/Infectious Disease Prevention Section in 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 3,600 clinic sites across the state;
- administering ImmTrac, the statewide immunization registry;
- contracting with local health departments to enhance 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 state general revenue funds.

Summary:

The purpose of the amendment is to improve immunization requirements in Texas elementary and secondary schools and adhere more closely to the latest CDC Advisory Committee on Immunization Practices (ACIP) recommended immunization schedule. The amendment would also clearly state that the requirements are given for each vaccination series as a window of time with an age/grade by which the vaccination must be given as well as an age/grade before which it should not be given.

DSHS recommends the rule changes become effective for School Year (SY) 2015-2016 to allow sufficient time for schools and physicians to become aware of and comply with the requirements.

The rule changes:

- continue the varicella vaccine requirement of two doses for students on or after the first birthday in order to be admitted to kindergarten;
- remove outdated schedule language for the SY 2008 - 2009 requirements;
- delete epidemiologic requirements for hepatitis A vaccine in endemic areas, which are otherwise required statewide for students K - 6th grade;
- continue the meningococcal vaccine requirement and update language to be consistent with the ACIP schedule, which recommends all students aged 11 - 12 years or entering 7th grade to be vaccinated with one dose of meningococcal vaccine; and
- comply with the four-year review of agency rules required by Government Code, Section 2001.039.

The rule changes are anticipated to increase the timeliness of immunizations, therefore further preventing vaccine-preventable diseases for the state of Texas. The rule changes will increase the covered ages for vaccines, will increase vaccine coverage, and provide clarification for constituents regarding the requirements. These requirements will be easier to follow and require vaccinations for a broader group rather than an incremental implementation as previously required for the public and health care providers.

Key Health Measures:

The expected outcome is an increase in immunization rates among children and adults to protect against vaccine-preventable diseases. The Immunization Branch conducts annual assessments and surveys, which include the Annual Report of Immunization Status and the annual audit of public schools.

The current data (baseline) includes assessments that have been conducted in public/private schools and child-care facilities. Surveys/audits will be used to collect information about the implementation of the amended rule in subsequent years to measure program impact.

Summary of Input from Stakeholder Groups:

The following stakeholders were contacted in September 2014 via email with the draft proposed rules to solicit comments. The stakeholders included:

- Regional and Local Health Department Immunization Program Managers
- San Antonio Metropolitan Health District
- Houston Department of Health and Human Services
- Texas Higher Education Coordinating Board
- Texas Education Agency
- Department of Family and Protective Services
- Texas Medical Association
- Texas School Nurses Association Alliance Committee
- Texas Medical Association
- Texas School Alliance

No changes to the proposed rule were made as a result of the stakeholder’s informal comments, because some requested changes were actually already in the rule, and one informal comment regarding the meningococcal vaccine schedule relates to an issue currently under consideration by DSHS.

Proposed Motion:

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

Approved by Assistant Commissioner/Director: Janna Zumbrun **Date:** 10/28/2014

Presenter: Wesley Hodgson **Program:** Immunization Branch **Phone No.:** 512-776-6470

Approved by CCEA: Carolyn Bivens **Date:** 10/28/2014

Title 25. HEALTH SERVICES
Part 1. DEPARTMENT OF STATE HEALTH SERVICES
Chapter 97. Communicable Diseases
Subchapter B. Immunization Requirements in Texas Elementary and Secondary Schools and
Institutions of Higher Education
Amendments §97.63

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 §97.63, concerning immunization requirements in Texas elementary and secondary schools.

BACKGROUND AND PURPOSE

Government Code, §2001.039, requires that each state agency review and consider for readoption every four years each rule adopted by that agency pursuant to Government Code, Chapter 2001 (Administrative Procedure Act). Section 97.63 has been reviewed and the department has determined that reasons for maintaining this rule section continue to exist, given the subject matter and the importance to public health.

For those Texas vaccination requirements which are organized in rule by individual school year, periodically those rules must be amended to extend the schedule into future years in order to prevent a lapse in the schedule at issue. This rulemaking action would make such schedule extensions. There are no new vaccinations being added in this rulemaking action. The department also proposes to take this opportunity to delete those parts of the schedule concerning years that have already passed. These amendments would also clarify wording to more clearly state that the requirements are given for each vaccination series as a window of time—with an age/grade by which the vaccination must be given as well as an age/grade before which it should not be given. This rulemaking proposal would also make a few minor non-sustantive amendments designed to improve the efficiency and readability of this rule section. The proposed language concerning vaccination requirements for future years is consistent with the national vaccine schedule recommendations for the immunizations at issue, per the Centers for Disease Control and Prevention (CDC), Advisory Committee on Immunization Practices (ACIP) recommended immunization schedule (see <http://www.cdc.gov/vaccines/schedules/>).

SECTION-BY-SECTION SUMMARY

There are only three categories of changes proposed for this rule section: 1) changes, for the vaccinations indicated herein, to extend the vaccination schedules forward into future years, to prevent a lapse in the requirements at issue, while also deleting those parts of the schedule related to years that have passed; 2) clarification of the global language regarding how the requirements apply; and 3) non-sustantive clerical wording changes to improve readability and the user-friendliness of the rules.

In the introductory paragraph to the rule section, clarifying language is proposed that would more clearly state that all the vaccination requirements are expressed as a window in time—with an age/grade by which the child must have the vaccination in order to be allowed to go to school, and an age before which the child should not have the particular vaccination at issue. This is not a change to how the requirements have applied, but rather an improvement in the wording to make the concept easier to understand.

For the Tetanus, Diphtheria, Pertussis (Tdap) vaccine, in §97.63(2)(B)(ii)(III)(-a-), the proposed amendment would remove outdated schedule language in rule subdivision item (-a-) for the School Year (SY) 2008 – 2009, since that requirement has no current relevance. Existing items (-b-) and (-c-) would be renumbered as items (-a-) and (-b-).

For the Measles, Mumps, Rubella (MMR) vaccine, in §97.63(2)(B)(iii)(I), the proposed amendment would remove outdated schedule language in subclause (I) concerning the SY 2008 – 2009, since that requirement has no current relevance. The numbering for subclause (II)(-a-) - (-m-) would be renumbered as subclauses (I) - (XIII).

For the varicella vaccine, in §97.63(2)(B)(v)(I), the proposed amendment would remove outdated schedule language in subclause (I) concerning the SY 2008 – 2009, since that requirement has no current relevance. Existing subclause (II) would be renumbered as subclause (I).

For the varicella vaccine, in renumbered §97.63(2)(B)(v)(II), the department proposes to clarify the rule language to prevent a lapse in the vaccine requirements. The current schedule reflects a graded approach tied to specific calendar school years. The proposed language would simply state that, beginning in the SY 2015 - 2016, all children must be vaccinated with two doses of varicella vaccine in order to be admitted to kindergarten. The language would also provide a minimum age before which the vaccination should not be given, based on the federal recommendations.

For the hepatitis A vaccine, in §97.63(2)(B)(vi)(I), the proposed amendment would remove outdated schedule language in subclause (I) concerning the SY 2008 – 2009, since that requirement has no current relevance. Subclause (II)(-a-) - (-m-) would be renumbered as subclauses (I) - (XIII).

For the meningococcal vaccine, in §97.63(2)(B)(vii)(II), an amendment requiring all students aged 11 - 12 years or entering 7th grade to be vaccinated with one dose of meningococcal vaccine is proposed to begin with the SY 2015 - 2016. The proposed amendment would avoid a lapse in meningococcal requirements.

Related to the third category of proposed changes in §97.63(1), the proposed amendment would change the phrase “for which” to “where;” the word “deadline” would be replaced with “birthday;” and the phrase “with that deadline” would be deleted. These clerical revisions are non-substantive wording changes, which would increase readability and improve user-friendliness.

FISCAL NOTE

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

MICRO-BUSINESSES AND SMALL BUSINESSES 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 section as proposed. This was determined by interpretation of the rule that small businesses and micro-businesses will not be required to alter their business practices, in a manner which would incur an adverse impact, in order to comply with the section. 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 section as proposed. There is no anticipated negative impact on local employment.

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 amendments would 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 BENEFIT

In addition, Ms. Garcia has determined that for each year of the first five years the section is in effect, the public will benefit from adoption of the section. The public benefit anticipated as a result of enforcing or administering the section is the protection of Texas residents against the vaccine-preventable diseases. The proposed amendments are beneficial to public health because the amendments would prevent lapses in the Texas vaccine requirement schedules. Vaccinations are a major part of Texas public health efforts to prevent and control communicable diseases. In addition, the non-substantive clerical changes would improve the rule's readability and user-

friendliness, which would have a positive impact on stakeholders who routinely reference this rule.

PUBLIC COMMENT

Comments on the proposal may be submitted to Wesley Hodgson, Department of State Health Services, Infectious Disease Prevention Section, Immunization Branch, Mail Code 1946, P. O. Box 149347, Austin, Texas 78714-9347, or by email to Wesley.Hodgson@dshs.texas.gov. 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 rule has been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

STATUTORY AUTHORITY

The amendment is authorized by Health and Safety Code, §81.023, which requires the department to develop immunization requirements for children; Health and Safety Code, §161.004, which allows the department to develop and implement immunization requirements for vaccine-preventable diseases; and by 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 review of the section implements Government Code, §2001.039.

The amendment affects Government Code, Chapters 531 and 2001; and Health and Safety Code, Chapters 81, 161 and 1001.

Legend: (Proposed Amendments)

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

§97.63. Immunization Requirements in Child-care Facilities, Pre-Kindergarten, Early Childhood Programs, and Texas Elementary and Secondary Schools.

Every child in the state shall be vaccinated against vaccine-preventable diseases caused by infectious agents, in accordance with the following immunization schedule. While the department recommends that providers immunize children according to the recommendations found on the department's website at www.ImmunizeTexas.com, this section sets out minimum immunization requirements for school entry for the child. The child must have the indicated vaccinations by the grade level indicated. The vaccination schedule also indicates the grade before which the child should not obtain the specific vaccination. A copy of the current recommended schedule is available at www.ImmunizeTexas.com, or by mail by writing the Department of State Health Services, Mail Code 1946, P. O. Box 149347, Austin, Texas 78714-9347.

(1) For those vaccines where **[for which]** it is stated in this section that a certain dose must be received on or after a certain birthday, a vaccine administered up to four days prior to the birthday **[deadline]** is considered compliant **[with that deadline]**.

(2) For diseases listed below, a child or student shall show acceptable evidence of vaccination prior to entry, attendance, or transfer to a child-care facility or public or private elementary or secondary school.

(A) Children enrolled in child-care facilities, pre-kindergarten, or early childhood programs shall be immunized against: diphtheria, pertussis, tetanus, poliomyelitis, *Haemophilus influenzae* type b (Hib), measles, mumps, rubella, hepatitis B, hepatitis A, invasive pneumococcal, and varicella diseases. In recognition of the fact that immunization needs vary depending on the age of the child, the minimum number of doses required for each vaccine is indicated in the schedule below:

25 TAC Figure §97.63(2)(A) (No change.)

(B) Students in kindergarten through twelfth grade shall have the following vaccines, according to the schedule listed.

(i) Poliomyelitis.

(I) Kindergarten entry. Students are required to have four doses of polio vaccine--one of which must have been received on or after the fourth birthday. Or, if the third dose was administered on or after the fourth birthday, only three doses are required. Four doses of oral polio vaccine (OPV) or inactivated poliovirus vaccine (IPV) in any combination by

age four to six years old is considered a complete series, regardless of age at the time of the third dose.

(II) Polio vaccine is not required for persons eighteen years of age or older.

(ii) Diphtheria/Tetanus/Pertussis.

(I) Kindergarten entry. Students are required to have five doses of a diphtheria/tetanus/pertussis-containing vaccine-one of which must have been received on or after the fourth birthday. Or, if the fourth dose was administered on or after the fourth birthday, only four doses are required.

(II) Students seven years of age or older. Students seven years of age or older are required to have at least three doses of a tetanus/diphtheria-containing vaccine, provided at least one dose was administered on or after the fourth birthday. Any combination of three doses of a tetanus/diphtheria-containing vaccine will meet this requirement.

(III) Tdap.

[(-a-) For the school year (SY) 2008 - 2009 through the end of any summer session of the SY 2008 - 2009, students are required to have one dose of a tetanus/diphtheria-containing vaccine within the last ten years.]

(-a-) ~~[(-b-)]~~ Seventh grade. Beginning SY 2009 - 2010, students will be required to have one booster dose of a tetanus/diphtheria/pertussis-containing vaccine for entry into the 7th grade, if at least five years have passed since the last dose of a tetanus-containing vaccine. If five years have not elapsed since the last dose of a tetanus-containing vaccine at entry into the 7th grade, then this dose will become due as soon as the five-year interval has passed. Td vaccine is an acceptable substitute, if Tdap vaccine is medically contraindicated.

(-b-) ~~[(-c-)]~~ Grades 8 - 12. Beginning SY 2009 - 2010, students who have not already received Tdap vaccine are required to receive one booster dose of Tdap when ten years have passed since the last dose of a tetanus-diphtheria-containing vaccine.

(IV) Children who were enrolled in school, grades K - 12, prior to August 1, 2004, and who received a booster dose of DTaP or polio vaccine in the calendar month of (or prior to) their fourth birthday, shall be considered in compliance with clause (i)(I) (polio) and clause (ii)(I) (DTaP) of this subparagraph.

(iii) MMR.

[(I) For the SY 2008 - 2009 through the end of any summer session of the SY 2008 - 2009, students are required to have two doses of a measles-containing vaccine, and one dose each of rubella vaccine and mumps vaccine.]

[(II)] Beginning SY 2009 - 2010, students are required to have two doses of MMR vaccine with the first dose received on or after the first birthday for the following grades and school years:

(I) **[(-a-)]** SY 2009 - 2010: K;

(II) **[(-b-)]** SY 2010 - 2011: K - 1;

(III) **[(-c-)]** SY 2011 - 2012: K - 2;

(IV) **[(-d-)]** SY 2012 - 2013: K - 3;

(V) **[(-e-)]** SY 2013 - 2014: K - 4;

(VI) **[(-f-)]** SY 2014 - 2015: K - 5;

(VII) **[(-g-)]** SY 2015 - 2016: K - 6;

(VIII) **[(-h-)]** SY 2016 - 2017: K - 7;

(IX) **[(-i-)]** SY 2017 - 2018: K - 8;

(X) **[(-j-)]** SY 2018 - 2019: K - 9;

(XI) **[(-k-)]** SY 2019 - 2020: K - 10;

(XII) **[(-l-)]** SY 2020 - 2021: K - 11; and

(XIII) **[(-m-)]** SY 2021 - 2022: K - 12.

(iv) Hepatitis B.

(I) Students are required to have three doses of hepatitis B vaccine no later than entry into kindergarten.

(II) In some circumstances, the United States Food and Drug Administration may officially approve in writing the use of an alternative dosage schedule for this vaccine. Such an alternative regimen may be used to meet the requirements under this section only when alternative regimens are fully documented. Such documentation must include vaccine manufacturer and dosage received for each dose of that vaccine.

(v) Varicella.

[(I) For the SY 2008 - 2009 through the end of any summer session of the SY 2008 - 2009, students are required to have one dose of varicella vaccine received on or after the first birthday for grades K - 12.]

(I) [(II)] Beginning SY 2009 - 2010, students are required to have two doses of varicella vaccine received on or after the first birthday for the following grades and school years (Two doses are required if the child was thirteen years old or older at the time the first dose of varicella vaccine was received):

(-a-) SY 2009 - 2010: K, 7;

(-b-) SY 2010 - 2011: K - 1, 7 - 8;

(-c-) SY 2011 - 2012: K - 2, 7 - 9;

(-d-) SY 2012 - 2013: K - 3, 7 - 10;

(-e-) SY 2013 - 2014: K - 4, 7 - 11; and

(-f-) SY 2014 - 2015: K - 5, 7 - 12[; **and**]

[(~~-g-~~) SY 2015 - 2016: K - 12].

[(II) Effective SY 2015 - 2016, students are required to have two doses of varicella vaccine on or after the first birthday in order to be admitted to kindergarten.]

(vi) Hepatitis A.

[(I) For the SY 2008 - 2009 through the end of any summer session of the SY 2008 - 2009, upon entry into kindergarten through third grade, two doses of hepatitis A vaccine are required for students attending a school located in a high incidence geographic area as designated by the department. The first dose shall be administered on or after the second birthday. A current list of geographic areas, for which hepatitis A is mandated for this time period, is available at www.ImmunizeTexas.com, or by mail request at Department of State Health Services, P.O. Box 149347, Austin Texas 78714-9347.]

[(II)] For SY 2009 - 2010, students are required to have two doses of hepatitis A vaccine with the first dose received on or after the first birthday for the following grades and school years:

(I) [(~~-a-~~)] SY 2009 - 2010: K;

(II) [(~~-b-~~)] SY 2010 - 2011: K - 1;

(III) [(~~-c-~~)] SY 2011 - 2012: K - 2;

- (IV) [(-d-)] SY 2012 - 2013: K - 3;
- (V) [(-e-)] SY 2013 - 2014: K - 4;
- (VI) [(-f-)] SY 2014 - 2015: K - 5;
- (VII) [(-g-)] SY 2015 - 2016: K - 6;
- (VIII) [(-h-)] SY 2016 - 2017: K - 7;
- (IX) [(-i-)] SY 2017 - 2018: K - 8;
- (X) [(-j-)] SY 2018 - 2019: K - 9;
- (XI) [(-k-)] SY 2019 - 2020: K - 10;
- (XII) [(-l-)] SY 2020 - 2021: K - 11; and
- (XIII) [(-m-)] SY 2021 - 2022: K - 12.

(vii) Meningococcal.

(I) Students are required to have one dose of meningococcal vaccine for the following grades and school years:

- (-a-) [(I)] SY 2009 - 2010: 7;
- (-b-) [(II)] SY 2010 - 2011: 7 - 8;
- (-c-) [(III)] SY 2011 - 2012: 7 - 9;
- (-d-) [(IV)] SY 2012 - 2013: 7 - 10;
- (-e-) [(V)] SY 2013 - 2014: 7 - 11; and
- (-f-) [(VI)] SY 2014 - 2015: 7 - 12.

(II) Effective SY 2015 - 2016, students aged 11 - 12 years or enrolling in 7th grade are required to have one dose of meningococcal vaccine.