

**Department of State Health Services
Agenda Item for State Health Services Council
January 12-13, 2006**

Agenda Item Title: Amend 25 TAC §§97.201-97.202, Rules Relating to Immunization Requirements for Residents of Texas Nursing Homes

Agenda Number: 3b

Recommended Council Action:

For Discussion Only

For Discussion and Action by the Council

Background: The Disease Prevention and Intervention Section, 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.

Summary: The rule amendments update the agency name from the Texas Department of Health to the Department of State Health Services. §97.202 (a) (2) (A) is amended to expand the mandatory time to provide influenza vaccine for employees hired or residents admitted after November 30, of each year from "through February of each year" to "through March of each year". This change will make these rules consistent with proposed Centers for Medicare and Medicaid Services (CMS) nursing homes regulations and is also in accordance with the most recent recommendation of the Advisory Committee on Immunization Practices. There are no new requirements within the amendments that have any fiscal or non-fiscal implications. There is no anticipated non-fiscal impact to local government.

Summary of Stakeholder Input to Date (including advisory committees): In August 2005, the Immunization Branch consulted with the Department of Aging and Disability Services, DSHS Division for Regulatory Services, and CMS about the up-coming four-year review of the rule and received comments based on their interrelated rules. In September 2005, the Immunization Branch consulted with ARC of Texas, Texas Association of Residential Care Communities, Texas Health Care Association, Texas Organization of Residential Care Homes (TORCH), Texas Advocates for Nursing Homes, and the Texas Association of Area Agencies on Aging.

Proposed Motion:

Motion to recommend HHSC approval for publication of rules contained in agenda item #3b.

Approved by: Debra Stabeno
Assistant Commissioner, Division for Prevention and Preparedness Services

Date Submitted

10/14/2005

Presented by: Mr. Jack Sims **Title:** Branch Manager
Program/Division: Disease Prevention and Intervention Section, Immunization Branch
Contact: Ms. Victoria Brice 458-7111 x6658

Title 25. HEALTH SERVICES
Part 1. DEPARTMENT OF STATE HEALTH SERVICES
Chapter 97. Communicable Diseases
Subchapter I. Immunization Requirements for Residents of Texas Nursing Homes
Amendments §§97.201-97.202

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 §§97.201 and 97.202 concerning the immunizations nursing homes are required to offer in accordance with the most recent recommendations of the Advisory Committee on Immunization Practices (ACIP) and the requirement to document the receipt or refusal of the vaccinations.

BACKGROUND AND PURPOSE

The proposed amendments provide the ACIP recommendations as an immunization reference for nursing homes, clarifies language, and expands the mandatory time to provide influenza vaccine for employees hired or residents admitted after November 30, of each year from "through February of each year" to "through March of each year". This change will make these rules consistent with proposed Centers for Medicare and Medicaid Services (CMS) nursing homes regulations and is also in accordance with the most recent recommendation of the ACIP.

The department consulted with the Department of Aging and Disability, CMS, Department of State Health Services Division for Regulatory Services, ARC of Texas, Texas Association of Residential Care Communities, Texas Health Care Association, Texas Organization of Residential Care Homes, Texas Advocates for Nursing Homes, and the Texas Association of Area Agencies on Aging.

Government Code, §2001.039, requires that each state agency review and consider for readoption each rule adopted by that agency pursuant to the Government Code, Chapter 2001 (Administrative Procedure Act). Sections 97.201 and 97.202 have been reviewed and the department has determined that reasons for adopting the sections continue to exist because rules on this subject are needed.

SECTION-BY-SECTION SUMMARY

A grammatical change was made to Amendment §97.201, replacing "which serve" with "serving". Amendment §97.202 provides the ACIP recommendations as an immunization reference for nursing homes, and expands the mandatory time to provide influenza vaccine for employees hired or residents admitted after November 30, of each year from "through February of each year" to "through March of each year".

FISCAL NOTE

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

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Mr. Blass has also determined that there will be no effect on small businesses or micro-businesses required to comply with the sections as proposed. This was determined by interpretation of the rules that small businesses and micro-businesses will not be required to alter their business practices in order to comply with the sections. There are no anticipated economic costs to persons who are required to comply with the sections as proposed. There is no anticipated negative impact on local employment.

PUBLIC BENEFIT

In addition, Mr. Blass has also determined that for each year of the first five years the sections are in effect, the public will benefit from adoption of the sections. The public benefit anticipated as a result of enforcing or administering the sections is to increase the accuracy of the sections involved in this proposal and provide additional time to offer vaccines.

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 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 proposal may be submitted to Victoria Brice, Disease Prevention and Intervention Section, Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756, (512) 458-7111, extension 6658, or (800) 252-9152. Comments will be accepted for 30 days following publication of this proposal in the Texas Register.

LEGAL CERTIFICATION

The Department of State Health Services Deputy General Counsel, Linda Wiegman, certifies that the proposal has been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

STATUTORY AUTHORITY

The amendments are proposed under Health and Safety Code, §81.021, which requires the department to develop immunization requirements; 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 reasonably necessary for the department to administer its regulatory and administrative functions.

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

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

§97.201. Facilities Included in Requirements

These requirements apply to nursing homes that are licensed institutions serving [which serve] residents who are elderly persons as defined by the Health and Safety Code, §242.002.

§97.202. Required Immunizations.

(a) Nursing homes are required to offer immunizations in accordance with the most recent recommendations of the Advisory Committee on Immunization Practices (ACIP). **[an immunization schedule adopted by the Texas Department of Health.]**

(1) Pneumococcal vaccine for residents. The facility must offer pneumococcal vaccination to all residents 65 years of age or older who have not received this immunization and to residents younger than 65 years of age who have not received this vaccine but are candidates for vaccination because of chronic illness. Pneumococcal vaccine must be offered both to residents who currently reside in the facility and to new residents upon admission. Vaccination must be completed unless the vaccine is medically contraindicated by a physician or the resident refuses the vaccine. Vaccine administration must be in accordance with the recommendations of the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention at the time of the vaccination.

(2) Influenza vaccine **[vaccinations]** for residents and employees. The facility must offer influenza vaccination to residents and employees in contact with residents. Vaccination must be completed unless the vaccine is medically contraindicated by a physician or unless the employee or resident has refused the vaccine.

(A) Influenza vaccination for all residents and employees must be completed by November 30 of each year. Employees hired or residents admitted after this date and during the influenza season (through March **[February]** of each year) must receive influenza vaccinations unless medically contraindicated by a physician or unless the employee or resident has refused the vaccine.

(B) Vaccine administration must be in accordance with the recommendations of the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention at the time of the most recent vaccination.

(b) Documentation of receipt or refusal of vaccinations. Immunization records will be maintained for each employee in contact with residents and will show the date of the receipt or

refusal of each annual influenza vaccination. The medical record for each resident will show the date of the receipt or refusal of the pneumococcal and the annual influenza [**vaccination and the pneumococcal**] vaccines [**vaccine**].