

RULE ANALYSIS

Introduction: THE AMENDMENTS ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS A PROPOSED RULE

Short Title: Immunizations

Rule Numbers: §295.15

Statutory Authority: Texas Pharmacy Act, Chapter 551-569, Occupations Code:

- (1) Section 551.002 specifies that the purpose of the Act is to protect the public through the effective control and regulation of the practice of pharmacy; and
- (2) Section 554.051 gives the Board the authority to adopt rules for the proper administration and enforcement of the Act.

Purpose: The amendments, if adopted, add requirements regarding hand sanitation for pharmacists administering immunizations.

1 TITLE 22 EXAMINING BOARDS
2 PART 15 TEXAS STATE BOARD OF PHARMACY
3 CHAPTER 295 PHARMACISTS

4 §295.15 Administration of Immunizations or Vaccinations by a Pharmacist under
5 Written Protocol of a Physician
6

7 (a) – (d) (No change.)
8

9 (e) Special Provisions. Pharmacists involved in the administration of immunizations or vaccinations
10 under their license to practice pharmacy shall meet the following restrictions and requirements.
11

12 (1) Pharmacists may only administer immunizations or vaccinations pursuant to a written protocol
13 from a physician authorizing the administration.
14

15 (2) Pharmacists may administer immunizations or vaccinations to a patient under 14 years of age
16 only upon a referral from a physician who has an established physician-patient relationship with
17 each patient. However, a pharmacist may administer an influenza vaccination to a patient over
18 seven years of age without an established physician-patient relationship.
19

20 (3) Pharmacists may administer immunizations or vaccinations under written protocol of a
21 physician within a pharmacy or at any other location specifically identified in the written protocol.
22 Such other location may not include where the patient resides, except for a licensed nursing home
23 or hospital.
24

25 (4) The authority of a pharmacist to administer immunizations or vaccinations may not be
26 delegated.
27

28 (5) Pharmacists may administer immunizations and vaccinations only when a licensed health-care
29 provider authorized to administer the medication is not reasonably available to administer the
30 medication. For the purpose of this section, "reasonably available" means those times when the
31 licensed health-care provider is immediately available to administer the immunization or vaccine
32 and is specifically tasked to do so.
33

34 (6) Under the provisions of the National Vaccine Injury Compensation Program (NVICP), the
35 health-care provider under whose authority a covered vaccine is administered (i.e., the physician
36 issuing the written protocol) must maintain certain information in the patient's permanent record. In
37 order for the physician to comply with the provisions of the NVICP, the pharmacist shall provide the
38 physician with the information specified in subsection (g) of this section.
39

40 **(7) Before preparing a vaccine and between each patient contact, the pharmacist shall**
41 **cleanse his or her hands with an alcohol-based waterless antiseptic hand rub or shall wash**
42 **his or her hands with soap and water. If gloves are worn, the pharmacist shall change**
43 **gloves between patients.**
44

45 **(8)** ~~(7)~~ The pharmacist shall comply with all other state and federal requirements regarding
46 immunizations or vaccinations.
47

48 (f) – (h) (No change.)

signs or symptoms of anaphylaxis occur, the patient should be placed in a recumbent position with the legs elevated if possible (81,82). Administration of epinephrine is the management of choice. Additional drugs also might be indicated (Table 8) (83). Maintenance of the airway and oxygen administration might be necessary. After the patient is stabilized, arrangements should be made for immediate transfer to an emergency facility for additional evaluation and treatment.

Reporting Adverse Events After Vaccination

Modern vaccines are safe and effective; however, adverse events have been reported after administration of all vaccines (84). More complete information about adverse reactions to a specific vaccine is available in the package insert for each vaccine and from CDC at <http://www.cdc.gov/vaccines/vac-gen/side-effects.htm>. An adverse event is an untoward event that occurs after a vaccination that might be caused by the vaccine product or vaccination process. These events range from common, minor, local reactions to rare, severe, allergic reactions (e.g., anaphylaxis). Establishing evidence for cause and effect on the basis of case reports and case series alone is usually not possible because health problems that have a temporal association with vaccination do not necessarily indicate causality.

Many adverse events require more detailed epidemiologic studies to compare the incidence of the event among vaccinees to the incidence among unvaccinated persons. Reporting adverse events, including serious events, to VAERS is a key mechanism for identifying potential vaccine safety concerns. Potential causal associations between reported adverse events after vaccination can be assessed through epidemiologic or clinical studies.

The National Childhood Vaccine Injury Act requires health-care providers and vaccine manufacturers to report to VAERS specific adverse events that occur after vaccination. The reporting requirements are different for manufacturers and health-care providers. Manufacturers are required to report all adverse events that occur after vaccination to VAERS, whereas health-care providers are required to report events that appear in the reportable events table on the VAERS website at <http://vaers.hhs.gov/reportable.htm>.

In addition to the mandated reporting of events listed on the reportable events table, health-care providers should report to VAERS all events listed in product inserts as contraindications, as well as all clinically significant adverse events, even if they are uncertain that the adverse event is related causally to vaccination. Persons other than health-care providers also can report adverse events to VAERS.

There are three ways to report to VAERS:

1. Submit the report online via a secure website at <https://vaers.hhs.gov/esub/step1>,
2. Fax a completed VAERS form to 877-721-0366, or
3. Mail a completed VAERS form: VAERS, P.O. Box 1100, Rockville, MD 20849-1100.

A VAERS form can be downloaded from the VAERS website at http://vaers.hhs.gov/resources/vaers_form.pdf. VAERS forms also can be requested by e-mail (info@vaers.org), telephone (800-822-7967), or fax (877-721-0366).

National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program, established by the National Childhood Vaccine Injury Act of 1986, is a no-fault system in which persons thought to have experienced an injury or to have died as a result of administration of a covered vaccine can seek compensation. The program became operational on October 1, 1988, and is intended as an alternative to civil litigation under the traditional tort system in that negligence need not be proven. Claims arising from covered vaccines must first be adjudicated through the program before civil litigation can be pursued.

The program relies on the Vaccine Injury Table, which lists the vaccines covered by the program and the injuries (including death), disabilities, illnesses, and conditions for which compensation might be awarded. The table defines the time during which the first symptom or substantial aggravation of an injury must appear after vaccination to be eligible. Successful claimants receive a legal presumption of causation if a condition listed in the table is proven, thus avoiding the need to prove actual causation in an individual case. Claimants also can prevail for conditions not listed in the reportable events table if they prove causation for covered vaccines. Additional information is available from the Health Resources and Services Administration (HRSA) (<http://www.hrsa.gov/vaccinecompensation>, telephone: 800-338-2382). Persons who would like to file a claim for vaccine injury should contact the U.S. Court of Federal Claims (717 Madison Place, N.W., Washington, DC 20005; telephone: 202-357-6400).

Vaccine Administration

Infection Control and Sterile Technique

General Precautions

Persons administering vaccinations should follow appropriate precautions to minimize risk for spread of disease. Hands

should be cleansed with an alcohol-based waterless antiseptic hand rub or washed with soap and water before preparing the vaccine and between each patient contact (85). Occupational Safety and Health Administration (OSHA) regulations do not require gloves to be worn when administering vaccinations, unless persons administering vaccinations are likely to come into contact with potentially infectious body fluids or have open lesions on their hands. If gloves are worn, they should be changed between patients.

Needles and Syringes

Needles and syringes used for vaccine injections must be sterile and disposable. A separate needle and syringe should be used for each injection. Changing needles between drawing vaccine from a vial and injecting it into a recipient is not necessary unless the needle has been damaged or contaminated. Different vaccines should never be mixed in the same syringe unless specifically licensed for such use, and no attempt should be made to transfer between syringes. Single-dose vials and manufacturer-filled syringes are designed for single-dose administration and should be discarded if vaccine has been withdrawn or reconstituted and subsequently not used within the time frame specified by the manufacturer. This typically is no longer than the same clinic day (typically recommended as a maximum for inactivated vaccines).

Sometimes providers prefill syringes themselves. ACIP discourages the routine practice of prefilling syringes because of the potential for administration errors and vaccine wastage. Because the majority of vaccines have a similar appearance after being drawn into a syringe, prefilling might result in administration errors. In certain circumstances in which a single vaccine type is being used (e.g., in preparation for a community influenza vaccination campaign), filling a small number of syringes may be considered. Vaccine doses should not be drawn into a syringe until immediately before administration. When syringes are filled, the type of vaccine, lot number, and date of filling must be labeled on each syringe, and the doses should be administered as soon as possible after filling. Unused syringes filled by the end user (i.e., not filled by the manufacturer) should be discarded at the end of the vaccination session. In addition to administration errors, prefilling of syringes is a concern because FDA does not license administration syringes for vaccine storage. Unused syringes that are prefilled by the manufacturer and activated (i.e., syringe cap removed or needle attached) should be discarded at the end of the clinic day. When in doubt about the appropriate handling of a vaccine, vaccination providers should contact the manufacturer.

Bloodborne diseases (e.g., hepatitis B, hepatitis C, and human immunodeficiency virus [HIV]) are occupational hazards for clinicians and other health-care providers. The

Needlestick Safety and Prevention Act was enacted in 2000 to reduce the incidence of needle-stick injury and the consequent risk for bloodborne diseases acquired from patients. The act directed OSHA to strengthen its existing bloodborne pathogen standards. The revised standards became effective in 2001 (86). These federal regulations require that safety-engineered injection devices (e.g., needle-shielding syringes or needle-free injectors) be used for injectable vaccination in all clinical settings. The regulations also require maintenance of records documenting injuries caused by needles and other medical sharp objects and that nonmanagerial employees be involved in the evaluation and selection of safety-engineered devices before they are procured.

Safety-engineered needles and syringes or needle-free injection devices are preferred and should be encouraged to reduce risk for injury. To prevent inadvertent needle-stick injury or reuse, safety mechanisms should be deployed after use and needles and syringes should be discarded immediately in labeled, puncture-proof containers located in the same room where the vaccine is administered. Used needles should never be recapped.

Needle-shielding or needle-free devices that might satisfy the occupational safety regulations for administering injectable vaccines are available in the United States (87–89). Additional information about implementation and enforcement of these regulations is available from OSHA (<http://www.osha.gov>).

Route of Administration

Oral Route

Rotavirus and oral typhoid vaccines are the only vaccines administered orally in the United States. Oral typhoid capsules should be administered as directed by the manufacturer. The capsules should not be opened or mixed with any other substance. Rotavirus vaccines are licensed for infants. There are two brands of rotavirus vaccine, and they have different types of applicators. Providers should consult the package insert for details. A dose of rotavirus vaccine need not be repeated if the vaccine is spit up or vomited. The infant should receive the remaining recommended doses of rotavirus vaccine following the routine schedule.

Intranasal Route

LAIV is licensed for healthy nonpregnant persons aged 2–49 years and is the only vaccine administered by the intranasal route. The administration device is a nasal sprayer with a dose-divider clip that allows introduction of one 0.1-mL spray into each naris. The tip should be inserted slightly into the naris before administration. Even if the person coughs or sneezes immediately after administration or the dose is expelled any other way, the vaccine