TITLE 26 HEALTH AND HUMAN SERVICES

PART 1 HEALTH AND HUMAN SERVICES COMMISSION

CHAPTER 558 LICENSING STANDARDS FOR HOME AND COMMUNITY SUPPORT SERVICES AGENCIES

SUBCHAPTER C MINIMUM STANDARDS FOR ALL HOME AND COMMUNITY SUPPORT SERVICES AGENCIES

DIVISION 4 PROVISION AND COORDINATION OF TREATMENT SERVICES

§558.303. Standards for Possession of Sterile Water or Saline, Certain Vaccines or Tuberculin, and Certain Dangerous Drugs.

An agency that possesses sterile water or saline, certain vaccines or tuberculin, or certain dangerous drugs, as specified by this section, must comply with the provisions of this section.

(1) Possession of sterile water or saline. An agency or its employees, who are RNs or LVNs, may purchase, store, or transport for the purpose of administering to their home health or hospice clients under physician's orders:

(A) sterile water for injection and irrigation; and

(B) sterile saline for injection and irrigation.

(2) Possession of certain vaccines or tuberculin.

(A) An agency or its employees, who are RNs or LVNs, may purchase, store, or transport for administering to the agency's employees, home health or hospice clients, or client family and household members under physician's standing orders the following dangerous drugs:

(i) hepatitis B vaccine;

(ii) influenza vaccine;

(iii) tuberculin purified protein derivative for tuberculosis testing;

(iv) pneumococcal polysaccharide vaccine; and

(v) any other vaccine approved, authorized for emergency use, or otherwise permitted for use by the United States Food and Drug Administration to treat or mitigate the spread of a communicable disease, as defined by Texas Health and Safety Code §81.003.

(B) An agency that purchases, stores, or transports a vaccine or tuberculin under this section must ensure that any standing order for the vaccine or tuberculin:

(i) is signed and dated by the physician;

(ii) identifies the vaccine or tuberculin covered by the order;

(iii) indicates that the recipient of the vaccine or tuberculin has been assessed as an appropriate candidate to receive the vaccine or tuberculin and has been assessed for the absence of any contraindication;

(iv) indicates that appropriate procedures are established for responding to any negative reaction to the vaccine or tuberculin; and

(v) orders that a specific medication or category of medication be administered if the recipient has a negative reaction to the vaccine or tuberculin.

(C) An agency or the agency's authorized employees may purchase, store, or transport vaccines or tuberculin in a sealed portable container only if the agency has established policies and procedures to ensure that:

(i) the container is handled properly with respect to storage, transportation, and temperature stability according to manufacturer’s instructions; and

(ii) the agency adheres to guidance from the Centers for Disease Control and Prevention and the Texas Health and Human Services Commission.

(3) Possession of certain dangerous drugs.

(A) In compliance with Texas Health and Safety Code §142.0063, an agency or its employees, who are RNs or LVNs, may purchase, store, or transport for the purpose of administering to their home health or hospice patients, in accordance with subparagraph (C) of this paragraph, the following dangerous drugs:

(i) any of the following items in a sealed portable container of a size determined by the dispensing pharmacist:

(I) 1,000 milliliters of 0.9 percent sodium chloride intravenous infusion;

(II) 1,000 milliliters of 5.0 percent dextrose in water injection; or

(III) sterile saline; or

(ii) not more than five dosage units of any of the following items in an individually sealed, unused portable container:

(I) heparin sodium lock flush in a concentration of 10 units per milliliter or 100 units per milliliter;

(II) epinephrine HCI solution in a concentration of one to 1,000;

(III) diphenhydramine HCI solution in a concentration of 50 milligrams per milliliter;

(IV) methylprednisolone in a concentration of 125 milligrams per two milliliters;

(V) naloxone in a concentration of one milligram per milliliter in a two-milliliter vial;

(VI) promethazine in a concentration of 25 milligrams per milliliter;

(VII) glucagon in a concentration of one milligram per milliliter;

(VIII) furosemide in a concentration of 10 milligrams per milliliter;

(IX) lidocaine 2.5 percent and prilocaine 2.5 percent cream in a five-gram tube; or

(X) lidocaine HCL solution in a concentration of 1 percent in a two-milliliter vial.

(B) An agency or the agency's authorized employees may purchase, store, or transport dangerous drugs in a sealed portable container only if the agency has established policies and procedures to ensure that:

(i) the container is handled properly with respect to storage, transportation, and temperature stability;

(ii) a drug is removed from the container only on a physician's written or oral order;

(iii) the administration of any drug in the container is performed in accordance with a specific treatment protocol; and

(iv) the agency maintains a written record of the dates and times the container is in the possession of an RN or LVN.

(C) An agency or the agency's authorized employee who administers a drug listed in subparagraph (A) of this paragraph may administer the drug only in the client's residence, under physician's orders, in connection with the provision of emergency treatment or the adjustment of:

(i) parenteral drug therapy; or

(ii) vaccine or tuberculin administration.

(D) If an agency or the agency's authorized employee administers a drug listed in subparagraph (A) of this paragraph, pursuant to a physician's oral order, the agency must receive a signed copy of the order:

(i) not later than 24 hours after receipt of the order, reduce the order to written form and send a copy of the form to the dispensing pharmacy by mail or fax transmission; and

(ii) not later than 20 days after receipt of the order, send a copy of the order, as signed by and received from the physician, to the dispensing pharmacy.

(E) A pharmacist that dispenses a sealed portable container under this subsection will ensure that the container:

(i) is designed to allow access to the contents of the container only if a tamper-proof seal is broken;

(ii) bears a label that lists the drugs in the container and provides notice of the container's expiration date, which is the earlier of:

(I) the date that is six months after the date on which the container is dispensed; or

(II) the earliest expiration date of any drug in the container; and

(iii) remains in the pharmacy or under the control of a pharmacist, RN, or LVN.

(F) If an agency or the agency's authorized employee purchases, stores, or transports a sealed portable container under this subsection, the agency must deliver the container to the dispensing pharmacy for verification of drug quality, quantity, integrity, and expiration dates not later than the earlier of:

(i) the seventh day after the date on which the seal on the container is broken; or

(ii) the date for which notice is provided on the container label.

(G) A pharmacy that dispenses a sealed portable container under this section is required to take reasonable precautionary measures to ensure that the agency receiving the container complies with subparagraph (F) of this paragraph. On receipt of a container under subparagraph (F) of this paragraph, the pharmacy will perform an inventory of the drugs used from the container and will restock and reseal the container before delivering the container to the agency for reuse.