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AND MEDICAID CERTIFICATION****SUBCHAPTER P****PHARMACY SERVICES****RULE §19.1501****Pharmacy Services**

A licensed-only facility must assist the resident in obtaining routine drugs and biologicals and make emergency drugs readily available, or obtain them under an agreement described in §19.1906 of this title (relating to Use of Outside Resources). A Medicaid-certified facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in §19.1906 of this title (relating to Use of Outside Resources). See also §19.901(12) and (13) of this title (relating to Quality of Care) for information concerning drug therapy and medication errors.

(1) Methods and procedures. The facility may permit unlicensed personnel to administer drugs, but only under the general supervision of a licensed nurse. The unlicensed individual must be a nursing student, a medication aide student, or a medication aide with a current permit issued by the Texas Department of Human Services.

(2) Accuracy in service delivery. A facility must provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident.

(3) Service consultation. The facility must employ or obtain the services of a pharmacist, currently licensed by the Texas State Board of Pharmacy and in good standing, who:

(A) provides consultation on all aspects of the provision of pharmacy services in the facility;

(B) establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation;

(C) determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled; and

(D) adheres to requirements in §19.1503 of this title (relating to Additional Supervision and Consultation Requirements).

(4) Drug regimen review.

(A) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist. The consultant pharmacist's drug regimen review must be maintained in the resident's clinical record.

(B) The pharmacist must report any irregularities to the attending physician and the director of nursing, and these reports must be acted upon.

(5) Labeling of drugs and biologicals. Drugs and biologicals used in the facility must be labeled in accordance with currently accepted professional principals and in compliance with the Texas State Board of Pharmacy Laws and Regulations, §291, including the appropriate accessory and cautionary instructions and the expiration date when applicable.

(6) Storage of drugs and biologicals.

(A) In accordance with state and federal laws, the facility must store all drugs and biologicals in locked compartments under proper temperature controls and permit only authorized personnel to have access to the keys.

(B) The facility must provide separately locked, permanently affixed compartments for storage of controlled drugs, listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976, and of other drugs subject to abuse, except when the facility uses single-unit-package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected (see §19.1509 of this title (relating to Controlled Substances)).

Source Note: The provisions of this §19.1501 adopted to be effective May 1, 1995, 20 TexReg 2054; amended to be effective July 1, 2002, 27 TexReg 5524

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RULE §19.1502**Choice of Pharmacy Provider**

(a) Unless the facility is paying for the drugs and biologicals, the resident's choice of pharmacy provider and any changes in his choice must be recorded on appropriate forms maintained by the facility.

(b) A Medicaid-certified facility must have written agreements with its provider pharmacies that define required services. These agreements will not be considered to abridge the resident's freedom of choice of pharmacy services when they require labeling, packaging, and a drug-distribution system according to facility policy. The drug-distribution system must be accessible to all pharmacies willing to meet the distribution system requirements. The agreements must require the following:

(1) that the resident's pharmacy services be provided by a pharmacy on a 24-hour basis for emergency medications; and

(2) that the resident's medications be delivered to the facility on a timely and reasonable basis.

(c) The resident's choice of pharmacy provider must be in accordance with §19.406(c) of this title (relating to Free Choice).

Source Note: The provisions of this §19.1502 adopted to be effective May 1, 1995, 20 TexReg 2054.

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RULE §19.1503**Additional Supervision and Consultation Requirements**

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- (a) The facility must provide pharmaceutical services under the responsibility and direction of the consultant pharmacist and the director of nursing.
- (b) The facility must ensure that notes on the monthly visits by the consulting pharmacist are entered in the resident's clinical record.
- (c) The number of hours per month the consultant pharmacist devotes to the pharmaceutical services for ordering, storage, administration, disposal, recordkeeping (documentation) of drugs and medications, and drug regimen review must be sufficient to meet the needs of the residents.
- (d) A record of consultant pharmacist services, consultations, and recommendations for pharmacy procedure must be maintained at the facility.
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Source Note: The provisions of this §19.1503 adopted to be effective May 1, 1995, 20 TexReg 2054.

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- (a) The facility must establish procedures for storing and disposing of drugs and biologicals in accordance with federal, state, and local laws.
- (b) When not in use, a medication cart must be secured in a designated area.
- (c) Small multiple-dose drug containers which are placed into another container must be labeled in a manner so that, if the two containers become separated, the small drug container still has a strip label attached containing the name of the resident and the prescription number.
- (d) Self-administered medications may be kept in a locked cabinet in the resident's room. When medications are self-administered, the facility remains responsible for medication security, accurate information, and medication compliance.
- (e) The facility must store each resident's drugs in their original containers.
- (f) The facility must store medications under appropriate conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security.
- (g) Medications of deceased residents, medications that have passed the expiration date, and medications that have been discontinued must be securely stored and reconciled. These medications must be disposed of according to federal and state laws or rules on a quarterly basis. Discontinued drugs may be reinstated if reordered prior to destruction. These medications cannot be given to a family member or representative.
- (h) When the directions for administration of a resident's medication have changed, but the existing supply of medication can still be administered accurately, the medication must not be destroyed. The facility must affix a change-of-direction ancillary sticker or similar system and use the remaining medication. The medication label must be updated at the time of next dispensing.
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Source Note: The provisions of this §19.1504 adopted to be effective May 1, 1995, 20 TexReg 2054; amended to be effective September 1, 2003, 28 TexReg 6939

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RULE §19.1506**Drug Orders**

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- (a) All drugs must be prescribed by the resident's physician or consulting physician, dentist, podiatrist, or other individual allowed by law to prescribe. If drug orders are verbal, they must be taken by a licensed nurse, pharmacist, physician assistant or a physician, and immediately recorded and signed by the person receiving the order. All drug orders must be counter-signed by the prescriber and returned to the chart in a timely manner.
- (b) The facility may permit verbal orders for Schedule II drugs only in an emergency.
- (c) Medications must be ordered and reordered on a timely basis so that no resident misses a dose.
- (d) The facility must have written policies and procedures for stopping the administration of drugs.
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Source Note: The provisions of this §19.1506 adopted to be effective May 1, 1995, 20 TexReg 2054.

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RULE §19.1507**Drug Release**

(a) Medications must be released to residents only on the written or verbal authorization of the attending physician. When a resident is transferred directly to another nursing facility or discharged to home, the resident's medications must be released to the new facility or to the resident or his family, respectively.

(b) If a resident is leaving the facility on a furlough, enough prescription drugs to last throughout the furlough must be released. The facility must inventory Schedule II, III, and IV drugs in and out. Nonschedule drugs should be listed by name. The pharmacist must handle any division of the prescription, and all information on the original prescription label must appear on the furlough medication supply.

Source Note: The provisions of this §19.1507 adopted to be effective May 1, 1995, 20 TexReg 2054.

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(a) The facility must establish drug administration procedures to ensure that:

- (1) drugs to be administered are checked against the physician's orders;
- (2) the resident is identified before the administration of a drug;
- (3) each resident has an individual medication record, where the dose of drug administered is properly recorded by the person who administered the drug;
- (4) drugs and biologicals are prepared and administered by the same person, except under unit-of-use package distribution systems and as outlined in §19.418 of this title (relating to Self-Administration of Drugs); and
- (5) drugs prescribed for one resident must not be administered to any other person.

(b) The facility nursing staff must report drug errors and adverse drug reactions to the resident's physician in a timely manner, as warranted by an assessment of the resident's condition, and record them in the resident's record. An incident report must be completed in accordance with §19.1923 of this title (relating to Incident or Accident Reporting). Medication errors include, but are not limited to, administering the wrong medication, administering at the wrong time, administering the wrong dosage strength, administering by the wrong route, omitting a medication, and/or administering to the wrong resident.

(c) Nursing facilities must have current medication reference texts or sources, including information on pediatric medications, dosages, sites, routes, techniques of drug administration, desired effects, and possible side effects, if facilities have pediatric residents.

(d) A licensed nurse may exercise professional judgment in the crushing of a medication, providing that the medication is not a time-released or enteric coated medication.

(1) If there is any question about crushing a medication for a resident, the licensed nurse must check with the treating physician, dispensing pharmacist, or consultant pharmacist.

(2) The crushed medication should be administered as soon as feasible once it has been added to another substance.

Source Note: The provisions of this §19.1508 adopted to be effective May 1, 1995, 20 TexReg 2054.

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RULE §19.1509

Controlled Substances

The facility must adhere to the following procedures governing the use of drugs covered by the Controlled Substances Act:

- (1) a separate record must be maintained for each drug covered by Schedules II, III, and IV of the Controlled Substances Act, Health and Safety Code, Chapter 481;
- (2) the record for each drug must contain the prescription number, name, and strength of drug, date received by the facility, date and time administered, name of resident, dose, physician's name, signature of person administering dose, and original amount dispensed with the balance verifiable by drug inventory at every shift change; and
- (3) Schedule V drugs are exempt from the requirements in paragraphs (1) and (2) of this section.

Source Note: The provisions of this §19.1509 adopted to be effective May 1, 1995, 20 TexReg 2054.

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RULE §19.1510**Emergency Medication Kits**

Stocks of inventoried emergency medications may be kept in facilities.

(1) Emergency medication kits must be maintained in compliance with 22 TAC §291.20(b) (relating to Remote Pharmacy Services), with the exception of emergency medication kits in veterans homes, as defined by Natural Resources Code, §164.002. In veterans homes, a United States Department of Veterans Affairs pharmacy or another federally operated pharmacy may maintain emergency medication kits.

(2) Facilities must have contracts with the pharmacy that provides the emergency medication kit. The contract must outline the services to be provided by the pharmacy and the responsibilities and accountabilities of each party in fulfilling the terms of the contract in compliance with federal and state laws and regulations.

Source Note: The provisions of this §19.1510 adopted to be effective May 1, 1995, 20 TexReg 2054; amended to be effective October 15, 1998, 23 TexReg 10496; amended to be effective May 1, 2002, 27 TexReg 1534; amended to be effective September 1, 2003, 28 TexReg 6939

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