3.5.26 Investigational Medications

(a) Procedure Overview

(1) An exception can be made to the prohibition against biomedical research pursuant to Penal Code (PC) Section 3502.5 for the case wherein a physician providing care to California Department of Corrections and Rehabilitation (CDCR) patients identifies a medically necessary drug available only through an investigational treatment protocol defined by Code of Federal Regulations, Title 21, Section 312, and obtains informed consent from the patient under PC Section 3521. Investigational medications shall:
   (A) Be part of the treatment arm of the investigational protocol only (active drug, not placebo);
   (B) Not be used unless drug information about the investigational drug is acquired by the physician and distributed to the pharmacy and nursing staff;
   (C) Follow the nonformulary medication policy and procedures;
   (D) Be administered as a Directly Observed Therapy medication;
   (E) Comply with the Health Care Department Operations Manual, Section 3.5.5, Prescription/Order Requirements; and
   (F) Be included in the patient medication profile.

(2) The pharmacy shall coordinate with the Principal Investigator (PI) to ensure acquisition, storage, distribution, and disposition of investigational medications.

(b) Purpose

To define processes for CDCR patients authorized to receive investigational medications.

(c) Procedure

(1) Investigational medications shall be available in conformance with an investigational treatment protocol approved initially by the Statewide Chief Medical Executive (CME) and reviewed by the California Correctional Health Care Services Systemwide Pharmacy and Therapeutics Committee.

(2) The facility CME shall request copies of:
   (A) Approved protocol from the PI;
   (B) Institutional Review Board approval form;
   (C) Safety Data Sheet (SDS);
   (D) Signed informed consent form; and
   (E) All other documents necessary for the safe administration of the investigational medication.
   These documents must be readily available to the pharmacy and nursing staff.

(3) The pharmacy shall utilize the drug information and documentation logs provided by the PI. The information shall include:
   (A) Drug designation and common synonyms;
   (B) Dosage form(s) and strength(s);
   (C) Usual dosage range, dosing schedule, and route of administration;
   (D) Indications;
   (E) Expected therapeutic effect;
   (F) Potential side effects and adverse effects, including symptoms of toxicity and their treatment;
   (G) Contraindications;
   (H) Instructions for dosage preparation and administration, including stability and handling guidelines;
   (I) Storage requirements;
   (J) Instructions for disposition of unused doses;
   (K) Drug interactions, if known; and
   (L) Names and telephone numbers of the PI and authorized co-investigators

(4) Copies of the approved protocol and the SDS shall be kept in the pharmacy and shall be distributed to all patient care areas where the medication will be used.

(5) The prescribing physician is responsible for obtaining an informed consent from the patient prior to prescribing the medication. The consent shall include the information from the SDS. A copy of the consent form shall be provided to the institution pharmacy.

(6) The pharmacy shall retain the files for three years of all investigational medications used. Information to be retained shall include SDS, protocols, inventory records, and dispensing records.

(7) The nurse shall dispose of, or the pharmacy shall return or transfer, all unused medications according to the specific instructions of the PI upon the conclusion of therapy.
(8) Investigational product(s) provided by the PI explicitly for an approved protocol shall be logged and inventoried in the pharmacy separately from regular inventory.
(9) Investigational materials requiring intravenous compounding shall follow United States Pharmacopeia (USP) 797 guidelines for compounding of sterile products.
(10) Investigational materials involving hazardous materials shall follow USP 800 guidelines for safe handling.
(11) If the investigational drug is administered parenterally, the patient must be transferred to a facility that has a sterile products preparation license.

References

- Code of Federal Regulations, Title 21, Chapter 1, Subchapter D, Section 312
- United States Pharmacopeia 797 guidelines
- The United States Pharmacopeia and the National Formulary http://www.usp.org/usp-nf
- California Penal Code, Part 3, Title 2.1, Chapter 2, Section 3502.5
- California Penal Code, Part 3, Title 2.1, Chapter 4, Section 3521
- Health Care Department Operations Manual, Chapter 1, Article 2, Section 1.2.12, Disposal of Regulated Waste Generated by Health Care Staff
- Health Care Department Operations Manual, Chapter 3, Article 5, Section 3.5.5, Prescription/Order Requirements

Revision History

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