VOLUME 9: PHARMACY SERVICES	Effective Date: 9/08
CHAPTER 26	Revision Date (s): 1/14
9.26 INVESTIGATIONAL MEDICATIONS	Attachments: Yes ☐ No ☒

I. PROCEDURE OVERVIEW

An exception can be made to the prohibition against biomedical research pursuant to California (CA) Penal Code Section 3502.5 for the case wherein a physician providing care to California prisoners identifies a medically necessary drug available only through an investigational treatment protocol defined by Code of Federal Regulations, Title 21, Section 312, and obtains from the patient-inmate informed consent under CA Penal Code Section 3521.

Investigational medications shall

- be part of the treatment arm of the investigational protocol only (active drug, not placebo),
- not be used unless drug information about the investigational drug is acquired by the physician and distributed to the pharmacy and nursing staff,
- follow the nonformulary medication policy and procedures,
- be administered as a Directly Observed Therapy (DOT) medication,
- comply with IMSP&P Volume 9, Chapter 9, Prescription Requirements, and
- be included in the patient-inmate medication profile.

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

II. PURPOSE

To define processes for CDCR patient-inmates authorized to receive investigational medications.

III. PROCEDURE

A. 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.

B. The facility CME shall request copies of

- approved protocol from the PI,
- Institutional Review Board approval form,
- Material Safety Data Sheet (MSDS),
- signed informed consent form, and
- all other documents necessary for the safe administration of the investigational medication.

These documents must be readily available to the pharmacy and nursing staff.

C. The pharmacy shall utilize the drug information and documentation logs provided by the PI. The information shall include:

1. Drug designation and common synonyms

2. Dosage form(s) and strength(s)
3. Usual dosage range, dosing schedule, and route of administration
4. Indications
5. Expected therapeutic effect
6. Potential side effects and adverse effects, including symptoms of toxicity and their treatment
7. Contraindications
8. Instructions for dosage preparation and administration, including stability and handling guidelines
9. Storage requirements
10. Instructions for disposition of unused doses
11. Drug interactions, if known
12. Names and telephone numbers of PI and authorized co-investigators

D. Copies of the approved protocol and the MSDS shall be kept in the pharmacy and shall be distributed to all patient-inmate care areas where the medication will be used.

E. The prescribing physician is responsible for obtaining an informed consent from the patient-inmate prior to prescribing the medication. The consent shall include the information from the MSDS. A copy of the consent form shall be provided to the institution pharmacy.

F. The pharmacy shall retain the files of all investigational medications used for three (3) years. Information to be retained shall include MSDS, protocols, inventory records and dispensing records.

G. The pharmacy will return, transfer or dispose of all unused medications according to the specific instructions of the PI upon the conclusion of therapy.

H. Investigational product(s) provided by a PI explicitly for an approved protocol shall be logged and inventoried in the pharmacy separately from regular inventory.

I. Investigational hazardous materials requiring intravenous compounding shall follow United States Pharmacopeia (USP) 797 guidelines for compounding of sterile products of biohazardous materials.

J. If the investigational drug is administered parenterally, the patient-inmate must be transferred to a facility that has a sterile products preparation license.

IV. REFERENCES

- Code of Federal Regulations, Title 21, Chapter 1, Subchapter D, Section 312
- United States Pharmacopeia (USP) 797 guidelines
- The US Pharmacopeia and the National Formulary (USPN-NF) http://www.usp.org/usp-nf
- California Penal Code, Sections 3502.5, 3521
- Inmate Medical Services Policies and Procedures Volume 9, Chapter 9 – Prescription Requirements