

Department of Pharmaceutical Services: Investigational Drug Service (IDS)

Date: 04/04/2025

To: Principal Investigators, Research Staff, IDS Pharmacy

From: Pharmacy and Research Leadership:

- Lisa Janssen Carlson, PharmD, BCOP, DPLA IDS Manager
- Nick Capote, PharmD, MS, BCSCP Pharmacy Director Infusion, Oncology and IDS
- Dominica Randazzo Associate Director, Clinical Trial Operation

Re: **Compliance with California Board of Pharmacy's (BOP) requirements for prescription orders, including acceptable forms, storage duration, and retention.**

Effective date: Interim plan in place January 28, 2025

Contact: Lisa Janssen Carlson, PharmD, BCOP, DPLA

 lisa.janssencarlson@ucsf.edu |  415.205.1387

WHO:

All UCSF Health and Campus providers ordering investigational products to be dispensed by IDS pharmacy. Study staff responsible for documentation.





WHAT:

To comply with California BOP regulatory requirements for prescription orders and in alignment with FDA requirements for 21 CFR Part 11, all prescription orders must be signed by a licensed healthcare provider.

Prescription orders must include: patient name, address, drug name, strength, dosage form, quantity prescribed, directions for use, prescribers, name, signature, license number and date of prescription.

- **For investigational product prescription orders that are not currently built in APeX (electronic medical record):** prescription orders must be signed in DocuSign by the ordering provider and scanned into APeX by the study team.
- **For investigational product prescription orders that are built electronically in APeX:** prescription orders must be entered in APeX and cosigned by the ordering provider.

Acceptable Prescription Forms:

-  Prescription order signed via DocuSign and scanned into APeX.
 - 1) The UCSF Office of Ethics and Compliance recommends using the 21 CFR Part 11 compliant version of DocuSign for prescription orders for FDA-regulated studies.
-  Electronic prescription orders in APeX.
 - 2) As of 01JAN2021, per the Drug Enforcement Agency (DEA), all controlled substances must be ordered and transmitted electronically for Schedule II-IV.
-  Email is **not** an acceptable form for prescription orders (per California BOP).
-  Paper order with a wet signature is not allowed unless approved by IDS.

Storage Requirements: Electronically transmitted prescription orders must be retained by the pharmacy as the "original" document in APeX. DocuSigned prescription orders must be scanned in APeX in the Clin Scan location for secure and easy access. All prescription orders must be stored at a minimum of 3 years from date of furnishing to that prescription order per the BOP and 10 years for FDA requirements (retention time may vary).

HOW:

For prescription orders signed via DocuSign, study teams will be responsible for uploading the original DocuSigned prescription order(s) into APeX. IDS will work with teams to ensure compliance.

Instructions to upload DocuSigned prescription orders to APeX:

- Go to Epic dropdown menu in upper left-hand corner of Apex
- Hover over "Patient Care"
- Select "Media Manager"
- Search for patient
- Select patient
- Select "Add New Media"
- Select document type "Orders (UCSF)"
- Select "Import"
- Find correct document on your computer
- Select document
- In description text box, enter "Research Provider Order [IRB number or CC number]" if oncology include cycle and day.
- Click "Accept"

WHY: Per the following California BOP and DEA regulatory requirements for prescription orders:

- Business and Professions Code Board of Pharmacy Regulations, California Code of Regulations, Division 17, Title 16:
 - Section 1717: Pharmacy Practice
 - Section 1717.4: Electronic Transmission of Prescriptions
 - Section 1717: Retention of Prescription Records
- California Code of Regulations, Title 16, Chapter 9, Division 2:
 - Article 2.4040: Prescription; Content Requirements
 - Article 4: 4070 Requirements for Prescriptions
- California Code of Regulations, Title 2, section 22003: Acceptable Technologies
- The California Uniform Controlled Substances Act, Health and Safety Code: Division 10, Chapter 4, Article 1: Requirements of Prescriptions (controlled substances)
- DEA Final Rule: Requirements for electronic orders and prescriptions (21 CFR Chapter 11 Part 1311)