Investigational Drug Service
Department of Pharmaceutical Services
UCSF Health Effective: July 1, 2023

Investigational Drug Service at University of California Medical Centers

This schedule describes the fixed fees associated with UCSF Health IDS participation in clinical research studies for fiscal year 2024. The fees are **standardized** and set based on the costs required to provide the associated services. The fees are **non-negotiable**, and the charges are only incurred when the specified services are required by the study.

1. Industry-Sponsored Protocol Set-Up

Set-up activities include protocol and budget reviews, site qualification and initiation visits, development of study specific dispensing procedures, medication assessment (special handling, preparation, stability, storage, etc. for non-FDA labeled medications), EMR (electronic medical record) entry and label design, IWRS training/set-up, study drug supply security, creating of prescription/order template, and in-service training for essential pharmacy personnel. **Please note that studies which require study medication management across multiple UCSF IDS campuses will be charged duplicate fees PER campus.** This fee is a one-time, non-refundable fee charged by the date of the site initiation visit or first study shipment receipt, whichever occurs first. *The listed set-up fees are starting fees for the type of studies, and additional effort will be billed in one-hour increments at the current hourly rate.*

Standard *Beyond 25 hours of service, institutional hourly pharmacist charge ($195/hr) will apply in 1-hour increments*	$4333* $4736**
Advanced: Oncology, Immunotherapy, Pediatrics, Vectors, Schedule 1 Controlled Substances, Inpatient *Beyond 30 hours of service, institutional hourly pharmacist charge ($195/hr) will apply in 1-hour increments*	$4967* $5430**
Off-Hours Dispensing/IDS Support – 24/7 coverage • *Covers off-hours pharmacy set-up, logistics planning and training* • *IP preparation, On-call support* • *Pharmacy will not be responsible for IWRS responsibilities* • *24/7 coverage feasibility review by IDS pharmacist is required to determine the extent of IDS pharmacy participation*	$5733
*Protocols that only include drugs or ancillary supplies stored at room temperature **Protocols that include at least one drug or ancillary supply that is stored refrigerated or frozen	

2. Industry-Sponsored Annual Maintenance Fee

Annual maintenance and inventory fees will be applied to multi-year studies on the anniversary of the pharmacy set up fee. The Annual Maintenance Fee covers, but is not limited to, study drug accountability and storage, receipt and disposition, and temperature monitoring.

Standard	$2740* $2972**
Advanced	$3060* $3291**
24/7 IDS Coverage and Support	$3625
*Protocols that only include drugs or ancillary supplies stored at room temperature **Protocols that include at least one drug or ancillary supply that is stored refrigerated or frozen	

3. Dispensing Fees*

Dispensing fees will be charged based upon protocol specific study drug dispensing requirements and drug handling and preparation requirements. Dispensing fees will vary based on the complexity of the preparation (e.g. simple dispense, compounded product, sterile compound, hazardous drug). Dispensing fees are charged for each prescription number generated (i.e., per each dosage strength and each dose dispensed), and for each dose identified and relabeled by an IDS pharmacist if the investigational drug has been previously dispensed. The dispensing fee provided in an IDS budget will be calculated based upon information provided during budget review but may be different at the time of dispense, depending on effort, study team- or Sponsor-specific requests and requirements (including IWRS entries and extra documentation/coordination) and non-standard materials required. *Additional IDS effort required per dispense will be billed in 15-minute increments at the current hourly rate.*

Non-sterile compounding ROUTINE dispense - Bottles or cartons of oral, topical, pre-filled syringes - Drug identification and labeling of previously dispensed product (includes Patient's Own Medication)	$64 per dosage strength
Non-sterile compounding COMPLEX dispense - Requiring elaborate procedures, such as non-sterile compounding or reconstitution, weighing powders/bottles, aliquoting or dilutions, medisets or filling blisterpaks/outpatient unit doses	$193 each Plus applicable non-standard materials costs
Sterile compounding ROUTINE dispense - Non-hazardous injectable; compounding required. Includes cost of standard infusion tubing.	$191 each Plus applicable cost for non-standard supplies
Sterile compounding COMPLEX dispense - Hazardous injectable; compounding required. Includes cost of CTSDs and standard infusion tubing - Requiring special procedures: vectors, serial dilutions, unit dose syringes, large doses, and cellular therapy	$318 Plus applicable non-standard materials cost

Controlled Substances Schedule I-V: dispensing + returns when applicable	$127 Plus applicable reverse distribution charges
Inpatient Unit Dose Not applicable if compounding is required or short-stability	$14 per dose and dosage strength
Additional time or action required per dispense IDS staff is required to complete extra documentation per dispense by Sponsor, including IWRS entry/confirmation or paperwork.	$195/hr billed in 15-min increments
Shipping and Courier Transport Fee to patients/other sites/Sponsor - *FedEx/UPS shipments without temperature monitoring: covers printing label/pack lists, packaging up shipment and delivering to loading dock for FedEx/UPS shipments without temperature monitoring* - *Courier +/- temperature monitoring: covers day-of-contact questions and coordination with courier and assistance with packaging up shipment and temperature monitoring device, if applicable, and signing/filing paperwork*	$195/hr billed in 15-min increments Plus applicable courier and shipping material charges

4. Other IDS Support Fees

Consultation/Clinical Oversight fee • Consulting on protocol logistics or drug preparation/handling • Creation of order template for non-IP containing trial or study arm • IDS patient management of study patients receiving standard of care treatments • Non-routine CMR or patient counseling/support	$195/hr billed in one-hour increments
Protocol Update Fees • Addition of new IP formulation, protocol arms, re-training or study-related updates	
Non-Standard Pharmacy Personnel Training Fees • Examples include protocol training of inpatient staff, liquid nitrogen training	

5. Monitoring Visits and Close Out Fee

Sponsor review of IDS records should occur during scheduled monitoring visits. This fee will be charged when temporary Vestigo Verify access is made available to one monitor per scheduled visit, which will provide access to drug accountability records, temperature logs and calibration records, and shipment information.

The close out visit should be scheduled when IDS involvement and maintenance is no longer needed for a study (i.e. enrollment is complete and all active patients completed study treatment). Study closure activities include return or destruction of study drug, final drug accountability, archiving of study documents, and storage of protocol specific documents. Maintenance fees will continue to be billed annually until an IDS close out visit is completed.

Sponsor Visit Fees • Charged per visit/Vestigo access set-up, even in cases of last minute cancelations or requests for remote monitoring • Beyond 1 hour, charge additional $195/hour in 15-min increments	$195 per 1-hour visit
Close Out Fee	$640
Request for IDS records AFTER close out visit	CURRENT annual maintenance fee + monitoring visit fee

Additional Notes

a. IDS Fee estimates are subject to change upon further review of study materials and release of updated study information.
b. All studies are subject to be updated to the current fee schedule upon budget review for all contract negotiations and any significant protocol updates that introduce updated workflow changes or new study drug/formulation, and/or treatment arm.
c. Commercially available medications for on-site use only may be procured by IDS for a study and will be billed to the Sponsor at the same procurement cost plus institutional-standard overhead. These costs are billed at the time of drug purchase and not upon use. All purchases made for a study are final and no refunds/credits are given for unused inventory.
    a. Commercial drug cost estimates provided are accurate at the time of budgeting. Because drug pricing fluctuates based on the market value and availability, it must be understood that the price of the medication may change at the time of procurement, and the sponsor will be charged accordingly.
    b. The ability for IDS to procure commercially available drugs is not guaranteed and subject to drug shortages outside of IDS' control.
d. For studies which need to utilize UCSF Specialty Pharmacy to dispense commercially available medications for home use and self-administration, refer to job aide. Dispensing fees and costs will be determined by UCSF Specialty Pharmacy.
e. *An annual 5% cost of living and inflation increase will apply to dispensing fees in Q1 of each fiscal year.