

**Investigational Drug Service
Department of Pharmaceutical Services
UCSF Medical Center**

UPDATE – December 15, 2009

Re: Charges for Pharmacy Services to Protocols

BASIS FOR BUDGETING:

When evaluating a study for fiscal impact on the pharmacy the following must be considered: How involved are the study's dispensing requirements - time and materials? Is the pharmacy generating a randomization schema for the protocol? How long will it take the pharmacy to prepare and deliver a dose? Are all doses STAT? Does drug need to be shipped to patients? Will the sponsor provide their FedEx number? Who is required to do the procedures, i.e., are duties restricted to the pharmacist vs. the technician.

BUDGETING STUDIES:

Beyond extraordinary materials costs (e.g. mailing, Medisets, special vials), the pharmacy charges will be the sum of the study fees detailed below.

Study set-up fee:

Standard Set up: \$ 3,198

Reimburses pharmacy for the time required for the IDS pharmacist to read the protocol, set up the dispensing procedures (label formats, instructions, paperwork) and to meet with sponsors over the course of the study. Based on a pharmacist salary and benefits rate of \$123/hour. Basic study rate assumes approximately 26 hours of pharmacist time throughout the study process. This would include, but not limited to, setting up Worx line items, creating pre-printed order sets, logging in inventory, stocking medications, providing in-service training to nursing and pharmacy.

Task Breakdown	Hours Associated with Task
Site qualification visit	1
Site initiation visit	1
Read And Summarize Protocol At Beginning Of Study	4
Set Up Dispensing Procedures (Worx)	2
Meeting With Sponsors (Qtrly) - 1 Hour Meeting	4
Logging Inventory / Stocking	7
Relabeling drug expiration date extensions/managing drug recalls	1
Randomization Assignment	2
Record Submission	2
Processing Information / Documentation To Sponsor During Study	2
Weekend /Evening Dispensing Of Product	dependant on study

Study Set up Fee Hour Total	26
------------------------------------	-----------

Oncology Study Set Up: \$3,690

In addition to the above Standard task listed above the items below are used in the set up of chemotherapy studies

Task Breakdown	Hours Associated with Task
Create pharmacy chemo orders	3
IVRS/Clinphone/etc. setup/training	1

Annual Maintenance Fee:

\$1,000 annually

- For multi year studies annual maintenance fee will be applied on the anniversary of the date from the initial Set Up Fee was applied.

Closure Fee:

\$500

- Closing Task includes but not limited to:
Closing appointment with the monitor, perform final drug accountability, drug destruction or send back, complete any inquiries, provide supporting documents such as refrigerator logs, drug receipts, etc., complete billing (if not done so before) and return documents/binder to regulatory people or file away

Ultra Low (-15 to -80 degrees) Freezer Fee:

\$300

- If the study requires the product to be in a freezer with temperatures between -15 or below, there will be a one time fee of \$300 per product.

Dispensing fees:

Injectable drugs (syringes/premixed bags/bottles or large volume):

\$ 40 per dose

- Assumes cost of materials/dose + 30 min. technician time at salary/benefits rate of \$55/hour

Chemotherapy/Complicated injectable:

\$ 80 per dose

- Extra time involved and cost of protective materials used in preparing dose

IV preparations requiring special procedures:

\$ 150 per dose

- IVs requiring elaborate preparations (e.g., large IVIG doses, unit-dose syringes). Pricing based on a one hour dispensing/delivery time

Oral drugs:

\$ 15 per dose

- Straight-forward, pull off the shelf, record and deliver. Assumes 15-30 minutes tech time per dose

Topical drugs:

\$ 15 per dose

- Straight-forward, pull off the shelf, record and deliver.

Oral preparations requiring elaborate procedures:

\$ 50 per dose

- Preparation of large quantities of unit-doses, reconstitution, compounding, etc.