

	Procedure Name	<b>IDS Billing for Services</b>
	SOP #05	<b>WVU IDS Pharmacy SOP-05</b>
	Date this Version is Effective	<b>01 January 2024</b>
	Responsible for Content	<b>IDS Pharmacy Manager</b>

## **I. Description**

This Standard Operating Procedure (SOP) details the billing processes of WVU Medicine's WVU Hospitals (WVUH) Investigational Drug Services (IDS).

## **II. Rationale**

The WVUH IDS team consists of multiple pharmacy technicians and pharmacists dedicated to serving the investigational product (IP) management of WVU's research community related to clinical trials on the WVUH campus.

Billable tasks performed by the IDS team include but are not limited to: protocol and study material review, electronic medical record order set development and maintenance, IP accountability, storage, and temperature monitoring, IP compounding, dispensation, destruction, and/or return to sponsor.

## **III. Procedures**

1. IDS staff will submit a pharmacy fee proposal for budget contract negotiations upon request to initiate a clinical trial (Appendix A).
2. Study-specific invoices are generated within Vestigo monthly and emailed to the study accounting contact.
3. Invoices are due 60 days after a billing cycle.

## **IV. Original Procedure Date and Revisions**

16 March 2022, 01 December 2022, 01 January 2023, 01 January 2024

Appendix A:

**WVU Hospitals Department of Pharmacy  
Clinical Trials Fee Calculation Worksheet**

**Protocol: Example**

**Date:**

**Principal Investigator:**

**Prepared By:**

I. Pharmacy Initiation Fees	Fee	Extension
<b>Full Administrative Set-Up</b>	\$3000	
<b>Protocol Review Only</b> (with investigational product stored & dispensed in clinic)	\$900	
<b>Additional Set-Up Fees</b> (choose all that apply)		
Pharmacy/Refrigerator/Freezer Storage <b>per study supply product*</b>	\$100	
Controlled Substance	\$250	
Maintenance of Temperature Logs	\$100	
Equipment Calibration Certification	\$100	
Investigational Product Data Sheet Preparation	\$75	
EMR Order Set Development	\$250	
Outpatient Prescription Label Preparation	\$50	
Study Specific Accountability <b>per study supply product*</b>	\$50	
Hazardous Drug Product Assessment Fee	\$25	
<b>Additional WVU Medicine Site Fee (additional \$300 per site)</b>	\$300	
<b>MAINTENANCE FEE Minimum of a 6-month maintenance fee</b>	\$100/month	
<b>TOTAL PHARMACY INITIATION FEES</b>		<b>\$__ at initiation + \$100 per month maintenance fee</b>
*varies if we are asked to store and account for multiple investigational product		

<b>II. Pharmacy Fees Per Patient</b> (unless otherwise noted)	<b>Fee</b>	<b>Extension</b>
<b>Enrollment Fee (applied per patient at enrollment)</b>	\$150	
<b>Dispensing Fee:</b>		
Pharmacy blinding (applied per patient at enrollment)	\$50	
Non-Compound Simple Dispense (e.g. oral, bulk, unit-dose; dispensing one kit or one full bottle of medication)	\$50	
Non-Compounded Complex Dispense (e.g. oral, bulk, unit-dose; dispensing multiple kits, medications that need to be counted, controlled substances)	\$75	
Non-Sterile Compound (e.g. reconstitution, extemporaneous)	\$100	
Non-Hazardous Sterile Compound	\$175	
Hazardous Sterile Compound	\$200	
Distribution and shipping fee	\$50 + shipping supply costs	
<b>Additional Options:</b>		
Pharmacy drug product acquisition cost	\$50 + cost of medication	
Pharmacy randomization (applied per patient at enrollment)	\$100	
Photographs of returned/expired IP, used vials, etc. (Applied per patient at enrollment)	\$50	
Destruction of IP (applied per occurrence)	\$50	
Monitor visit (\$100 per visit)	\$100	
On-call IDS services (applies to studies that require a dispense or consult outside of Mon-Fri 7am to 5pm and on holidays. Minimum of a one-hour charge.)	\$100/hour	
<b>Pharmacy Close Out**</b>	\$500	
<b>Consultation Fee - calls and questions (\$100/hour with a minimum of a one-hour charge)</b>	Variable	
<b>Other (if applicable)</b>	Variable	

<b>TOTAL PHARMACY FEES PER PATIENT</b> <b>Please note: Adaptive studies may incur multiple of the above fees throughout the lifetime of site participation.</b>	<b>\$__ at enrollment + \$__ per dispense</b>
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\*\*Abandoned and terminated studies will be charged a reduced close out fee at the time of abandonment/study termination.