

	Procedure Name	<b>IDS Billing for Services</b>
	SOP #05	<b>WVU IDS Pharmacy SOP-05</b>
	Date this Version is Effective	<b>16 March 2022</b>
	Responsible for Content	<b>IDS Pharmacy Manager</b>

## **I. Description**

This SOP details the billing processes of WVU Medicine's Investigational Drug Services (IDS).

## **II. Rationale**

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

Billable tasks performed by the IDS team include but are not limited to: Protocol and study material review, EMR 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

Appendix A:

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

**Protocol: Example**

**Date:**

**Principal Investigator:**

**Prepared By:**

<b>I. Pharmacy Initiation Fees</b>	<b>Fee</b>	<b>Extension</b>
<b>Full Administrative Set-Up</b>	\$2100	
<b>Protocol Review Only</b> (with study drug stored & dispensed in clinic)	\$500	
<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	
Calibration Certification	\$100	
Drug Data Sheet Preparation	\$50	
EMR Order Set Development	\$250	
Outpatient Prescription Label Preparation	\$50	
Study Specific Accountability <b>per study supply product*</b>	\$50	
<b>ANNUAL FEE – \$400 (applied annually after the first year)</b>	\$400	
<b>TOTAL PHARMACY INITIATION FEES</b>		<b>\$__ at initiation + \$400 annual 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>Dispensing Fee:</b>		
Non-Compound (e.g. oral, bulk, unit-dose)	\$50	
Sterile Compound	\$175	
Non-Sterile Compound (e.g. reconstitution, extemporaneous)	\$100	
<b>Additional Options:</b>		
Pharmacy drug acquisition cost	Variable	

Pharmacy randomization (applied per patient at enrollment)	\$15	
Pharmacy blinding (applied per patient at enrollment)	\$50	
Saving labels, used vials, etc. (applied per patient at enrollment)	\$50	
Destruction of IP	\$25	
On-call IDS services (apply outside Mon-Fri 7am to 5pm)	\$100/hour	
<b>Enrollment Fee (applied per patient at enrollment)</b>	\$125	
<b>Other</b> (if applicable)	Variable	
<b>TOTAL PHARMACY FEES PER PATIENT</b>		<b>\$__ at enrollment + \$__ per dispense</b>