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|  | Procedure Name | IDS Billing for Services |
| | SOP #04 | WVU IDS Pharmacy SOP-04 |
| | Date this Version is Effective | 01 January 2026 |
| | Responsible for Content | IDS Pharmacy Manager |

I. Description

This Standard Operating Procedure (SOP) details the billing processes of 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 appropriate WVU/WVUH/WVUM accounting contact.
3. Invoices are due 60 days after a billing cycle closes and invoice is generated.

IV. Original Procedure Date and Revisions

16 March 2022, 01 December 2022, 01 January 2023, 01 January 2024, 01 January 2025, 01 January 2026

Appendix A:

Clinical Trials Fee Calculation Worksheet

Protocol:

Date:

Principal Investigator:

Prepared By:

| I. Pharmacy Initiation Fees | Fee | Extension |
|--------------------------------|-------------|---|
| Full Administrative Set-Up | \$4500 | |
| Protocol Review Only | \$900 | |
| Controlled Substance | \$250 | |
| Miscellaneous | Variable | |
| MAINTENANCE FEE | \$1200/year | |
| TOTAL PHARMACY INITIATION FEES | | \$__ at initiation + \$ 1200/year maintenance fee |

| II. Pharmacy Fees Per Patient (unless otherwise noted) | Fee | Extension |
|---|----------|--|
| Enrollment Fee | \$200 | |
| Dispensing Fees: | | |
| Standard of Care Dispense | \$25 | |
| Non-Compound Dispense | \$75 | |
| Non-Sterile Compound | \$100 | |
| Non-Hazardous Sterile Compound | \$175 | |
| Hazardous Sterile Compound | \$225 | |
| Miscellaneous | Variable | |
| TOTAL PHARMACY FEES PER PATIENT Please note: Adaptive studies may incur multiple of the above fees throughout the lifetime of site participation. | | \$__ at enrollment + \$__ per dispense |

| III. Optional Pharmacy Fees | Fee | Extension |
|--|------------|--------------------------|
| On-call IDS time (minimum 1-hour charge) | \$100/hour | Per business coordinator |
| Consultation Fee (minimum 1-hour charge) | \$100/hour | Per business coordinator |
| Miscellaneous | Variable | |