**FACTS about Billing for the Investigational Study Pharmacy**

The form titled “Release of Drugs for Human Research Use” is a contract between the signing PI (or replacement PI) and the pharmacy for services expected to be provided by the Investigational pharmacy and service fees paid for by the study group as it relates to the titled Protocol. A description of services is printed on the lower half of each form as it pertains to that study. Services and fees are reviewed and approved by the pharmacy director prior to the principal investigator’s signature.

1. The Start up Fee is initiated the day if site initiation or site startup (if no official SIV occurs).
2. The Closeout Fee is charged when all investigational product related work is completed.
3. Storage Fees begin accruing the date of any shipment arrival as it relates to investigational products (IP) and items that will be stored in the pharmacy department.
   1. Storage Fees are assessed monthly for unused and used IP, expired or current and related materials until IP and materials are returned or destroyed after sponsor approval.
   2. Please be mindful that storage fees can be minimized by removal of excess IP through destruction or return to Sponsor on a frequent schedule.
4. Pharmacy has the right to charge for unanticipated work hours, extended monitoring visits and extra supplies needed to complete a task related to the study.
5. Billing invoices will be sent electronically through email quarterly to the person of contact provided.
   1. If the PI requires more frequent billing cycles, he/she must request the change.
   2. Payment is expected at the time of receipt of invoice.
   3. Examples of unacceptable delinquent accounts
      1. Deadline for budget submission has passed
      2. Lost invoices
      3. Awaiting payment from sponsor
   4. The investigational study pharmacist can be contacted for any invoices expected but not received.

**Explanation of fees**

**Start-up Fee**

1. One-time fee
2. Non-refundable
3. Charged upon pharmacy site initiation
4. Includes protocol review, budget review, SQV, SIV, electronic system set-up, creation of preprinted prescription (if applicable), training for pharmacy personnel

**Storage Fee**

1. Charged monthly as long as IP (used/unused/expired) remains on site
2. Excessive space usage and prolonged storage may incur higher monthly charges

**Dispensing Fee**

1. Charged per medication and per specific protocol requirements
2. Includes board required labeling
3. Fees vary based on complexity

**Compliance Fee**

1. Applies to protocol required documentation of patient compliance

**Pharmacist Service**

1. Consultation fees include protocol related review, editing or authoring
2. In-services for non-pharmacy personnel will incur a fee of pharmacist's time
3. Excessive documentation/email requests will incur a fee of pharmacist's time

**After Hours Service**

1. Applies to any time outside of normal investigational pharmacy/clinic hours

**Randomization Fee**

1. Includes pharmacy created randomization scheme for protocol specific use

**IP Management Fee**

1. On site destruction is the preferred method of disposal
2. Destruction will be charged once all IP is removed from study pharmacy
3. Shipment fees apply to ship to depot for destruction or to patient's home
4. Supplies and shipping costs for shipment will be applied. Shipping not for "distribution"
5. Narcotic inventory counts are required weekly
6. Non-narcotic inventory will occur at frequency of protocol requirement

**Closeout Fee**

1. One-time fee
2. Includes final drug accountability, IP documentation completion, provision of ALL IP related documents including temperature logs
3. Final pharmacy bill

**Amendment Fees**

1. Includes training for new formulations, arms or manual updates