Investigational Drug Service (IDS) Pharmacy Fee Schedule

Effective: September 2, 2025

This document outlines the tiered fee structure for IDS Pharmacy services based on protocol complexity and sponsor type.

Fees will be assessed **per protocol**, **per site**, for services provided by the Main IDS Pharmacy or independent site pharmacies, as applicable.

Tier Definitions

Tier	Complexity Criteria
Tier 1 (Low Complexity)	Minimal protocol complexity, basic dispensing requirements (orals, prefilled-syringes). One to two investigational medications that are ready to use (no manipulation or preparation required); few dispensing visits.
Tier 2 (Moderate Complexity)	Multiple drugs or dosage forms, standard randomization, moderate visit volume. Drug preparation required (Sterile IV Infusion, Sterile IV Syringe)
Tier 3 (High Complexity)	Adaptive or complex protocols, blinded/randomized, dose escalation, frequent amendments or dispensing. Trial designs involving significant operational and logistical challenges. Unblinded Monitor dedicated specifically to unblinded team only. Highly complex, stringent drug preparation requiring special handling or equipment (e.g., Blinded therapy, gene therapy requiring BSL2 Hood, vortex)

Sponsor Type Definitions

Sponsor Type	Definition
Industry	A pharmaceutical, biotech, or medical device company sponsors and fully funds the trial. They typically design the study, own the data, and may use a contract research organization (CRO) to manage it.
Consortium	Multiple organizations or institutions pool resources to fund a study. This often includes academic centers, foundations, government, and sometimes industry partners.
National Cooperative Group	Funded by the National Cancer Institute (NCI) and run by networks of academic institutions. Trials are designed collaboratively and often focus on specific cancers.
Federal	Federal funding means money provided by the U.S. federal government. Federal funding usually implies funding from federal agencies at the national level (as opposed to state or private sources).
Investigator Initiated Trials (IIT's)	A study developed and led by a researcher (physician or scientist), not by a sponsor. Funding may come from grants, foundations, or companies (who may provide drug or device support but not manage the trial). Mixed Funding is a combination of federal grants, institutional support, and possibly drug donations from industry.

Pharmacy Site Definitions

Pharmacy Type	Definition
Main Investigational Drug Service (IDS) Pharmacy	The central Investigational Drug Service location provides primary oversight, storage, dispensing, accountability, and regulatory compliance for all investigational products (IPs) conducted under the institution's authority. Main IDS Pharmacy serves as the central hub for all Investigational drug operations within the institution's scope. (e.g. Nebraska Medicine IDS Pharmacy)
Independent Pharmacy Site	A pharmacy that participates in clinical research outside the operational control of the Main IDS Pharmacy. The site operates independently from the Main IDS, even if participating in the same trial. The site maintains its own SOPs and accountability records. It manages its own staff training, storage, temperature monitoring, and dispensing processes. (e.g. Kearney Heartland Hematology Oncology, Specialty Care Services)
Satellite Pharmacy Site	A pharmacy location that is physically separate from the Main IDS Pharmacy but operates under its direct oversight. The satellite site functions as an extension of the Main IDS to provide convenient access to IP for certain clinics or infusion areas. (e.g. Village Pointe, Bellevue)

Start-Up Fee (Per Protocol-Once)

Sponsor Type	Tier 1	Tier 2	Tier 3
Industry	$2,500	$3,500	$5,000
Consortium	$1,250	$1,750	$2,500
National Cooperative Group	$500	$1,000	$1,500
IITs/Federal	$500	$1,000	$1,500

Maintenance Fee (Per Protocol/Month)

Sponsor Type	Tier 1	Tier 2	Tier 3
Industry	$83/month	$145/month	$200/month
Consortium	$42/month	$73/month	$105/month
National Cooperative Group	$20/month	$42/month	$63/month
IITs/Federal	$20/month	$42/month	$63/month

*Dispensing Fee (Per Dispense/Subject)

Sponsor Type	Tier 1	Tier 2	Tier 3
Industry	$75	$150	$200-$500
Consortium	$50	$75	$125-$250
National Cooperative Group	$25	$50	$75-$125
IITs/Federal	$25	$50	$75-$125

Notes:** A single trial may involve activities across multiple tiers. While start-up and maintenance fees are typically assigned to a single tier level based on overall protocol complexity, dispensing fees may vary by visit or subject cohort depending on the specific activities involved. Fee tiering will be assigned accordingly and documented. ***No waivers will be available for this service.

Close-Out Fee (Per Protocol)

Sponsor Type	Tier 1	Tier 2	Tier 3
Industry	$1,500	$2,000	$3,000
Consortium	$750	$1,500	$2,500
National Cooperative Group	$500	$1,000	$1,500
IITs/Federal	$500	$1,000	$1,500

Non-Investigational Drug Procurement (Per Drug-Annually)

Sponsor Type	Fee
Industry	$250
Consortium/ Cooperative/IIT/Federal	$125

Satellite Fee (Per Satellite Site- Annually)

Sponsor Type	Fee
Industry	$350
Consortium/Cooperative/IIT/Federal	$150

Other Common Fees / Incidentals

Fee Type	Description	Standard Rate
Send-Out/ Shipment Fee	Traceable courier send-out direct to patient	$100 per shipment
Amendment Review Fee	New treatment arms or new medications added for adaptive, umbrella and platform studies will be considered new studies and a new start-up charge will be applied	$0–$5,000/occurrence *Assessment based on Tiered Start-up Fee
Audit Support Fee	A “Not For Cause” audit conducted by the FDA or sponsor	$500/per protocol
Pharmacy Management Fee (No investigational product provided)	Oversight and coordination of study-related medications sourced outside of IDS, including locally obtained or standard-of-care drugs.	$250-$500 per protocol

Pharmacy Fee Schedule for Clinical Trial Services

Study start-up

One-time, non-refundable fee charged upon site activation (i.e. open to accrual in CTMS)

Includes:

- Protocol review and feasibility (identification of any pharmacy issues)
- Review of the investigational product(s) (IP)
- Providing and completing documents necessary for study initiation (e.g. Site Blinding Plan, Equipment Surveys)
- Preparation of pharmacy procedures and dispense guidelines
- Attendance of qualification visits
- Attendance of site initiation visits
- Training and education for study initiation
- IXRS training/set-up
- Provision of GCP-compliant storage
- EPIC build (EMR entry)
- Treatment Plans, Order-sets, Smart-sets, Therapy Plans, Procedural Orders
- Vestigo build (Label design)'Randomization scheme (if applicable)

Study maintenance fee

Monthly maintenance fees will be charged upon site activation (i.e. open to accrual in CTMS)

Includes:

- Equipment maintenance and calibration for storage
- Continuous and Daily temperature monitoring
- Meetings with Investigators, Study teams, Sponsors and Monitors
- Inventory control/Accountability (appropriate stock on hand, ordering, expirations, cycle counts)
- Drug Receipt (update accountability logs, register receipt in IWRS, upload temperature reports)
- Date Extensions
- IP Relabeling
- Training
- Billing Administration
- Scheduled Monitor/CRA visits
- Patient IP return accountability
- On-site Destruction

Close-out fee

Includes:

- Close-out visit and completion of any documents
- Reconcile drug accountability logs
- IP destruction/return
- EPIC order deactivation

Satellite fee

Includes:

- Inventory control
- Temperature monitoring

- Accountability
- IP transport
- Patient Returns (accountability and destruction)
- Training

Amendment fee

Includes:

- Any amendment to the protocol which requires revisions to pharmacy procedures and systems
- New treatment arms or new medications added for adaptive, umbrella and platform studies will be considered new studies and a new start-up charge will be applied.

Send Out/Shipment fee

Includes:

- If a protocol allows for IP delivery direct to a subject via a contracted courier (e.g. FedEx, UPS, World Courier, etc.) a fee will be assessed for packaging, documents, tracking, etc.).

Dispense fees (costs per preparation)

Note for Budget Negotiations: A single trial may involve activities across multiple tiers. While start-up and maintenance fees are typically assigned to a single tier level based on overall protocol complexity, dispensing fees may vary by visit or subject cohort depending on the specific activities involved. Fee tiering will be assigned accordingly and documented.

Includes: IP drug preparation and dispensing, IP accountability, Blinding , IWRS

TIER 1	Simple ready to use investigational products (oral, topical, pre-filled injectable)
TIER 2	Increased IP preparation time requiring manipulation or compounding (Unit dose oral, multiple kits (10 or more), controlled substance, repackaging from bulk supply, small volume parenteral (SMP) for injection preparation
TIER 3	Complex preparation and time required (Complex-Compounded sterile IV admixture, Compounded sterile hazardous IV admixture). Highly complex (high risk compounded products, gene therapy, cellular therapy)

Dispensing fees represent direct labor and resource costs and will not be written off. All dispensing activities require dedicated pharmacy time and documentation and are charged per subject/visit according to the established tier.

This applies regardless of funding source or study design.

Procurement fee (charged annually)

Includes:

- Procurement of a non-investigational product required for the protocol
    - Acquisition costs are charged separately
    - Dispense fee is applied
- Inventory control
- Manual ordering
- Accountability
- Storage
- Temperature monitoring
- Destruction

Audit Support fee (per protocol)

Includes:

- A fee assessed to support routine or sponsor-initiated audits that are not triggered by suspected noncompliance or a specific event. This includes time spent preparing documentation, retrieving records, participating in audit meetings, and responding to auditor requests. The fee reflects administrative and personnel effort and ensures readiness and compliance support, even in the absence of findings.

Pharmacy Management fee (per protocol)

Includes:

- A fee charged for the oversight, coordination, and documentation of study-related medications that are sourced outside of the IDS Pharmacy. This includes activities such as review of study protocols and pharmacy manuals, coordination with external pharmacies or manufacturers, managing non-investigational product workflows, and maintaining costs and efficient billing logistics.

Notes

- Other Common Fees/Incidentals should be verified with IDS Pharmacy
- Pharmacy may consider bundled pricing for cooperative group or in-house IITs with limited funding.
- Waivers for any fees must be submitted to IDS (**InvestigationalPharmacy@nebraskamed.com**) on an individual basis and approval granted and documented.
    - All dispensing activities require dedicated pharmacy time and documentation and are charged per subject/visit according to the established tier.
    - Dispense fees will not be waived for federally funded studies. Investigators are encouraged to budget for these services in grant proposals. Fee reductions may be considered on a case-by-case basis if justified and approved through institutional review.
- Justification for fee tiers should be documented and available for sponsor transparency.
- Consortium and National Cooperative group trials will be variable based on funding source