



**Center for Clinical and
Translational Research
Standard Operating Procedure**



Section: **Clinical Research Center**

Date Created: **December 23, 2024**

Title: **Determining Medication Costs in Clinical Studies**

Version Date: **December 23, 2024**

SOP Number: **SM53**

PURPOSE: To provide a standardized workflow for determining and documenting medication costs in clinical studies, ensuring accuracy, consistency, and compliance with regulatory and budgetary requirements.

SCOPE: This SOP applies to all personnel involved in clinical study start-up requiring the calculation of medication costs.

PERSONNEL RESPONSIBLE: Principal Investigator, Project coordinator, Research Coordinator, Budget Negotiator, Investigational Drug Services (IDS), Pharmacy Operations (outpatient and inpatient)

DEFINITIONS:

- National Drug Code (NDC): a unique 10- or 11-digit number that identifies a human drug in the United States. It's used in pharmacies to identify and report drugs, and to ensure interoperability between different electronic systems.
- Medication Source: entity that is physically providing or purchasing the medication. This could include sponsor or Nebraska Medicine.
- Investigational Drug Service (IDS) Pharmacy: is a type of pharmacy that is responsible for managing and dispensing investigational drugs to clinical trial participants in accordance with regulatory agencies such as the FDA and ICH guidelines.
- Specialty Pharmacy: a type of pharmacy that provides medications and services specifically for patients with complex, chronic, or rare medical conditions that require specialized care. Specialty medications are FDA approved and are typically high-cost, often biologic or injectable, and may require special handling, administration, or monitoring.
- Outpatient Clinic Pharmacy: a pharmacy located within or associated with an outpatient clinic or medical facility that primarily serves patients who are receiving care on an outpatient basis. The pharmacy dispenses prescribed medications to patients seen at the outpatient clinic. Patients seen in outpatient settings often require regular medication refills. The outpatient clinic pharmacy may handle refill requests, ensuring continuous access to necessary medications.



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PROCEDURES:

Step 1: Identify the type of study.

- Objective: Identify if the study includes a drug or device
- Review:
 - Review the study protocol.
 - Generate a list of medications if applicable
 - Obtain the source of the medication
 - Sponsor (Centrally)
 - Provided a subject free of charge
 - Site (Locally)
 - Provided to subject free of charge (Sponsor Funded)
 - Subject payment (Insurance)
- Actions:
 - If the study is identified as a device study or a drug study and there are NO medications required to be supplied to a subject, no other actions to obtain medications costs are necessary.
 - If the study is identified as a device study or a drug study and YES, medications are required to be supplied to a subject, identify the source/funding of medication(s).
 - Sponsor (centrally) sourced medication(s) will be handled by IDS Pharmacy following standard workflows. Contact InvestigationalPharmacy@nebraskamed.com for more information.
 - Site (locally) sourced medication(s) that will be covered by the subject or insurance requires no further action.
 - Site (locally) sourced medication(s) that will be sponsor funded will need further review to determine treatment location(s). Proceed to Step 2.

Step 2: Identify the treatment location

- Objective: Identify the location where the patient will receive the medication.
- Review:
 - Treatment Locations:
 - Inpatient
 - OP Infusion
 - Clinical Research Center
 - OP Clinic



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Home

Actions:

- If site (locally) sourced medication(s) will ONLY be administered in the Inpatient setting or the Outpatient Infusion Center, contact Joni Johnson, jonjohnson@nebraskamed.com or Anna Pike, APIKE@nebraskamed.com for more information.
If site (locally) sourced medication(s) will ONLY be administered in the Clinical Research Center or an Outpatient Ambulatory Clinic, contact Pharmacy Operations, pharmacyoperations@nebraskamed.com.
If site (locally) sourced medication(s) is required by the study to be taken at home, proceed to Step 3.

Step 3: Identify if home medication is required

- Objective: Identify if the patient will require medication at home.
Review:
o Treatment Location: Home
Actions:
o If home medication WILL be required, contact Pharmacy Operations team at PharmacyOperations@nebraskamed.com

ASSOCIATED FORMS:

Medication Cost Workflow

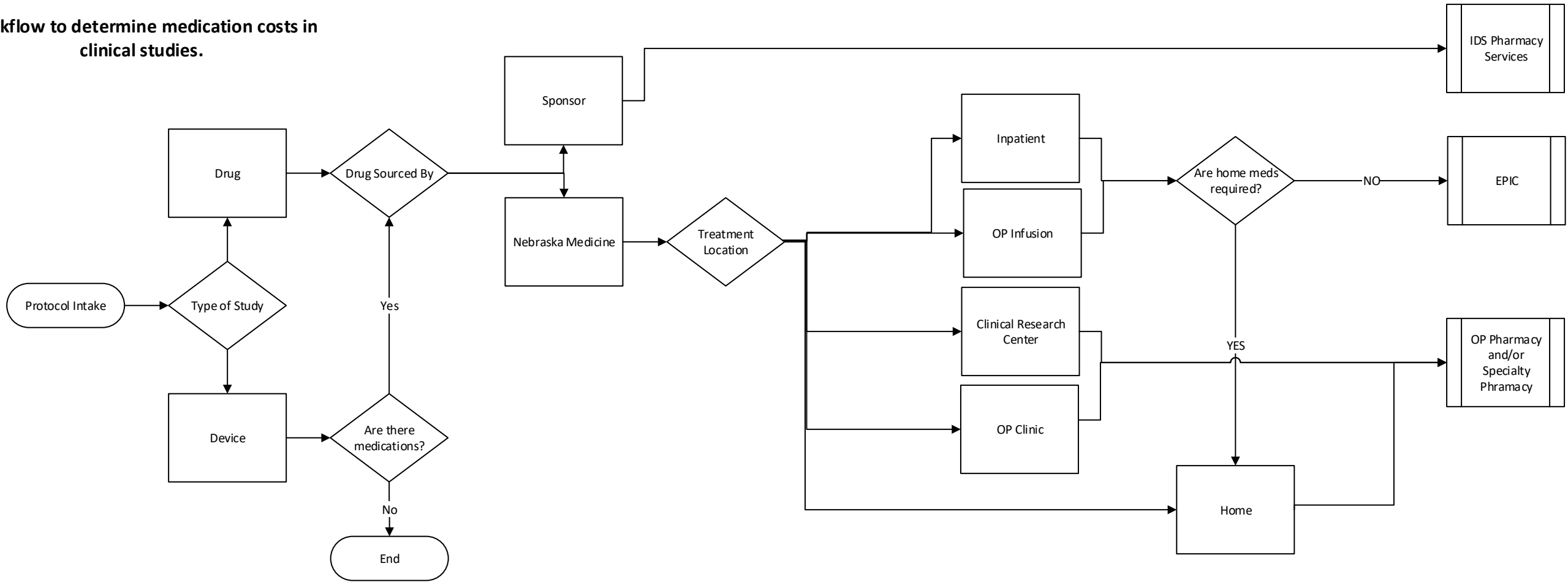
RESOURCES:


SOP # RxOPS45- Research and Grant Clinic Billing Standard Operating Procedure

Department Approval:

Signature block containing two signatures: Katie Penas, Clinical Research Manager (dated 1/24/2025) and Assistant Vice Chancellor for Clinical Research (dated 1/31/2025).

Workflow to determine medication costs in clinical studies.



 Nebraska Medicine <small>SERIOUS MEDICINE. EXTRAORDINARY CARE.®</small> PHARMACY STANDARD OPERATING PROCEDURE	SOP Number	RxOps45
	Version	1
	Approval Date	12/17/24
	Review Date	12/17/25
Title	RESEARCH AND GRANT CLINIC BILLING STANDARD OPERATING PROCEDURE	

Author	<i>Staci Keith (Manager, Community-Based Pharmacy Operations)</i>
Keywords	<i>Clinic billing, grant, investigational, clinical research, study</i>

1. Summary

- **The Research and Grant Clinic Billing standard operating procedure outlines the process for pricing logic and end of month reporting for medications provided for patients with scripts ordered through research/grant fundings.**

2. Scope

- **The pharmacy operations analysts assigned to clinic billing will follow this SOP to ensure the reporting of claims provided under the Research and Grant Clinic Billing plan is accurate and provided to accounting each month.**

3. List equipment and resources required

- *Pharmacy Operations analyst, Clinical Research Analyst, Investigational Pharmacy, EnterpriseRx, Accounting analyst*

4. Procedure

1. Clinic Trial Analyst/Budget Negotiator or member of Investigational Pharmacy reaches out to pharmacyoperations@nebraskamed.com for price quote using email template in reference section.
2. Pharmacy Operations team member provides price quote of currently utilized NDC of requested product at WAC price +\$5 dispense fee per fill.

- a. If not a product currently stocked, pharmacy operations analyst to connect with outpatient Purchasing analyst on availability and pricing before providing price quote.
- 3. During response back to Clinic Trial Analyst/Budget Negotiator or investigational pharmacy, Pharmacy Operations analyst will respond with pricing and the pharmacy operations response template in the reference section.
 - a. Pharmacy Operations team will need:
 - i. Start date.
 - ii. Grant/Cost Center number to provide Accounting monthly
 - iii. End date if known.
- 4. Pharmacy Operations Analyst will place completed price quote into Research&Grant-Billing folder in Pharmacy Business Operations Sharepoint> Bus Ops Share> [Research&Grant-Billing](#)
- 5. When provided with the information, Pharmacy Operations team creates new group formulary with drugs requested using Veridikal.
 - a. Group Formulary reference the grant/study number/cost center, excluding dashes.
- 6. Pharmacy Operations analyst with notify Clinical research or investigational pharmacy once plan is live.
- 7. Clinical research or investigational team will update prescribing team members to include the following note when sending prescriptions down to OPP:
 - a. "Please bill to plan code 3148800 - Research Clinic Billing. Use group ID **TBD**"
- 8. At month end, pharmacy operations analyst will complete clinic billing for plan code 3148800.
 - a. Claims will be separated out by group number, indicative of the grant cost center that should be billed.
 - b. Cost centers will not need dashes added back in.

5. References, related resources and acknowledgments

Request Template:

Please send request template to pharmacyoperations@nebraskamed.com and CC investigationalpharmacy@nebraskamed.com			
Study Medication (include information such as name, dose, frequency, qty, etc.)	FOR PHARMACY		
	NDC used	Cost	dispense fee
			\$5
			\$5
		\$5	
Additional Comments to Pharmacy Operations team:			

Pharmacy Operations response template:

Upon confirmation that the team would like to move forward, please allow 2 business days for the new group to be processed in the pharmacy system. Pharmacy operations will confirm complete set up. For prescribing, please inform team members to include the following note:

"Please bill to plan code 3148800 - Research Clinic Billing. Use group ID ***Cost Center***"

Set Up Cost Centers

Study/Grant	Cost Center
IRB 051-24, Epion	3652702219888 (previously 1005105)
IRB BL, LASIK	3652702221888 (previously 1005105)

Contacts

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6. Attachments or related documents