STANDARD OPERATING PROCEDURE

Pharmacy Cold Chain SOP

Document no.	SOP-PHA-006
Revision	1.0
Owner	Pharmacist in Charge
Effective date	September 15, 2026
Review cycle	Every 12 months

1. Purpose

To keep temperature-sensitive medication within its required range from receipt through patient pickup, and to respond quickly and document any temperature excursion.

2. Scope

Applies to refrigerated and frozen medications, including vaccines and biologics, stored or dispensed by the pharmacy. Does not cover non-refrigerated inventory, covered by the inventory management SOP.

Definitions

Temperature excursion	A period where a refrigerator or freezer reading falls outside its required range.
Continuous temperature logger	A device that records refrigerator or freezer temperature at set intervals for later review.
Cold pack shipment	A delivery packed with ice or gel packs and a temperature indicator to keep contents within range in transit.

3. Responsibilities

Pharmacy Technician	Receives cold-chain shipments, logs temperatures and stocks the refrigerator or freezer.
Pharmacist	Assesses product viability after an excursion and decides whether stock can still be used.
Pharmacist in Charge	Maintains the temperature monitoring program and approves the backup power plan.
Delivery Driver	Transports patient take-home cold-chain items in an insulated container.

RACI matrix

Activity	Pharmacy Technician	Pharmacist	Pharmacist in Charge	Delivery Driver
Check unit temperature before accepting shipment	R/A	I	-	-
Record twice-daily temperature log	R/A	I	-	-
Assess product viability after an excursion	I	R/A	C	-

Activity	Pharmacy Technician	Pharmacist	Pharmacist in Charge	Delivery Driver
Maintain backup power plan	I	-	R/A	-
Transport cold-chain item to patient	C	I	-	R/A

R = Responsible, A = Accountable, C = Consulted, I = Informed

4. Materials and PPE

Materials, tools and systems

- Calibrated pharmacy-grade refrigerator and freezer
- Continuous temperature logger or min/max thermometer
- Cold chain temperature log
- Insulated bags and gel packs for patient pickup
- Backup power or generator plan documentation
- Manufacturer package inserts for storage requirements

Personal protective equipment

- Disposable nitrile gloves

5. Procedure

Step	Task	Owner	Done
5.1	**Verify unit calibration before receiving** Confirm the pharmacy refrigerator or freezer thermometer is within its calibration date and reading correctly before accepting a cold-chain shipment.	Pharmacy Technician	☐
5.2	**Inspect the shipment on arrival** Check the shipping container's temperature indicator, ice pack condition and packaging integrity as soon as the delivery arrives.	Pharmacy Technician	☐
5.3	**Record the arrival temperature** Read and record the shipment's temperature indicator or logger result immediately, before moving the product into storage. **Checkpoint:** The arrival temperature is recorded before the shipment is opened and shelved.	Pharmacy Technician	☐
5.4	**Quarantine an out-of-range shipment** If the shipment arrives outside its required range, place it in a clearly marked quarantine area and do not shelve it with active stock. **Warning:** Never dispense or return an out-of-range shipment to active stock until a pharmacist has assessed it.	Pharmacy Technician	☐
5.5	**Move stock into storage promptly** For shipments within range, move the product into the refrigerator or freezer promptly to minimize time outside required temperature.	Pharmacy Technician	☐
5.6	**Log temperature twice daily** Read and record the refrigerator or freezer temperature at the start and end of each business day, or review the continuous logger download.	Pharmacy Technician	☐
5.7	**Respond to an alarm or out-of-range reading** If a reading is out of range, check the door seal and power connection, note the duration of the excursion, and notify the pharmacist immediately.	Pharmacy Technician	☐

Step	Task	Owner	Done
5.8	**Assess product viability** Review the excursion's duration and temperature against the manufacturer's stability data or contact the manufacturer to decide whether affected stock can still be used. **Checkpoint:** No affected product is dispensed until a viability decision is documented.	Pharmacist	☐
5.9	**Document the excursion and corrective action** Record the excursion's cause, duration, affected products and the viability decision on the cold chain temperature log.	Pharmacist	☐
5.10	**Maintain the backup power plan** Confirm the backup power or generator plan for refrigeration is current and test it on the schedule set by the pharmacist in charge.	Pharmacist in Charge	☐
5.11	**Rotate stock within the unit** Shelve refrigerated and frozen stock by FEFO within the unit so soonest-expiring product is used first.	Pharmacy Technician	☐
5.12	**Pack cold-chain items for patient pickup** Place dispensed refrigerated items in an insulated bag with a gel pack for patient pickup or delivery, and remind the patient to refrigerate on arrival home.	Delivery Driver	☐

6. Quality checks

- Every cold-chain shipment has a recorded arrival temperature.
- Refrigerator and freezer temperatures are logged twice daily without gaps.
- Every excursion has a documented viability decision before affected stock is used.
- The backup power plan has been tested within the last year.

7. Records

- Cold chain temperature log
- Shipment arrival temperature records
- Excursion and corrective action documentation
- Backup power plan test records

8. KPIs

- Number of temperature excursions per quarter
- Percentage of scheduled temperature logs completed on time
- Average time to respond to an out-of-range alarm
- Dollar value of cold-chain stock lost to excursions

9. Common mistakes

- Shelving a cold-chain shipment before reading its arrival temperature.
- Skipping a daily temperature log entry when the pharmacy is busy.
- Assuming a brief door opening caused an excursion without checking the actual duration.
- Dispensing from a quarantined shipment before a viability decision is made.

10. Revision history

Revision	Date	Description	Reviewed by
1.0	September 15, 2026	Initial release	Ilia Pirozhenko

Approval

Prepared by	Approved by	Date

This is a template. Adapt it to your organization, equipment and local regulations before use.

Scan for the latest version

Opens this template online, where you can download it again in Word, PDF, Excel or CSV — free, no sign-up.

Or add it to Perfect Wiki so your team can find it and ask questions about it in Microsoft Teams, Slack, kChat or Mattermost.