IREDELL HEALTH SYSTEM

Controlled Substances				
Approved by:	Last Revised/Reviewed Date:			
B. Wagner, RN, VPN	06/2023			
Randi Raynor, PharmD, MBA, BCPS				
Nursing Leadership	Date: 06/2023			
P&T Committee	Date: 06/2023			

Policy:

The procurement, receiving, storage, dispensing, administration, and destruction of controlled substances within the hospital will be performed in accordance with State and Federal guidelines. All controlled substance records shall be maintained for a period of at least 3 years.

Procedure:

I. Procurement

- **A.** The automated dispensing cabinets are replenished by pharmacy based on reports generated by the system.
- **B.** Authorized practitioners shall order controlled substances for individual patients. Pharmacy will assure that these medications are available to the nursing staff.
- **C.** Pharmacists, or designee who has a power of attorney on file, will obtain controlled substances from the wholesaler or manufacturer as needed.
 - **i.** Schedule II drugs will be ordered by completing an Official Order Form (DEA-222) or via electronic order form (DEA-e222). If non-electronic, the completed form should be given to the wholesaler driver or mailed to the manufacturer.
 - **ii.** Schedule III V drugs will be ordered and transmitted using the wholesaler procedures.

II. Receiving

- A. The Pharmacist verifies and documents receipt of all controlled substances by signing and dating the Purchaser's copy of the Official Order Form for Schedule II's or the printed PO generated from narcotic inventory program for Schedule III V. The pharmacist also signs and dates the invoice received from the wholesaler.
- **B.** The receipt of all controlled substances is recorded in the narcotic inventory program.
- C. Invoices of Schedule II and Schedule III V controlled substances will be filed separately.

III. Storage

- A. Controlled substances shall be stored in an automated dispensing cabinet or securely locked cabinet on individual nursing units. Controlled substances stored in the locked cabinet will be dispensed using the automated dispensing cabinet software (if available). Controlled substances stored in the locked cabinet will be replaced based on the automated dispensing cabinet par level at the same time other controlled substances are replaced in the dispensing cabinet. When the pharmacy technician delivers controlled substances to the unit, nurses will obtain the narcotic keys from the dispensing cabinet and place the medications in the locked cabinet.
- **B.** Controlled substances in the Pharmacy shall be stored in a securely locked vault or cabinet.
- **C.** Controlled substances dispensed for an individual patient shall be stored in a locked cabinet if not immediately administered to the patient.

IV. Dispensing

- A. The dispensing of all controlled substances from the pharmacy shall be recorded in the computerized narcotic inventory system. Information recorded will include date issued, unit, quantity dispensed, balance remaining after dispensation and name of pharmacist or designee obtaining controlled substances from the vault. Verification of inventory will occur at the time of dispensing. All discrepancies shall be reconciled at the time of discovery.
- B. Controlled substances stored in automated dispensing cabinets on nursing units will be delivered and stocked in the cabinets by pharmacy personnel. Nurses will obtain controlled substances from automated dispensing cabinets for patients when needed.
- C. For Controlled Substances Not Stored in Dispensing Cabinets:
 - i. A "Controlled Substances Administration Record" (*CSAR*) shall be issued with all controlled substances not stored in the dispensing cabinets. The CSAR may be used for multiple medications (for units that do not have an automated dispensing cabinet) or a single medication.
 - ii. The CSAR will contain the following information: drug dispensed, strength description, dosage form, quantity dispensed, nursing unit, date, and signatures of pharmacist and nurse.
 - iii. Nursing may obtain one or more doses of a single medication from the pharmacy using the "single CSAR". The pharmacist issuing the drug and the nurse receiving the drug shall sign the CSAR and the receipt.
 - iv. If a CSAR is used, the controlled substance will be assigned to the virtual 'remote location' in the automated dispensing cabinet as soon as possible (the following day if the medication is required on the evening or night shift.) The receipts will remain in Pharmacy and be filed in numerical order. The CSAR will remain with the drug.
- V. Disposition of CSAR: After all doses on the CSAR have been administered; the sheet will be checked for accuracy and completeness, and returned to Pharmacy. The Pharmacy technician will attach the corresponding receipt and file the CSAR.

VI. Administration

- A. When a controlled substance is obtained from the automatic dispensing cabinet, the following information is automatically recorded: patient's name, quantity removed from cabinet, nurse removing the drug, date and time drug removed, beginning inventory and ending inventory. If the drug is dispensed from the Pharmacy on a CSAR, the following information is recorded on the CSAR each time a dose of medicine is administered: the date, time, patient's name, room number (if applicable), amount of drug administered, amount wasted (if applicable) and nurse(s)' signature.
- B. Controlled substances removed from stock are to be administered immediately to the patient or returned to the storage area. The administration of the controlled substance will be recorded in the patient's medical record per hospital policy and procedure for medication administration. Nurses should verify that all controlled substances are documented on the eMAR prior to end of shift.

VII. Destruction

Any contaminated, unusable, or partially used controlled substance shall be destroyed per procedure. Destruction shall occur by discarding <u>in the approved disposal container</u>.

Nursing Stations, Special Care Areas, and Other Areas

- 1. Partially used controlled substances Destruction should occur at the time the medication is obtained from the automated dispensing cabinet or locked cabinet and witnessed by a second nurse (or licensed personnel authorized to witness).
- 2. Refused Doses or Wastage of the Entire Dose Destruction should be witnessed immediately upon leaving the patient's room by a registered nurse.
- 3. Transdermal patches: Some transdermal patches (e.g., Fentanyl) are controlled substances. Two licensed staff members (RN or LPN) must witness the disposal of the patch. The patch should be cut or folded in half and <u>placed in the approved disposal container in the medication room</u> (this includes post mortem care). Pharmacy staff will include in special instructions for the application of a controlled substance patch that the old patch must be removed, wasted and witnessed by two licensed staff. Destruction of the patch will be documented by two licensed staff persons in the automated dispensing cabinet or, on the CSAR.
- **4.** PCA's and Epidurals: The remaining contents should be wasted in the medication room <u>approved disposal container</u> in the presence of a witness at the time the medication is discontinued.
- **5.** Documentation: Destruction of controlled substances shall be recorded on a Controlled Substance Administration Record (CSAR) for controlled substances issued with such records or in the automated dispensing system software utilizing the "medication waste function". Information recorded shall include the date, time, drug name and strength, quantity, manner of destruction, and the initials or signatures of the nurses destroying and witnessing the destruction.

If the second nurse is asked to witness controlled substance destruction several hours after the original dispensing and/or the nurse is not comfortable documenting the witness of wastage, he/she should contact the unit charge nurse, Nurse Director, or Administrative Nurse Supervisor immediately.

Pharmacy

- 1. Contaminated or partially used controlled substances may be destroyed in the Pharmacy by a Pharmacist in the presence of a witness. The record of destruction shall be recorded on a computerized record system or on the "Record of Destruction of Contaminated Controlled Substances". The record shall include date, time, drug name and strength, quantity, manner of destruction and initials or signatures of the persons destroying and witnessing the destruction.
- **2.** Destruction of controlled substances (*other than contaminated controlled substances*) shall be by a licensed reverse distributor. This may include both in-date and expired controlled substances.

VIII. Charging

- A. Charging will be done by nursing upon documentation of administration in the electronic health record (EHR) for units that use the eMAR function.
- B. Charging for Anesthesia and other procedural areas not using the eMAR will be done when the medication is dispensed from the automated dispensing cabinet.

IX. Returns

A. Controlled substances stored in the drug dispensing cabinets may be returned to the pharmacy by the pharmacist or pharmacy technician.

- **B.** Controlled substances not stored in the drug dispensing cabinets may be returned to the pharmacy by the nurse along with the CSAR. The drug name and strength, quantity, date returned, and initials of pharmacist receiving the returns shall be recorded on the CSAR.
- **C.** The return of controlled substances to the Pharmacy shall be recorded in the narcotic inventory system.
- **D.** Controlled substances stored in the pharmacy may be returned to the manufacturer or wholesaler as needed.

X. Storage of Narcotic Keys in Drug Dispensing Cabinets

- **A.** Each set of controlled drug cabinet keys will be placed in a separate locked, lidded box in the drug dispensing cabinet.
- **B.** At the local list screen, the nurse will select floor stock and "remove meds" option.
- **C.** Nurse will select "stocked meds" then pick "keys" which will prompt for intended quantity to remove.
- **D.** After entering quantity of keys to remove, select "remove now".

XI. Inventory

Controlled drugs shall be inventoried regularly:

- **1.** General Nursing and Special Care areas: each time a controlled substance is administered.
- 2. Ancillary Care areas: twice daily (at opening and closing of department on days open).
- 3. Pharmacy: Each time a controlled drug is issued, weekly, and biennially
- 4. Controlled substances stored in the automated dispensing cabinets will be inventoried <u>monthly</u>.
- 5. All controlled substances located in a locked cabinet will be counted at the end of each shift and anytime a licensed nurse is ending her shift on a unit to leave the hospital (*Ex. Nurse going home two hours early due to low census*).

Procedure for Inventory of Controlled Substances in a Locked Cabinet:

- 1. Off-going nurse will check the cabinet to see if it contains a controlled substance. If drugs are in the cabinet, two nurses will count the controlled substances. One nurse will be responsible for counting the drugs in the cabinet and the other nurse will be responsible for verifying the count on the CSAR. The charge nurse may delegate this responsibility to a staff nurse but the charge nurse will be held accountable for completion of the inventory.
- 2. To complete the count, obtain the keys from the automated dispensing cabinet. Two nurse will count the medication in the lockbox and verify that count against the CSAR.
- **3.** Once the inventory is complete, the two nurses will sign their names on the Narcotic Check Sheet. The completed Narcotic Controlled Drug Check Sheets will be collected by the Nurse Director and will be filed for reference on the unit.

XII. <u>Variances</u>

Nursing: The Nurse Director, or the Administrative Nurse Supervisor in his or her absence, will be notified at the time a variance is discovered. A variance is defined as any time the sum of the events of medication administration, return and/or waste transactions do not add up to zero or when an irreconcilable inventory discrepancy is discovered. If the variance involves an irreconcilable inventory discrepancy, the pharmacist on duty shall also be notified.

Pharmacy: The Director of Pharmacy (or designee) will be notified at the time the irreconcilable inventory discrepancy is discovered. All variances are to be investigated using available documentation, interviews with pharmacy personnel, and/or review of security cameras.

If the variance involves a suspected theft or security breach, the Director of Pharmacy, Security, and the Administrator-on-Call shall be notified as well.

The responsible employee (if applicable) will be notified of the variance and may be required to return to the hospital. If the employee is unable to return to the hospital, and a controlled substance needs to be returned to the automated dispensing cabinet or wasted, it may be done by the Nurse Director, Charge Nurse, or Administrative Nurse Supervisor.

XIII. Variance Review and Resolution

- A. Variances will be identified via the ControlCheck software system and defined as open variances. The pharmacy representative reviewing open variances will investigate and gather information.
- B. Open variance communication will be sent via encrypt email to the responsible employee, Nurse Leader, and Director of Pharmacy. Response to the open variance is expected within 72 hours of communication being sent.
- C. The pharmacy representative will securely store communications for 3 years. Additionally, documentation will be notated in ControlCheck and the open variance will be manually closed.
- D. Significant variances may be reported to the CEO, DEA, and Board of Pharmacy as required by law. (see Drug Diversion Policy)

XIV. Disciplinary Enforcement of Controlled Substances Variances:

Examples of controlled substances variances:

- Failure to reconcile controlled substance inventory based on clinical setting.
- Leaving prior to the count being corrected if found to be incorrect.
- Failure to return keys to the hospital at the request of the charge nurse, Nurse Director, or Administrative Nurse Supervisor.
- Failure to document administration of the controlled substance on the MAR or Anesthesia Record.
- Failure to complete return and/or waste transaction of controlled substances.
- Failure to follow policy and procedure for destruction of controlled substances.
- Failure to account for the entire contents of all controlled substances dispensed.

Disciplinary Action for Controlled Substances Variances:

3 occurrences	Coaching
5 occurrences (within rolling 12 months)	Final Written Warning
6 occurrences (within rolling 12 months)	Termination

In addition, violations may be reportable to North Carolina Board of Nursing and/or North Carolina Board of Pharmacy as required by law.

INITIAL EFFECTIVE DATE: 12/2003 DATES REVISIONS EFFECTIVE: 06/2006, 07/2008, 05/2009, 02/2010, 09/2011, 04/2013, 01/2016, 02/2021, 02/2023, 06/2023 DATES REVIEWED (no changes):

Iredell Memorial Hospital – Narcotic Controlled Drug Check Sheet Unit/Area

Date	Time	On Nurse	Off Nurse	Discrepancy	Reported To
	7AM				
	11AM				
Monday	3PM				
	7PM				
	11PM				
Tuesday	7AM				
	11AM				
	3PM				
	7PM				
	11PM				
	7AM				
	11AM				
Wednesday	3PM				
	7PM				
	11PM				
	7AM				
	11AM				
Thursday	3PM				
	7PM				
	11PM				
	7AM				
	11AM				
Friday	3PM				
	7PM				
	11PM				
Saturday	7AM				
	11AM				
	3PM				
	7PM				
	11PM				
Sunday	7AM				
	11AM				
	3PM				
	7PM				
	11PM				