PharMerica Policy and Procedure for the Operation of a RxNow E-Kit in a Residential Health Care Facility in the State of Iowa

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Overview

RxNow is an in-facility secure electronic e-kit used to provide medications for residents' emergent needs such as emergency and first doses as allowed by law and regulation. This main body of this document provides a general policy and procedure for kits installed in the facilities within the state of Iowa.

Security and User Roles

Policy – Security & Users

The PHARMACY defines and maintains appropriate security features and user roles for all shifts.

Procedure - Security

1. The kit uses secure technology to only provide access to one unit dose drawer at a time based on the medication order.
2. The kit utilizes barcode verification to insure the correct medication has been retrieved from the kit.
3. Controlled substances are stocked in a locked automated unit dose dispense module to prevent theft or diversion.
4. The automated unit dose dispense module restricts access to controlled substances and delivers one unit dose of medication at a time.
5. The kit shall be locked at all times.

Procedure - Users

Each person accessing the kit is required to have his or her own biometric and individual electronic authentication credentials.

Defining User Roles

1. The Facility Administrator, Director of Nursing (DON), and PharMerica RxNow Manager defines user roles for the following and assigns levels of access appropriate to the role. Below is a list of the general user roles. Actual user access may vary by individual based on need of the facility. For example, limiting the removal of controlled substances to certain individual.
    a. Floor Nurse – remove and return all classes of medications
    b. Shift supervisor/Charge Nurse – remove and return all classes of medications, add a resident, witness
    c. Assistant Director of Nursing - remove and return all classes of medications, add a resident, witness (optional), resolve discrepancies, audit, review reports, add temporary user (valid for 5 days), disable users.
    d. Director of Nursing - remove and return all classes of medications, add a resident, witness (optional), resolve discrepancies, audit, review reports, add temporary user (valid for 5 days), disable users.
    e. Facility administrator – same as DON, if licensed nurse, otherwise limited to auditing and reports.

Setting up Authentication Credentials

2. DON submits the user list to the servicing pharmacy by name and the last four digits of each user's social security number using the format required by the servicing pharmacy.
    a. The required Card ID format is:
        i. First initial
        ii. Last Initial
        iii. Last four digits of the user's Social Security Number
        iv. For example: AB1234

Setting up Biometric Security

1. Authorized person and a witness open the Biometric setup screen.
2. Witness must enter their Card ID and PIN to verify new biometrics set-up
3. The display will show an image of both hands on the screen.
4. Decide which finger on the left hand will be used for the biometric (the index finger or thumb are recommended).
5. Tap the screen on the designated digit to be scanned and the finger image changes from solid lines to broken lines.
6. You will be prompted to put your finger on the biometric scanner.
7. The scanner will turn red and a picture of the finger print will appear on monitor. You must lift the finger off of the scanner to repeat this process.
8. The above step must be repeated three more times. If the scan is accepted the finger image on the monitor will turn to green. If the scan is not accepted the finger on the monitor will turn red.
9. The entire process is repeated for a finger on the right hand.
10. When both fingers are green, tap OK to save the information.

Operations

Policy – Medications

1. A record of all kit transactions will be maintained by the pharmacy.
2. A licensed pharmacist shall verify all controlled substances to be stocked in the kit prior to delivery.
3. Controlled substances will be owned by the pharmacy.
4. Controlled substances medications for emergency use are locked in the automated unit dose dispense module.
5. A written record of the Pharmacist's verification of the controlled substances will be maintained at the pharmacy.
6. Pharmacies shall keep a separate written record of all controlled substances received, delivered and disposed of by them.
7. Unit dose packaging shall be provided for the controlled substances that identifies medication by drug name, strength, lot number and expiration date.
8. The pharmacy will monitor for outdates, deterioration, etc on a regular basis.

Policy – Removing Medications

The nurse will only remove medications as prescribed by the physician and allowed by State and Federal law and regulation.

Procedure - Removing Medications

1. Before ANY medication can be removed from the kit, the nurse must obtain a valid physicians order appropriate to the medication in accordance with State and Federal law and regulation.
2. A controlled substance cannot be removed from the kit without following the appropriate documentation process required by State and Federal law and regulation.
    a. Nurse MUST provide the required information to the pharmacist at the servicing pharmacy.
3. The nurse will log into the machine using their unique login AND scanning their finger on the biometric scanner.
4. The nurse will locate a resident by typing in the first few letters of the resident's name OR by scrolling through a list of active residents.
5. Select the resident and select continue.
6. Select the medication and enter the quantity to be dispensed.
7. Select Accept and then select Dispense
8. When the drawer opens, a window will be displayed on the screen showing the medication to be dispensed with the kit location.
    a. Locations are displayed by ROW-DRAWER | SLOT where 1-3A would be the first row of drawers, third drawer from the left and first slot in the drawer from front to back.
9. Remove the requested medications from their location in the requested amounts.
10. Tap the medication and scan the barcode on the medication for verification.
11. Upon receiving an indication in green that the process in complete, tap Accept
12. Tap Back or Logout when finished.

Policy - Restock

The kit will be restocked in accordance with State and Federal law and regulation.

Procedure - Restock

1. Pharmacy personnel will supply, stock, and maintain the RXNOW.
2. Pharmacy ADS stock of controlled medications will not be stored at the RHCF outside of the RXNOW.
3. Any expiring medications shall be securely packaged and sent back to the pharmacy with controlled substances segregated from the non-controls. Any non-controlled medications that have been damaged so that the efficacy of the medication may be compromised shall be sent back to the pharmacy. Controlled substance shall be destroyed at the facility according to current procedure and a report sent to the pharmacy detailing the drug name, barcode number, quantity destroyed and person(s) conducting the destruction.
4. The person authorized to restock the kit will log into the machine using their unique login and scanning their finger on the biometric scanner.
5. Select Restock
6. A list of medications available for dispense will be displayed.
7. Select the medication to be stocked
8. Enter the quantity to be restocked and press enter
9. The drawer containing the medication will open.

10. When the drawer opens, a window will be displayed on the screen showing the medication to be restocked with the kit location.
    - Locations are displayed by ROW-DRAWER | SLOT where 1-3A would be the first row of drawers, third drawer from the left and first slot in the drawer from front to back.
11. Verify available quantity in the drawer, add the quantity to the drawer and close the drawer.
12. Continue this process until all medications needing to be restocked are placed into the kit.
13. If the medication to be restocked is a controlled substance
    - The door to the locked automated unit dose dispense module will open; revealing the shelves for all controlled medications.
    - The location of the controlled medication that is being restocked will be indicated by a green flashing light.
    - Lift up on the latches on either side of the drawer and slide it gently forward
    - Place the new doses on the spiral coil behind any currently stocked doses.
    - Verify inventory.
    - Slide the drawer gently back into place.
    - Close the door to the locked automated unit dose dispense module.
14. When restock is complete; log out.

Policy – RETURNING MEDICATIONS TO THE RXNOW

1. Non-Controlled medication removed from the RXNOW that is in the original tamper evident packaging and is re-dispensable or reusable can be returned to its original drawer.
2. Controlled medication removed from the RXNOW that is in the original tamper evident packaging and is re-dispensable or reusable can be returned to the RETURN DRAWER.
3. ANY MEDICATION THAT IS NOT IN ITS ORIGINAL TAMPER EVIDENT PACKAGING, OR IS UNUSABLE FOR ANY REASON, CANNOT BE RETURNED TO THE RXNOW AND SHOULD BE WASTED. A WITNESS IS REQUIRED FOR ANY WASTED MEDICATION.

Policy – Diversion Control

The PHARMACY will generate reports to monitor the use and inventory of the kit and will inform the Administrator or DON immediately upon finding an issue. The Administrator/DON shall inform the pharmacy if diversion is suspected. The PHARMACY will monitor use of RxNow and report any irregularities.

Procedure – Diversion Control

The Pharmacy and Facility will work cooperatively to identify the user or users that may be involved with diversion from the kit and take appropriate action. Persons operating the kit shall notify the authorities of theft or loss of any controlled substances.

Disaster Recovery

Policy – Loss of Data Connection

Facility will report a loss of the data connection (as defined by an “offline” message on RxNow) immediately to the pharmacy.

Procedure – Loss of Data Connection

1. Most data connection issues will be resolved automatically within 10 minutes of loss.
2. DO NOT turn off or restart the computer in an attempt to correct the problem. The system requires a data connection for continuous operations, and will not function at all until reconnected if restarted.
3. When an offline message has been observed, call the PharMerica Technology Support using the number attached to the kit to report the issue.
4. If a medication is needed from kit while connection is lost, Nurse will follow same protocol as for dispensing a controlled substance.
    a. Nurse MUST provide the required information to the pharmacist at the servicing pharmacy
    b. Nurse can only remove the controlled medication from the kit after being provided approval from the pharmacist in accordance with State and Federal law and regulation.

Policy – Loss of Power

The facility will provide backup power for extended power outages

Procedure – Loss of Power

1. If the kit is connected to a generator-backup outlet, the kit will function normally as long it is supplied power.
2. If the kit is NOT connected to a generator-backup outlet:
    a. The kit's battery backup will allow functioning of the kit for short power outages usually about an hour and will beep during that time.
    b. After 10 minutes of battery operation, the DON will direct an extension cord of sufficient length and grade to be plugged into the nearest available generator outlet.
    c. The kit will function normally as long as it is not turned off or restarted. When power is restored the kit will then automatically reconnect the data connection and update the server.
3. In the event of complete power failure
    a. The kit can be operated with key just like a traditional ekit.
    b. The DON must call the pharmacy to obtain the combination to the key box to retrieve the keys.
    c. A resident specific log (Appendix B) must be kept and faxed to the pharmacy as soon as it is possible.

Procedure – Record Keeping

1. The facility should request any RxNow reports from their pharmacy as needed.
2. The pharmacy monitors the dispenses, transaction discrepancies, expiration dates and stock levels and will alert the facility as required
3. The following standard reports are monitored at the frequency indicated:
    a. Yesterdays Billing Report' – daily
        i. List items removed in the last 24 hours
    b. Patients Added at the DT (Data Terminal) Last 7 Days' – daily
        i. Lists patients added to the system in the last 7 days
    c. Unresolved Discrepancy Events for Previous 7 Days' – daily

    i. Lists discrepancies not resolved by an administrator

d. Return & Retrieve Drawer Activity' – daily
    i. Log of user and medications placed in the return drawer and removed from the retrieve drawer

e. Station Below Minimum – weekly
    i. List of items below their minimum stock level

f. Meds Expiring – monthly
    i. List of medications expiring

g. Inventory Summary' Report – as needed
    i. List of all inventory items

h. Restock All Positions Report – as needed
    i. List of all items that need to be brought back to their maximum stock level

Appendix A

RxNow System Authorization

Complete *both* the User Authorization and PIN Verification Statement forms

User Information ☐ **Add User** ☐ **Change Access** ☐ **Remove Access**

Please Print

Facility Name:_____

USER I.D._____(First initial, last initial, last 4 digits of SSN)

FIRST NAME_____**LAST NAME**_____

YOUR INITIAL "PIN" - "9999"

GROUP PROFILE (Check one*)* ***(examples listed below)***

☐ Nurse - Staff

☐ Nurse - Charge

☐ Nurse – Intermittent (ending date_____)

☐ Other _____

☐ ED Business Office

☐ CRNA / SRNA

☐ Doctor

☐ Pharmacist

☐ Pharmacy System Manager

☐ Pharmacy Tech

PLEASE LIST **ALL** AREAS IN WHICH THIS USER WILL NEED PERMANENT ACCESS:

Nursing Area (wing, department, floor, etc):

_____

AUTHORIZED BY:_____DATE: _____

PHONE EXTENSION: _____

Send to the Pharmacy, Attn.: - RxNow

For pharmacy use only

ENTERED INTO THE RxNow SYSTEM: BY: _____

DATE: _____

Appendix A (con't)

RxNow Personal Identification Number (PIN) Verification Statement

FACILITY NAME:_____

Please read below and sign at the bottom to verify that you have read and understand the following statement:

Attached is a copy of my ID to the RxNow System. I understand that in combination with my PIN, this will be my electronic signature for all transactions in the system. It will be used to track all of my transactions in the system and will be permanently attached to those transactions with a time stamp and date. These records will be maintained and archived as per the policies of your facility, and be available for inspection by the Drug Enforcement Administration (DEA) and the Department of Professional Regulation (DPR), as is presently done with my handwritten signature for controlled substance records.

I also understand that to maintain the integrity of my electronic signature, I must not give this PIN to any other individual.

_____ _____

Signature Date

Appendix B – Manual Administration Form

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RxNow Form for Manual Medication Removal

This form is intended to be used in the event of a prolonged power outage that requires the medications to be removed with a key.

Date	Time	Complete Resident Name	Medication Name	Strength	Quantity Removed	Nurse's Signature

This form is to be utilized if the cabinet must be opened with the keys to document the medications that are removed. Each line item must be completed at the time the medication is removed from the cabinet. Start a new form each day with the start of the day shift.
The completed sheet must be faxed to the pharmacy prior to starting a new sheet. Once it has been faxed retain a copy in the accordian file.