Subject: Automated Medication Distribution Systems (AMDS)  
(Formerly Policy #3.19 AND Pyxis Anesthesia System #3.24)

Purpose: Provide standards for the utilization of AMDS in the practice of pharmacy

Procedure:
1) Quality Assurance and Performance Improvement
   a) Pharmacists utilizing an AMDS shall develop a written quality assurance and monitoring plan prior to implementation of the AMDS. The quality assurance plan shall target the preparation, delivery and verification of AMDS unit contents during fill and refill processes and shall include, but not be limited to the following: Requiring continuous monitoring of the system; Establishing mechanisms and procedures to test the accuracy of the system; Establishing a protocol for measuring the effectiveness of the system; Requiring the pharmacy to report to the board each recurring error of the system
      i) Quality Assurance Reports Pyxis CII Safe System:
         (1) Discrepancy Alert/Resolved Discrepancy Record
         (2) Open Discrepancies - lists all controlled substances for which the actual physical count does not match the internal count (DAILY)
         (3) All CIISafe Events - provides a detail of all transaction for one or more controlled substances for a specific time period. (DAILY)  
            (a) Med Refill Activities (Pyxis Compared)  
            (b) Loading and Unloading (Pyxis Compared)
         (4) Pyxis vs CIISafe Compare Report - verifies the integrity of the movement of medications between the CII safe system and pyxis medstation system. Verifies the restock and return functions, reporting the errors or discrepancies that occurred between the floor and the pharmacy. Verifies the accuracy of the correct medication, quantity, and pyxis medstation system and links medication unloaded from a pyxis medstation system to return transactions in the pharmacy. (DAILY)
      ii) Quality Assurance Reports Pyxis Medstation:
         (1) Override Meds - transactions on the report are compared to the patient record to verify that override medications have an order and are being accessed, used, and charted appropriately. (DAILY)
         (2) Inventory by Outdated Meds - verify that outdated medications are being monitored and removed. (WEEKLY)
         (3) All Station Events (DAILY) – includes all controlled substance activity (cancelled transactions reviewed, dispenses >2 reviewed, discrepancies)
      iii) General Management and Monitoring
         (1) User IDs and initial passwords will be assigned by a station administrator. Users who are unable to consistently use BioID will be permitted to use a password by the Pharmacy Director. Users who forget their password must present to the pharmacy in person and request a station administrator reset their password.
         (2) Each user is assigned a unique temporary password upon initial use of the system by a station administrator.
         (3) Access to controlled drugs will be assigned only to authorized personnel by a station administrator
The ability to create temporary users will be restricted to as few persons as possible. Temporary user creation will be closely monitored by pharmacy.

The assignment of station access in All Areas will be limited to only those individuals who require this level of access. 7/17/17

Users who are unable to consistently use BioID are instructed and permitted to change their password immediately if password confidentiality is compromised.

Users are removed from the system upon termination of employment. Users are regularly reviewed. (CODE N)

Pharmacy will avoid keeping emergency medications (such as the crash cart) exclusively in the stations because this might compromise user accountability during an emergency situation.

Station keys for emergency access will be stored in the pharmacy and will be accounted for on a regular basis.

A Pharmacist or Pharmacy Technician will remain with the CareFusion representative at a station at all times when it is necessary for the technician to access drawers.

Based on facility confidentiality procedures and needs, printouts will be placed in HIPAA bins or shredded.

iv) Controlled Substance Management and Monitoring
1. Individual pocket access will be used for all controlled drugs
2. Refrigerated controlled substances will be minimized
3. Keys will be placed in an individual pocket when possible to control and document access
4. Controlled drugs will be loaded into stations, including special patient-specific orders when possible
5. Controlled drugs in each station will be inventoried on a periodic basis (MONTHLY)
6. The verify count option will be activated for all formulary items that are controlled substances. 7/17/17
7. Pharmacy maintains a system utilizing stations for controlled substance drips, including PCAs and EPIDURALS which meet state requirements
8. System data will be readily retrievable and hard copies of console and station reports will be maintained as required to comply with state and federal requirements
9. Facility policies and procedures to handle discrepancies involving controlled substances will be implemented and enforced (Incident Reporting)

v) Drawer Configuration and Medication Location Management and Monitoring
1. When possible, the use of matrix drawers will be restricted to over the counter drugs, and those medications which have minimal if any clinical risk
2. Internal and external preparations will be clearly separated
3. When possible, pharmacy will avoid placing medications with similar appearance or similar names in the same matrix drawer and certainly not in proximate pockets
4. Injectable drugs will be separated as much as possible, especially those in similar containers
5. When possible, more commonly used medications will be placed in top drawers for easy access
6. Emergency medications (code blue) will not be kept exclusively in stations

vi) Station Formulary List Control Management and Monitoring
1. Nearly all medications will be distributed via the medstation profile mode system. The display formulary options will be activated with a value of always at the console for the entire formulary

vii) Order Entry and Verification Management and Monitoring
1. The host pharmacy system will be configured to send orders to the medstation profile mode system console only upon entry or verification by a pharmacist

viii) Medication Distribution Management and Monitoring
1. Technicians pick and prepare medications for load or refill into a station under the supervision of a registered pharmacist. The pharmacist checks medications prepared by a technician before they are placed into a station.
2. Stations are physically loaded or refilled by trained technicians.
(3) Nurses are instructed to report any suspected load or refill error to pharmacy by calling immediately.
(4) Pharmacists maintain an ongoing quality monitoring program to review technician load/refill activities.
   (a) Following technician load/refill activities, periodically print loading and unloading and med refill reports
   (b) Compare the med refill report activities with the refill pick and delivery report used by the technician

3) All policies and procedures shall be in writing and shall be maintained in the pharmacy responsible for the AMDS. All policies and procedures shall be reviewed at least annually and revised as necessary, and the review shall be documented. Additions, deletions, amendments, and other changes to policies and procedures shall be signed or initialed by the pharmacist in charge, shall include the date on which the change was approved, and shall be maintained for a minimum of two years. Policies and procedures shall address at a minimum the following:
   a) Type of equipment, system components and location of each system component including: Name and address of the pharmacy, including identification of the specific location within an institution but outside the pharmacy where any component of the AMDS is being used; Name and address of any remote dispensing site where a component of the AMDS is being used; Manufacturer’s name and model of each system component
      i) Name/ Address -
         1. UnityPoint Health – Marshalltown Hospital (North)
            3 South 4th Avenue
            Marshalltown, IA 50158
         2. UnityPoint Health - Marshalltown Medical Park (South)
            55 Central Iowa Drive
            Marshalltown, IA 50158
      ii) AMDS Specific Locations -
         1. See Table I (North Site) and Table II (South Site)
      iii) Manufacturer’s Name/ Model
         1. See Table I (North Site) and Table II (South Site)

Table I (North Site)

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<th>Location</th>
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*Pyxis CII Safe dispenses controlled substances for the North Site*
*CII Safe Central Iowa Healthcare dispenses controlled substances for the South Site 7/17/17*
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b) Drug access and information access procedures
   i) The Station Administrator creates or modifies AMDS users and their privileges, including the nursing unit areas to which they have access. Templates are created to simplify the process of creating users that have the same privileges.

c) Security and confidentiality of records
   i) The hospital understands that it is responsible for maintaining the contents, confidentiality and privacy of electronic patient data, including protected health information (PHI) in compliance with applicable federal and state laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH), and related rules and regulations. Any reports obtained from the Advisor that contain PHI shall be handled in compliance with HIPAA’s Privacy Rule and Security rules.

d) Description of how each component is being utilized, including processes for dispensing and distributing drugs
   i) Components
      1) Console - communicated data to and updates activity information in all the stations; maintains copies of all patient, user, formulary and activity information used to generate pharmacy reports
      2) Console Workstation - an additional computer, monitor and keyboard acting as another console access point
      3) Stations - provide secure and reliable storage for medications of all types. They communicate with the console, receiving patient, order (profile mode only) and inventory information, while continuously reporting all medication transactions.
(4) Printer - the console includes a high speed laser printer for printing reports
(5) Scanner - a scanner capable of reading linear and 2D barcode symbols is standard
equipment on both the station and the console

ii) Process for Dispensing and Distributing Drugs
(1) See Quality Assurance and Performance Improvement
(2) See Decentralized Unit Dose AMDS

e) Staff education and training
i) The AMDS provides a tutorial that includes the basic steps of the major tasks available at the
station. Documentation of completion is available per HR. (Appendix C)

f) Review including prospective drug use review of medication orders and prescriptions in
accordance with federal and state laws and regulations
i) A pharmacist shall review the patient record, information obtained from the patient and each
prescription drug or medication order to identify: overutilization/ underutilization, therapeutic
duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or
duration of drug treatment, drug-allergy interactions, clinical abuse/ misuse, drug prescriber
contraindications. Upon recognizing any of the above, the pharmacist shall take appropriate
steps to avoid or resolve the problems.

g) Quality assurance and performance improvement
i) See above

h) Downtime or system failure procedures
i) If a catastrophic power failure occurs, an internal battery backup at the station provides about
two minutes of power to automatically initiate a safe shutdown of the station. If the power
failure continues, you can gain access to the medications through the following override
process:
(1) Turn off power to the station by switching the power switch (located on the right rear of
the station) to the off position.
(2) Obtain the two keys (from pharmacy) required to remove the access panel from the back
of the station.
(3) Remove the back access panel.
(4) Press the red release lever on the right side of the appropriate drawer and push the
drawer out.
(5) Repeat for each drawer that you need to access.
(6) Using the log sheet provided, record any medication removals. (Appendix A)
(7) Using the Controlled Substance Disposition Records and 24-hour Nursing Audit Record,
record any controlled substance waste.
(8) When power returns, close all drawers and contact the system manager for instructions
on bringing the station current with the medications you removed during the outage.

i) Periodic system maintenance and preventive maintenance
i) Station maintenance occurs every 24 hours, usually late at night, to purge unneeded data
from the console databases.

j) Drug security and control including: Drug loading/ storage and records; Drugs removed from
system components but not used; Inventory; Cross contamination; Lot number control; Wasted or
discarded drugs; Controlled substances

i) Drug loading/ storage and records -
(1) Loading - Medications can be assigned to a station from the console and are considered
pending when they have been assigned but not yet physically loaded. Medications can
also be assigned and loaded at the station through the Assign and Load feature.
(2) Storage - You can configure a station with a variety of drawers to suit demand,
medications, and storage requirements
(3) Records - Each time that you perform an activity at the station it is recorded by the
system as a transaction. Transaction information is sent from the station to the console
and stored in a database. You can generate reports from this data, which is also used by
the system to track inventory levels and to generate refill requests and restock reports to
maintain the inventory of medications.

ii) Drugs removed from system components but not used -
If the wrong item from the station has been removed or the doctor cancels the order, use the Return function to return items to the system and credit the patient’s account. A returned medication must be intact and in its original, tamper-evident packaging.

When returning a medication to the Return Bin, make certain that you turn the one-way slot until the medication drops into the bin.

iii) Inventory -
(1) The Inventory function allows you to count, verify and outdate medications.

iv) Cross contamination - NA

v) Lot number control -
(1) The CII Safe System can track and monitor medications by an internal number that the manufacturer assigns to each batch of product produced. If a problem is identified with a batch of product, the lot number is used to identify all product manufactured at the same time.

vi) Wasted or discarded drugs -
(1) The Waste function: • Allows you to create an audit record for wasting all or part of a previously removed medication for a specific patient. • Allows you to credit the patient’s account to ensure that the patient is not charged for medication not received. • Is used if you were unsure of how much you were going to waste at the time that you originally removed the medication. After the medication is given to the patient, use the Waste function to waste the medication and to document the amount not given

(2) The process for discarding a medication requires a nurse licensed witness for controlled substances.

vii) Controlled substances -
(1) Use of individual pocket access for all controlled drugs

(2) See Policy Controlled Substance IAC.657-10

4) System, Site and Process Requirements - each AMDS complies with the minimum requirements of Iowa Pharmacy Law 657-9.12(147,155A)

5) Records
a) All records shall be retained for two years

6) Decentralized Unit Dose AMDS

7) Components of a decentralized unit dose AMDS utilized for the storage and dispensing of drugs in an institutional setting may be restocked with drugs by an appropriately trained pharmacy technician following pharmacist verification in the pharmacy of each dose of the drug to be restocked.

a) When bar coding or other technology based verification is utilized to check the accuracy of drug doses stocked in a dispensing component and a non-pharmacist fills the component, a pharmacist shall check each drug dose prior to releasing the drugs from the pharmacy.

i) Electronic records available (Pyxis PARX Report)

b) One day each month, all drug doses or bins contained in 5 percent of the components utilized within the system shall be verified by a pharmacist. If the system contains fewer than five components, a pharmacist shall verify all drug doses or bins.

i) Electronic records available (Pyxis Inventory Report)

c) All identified errors shall be logged as provided by the quality assurance and monitoring plan and shall categorize as follows: incorrect drug, incorrect dose, incorrect dosage form, other errors identified in writing

i) Written records available (AMDS/ CII Safe/ Controlled Inventory Log) APPENDIX B

Additional Information:

8) CMS Survey Procedure

a) All drugs and biologicals must be kept in a secure area, and locked when appropriate (CMS A-0502 482.25(b)(2)(i))

i) Review hospital policies and procedures governing the security of drugs and biologicals to determine whether they provide for securing and locking as appropriate

b) Drugs listed in schedules II, III, IV, and V of the comprehensive drug abuse prevention and control act of 1970 must be kept locked within a secure area (CMS A-0503 482.25(b)(2)(ii))
i) Determine whether there is a hospital policy and procedure that requires schedule II, III, IV, and V drugs to be kept in a locked storage area.

ii) Determine whether there is a hospital policy and procedure defining authorized personnel that are permitted access to locked areas where drugs and biologicals are stored.

iii) Determine whether there is a hospital policy and procedure for limiting access to locked storage areas to authorized personnel only.

Closing Banner:
Originated by: Pharmacy Department
Effective date: 3/01
Authorized by: P&T Comte/ Date: 07/16
Authorized by: Jessica Rosenhamer, Pharmacy Director
Revision date: 4/24; 7/09, 6/15, 9/15, 07/16, 9/16, 7/17
Review date: 5/16

References:
Iowa Pharmacy Law Ch 9
CMS
Pyxis Medstation 4000 System Station User Guide
Pyxis CIISafe System User Guide
Pyxis Anesthesia System 4000 User Guide
Pyxis Medstation 4000 System Console User Guide

APPENDIX A
Downtime or System Failure Log Sheet (with example)

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Appendix C
ID/ Password/ BioID
Confidentiality Agreement

Pyxis Medstation 4000 System
The following is your User ID/ Initial Password for Pyxis MedStation System. It will be used to access patient medications or supplies on your assigned nursing unit(s). The first time you access a Pyxis MedStation, you will be required to enter a new, confidential password and enroll four finger scans using BioID. It is your responsibility to keep your new password secret and utilize your BioID access for personal access only. You will be accountable for all transactions performed under this statement, and will maintain the integrity of your password/ BioID access once it has been changed.

Below is a copy of my User ID and my initial password to the Pyxis MedStation System. Upon accessing Pyxis MedStation for the first time, I will change my password to a new confidential password and enroll my finger scan for BioID. I understand that my User ID and password/ BioID will be my electronic signature for all transactions to the Pyxis MedStation System. I understand that no retrievable record of my new password or BioID exists. All of my transactions on the Pyxis MedStation system will be permanently recorded with my User ID and a date and time stamp. These records will be maintained and archived per the policies of this hospital; and will be available for inspection by the Drug Enforcement Administration (DEA) and the State Board of Pharmacy, State Board of Health or other auditing agency, as is presently done with my handwritten signature for all controlled substance records.

I also understand that to maintain the integrity of my electronic signature, I must not give my password to any other individual Unauthorized access, release or dissemination of this information shall subject me to disciplinary action. Should I have any suspicion that my personal password has become known to another individual, I will change it immediately and, if deemed appropriate, will immediately report such to my supervisor.

Signature: ______________________________  Date: _________________________________
Print Name: _____________________________ Dept/ Unit: _____________________________
Authorized By:  
Supervisor: _____________________________  Date: _________________________________
Print Name: _____________________________ Dept/ Unit: _____________________________
This user is a/an:  
□ FT/PT RN □ Nurse Manager □ Pharmacy Supervisor 
□ Per Diem RN □ Nursing Supervisor □ Pharmacist 
□ Respiratory Therapist □ Instructor □ Pharmacy Technician 
□ Physician

Please enter above information correctly and return to Pharmacy.
To obtain your confidential User ID and Password show proof of ID to Pharmacy Dept.

Pharmacy/ Manager Authorization:
Signature: ______________________________  Date: _________________________________
Print Name: _____________________________ Entered into Console: _____________________

Confidential
Use this User ID and First Time Password to Access the Pyxis MedStation System.

User ID #: ______________________________  Temporary Password: ____________________