Subject: Pyxis Anesthesia System

Purpose: To establish guidelines for the proper and safe administration of medications, and appropriate use of the Pyxis Anesthesia System

Policy: MMSC will provide secure and identifiable access to medications. Due to the unique nature of medication access and use in the OR setting, the medication system is designed to insure compliance with regulatory requirements by:

- Strictly managing access privileges to the Pyxis® Anesthesia System 3500 and to automate manual storage areas.
- Providing adequate security for medications, including controlled substances.
- Defining the best practice for the storage, dispensing, delivering, charging, and quality assurance of medication usage with the Pyxis® Anesthesia System 3500.

Authorized Privileges for Access

1. ID’s will be assigned using the confidentiality statement and entered into the Pyxis Anesthesia System 3500 by Pharmacy staff.

2. All users must complete the tutorial, competency check-list and sign that they have reviewed the Marshalltown Medical and Surgical Center (MMSC) Pyxis® Anesthesia System 3500 Policy’s and Procedures prior to receiving privileges.

3. Access authorization is managed through the Pharmacy Department.

4. Access into the Pyxis® Anesthesia System 3500 will be controlled by using the assigned User ID, and BioID.

5. If a user fails BioID login, the setting to use is the following:
   a) Push to Password (as per Anesthesia Provider request)

6. If a user forgets their password or needs their BioID reset, Pharmacy is to be contacted and a temporary password will be established. It is known that MMSC
does not provide 24 hours in-house coverage: MMSC Pharmacists cannot remotely change or reset passwords.

a. If the User is a Locums or Traveler, the Anesthesia Provider must present to Pharmacy during regular Pharmacy hours with their MMSC issued badge for identification, or accompanied with the Anesthesia Coordinator or Human Resources personnel to vouch for their identity.

b. Upon next entry in the Pyxis® Anesthesia System 3500, the user must select “change password” and establish a new password.

7. The following personnel will have access to the Pyxis® Anesthesia 3500 system:

a. Anesthesia Providers - Full privileges
b. Locum/Traveler anesthesia providers – Full privileges
c. OR/Surgical Technicians – Access to supplies
d. OR RNs – Witness to waste privileges, Access supplies/limited medications (non-controls) for case preparation
e. Pharmacists – Full privileges
f. Pharmacy Technicians - Refill and inventory privileges

8. Enter all users including Locums as permanent users. This will be coordinated with the Anesthesia Coordinator or Human Resources, and the Director of Pharmacy or designee.

9. Privilege to create temporary users should be restricted to Anesthesia/OR management. Temporary users will be created at the workstations by Anesthesia Physicians, CRNA’s or Management.

10. Information on user activity will be provided to Anesthesia Coordinator and be monitored by the Director of Pharmacy or CODE N designee.

11. Users are inactivated by the Director of Pharmacy/designee upon notification to the Director of Pharmacy/designee by the Anesthesia Coordinator or from the Human Resources Department.

12. Users access can also be restricted

a) When User Privileges identified in this policy are violated

b) By direction of the Code N team, during the course of a pending investigation

Medication Access

A. Removing Medications
1. Patients not appearing on the census screen will be added at the workstation by the provider utilizing the patients last name, first name and date of birth and allergies.

2. Patient-to-patient transfer feature will be enabled.

3. The following kits will be available for users:
   a. My Kits
   b. System Kits

4. The Anesthesia provider will be required to log off of the Pyxis® Anesthesia System 3500 workstation at the end of the case and secure all medications.

5. Multiuse (MDV) vials removed from the Pyxis® Anesthesia 3500 system are patient specific to be used one/patient and discarded after the case. For “eye patients” MDV of midazolam may be used, however they are removed from the OR Pyxis machine: use and waste as documented on the appropriate paperwork.

B. Refrigerated medications

   1. Medications requiring refrigeration and not stored in the Pyxis® Anesthesia System 3500 will be kept in the Pyxis® MedStation refrigerators in the OR core using the Pyxis Remote Manager.

C. Returning Medications

   1. All unused medications will be returned directly to the return bin if it is a full dose and in its original packaging.

   2. Unused partial controlled substances are to be wasted with a witness and not returned to the return bin or stock.

Wasting Medications

   1. The Anesthesia Provider will waste controlled substances with a witness. A witness is the OR or Recovery Nurse or another Anesthesia Provider.

End–of-shift Resolutions

   1. At the end of the shift, the Anesthesia Provider will run resolution reports to identify any outstanding or unresolved medications issues

   2. All medications and charges will be reconciled before leaving the facility
3. The Anesthesia Provider will complete a controlled drug inventory at the completion of the day, with the assistance of the circulating or charge nurse as verification.

**Controlled Substance Discrepancy Resolution**

1. Every user is responsible to resolve any discrepancy under their own name.
   a. Upon discovery of a non-controlled discrepancy, the user will resolve the discrepancy immediately, or upon completion of the current case.
   b. In the event the discrepancy involves a CONTROLLED SUBSTANCE, another member of the department will serve as witness in the resolution of the discrepancy. Such witnesses are restricted to Anesthesia Providers or RN’s. Per hospital wide policy, all controlled drug discrepancies must be resolved by end of shift.

2. All controlled drug discrepancies deemed un-resolvable will be reported to the;
   1) OR Director/designee or House Supervisor
   2) The Director of Pharmacy or Pharmacist in charge.

3. If discrepancies are resolved incorrectly, or remain unresolved > 24 hours, they will be further reported to Administration for immediate action/follow-up, and, if warranted, the CODE N team for further action.

4. Failure to resolve a discrepancy in a timely fashion is subject to disciplinary action, and the user may be subject to the loss of station privileges at the discretion of the Director of Pharmacy, or under the direction of MMSC Administration.

5. Daily discrepancy reports are evaluated by the Pharmacy Department, and all user trends reported monthly to the Director of Surgical Services and/or CODE N Committee for review.

**My Items**

1. The user is responsible for reconciling all items assigned to My Items at the end of the day

2. “My Items” is a user privilege and compliance will be monitored by Pharmacy via daily batched reports

3. Users who fail to properly reconcile removals by end of day will not be allowed to access this feature
**System Management**

*System Set Up*
1. Supplies will be stocked in the Pyxis® Anesthesia System 3500 by the Surgical Technicians and manually charged.

2. Time Out Settings for the Anchor Page for each device is 4 hours.

3. User re-verification for controlled substances is 15 minutes.

4. Patients entered at the Pyxis® Anesthesia System 3500 will remain on the Station’s patient list for 24 hours.

6. Patients discharged or transferred from a clinical unit remain on that Station’s patient list for 24 hours.

7. Billing will be in full doses, and not in fractional doses.

8. Non-formulary medications will not be in the Pyxis® Anesthesia 3500 System.

9. Request for non-formulary items will be on a case-by-case basis and submitted to the Director of Pharmacy for P&T approval.

10. Stock outs below PAR and critical lows and bulletins will be set up at the Pyxis Console® in the Pharmacy for viewing and/or printing. All stock outs will be set “to print” and “view” by the Pharmacy.

**Maintaining Formulary and Station**

*A. Inventory*

1. All medications in the Pyxis® Anesthesia System 3500 will be approved by Pharmacy and Anesthesia Coordinator.

2. Min: max ratio will be based on a four day supply and refilled to max Monday through Friday (not including holidays)

3. Any inventory change request will be made to Pharmacy Director either verbally or via e-mail by Anesthesia Coordinator. Additions of new medications not previously used on site, will be subject to the Non-Formulary Approval Process through Pharmacy and Therapeutics (P&T)
4. Random narcotics audits (inventories) will be completed once a week. The Director of Surgery/designee and a RN witness will be responsible for compliance.

5. All unaccounted medications will be billed to the Anesthesia department.

6. A designated “my items” compartment in each Pyxis® Anesthesia System 3500 will be designated for users to secure medications when not in the room.

7. No medications will be left unattended at any time. All users will insure that the drawers are locked and exit out of the system before leaving the room.

B. Loading, Unloading, and Checking for Outdated Medications

1. Pharmacy will have unique privileges for loading, unloading and checking for outdated medications.

2. The Anesthesia Coordinator and Director of Pharmacy authorize changes to the Pyxis® Anesthesia System 3500 inventories.

3. All medications unloads will be handled by the Pharmacy.

4. Outdate Tracking function will be used on all medications.

5. Pharmacy will remove and handle outdated medications.

6. Medications will be removed at least one week prior to their end of use date.

C. Refilling Stations

1. Pharmacy will be responsible for refilling medications, as determined by the refill pick-list.

2. OR/Surgical Technicians will be responsible for refilling supplies.

3. All medications will be checked by a Pharmacist before they leave the Pharmacy.

4. All Stock Out / Stock Low bulletins will be handled immediately by the Pharmacy.

5. Refills performed on holidays and weekends will follow standard refill procedures based on stock needs.

Monitoring the Pyxis® Anesthesia System

A. Reports
1. Reports will be run at the Station at the end of each day.
2. Inventory verification reports will be run at the Console® in Pharmacy on a weekly basis.
3. Electronic archiving will be used to store reports.
4. Pharmacy will review and file reports printed from the Console® in Pharmacy.
5. Confidentiality will be maintained per hospital and Code N policy.

B. Quality Management

1. The Director of Surgical Services and Director of Pharmacy will review all controlled drug discrepancies, and investigate all un-resolved or questionable discrepancy reports. Summary reports are provided monthly to CODE N.
2. Discrepancies are to be resolved when they occur. For controlled discrepancies, only authorized users are granted resolution functions. A second authorized Anesthesia or OR is required for resolution.
3. The Director of Surgical Services is responsible for assuring that inventory is performed weekly.
4. Unit checks/safety checks are performed monthly by a certified Pharmacy Technician.
5. Monthly audits will be performed between Pharmacy and the Director of Surgical Services or Code N designee to verify that all controlled substance use and wastes are documented.
6. Appropriate disciplinary action up to termination will be taken regarding individuals who are frequently involved in discrepancies. Such actions are subject to review of performance and will be subject to the Medical Staff Policy on disciplinary action.
7. Devices will be maintained with regards to infection control. Pyxis® Anesthesia System 3500 machines will be wiped down daily and as needed with an approved germicidal agent.

System Support and Maintenance

1. The Pyxis® Anesthesia System 3500 will be maintained by the OR Director and Pharmacy.
2. All Pharmacy staff will be trained to provide basic technical support.
3. The end user will access support during regular work hours, off-shifts, weekends, and holidays through Pharmacy.
4. To recover a failed drawer the user will make the first attempt with a witness.

5. Unsuccessful recoveries are coordinated through Pharmacy.

6. Pyxis® Technical Support Center for troubleshooting will be coordinated through the Pharmacy or Nurse Supervisor.

7. Pyxis® Field Service and support personnel will be accompanied and escorted by the Pharmacy or Director of Surgical Services/designee into the surgical and procedural areas when necessary.

**Archiving System Data**

1. Pharmacy will be responsible for archiving the Pyxis® Anesthesia System data. Pharmacy will coordinate activities with the Hospital IT Department. Data will be stored securely for safekeeping.

2. Pyxis activity/files are captured by the daily network backup. All files will be manually transferred (archived) by the Director of Pharmacy or designee every two weeks.

3. Archived data will be stored electronically and easily accessible.

**Emergency Access Issues Clarification**

The use of the Pyxis® Anesthesia System 3500 introduces an automated system where previously a manual system existed. It is important to differentiate between “downtime” of the automated system versus “emergency access” for unexpected patient events.

**Insure that the “crash cart” medications are readily available in the event of an emergency and that users know the location and how to access these medications. These medications and emergency medications specific to anesthesia procedures are available outside the automated storage devices. Policies and procedures have been developed that clearly identify the process and provided to the users.**

**Emergency Access Procedures**

1. All Pyxis® Anesthesia System 3500 devices are on emergency power.
2. Crash Carts will be used if access to the system is unavailable.
3. Emergency Access Box on the Pyxis Anesthesia System 3500 will be used. It will be secured to the machine and security will be assured with breakaway locks supplied from pharmacy.
4. Only non-controlled medications are intended for use in the Emergency Access Box.
5. Use of the Emergency Access Box will be documented on existing manual sheets and replenished through Pyxis® to the patient the drugs were administered.

6. On replenishment, Pharmacy will secure the box with a green lock (green = go) as a visible indicator the box is replenished and ready to go.

7. The outdating for the contents of the box will be kept through the Pyxis Anesthesia System 3500. The date for the closest outdating item will be logged under the inventory item “ER Box Outdates” at the time of replacement.

5. Crash Cart/Pharmacy/Pyxis® MedStations will be used in case of Pyxis® Anesthesia System 3500 equipment malfunction during a case.

**Downtime Procedures**

1. The hospital’s emergency policy will be implemented in the event of downtime due to equipment failure or power loss or routine maintenance.

2. If a Pyxis Anesthesia System 3500 becomes inaccessible, Pharmacy is to be notified and Pyxis® Anesthesia System 3500 can be unlocked. If the event occurs after-hours, the on-call pharmacist will be contacted for follow-up. The AS System will be removed from service and an alternative AS System be used.

3. In the event of total system failure, call Pharmacy and they will respond immediately with a key to access the back of the machine.

4. Pyxis® MedStations may be used as a secondary back-up.

5. Pyxis Anesthesia System 3500 keys will be secured in the Pharmacy and only Pharmacy will have access to system keys.

6. A manual charge sheet will be maintained for all transactions during periods where the Pyxis Anesthesia System 3500 is used during downtime.

 Originated by: Department of Pharmaceutical Services
Effective date: 07/2011

Authorized by: ______________________________
Julie Burian, Director of Pharmaceutical Services Date

Theresa Sheer, Directors of Women’s Care and Surgical Services

Revision date:
Review date: