CONTROLLED SUBSTANCES POLICY

Purpose:

To define, control, and secure the handling of all controlled substances in each patient care area, so as to conform to the policies of the Pharmacy and Therapeutics Committee, JCAHO, and Federal and State Regulations.

Policy:

All DEA Schedule II, III, IV and V controlled substances shall be secured in a locked Automated Drug Distribution System (ADS). These drugs will be removed from the ADS by authorized users per order of a licensed prescriber and are to be administered to registered patients of the medical center. The ADS will maintain electronic DEA controlled substance records. These records are not a substitute for proper charting of the administered medications. Detailed procedures for the use of the ADS can be found in Pharmacy and Nursing policies and procedure manuals.

A. User Access:

Only individuals authorized to administer, dispense or stock medications will be given access to the system.

1. An authorized unit manager must complete an ADS Account Application for each new user. The five (5) digit employee ID badge number that will serve as the user’s identification number must be entered on the application in the appropriate space. The completed application is sent to the Pharmacy Department.

2. Authorized Pharmacy Department personnel will assign the new user access to a dispensing machine or machines depending on the user’s primary work area. A password or personal identification number (PIN) is chosen by the user at the time of initial system entry. This PIN number along with the employee ID badge or ID number is used to gain system access. No other person, including Pharmacy personnel, shall have knowledge of a user PIN.
3. User training is the responsibility of unit personnel in the user’s primary work area. Once training is completed a written competency assessment is required. The manager for the user’s primary work area is responsible for assuring that proper training and competency assessment is performed.

4. Each unit manager will notify appropriate pharmacy personnel as soon as possible when an employee with ADS access rights terminates, transfers to another work area, or is demoted and no longer needs access privileges. User access to the ADS will be immediately removed once this notice is received.

B. Dispensing

Controlled substances are stored in the ADS in a unit dose module, a drawer module, a supply cabinet or a locked refrigerator. Adequate supplies of designated controlled substances are maintained in each ADS by the Pharmacy Department.

1. Unit dose module (UDM):

   The unit dose module dispenses a single dose of medication for each dose requested. Each user will assure the correctness of the drug and quantity dispensed by the UDM. Each user will report all failures by the UDM to dispense correctly through the use of a discrepancy button.

2. Drawer, supply cabinet, or refrigerator:

   When a controlled substance stored in one of these areas is requested, the drawer or door of the supply cabinet or refrigerator opens. The user then removes the requested drug and the requested number of doses. The user must count and enter into the ADS the number of doses remaining in the position.

3. Waste

   If necessary to administer a partial dose, an authorized witness must observe the entire waste process (from opening the container, drawing up the dose to disposal of the unused portion). The disposal must render the product unrecoverable. User and witness must document waste in the ADS.
4. Returns

All unused controlled substances are to be returned to the ADS from which they are removed. When a return is entered into the ADS, the return drawer or the original supply position will open to allow placement of the medication. No partial or opened containers shall be returned to the ADS. Partial or opened container contents should be wasted as described above.

C. Discrepancies

The ADS maintains a perpetual inventory for each stocked and returned controlled substance. A count discrepancy occurs when a user enters a count, either on a supply position or return drawer that does not agree with the count maintained by the ADS.

1. All ADS users are responsible for the maintenance of accurate supply counts and accurate controlled substance records.

2. Dispensing and count discrepancies are noted through the use of the ADS discrepancy button.

3. If a user fails or cannot note a discrepancy through the use of the ADS discrepancy button, then the user will submit a written explanation of the discrepancy to the Pharmacy Department through the use of a problem reporting form. Problem reporting forms can be found on each unit where an ADS is located.

4. All controlled substance discrepancies must be resolved through the entry of an acceptable explanation into the ADS. Pharmacy personnel will attempt to resolve each discrepancy on the day that it is first noted through the use of available reports or contact with involved users or unit managers.

5. A variance report will be completed and submitted to the Hospital Quality Management department for each discrepancy that cannot be resolved or explained in a timely manner.

6. Pharmacy management will monitor and track discrepancies and discrepancy resolution. Discrepancy reports will be
submitted to hospital and nursing administration and the hospital Pharmacy and Therapeutics committee on a regular basis.

D. ADS Problems

All problems with the ADS should be immediately reported to Pharmacy department personnel.

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Administrator

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Date

Approved by P & T Committee 6/20/2000
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