Name of Policy:	Controlled Substances	≈
Policy Number:	3364-133-04	MEDICAL CENTER
Department:	Pharmacy	
Approving Officer:	Senior Hospital Administrator	
Responsible Agent:	Director of Pharmacy	
Scope:	University of Toledo Medical Center	Effective Date: 04/25/2022 Initial Effective Date: January 7, 1981
New polic Maior revi		/technical revision of existing policy

(A) Policy Statement

Utilization and administration of controlled substances must be done in accordance with established policies which are in compliance with federal and state regulations.

(B) Purpose of Policy

To establish safe and consistent guidelines for the utilization and management of controlled substances by all involved personnel. The use of controlled substances is regulated by the Ohio Revised Code and Public Law #01-513, The Controlled Substance Act of 1970 and enforced by the Drug Enforcement Agency.

(C) Procedure

- 1. Controlled substances in Schedule II and selected drugs in Schedule III, IV, and V must be maintained in locked quarters at all times. These selected drugs are determined in cooperation with nursing service. These drugs are preferably stored in the Automated dispensing cabinets (ADC).
- 2. In situations where it is not possible to load a controlled substance in an ADC, a single dose will be dispensed to the nursing unit. Placement of the controlled substance into the ADC will be done as soon as possible. Controlled substances must be obtained from Pharmacy by an R.N. or a designated agent or sent secure send per Inpatient pharmacy procedure IPP-36. The RN must present a valid UTMC ID picture badge at the time of pickup. The control sheet receipt must have the signature of the designated agent with date.
- 3. Discrepancies in the shift inventory should be investigated and reconciled by the nurse manager by the end of each shift. The pharmacist on duty should be notified of the discrepancy by the nurse manager. Pharmacy managers will investigate for obvious restocking errors. If none found, the Campus police, hospital Executive Director, Hospital Associate Executive Director, and Director of Employee and Labor Relations will be notified. The State Board of Pharmacy will also be notified.
- 4. Any unresolved discrepancy must have a patient safety net event initiated. All incidents of diversion are investigated by a multidisciplinary team consisting of pharmacy, nursing, campus police, and as needed compliance, graduate medical education, administration, Chief Medical Officer, and legal. . Any substantial loss will be reported to appropriate regulatory agencies including the Ohio Board of Pharmacy, Ohio Board of Nursing, Ohio Medical Board, and DEA
- 5. Multiple use of single use units (i.e., Tubex cartridges, single tablets, or unit dose liquids) is prohibited.
- 6. Wastage of controlled substances is documented on the Narcotic Drug Administration Record, ADC or appropriate form (e.g., Nursing Flow Sheet for that specific unit or clinic). One nurse (or physician) wastes the medication and another nurse, physician, or authorized personnel serves as a witness to the discard (e.g., giving 25 mg of meperidine from a 50 mg tubex) and signs appropriately. In addition, individuals licensed in any medically-related field in Ohio will be allowed to serve as witness to the discard (e.g., EMT-Paramedics, Radiology Technicians, EEG Technicians). Waste will be defined as partial doses of medication or dropped or contaminated doses not administered to the patient.

- 7. All PCA and controlled substance infusions not commercially available or available through appropriate licensed compounding pharmacies will be prepared by Pharmacy either by patient or batches per inpatient pharmacy procedure IPP-32..
- 8. Wholesale transactions and retail transactions are reported to through the Ohio Automated Rx Reporting System (OARRS)
- 9. The narcotic safe will be used for both storage, dispensing, and inventorying C-II medications. Each pharmacist and technician has been given instruction in its correct use, especially when logging in medications to be destroyed.

(D) Definitions

Controlled substances are classified in five categories as follows:

Schedule I: The drug has a high potential for abuse, has no accepted medical use in the U.S., or may be a research drug, and there is a lack of accepted safety for use of the drug. Example: Heroin.

Schedule II: The drug has a high potential for abuse, has accepted medical use in the U.S. with severe restrictions and abuse of the drug may lead to severe psychological or physical dependence. Example: Percodan, Demerol.

Schedule III: The drug has potential for abuse less than drugs in Schedule I and II, has accepted medical use in the U.S. and abuse of the drug may lead to moderate or low physical dependence or high psychological dependence. Example: Tylenol #3, Fiorinal.

Schedule IV: The drug has low potential for abuse relative to the drugs in Schedule III, has a currently accepted medical use in the U.S. and abuse of the drug may lead to limited physical dependence or psychological dependence relative to the drugs in Schedule III. Example: Valium, Phenobarbital.

Schedule V: The drug has a low potential for abuse relative to the drugs in Schedule IV, has currently accepted medical use in the U.S. and abuse of the drug may lead to limited physical dependence or psychological dependence relative to the drugs in Schedule IV. Example: Lomotil, Robitussin AC.

Approved by:		
	5/83	7/04
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04/25/2022	3/87	8/07
Date	7/88	7/09
	3/90	8/11
	12/90	1/14
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