POLICIES-B

Ohio Department of Rehabilitation and Correction
Office of Correctional Health Care

Protocol: Pharmacy Definitions
Number: E-1

Policy Reference: 68-MED-11

Responsibility: Pharmacists, Staff Nurses, Staff Physicians, Medical Directors, Health Care Administrators

DRC Medical Director:

Scott Savage, D.O.

Institution Medical Director:

_____ Date

Signature Date: 8/18/06

Effective Date: 12/4/06

I. Purpose:

The purpose of this protocol is to establish pharmacy definitions that are consistent with Ohio Revised Code and Ohio Administrative Code within Department of Rehabilitation and Correction institutions.

II. Exceptions:

None

III. Directive:

The following definitions shall apply with respect to pharmacists, pharmacies, or pharmacy operations:

1. **One (1) Month:** For the purposes of calculating duration of medication, thirty (30) days each month.
2. **Adulterated Drug:** A drug which is beyond the expiration date as stated by the manufacturer, packer, or distributor in its labeling or if it is not stored or dispensed according to the requirements of the federal act as indicated in the product labeling.
3. **After Hours Drug Cabinet:** Cabinet or storage area for contingency drugs.

4. **Automatic Stop Orders:** A practice whereby a prescribed drug order is discontinued automatically after a specified duration as designated by protocol.
5. **Compounding:** The preparation, mixing, assembling, packaging, and labeling of drugs pursuant to a prescription or in anticipation of a prescription.
6. **Contingency Drug Cabinet:** Cabinet or storage area for contingency drugs.
7. **Contingency Drugs:** Those drugs which may be required to meet the therapeutic needs of inpatients when a licensed pharmacist is not available and personally in full and actual charge of the institutional pharmacy.
8. **Controlled Substance:** A drug, substance, or immediate precursor included in schedule I, II, III, IV, or V of the Federal Controlled Substance Act.
9. **Dangerous Drug:** A drug that may be dispensed only upon a prescription, as restricted by federal or state law.
10. **Dispensing:** The final association of a drug with a particular patient pursuant to the prescription, drug order, or other lawful order of a prescriber and the professional judgement of and the responsibility for: interpreting, preparing, compounding, labeling, and packaging a specific drug.
11. **DRC Drug Formulary**: a list of standardized medications that may be prescribed and dispensed for inmates without prior authorization by the bureau of medical services medical director or bureau of mental health services clinical director. Also see protocol E-5, Pharmacy Dispensing and Distribution Operations.
12. **Drug:** Any article, other than food or a device, intended to affect the structure or function of the body, or for use in diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals.
13. **Emergency Drug:** A drug that is required to meet the immediate therapeutic needs of inpatients in order to sustain life in an emergency crisis.
14. **Emergency Drug/Crash Cart:** Drugs secured within a designated area that have been pre-approved by the Pharmacy and Therapeutics Committee for use in emergencies.
15. **Inmate Drug Profile:** An inmate data record that includes demographic information, pertinent historical information, and the record of drug therapy.
16. **Inpatient:** Any person who receives drugs for use while within the institutional facility.
17. **Inpatient Prescription:** A written, electronic, or oral order for a drug to be dispensed for use in treating an inpatient.
18. **Institutional Facility:** A facility licensed by the Ohio State Board of Pharmacy and the Ohio Department of Rehabilitation and Correction at which medical care is provided on site and a medical record documenting episodes of care, including medications ordered and administered, is maintained.

19. **Interpret Prescriptions:** The professional judgement of a pharmacist when reviewing a prescription order of a prescriber for a patient.
20. **Licensed or Registered:** As pertaining to pharmacists or pharmacies, means that an individual or facility has met initial qualifications for registration and licensure with the state board of pharmacy and, if they are still actively practicing pharmacy or distributing drugs, have complied with annual renewal procedures.
21. **Non-Formulary Medication:** A medication not listed by the DRC Drug Formulary. These medications require prior authorization from the Bureau of Medical Services Medical Director or Bureau of Mental Health Services Clinical Director prior to prescribing or dispensing to patients.
22. **Outpatient:** Any person who receives drugs for use outside of the institutional facility.
23. **Over the Counter Medication:** Drugs not requiring prescriptions for lawful distribution.
24. **Personal Supervision:** A pharmacist shall be physically present in the pharmacy and provide personal review and approval of all professional pharmaceutical activities.
25. **Pharmacist:** An individual who holds a current pharmacist identification card pursuant to section 4729.08 or section 4729.09, or section 4729.12 of the Revised Code.
26. **Person:** Any individual, partnership, association, limited liability company, or corporation, the state, any political subdivision of the state, and any district, department, or agency of the state or its political subdivisions.
27. **Pharmacy & Therapeutics Committee:** An interdisciplinary professional group formed to address procedural, clinical, and therapeutic issues related to the provision of pharmaceutical care.
28. **Pharmacy:** Except when used in a context referring to the practice of pharmacy, means any area, room, rooms, place of business, department, or portion of any of the foregoing where the practice of pharmacy is conducted.
29. **Pharmacy Consultant:** An experienced pharmacist who coordinates DRC Pharmacy and Therapeutics Committee activity and chairs the committee.
30. **Pharmacy Formulary:** The list of drugs, promulgated by the DRC Pharmacy and Therapeutics Committee, that are made available for treatment of inmate clinical conditions.
31. **Positive Identification:** A method of identifying an individual who prescribes, administers, or dispenses a dangerous drug whereby a physical means of identification is used.
32. **Practice of Pharmacy:** Providing pharmacist care requiring specialized knowledge, judgement, and skill derived from the principles of biological, chemical, behavioral, social, pharmaceutical and clinical sciences including the following:
    a. Interpreting prescriptions

b. Compounding or dispensing drugs and related devices
c. Counseling individuals regarding their drug therapy, recommending related devices, assisting drug selection for treatment of common diseases and injuries, providing instruction in proper use of drugs and appliances
d. Performing drug regimen reviews with individuals by discussing all of the drugs that the individual is taking and explaining the interactions of the drugs
e. Performing drug utilization reviews with prescribers when the pharmacist determines that an individual with a prescription has a drug regimen that warrants additional discussion with the prescriber
f. Advising an individual and the health care professionals treating an individual with regard to the individual's drug therapy.

30. **Prescriber:** An individual who is authorized by law to prescribe drugs or dangerous drugs or drug therapy related devices in the course of the individual's professional practice.
31. **Prescription:** a written, electronic, or oral order for drugs or combinations or mixtures of drugs to be used by a particular individual, issued by a prescriber.
32. **Medication Protocol:** A definitive set of treatment guidelines that include definitive orders for drugs and their specified dosages, authorized by a prescriber and approved by the state board of pharmacy to be used by licensed health care professionals when providing limited medical services to individuals when the services of a prescriber are not immediately available or when administering biologicals or vaccines to individuals for the purpose of preventing diseases.
33. **Responsible Pharmacist:** The pharmacist whose name appears on the terminal distributor of dangerous drugs license for a pharmacy and is responsible for the practice of pharmacy including but not limited to supervision and control of dangerous drugs, adequate safeguards, and maintaining all required drug records.
34. **Telephone Orders/Verbal Orders:** A medical order for medication or treatment that is issued verbally from an authorized prescriber to a Registered Nurse or Pharmacist.
35. **Terminal Distributor of Dangerous Drugs:** A person who has possession, custody or control of dangerous drugs for any purpose other than for that person's own use and consumption, and includes pharmacies, hospitals, facilities, and all other persons who procure dangerous drugs for distribution by or under the supervision of a pharmacist.

Ohio Department of Rehabilitation and Correction
Office of Correctional Health Care

Protocol: Pharmacy Administrative Operations
Number: E-2

Policy Reference: 68-MED-11

Related ACA Standard: 3-4341

Replaces: E-2 Responsible Pharmacist, E-3 Position Descriptions, E-4 Pharmacy Security, E-5 Key Control, E-6 Minimum Standards, E-11 Pharmacy Records, E-28 Institutional Pharmacy and Therapeutics Committee, E-29 ODRC Pharmacy and Therapeutics Committee, E-30 Pharmacy Unit Inspections

Responsibility: Pharmacists, Staff Nurses, Staff Physicians, Medical Directors, Health Care Administrators

DRC Medical Director:

Scott Savage, D.O.

Institution Medical Director:

Date

Signature Date: 8/18/06

Effective Date: 12/4/06

I. Purpose:

The purpose of this protocol is to establish requirements and standards for pharmacy administrative operations within the Department of Rehabilitation and Correction.

II. Exceptions:

None

III. Directive:

A. Licensure: [replaces E-2]

1. Each institutional pharmacy shall be directed by a Registered Pharmacist who holds a current identification card to practice pharmacy in Ohio, and shall be the pharmacist-in-charge pursuant to section 4729.27 of the Revised Code and the responsible pharmacist pursuant to rule 4729-5-11 of the Ohio Administrative Code.
2. Each institutional responsible pharmacist shall sign and maintain the facility pharmacy Terminal Distributor of Dangerous Drugs license and

ensure compliance with all relevant accreditation standards, agency policies or protocols, federal and state laws including 4729-17-02 (Pharmacist-in-charge of an institutional pharmacy) Ohio Administrative Code.

3. Each institutional responsible pharmacist shall be responsible for the maintenance of all records required by state or federal law to be kept at the licensed location, of the acquisition, use, distribution, and disposition of all drugs.
4. In the event a pharmacist ceases to be the Responsible Pharmacist, that pharmacist shall file appropriate written notice with the Ohio State Board of Pharmacy within 30 days and complete an inventory of controlled substances to be maintained in the pharmacy.

B. Minimum Standards: [replaces E-6]

1. Each institutional pharmacy library shall include current Drug Laws of Ohio, telephone number of a poison control center, ODRC Pharmacy Services Protocol Manual, and other references necessary to conduct pharmacy in a manner in the best interest of the patients served.
2. Drug inventory, fixtures, and space shall be commensurate with the scope of pharmacy services provided and be well-lighted, well-ventilated rooms in a clean and sanitary area.

C. Pharmacy Security and Key Control: [replaces E-4, E-5, E-26]

1. All areas occupied by an institutional pharmacy shall be capable of being secured by key, or other effective mechanism, so as to prevent access by unauthorized personnel.
2. In the absence of a licensed pharmacist, all areas occupied by an institutional pharmacy shall be secured so as to prevent access by unauthorized personnel.
3. The pharmacist–in–charge shall develop and implement methods that will detect and deter the diversion and/or adulteration of drugs.
4. Institutional administrative, security, and pharmacy personnel shall implement appropriate institutional procedures restricting issuing keys accessing the pharmacy to pharmacists only.
5. Issuing pharmacy keys to anyone other than a pharmacist and/or emergency entry into the pharmacy by anyone other than a pharmacist is not permissible at anytime for any reason other than to rescue persons inside the pharmacy in the event of crisis or disaster.
6. Institutional administrative, security, and pharmacy personnel shall implement appropriate institutional procedures restricting security testing

of emergency pharmacy keys to occur during the times that a pharmacist is present in the pharmacy.

7. Inmate workers shall not work in the pharmacy or medication storage areas under any circumstances.

D. Pharmacy Records: [replaces E-11]

The following records shall be maintained for a period of three years in a readily retrievable manner pursuant to section 4729.37 of the Revised Code:

1. A record of all drugs purchased, the quantity received, and the name, address, and wholesale distributor registration number of the person from whom the drugs were purchased.
2. All drug orders and records relating to the practice of pharmacy.
3. A record of all drugs compounded or repackaged for use only within the institution.
4. A record of the distribution of dangerous drugs to other areas of the institution for administration or use as floor stock.

E. Unit Inspections: [replaces E-30]

1. Each institutional Responsible Pharmacist shall maintain records, for a period of at least three years from the date of last entry, documenting inspection of medication storage areas or units located outside of the pharmacy, to occur no less frequently than each month.
2. Inspection records should include identification of the person performing the inspection, the date of the inspection, relevant comments and evaluation or assessment of the following:

   a. Security

   b.Cleanlines s

   c. Organization

   d.L ighting

   e. Refrigeration

   f. Labeling

   g.Pr esence of adulterated medications

   h.Acc ountability

3. Each Responsible Pharmacist shall devise, recommend, and implement, in conjunction with the appropriate agency or institutional administrators or staff, any corrective action necessary in order to remedy problem areas identified through unit inspection performance.

F. Pharmacy and Therapeutics Committee: [replaces E-28 and E-29]

1. ODRC shall provide a forum to address all issues relevant to the provision of pharmacy services and;
   a. Shall convene meetings no less frequently than every two months.
   b.Mem bership shall minimally consist of the Bureau of Medical Services Medical Director (chairperson), Bureau of Mental Health Services Chief Clinical Officer, two institution pharmacists, two institution physicians, one institution psychiatrist, one Health Care Administrator, Pharmacy Consultant
   c. Membership shall be assigned by the committee chairperson or by the ODRC Director/designee.
   d.Res ponsibilities shall include monitoring drug utilization, development of a standardized drug formulary, participation in pharmacy policy and protocol development, establishing and maintaining Pharmacy Services protocols as required, and providing a standard and uniform method of delivery of appropriate pharmaceutical services within ODRC.
   e. A quorum of the ODRC Pharmacy and Therapeutics committee shall consist of a simple majority of the membership
2. Each institutional Responsible Pharmacist shall organize and chair an institutional Pharmacy and Therapeutics Committee.
   a. Which shall meet no less frequently than each quarter.
   b.Phar macy and Therapeutics Committee membership shall be determined by the Responsible Pharmacist, in consultation with the Health Care Administrator and Medical Director, and shall minimally include a pharmacist, the Health Care Administrator (or designee) a nurse, and a physician.
   c. Each meeting agenda is not limited to, but shall address, the following topics:
      i. Development and implementation of institutional procedures necessary for provision of appropriate pharmaceutical care
      ii. Presentation and discussion of relevant medication prescribing, dispensing, administration, and educational monitoring activities
      iii. Presentation and discussion of reported adverse drug reactions and medication errors
      iv. Drug utilization and formulary adherence
      v. Other topics as necessary in order to improve quality or cost effectiveness of pharmaceutical services

Ohio Department of Rehabilitation and Correction
Office of Correctional Health Care

Protocol: Pharmacy Inventory Management Operations
Number: E-3

Policy Reference: 68-MED-11

Related ACA Standard: 3-4341

Replaces: E-7 Medication Procurement, E-8 Contingency Drug Cabinet, E-9 Emergency Medication Procurement, E-10 Pharmacy Storage, E-12 Controlled Substance Accountability, E-13 Loss or Theft of Dangerous Drugs, E-14 Adulterated Drug Disposal

Responsibility: Pharmacists Staff Nurses Staff Physicians
Health Care Administrators Medical Directors

DRC Medical Director:

Scott Savage, D.O.

Institution Medical Director:

Date

Signature Date: 8/18/06

Effective Date: 12/4/06

I. Purpose:

The purpose of this protocol is to establish requirements and standards for pharmacy inventory management operations within the Department of Rehabilitation and Correction.

II. Exceptions:

None

III. Directive:

A. Medication Procurement [replaces E-7 and E-9]

1. The Ohio Department of Mental Health, Office of Support Services, Pharmacy Service Center shall serve as the primary source for procurement of pharmaceuticals and medical supplies.
2. Alternate sources such as local retail pharmacies, hospitals, or drug wholesalers may be used to procure necessary pharmaceuticals or medical supplies in the event that the Pharmacy Service Center is unable to provide the necessary items within the required time period.

3. Emergency Medication Procurement

   a. Each Responsible Pharmacist, in consultation with the Health Care Administrator, shall establish and maintain proper and appropriate methods of emergency medication procurement from local sources in the event that emergency medications are required and the pharmacy is closed.

   b. The Responsible Pharmacist shall identify appropriate local sources for emergency procurement and/or establish methods whereby institutional healthcare personnel may contact the pharmacist in emergency situations when the pharmacy is closed.

   c. The Responsible Pharmacist shall establish appropriate written procedures for use by authorized health care personnel in the event emergency medications require procurement when the pharmacy is closed

   d. The Responsible Pharmacist shall maintain for a period of three years from the date of procurement, records documenting emergency medication procurement when the pharmacy is closed, to include at least the following information:

      i. The date of procurement,

      ii. The medication source name and address,

      iii. The name of the authorized person procuring emergency medication,

      iv. The name of the medication prescriber,

      v. The name and number of the patient,

      vi. The medication name, strength, quantity, and

      vii. The cost of the medication.

B. Medication Storage [replaces E-10]

1. The Responsible Pharmacist shall establish proper methods for appropriate storage of institutional medications in conformance with manufacturer's labeling and/or USP requirements.

2. The Responsible Pharmacist shall ensure that medications requiring refrigeration shall be kept in a refrigerator that provides adequate safety and security for medications.

3. No items other than medications shall be stored in a refrigerator used for medication storage.

4. A refrigerator used for medication storage shall be equipped with an approved control thermometer with alarm or a control thermometer and daily log for documenting refrigerator temperatures.

5. Adulterated medication storage

   a. To prevent their use, adulterated drugs shall be stored in a separate and secure area apart from the storage of drugs used for dispensing and administration.

   b.Adulter ated drugs shall be stored no longer than one year from the date of adulteration or expiration.

C. Disposal of Drugs [replaces E-14]

1. Pharmacy staff may dispose of drugs other than controlled substances using Certificate of Drug Destruction form DMH-0254 to record disposal.

2. Pharmacists may dispose of drugs that are controlled substances upon maintenance of appropriate records and written permission of the state board of pharmacy pursuant to provisions of 4729-9-06 (Disposal of dangerous drugs which are controlled substances) Ohio Administrative Code.

D. Reporting Theft or Loss of Medication [replaces E-13]

1. Each institutional Responsible Pharmacist shall immediately notify the institutional Health Care Administrator and Warden of any theft or unaccounted loss of federally controlled substances upon discovery of such theft or loss.

2. Pursuant to provisions of Ohio Administrative Code 4729-9-15 **(Report of theft or loss of dangerous drugs, controlled substances, and drug documents)** significant loss or theft shall be reported to the following:

   a. The state board of pharmacy, by telephone immediately upon discovery of the theft or significant loss

   b.If a controlled substance, the drug enforcement administration (DEA) pursuant to section 1301.76(b), Code of Federal Regulations

   c. Law enforcement authorities pursuant to section 2921.22 of the Ohio Revised Code

3. Controlled substance thefts must be reported by using the federal DEA report form whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them. A copy of the federal form regarding such theft or loss shall be filed with the state board of pharmacy within thirty days following the discovery of such theft or loss.

4. Immediately upon discovery of any theft or loss of official written order forms for schedule II drugs, each Responsible Pharmacist shall notify the state board of pharmacy and law enforcement authorities, and the DEA pursuant to section 1305.12(b), Code of Federal Regulations

E. **Contingency Drug Cabinet [replaces E-8]**

1. Each institutional Responsible Pharmacist may establish and maintain a Contingency Drug Cabinet located outside of the institutional pharmacy in order to fulfill institutional pharmaceutical requirements.
2. Each institutional Responsible Pharmacist shall ensure that Contingency Drug Cabinets meet all provisions of 4729-17-03 (**Security and control of drugs in an institutional facility**) of the Ohio Administrative Code.
3. Each institutional Responsible Pharmacist shall:
   a. Designate those who may obtain access to the drug supply
   b. Determine, in conjunction with the appropriate interdisciplinary committees, the drugs that are to be included in the contingency drug supply
   c. Ensure that such drugs are properly labeled and packaged in sufficient quantities to provide drug therapy during the period when the institutional pharmacy is not open
   d. Provide controls adequate to prevent diversion of the drugs, and institute recordkeeping procedures to account adequately for the drugs when used and who obtained the drugs from the drug supply
   e. Perform and document inspection of the contingency drug inventory to assure proper utilization and replacement of the drug supply no less frequently than monthly

F. **Controlled Substance and Needle Accountability [replaces E-12]**

1. Each institutional Responsible Pharmacist shall develop and maintain a safe and secure method of storage, distribution, and disposal of controlled substances, needles with syringes, and needles.
2. Historic perpetual pharmacy inventory records will be maintained, for a period of at least three years, of each controlled substance, needle with syringe, needle, scalpel or other controlled sharp instruments received or dispensed by the pharmacy. This shall include needles that are supplied with certain medications as supplied and packaged by the manufacturer (i.e. Epipen, Lovenox, Risperdal Consta, etc).
3. A shift reconciliation count, performed at each shift change by on-going and off-going shift nurses is required for all controlled substances, needles with syringes, and needles stored outside the pharmacy. Reconciliation shall include physical counts of controlled substances; physical counts of needles with syringes, and needles, verification of proof of use logs,

inspection of packaging integrity, and positive identification of persons performing the reconciliation.

4. Reconciliation discrepancies shall immediately be reported to the Responsible Pharmacist, Health Care Administrator, and Shift Captain. Quality Assurance and incident reports per institutional directive shall also be completed
5. Reconciliation records and proof of use logs must be maintained for 3 years from the date of last entry.
6. Each needle with syringe, and needle shall be disposed of in an approved safety container.
7. The pharmacist will audit reconciliation counts when performing periodic unit inspections no less frequently than monthly.

Ohio Department of Rehabilitation and Correction
Office of Correctional Health Care

Protocol: Pharmacy Distribution And Dispensing Operations
Number: E-4

Policy Reference: 68-MED-11

Related ACA Standard: 3-4341

Replaces: E-15 Floor Stock Distribution, E-16 Drug Orders, E-17 Telephone and Verbal Orders, E-18 Patient Profiles, E19 Prospective Drug Utilization Review, E-20 Patient Counseling, E-21 Prescription Labeling, E-22 Blister Packaging for Medications, E-23 Self Carry Medications, E-24 Automatic Stop Orders, E-27 Experimental or Investigational Dugs

Responsibility: Pharmacists Staff Nurses Staff Physicians
Health Care Administrators Medical Directors

DRC Medical Director:

Scott Savage, D.O.

Institution Medical Director:

Date

Signature Date: 8/18/06

Effective Date: 12/4/06

I. Purpose:

The purpose of this protocol is to establish requirements and standards for pharmacy distribution and dispensing operations within the Department of Rehabilitation and Correction.

II. Exceptions:

None

III. Directive:

A. Floor Stock Distribution:

1. Each Responsible Pharmacist shall develop and implement written policies and procedures for maintaining supplies of dangerous drugs as floor stock stored in patient care areas. The policies and procedures shall:
   a. Provide for a limited quantity of dangerous drugs to be maintained at any one location.
   b. Provide for the proper security, storage and labeling of all such drugs.

c. Provide for routine inspection of the dangerous drug supply.

d. Provide adequate recordkeeping procedures to document the disposition of drugs from the supply.

2. Each Responsible Pharmacist shall maintain records of distribution of dangerous drugs from the pharmacy to other areas of the institution including:

   a. The name, strength, dosage form, and amount of the drug distributed,

   b. The area receiving the drug,

   c. The date distributed,

   d. Positive identification of the individual receiving the drug if it is a controlled substance, and

   e. Administration record, completed by the area receiving the dangerous drug.

B. Drug Orders

1. A pharmacist shall dispense drugs for inpatients or outpatients pursuant to an original patient-specific order issued by a physician or other provider authorized by law to prescribe medication.
2. It shall be the responsibility of the prescribing physician or advanced care provider to thoroughly evaluate each order before renewing it.
3. Psychotropic medications are ordered only when indicated and only as one aspect of the inmate's treatment plan. This area is fully addressed in DRC policy 67-MNH-07, Psychotropic Medication.
4. All orders shall include, but are not limited to, at least the following:

   a. Name and ODRC number of the patient,

   b. Name, strength, and dosage form of the drug,

   c. Directions for use, including route of administration,

   d. Date and time prescribed,

   e. Positive identification of the prescriber, and

   f. Duration or quantity.

5. Verbal and telephone orders

   a. A Registered Nurse or Registered Pharmacist may accept a telephone or verbal order from a physician, within the physician's scope of practice, for a medication or medical supply.

   b. The person accepting a telephone or verbal order from a physician shall record the order on the physician's order sheet. The following information must be recorded:

i. Date and time the order was received,

ii. The fact that the order is a verbal or telephone order,

iii. Physician's name,

iv. Name and number of the patient,

v. Medication name, strength, and dosage,

vi. Directions for use, administration frequency and route,

vii. Medication quantity or duration of the order, and

viii. Signature of nurse or pharmacist receiving the order.

g.T he person accepting a telephone or verbal order shall read the order back to the issuing physician for confirmation.

h.A physician shall countersign the telephone or verbal order within seventy-two hours or upon the next institutional visit, whichever occurs first.

C. Automatic Stop Orders

1. **Prescribers must specify duration or quantity for all medication orders.** There are clinically defined or administrative policy limits to the length of drug therapy for all medications that provide an opportunity for prescribing practitioners to evaluate the clinical effectiveness of medication(s). Following the evaluation period the prescribing practitioner may:

   a. Discontinue the drug due to clinical resolution of the condition;

   b.Discontinue the drug due to clinical failure of the treatment regimen; and

   c. Continue the drug due to clinical progress but absence of desired clinical resolution of the condition.

2. The following drugs may be ordered by the prescribing practitioner for a specified quantity and/or period of time beyond the designated length of therapy, as clinical evaluation deems necessary. This evaluation must be clearly noted and justified in the Interdisciplinary Progress Note by the prescribing practitioner.

a. Ketorolac (oral dosage forms)	5 days
b.Control led Substances	14 days
c. Tramadol	14 days
d.Clonazepam	not to exceed 6 weeks
e. Phenobarbital	not to exceed 6 weeks
f. Anti-tubercular – Latent Infection Treatment	9 months

3. The maximum stop date for medications prescribed by mental health practitioners shall be 90 days.
4. The maximum stop date for medications prescribed by medical practitioners shall be 180 days

D. Experimental or Investigational Drugs

1. Experimental or investigational drugs may only be administered when these medications may be the only option to treat a medical condition and with the written approval of the DRC Bureau of Medical Services Medical Director and the DRC Human Subjects Review Committee.
   a. Written application to the Bureau of Medical Services Medical Director and the DRC Human Subjects Review Committee for use of experimental or investigational drugs must include:
      i. Justification for use, and
      ii. Informed consent statement signed by the inmate.
   b. Contents of the informed consent statement must have prior approval of the Bureau of Medical Services Medical Director.
   c. Application for approval to use experimental or investigational drugs must be submitted to the Human Subjects Research Review Committee in accordance with DRC policy 114-02, Human Subjects Research Policy.
   d. The application for using experimental or investigational drugs, signed informed consent statement, and written response of the Bureau of Medical Services Medical Director and the Human Subjects Research Committee allowing such administration will be maintained in the pharmacy and in the patient's medical record.
2. Close contact should be maintained between the manufacturer of the drug and the institutional pharmacist regarding dispensing, distribution, accounting of, administration of, and disposal of any experimental or investigational drug.

E. Patient Profiles

1. Each institutional pharmacy shall maintain a patient profile system providing immediate retrieval of information regarding patients who have received prescriptions from the pharmacy.
2. The patient profile shall be maintained for a period of at least one year from the date of the last entry in the profile record.
3. The dispensing pharmacist shall ensure that a reasonable effort has been made to obtain, record, and maintain at least the following records:
   a. Patient data record consisting of:
      i. Patient name and DRC number,

ii. Patient date of birth,

iii. Any known drug allergies or previous drug reactions,

iv. History of chronic conditions or disease states,

v. Other drugs, nutritional supplements, and non-prescription drugs used routinely, and

vi. Pharmacist's comments relevant to the patient's drug therapy or other information peculiar to the patient or drug.

b.Patient drug therapy record of prescriptions filled at the pharmacy within the last twelve months consisting of:

i. Name and strength of the drug,

ii. Prescription number,

iii. Quantity dispensed,

iv. Date dispensed, and

v. Name of the /prescriber.

F. Prospective Drug Utilization Review

In compliance with provisions of 4729-5-20 (Prospective drug utilization review) Ohio Administrative Code:

1. Prior to dispensing any prescription, a pharmacist shall review the patient profile for the purpose of identifying:

   a. Over-utilization or under-utilization,

   b.T herapeutic duplication,

   c. Drug-disease state contraindications,

   d.Drug -drug interactions,

   e. Incorrect drug dosage,

   f. Drug-allergy interactions,

   g.Abuse/m isuse,

   h.Inappr opriate duration of drug treatment, and

   i. Documented food-nutritional supplements-drug interaction.

2. Upon recognizing any of the above, a pharmacist, using professional judgment, shall take appropriate steps to avoid or resolve the potential problem. These steps may include consulting with the prescriber and/or counseling the patient.

3. Prospective drug utilization review shall be performed using predetermined standards consistent with, but not limited to, any of the following:

a. Peer-reviewed medical literature, and

b. American hospital formulary service drug information,

c. United States pharmacopoeia drug information, or

d. American Medical Association evaluations.

G. Patient Medication Counseling

1. A pharmacist or pharmacist's designee shall personally offer to counsel the patient whenever any outpatient prescription, new or refill, is dispensed for use outside of the institutional facility. If the patient is not physically present, a written offer to counsel, including the pharmacy hours and phone number, shall accompany the prescription.
2. A pharmacist is not required to counsel inpatients of an institutional facility nor outpatients who refuse or do not respond to the offer to counsel.
3. The pharmacy shall maintain records documenting provision of counseling or refusal of an offer to counsel, for a period at least three years from the date of service or refusal.
4. A pharmacist or pharmacist's designee shall counsel the outpatient. Such counseling may include, but is not limited to:

   a. The name and description of the drug;

   b. The dosage form, dose, route of administration, and duration of drug therapy;

   c. The intended use of the drug and the expected action;

   d. Special directions and precautions for preparation, administration, and use;

   e. Common adverse effects or interactions and therapeutic contraindications that may occur, including possible methods to avoid them, and the action to take if they occur;

   f. Techniques for self-monitoring drug therapy;

   g. Proper storage;

   h. Prescription refill information;

   i. Action to be taken in the event of a missed dose; and

j. The pharmacist's comments relevant to the individual's drug therapy, including other information peculiar to the specific patient or drug.

H. Prescription Labeling

1. Inpatient prescriptions dispensed for use inside the institutional facility and not in the possession of the ultimate user shall comply with provisions of 4729-17-10 **(Labeling of prescriptions for patients of an institutional facility)** Ohio Revised Code, such that the drugs shall be dispensed in blister card packaging, to which is affixed a label containing at least the following information:

   a. Identification of the dispensing pharmacy,

   b.Th e patient's name,

   c. The non proprietary and/or proprietary name of the drug, and

   d.Th e strength, expressed in the metric system whenever possible.

2. Multiple drugs and/or multiple strengths may be dispensed in the same container only upon compliance with all conditions as specified by provisions of 4729-17-10-(A), (3) Ohio Revised Code.

3. Prescriptions dispensed whereby the drug is in the possession of the ultimate user (self carry) and outpatient prescriptions dispensed for use outside the institutional facility and shall comply with provisions of 4729-5-16 **(Labeling of drugs dispensed on prescription)** and 4729-17-11 **(Labeling of prescriptions for outpatients)** Ohio Administrative Code, such that labeling is affixed to the prescription container and includes:

   a. The name of the patient for whom the drug is prescribed;

   b.T he name of the prescriber;

   c. Directions for use of the drug;

   d.Th e date of dispensing;

   e. Any cautions which federal or state law may require;

   f. The serial number of the prescription;

   g.T he proprietary name, if any, or the generic name and name of the distributor of the drug dispensed; and the strength, if more than one strength of the drug is marketed. The dispensing pharmacist may omit the name and strength of the drug only if the prescriber specifically requests omission in writing;

   h.The quantity of the drug dispensed;

   i. At least the prescription number and name of the patient if the prescription container is too small to bear a complete prescription label, and dispensed in a larger container bearing a complete prescription label; and

j. The label bearing only the prescription number and patient name does not need to be applied to any product whose function would be impaired by such a label.

I. Blister Packaging for Nurse Administration

1. Blister packaging shall be prepared in accordance with requirements of 4729-9-20 (**Drugs repackaged by a pharmacy**) Ohio Administrative Code.
2. Blister packaging and nurse administration is required for the following drugs:
   a. All psychotropic medications (antipsychotic, antidepressant, mood stabilizing, anxiolytic, or stimulant drugs);
   b.Federally controlled substances;
   c. Tramadol;
   d.Gaba pentin;
   e. Antitubercular medications;
   f. Warfarin; and
   g.Me dications prescribed for inmates found guilty of **Misuse of Authorized Medication** rule infraction.
3. Blister packaging and nurse administration may be required for other medications or inmates as deemed necessary by consultation among, or at the discretion of institutional medical, nursing, and pharmacy staff.
4. Blister packaging for medications, unless otherwise requiring blister packaging, is not required for inmates under administrative control, local control, or special security status.

J. Self Carry Medications

1. Prescribed oral or topical medications not otherwise requiring nurse administration may by dispensed and issued to inmates on a self carry basis at the discretion of medical and pharmacy staff.
2. Medication self-carry privileges may be revoked based on evidence of medication hoarding, selling, or misuse.

K. Prescription dispensing

1. Newly prescribed medications shall be dispensed within 24 hours of the time the prescription is received by the pharmacy with the exception of:
   a. Prescriptions that require stocking,
   b.Pr escriptions that require clarification prior to implementation,

c. Prescriptions that require intervention, or

d. Prescriptions that require approval by the bureau of medical services medical director or bureau of mental health services clinical director prior to dispensing.

2. The pharmacist shall notify the nursing staff if a prescription cannot be filled within 24 hours.

3. Every month pharmacy staff shall be responsible for reporting to the institution health care administrator number of prescriptions not dispensed within 24 hours of the time the prescriptions were received and the reason the prescriptions were not filled within 24 hours.