

SECTION IX
INVESTIGATIONAL DRUGS

WHITING FORENSIC HOSPITAL PHARMACY POLICY AND PROCEDURE MANUAL

SECTION IX: INVESTIGATIONAL DRUGS CHAPTER 9.1: USE OF INVESTIGATIONAL DRUGS

POLICY: Initiation of new investigational drug protocols come under the direct supervision of the principal investigator and must be approved by the research review committee. Patients admitted on investigational drugs may continue to use them without the approval of the Research Review Committee if the drug use is sanctioned by the principle investigator and the attending physician, and sufficient information is provided concerning the drugs pharmacology to allow appropriate clinical monitoring.

PROCEDURE:

1. Investigational drug protocols initiated must be approved by the Total Medical Staff before an investigational medication may be administered.
2. The following procedure will be followed if a patient is admitted with an investigational drug:
 - A. Immediately notify the principal investigator of the patient's hospital admission.
 - B. Determine if the medication is to be continued.
 - C. Obtain a copy of the signed informed consent.
 - D. Obtain information from the investigator concerning drug dosage form, dosage range, storage requirements, adverse reactions, usage, and contraindications.
 - E. Investigational drugs may be administered only after the attending physician and administration nurse receives basic pharmacologic information about the drug.
3. Investigational drugs will be destroyed according to manufacturer's policy or hospital policy.

SECTION X

USE OF FDA-APPROVED DRUGS

FOR NON FDA-APPROVED INDICATIONS

WHITING FORENSIC HOSPITAL PHARMACY POLICY AND PROCEDURE MANUAL

SECTION X: USE OF FDA APPROVED DRUGS FOR NON FDA- APPROVED INDICATIONS

CHAPTER 10.1: USE OF FDA APPROVED DRUGS FOR NON FDA- APPROVED INDICATIONS

POLICY:

Use of FDA Approved Medications for Non FDA-approved Indications is allowed per the physician's judgement based on documented use in the literature. Such use should be documented in the physician progress notes. Non FDA-approved use may be restricted through the actions of the PNT Committee.

SECTION XI

GUIDELINES FOR ORDERING MEDICATIONS

**STATEMENT ADVISING OF
SPECIAL CONSIDERATIONS IN DRUG USE**

WHITING FORENSIC HOSPITAL PHARMACY POLICY AND PROCEDURES MANUAL

SECTION XI: GUIDELINES FOR ORDERING MEDICATION AND SPECIAL CONSIDERATIONS IN DRUG USE. CHAPTER 11.1: CLOZAPINE USE

POLICY:

The WFH Pharmacy bases its Clozapine Policy and Procedures on established FDA Regulations including the Clozapine Risk Evaluation and Mitigation Strategy (REMS), the WFH Drug Therapy Guidelines, and information provided by the manufacturer's package insert .

1. Clozapine REMS

The Pharmacy Supervisor is responsible for the registration of the hospital and maintenance of a current roster of physicians as provided by the Chief Medical Officer with the Clozapine REMS. With every modification of the privileged medical staff that occurs at WFH, the Chief Medical Officer will send the Pharmacy Supervisor an updated medical roster.

2. PHARMACIST KNOWLEDGE BASE

A. The pharmacists understand and demonstrate knowledge of the information provided in the Drug Therapy Guidelines, including but not limited to, the package insert, black box warnings, indications for use, dosing, laboratory assessments, contraindications and precautions, and drug interactions. The pharmacist understands that death can occur as a result of agranulocytosis or myocarditis and oversees the dispensing of all clozapine preparations.

B. The pharmacists demonstrate an appreciation of the requirements of the Clozapine REMS, including the need for physician's registration and patient registration, verification of re-challenge status, and on-going patient monitoring.

3. REQUIRED FDA REPORTING OF WBC AND ANC FOR CLOZAPINE PATIENTS

The pharmacist provides the registry with up-to-date information and necessary documentation to register, maintain, change therapy, or

discontinue therapy for all clozapine patients.

PROCEDURE:

A. Initiation of Treatment

1. Clozapine therapy may be initiated when the assigned pharmacist can register the patient in the Clozapine REMS program.
2. The pharmacist will review the written clozapine order. This will occur prior to initiation of clozapine therapy.
3. When reviewing the physician's order, the pharmacist will check to insure that they include the following:
 - a. Acceptable lab values of White Blood Count (WBC) not less than $3500/\text{mm}^3$ and Absolute Neutrophil Count (ANC) not less than $1500/\text{mm}^3$
 - b. The WBC and ANC have been obtained within 30 days of initiation of treatment.
4. The pharmacist will then review the medical record to insure the necessary baseline studies, as per the Clozapine Drug Therapy Guidelines, have been implemented per physician's order and documented accordingly.
5. After reviewing the order, the pharmacist will register the patient in Clozapine REMS program. The registry must be notified for newly admitted patients who were on clozapine prior to admission, as well as those patients who have been hospitalized at WFH for any length of time, and who are being started on clozapine.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

B. Continuation of Treatment for Patients Being Admitted

1. When a patient on clozapine is admitted to WFH and the prescriber would like to continue the drug, the assigned pharmacist must follow the same steps as above. Because the system of care has changed, the pharmacist must re-register the patient with the appropriate registry.

WHITING FORENSIC HOSPITAL PHARMACY POLICY AND PROCEDURES MANUAL

SECTION XI: GUIDELINES FOR ORDERING MEDICATION AND SUBSTANTIAL RISK IN DRUG USE CHAPTER 11.2 ANTICOAGULATION THERAPY

Policy: Whiting Forensic Hospital provides individualized quality anticoagulation management, monitoring, and education for the patients at Whiting Forensic Hospital, and works to reduce the likelihood of patient harm associated with the use of anticoagulation therapy.

Procedure:

1. WFH uses approved protocols for the initiation and maintenance of anticoagulation therapy.
 - a. Warfarin is a narrow therapeutic index medication affected by many factors including age, diet and other medications. The Oral Anticoagulation Protocol (appendix 1.) is intended to guide oral anticoagulation therapy in the hospitalized patient and is based on the recommendations from the American College of Chest Physicians.
 - b. The Enoxaparin Protocol (appendix 2.) is intended to guide low molecular weight heparin therapy in the hospitalized patient and is based on manufacturer recommendations for the specific condition(s) being treated.
2. Before starting a patient on warfarin, the patient's baseline coagulation status assessed; for all patients receiving warfarin therapy, a current INR is used to adjust this therapy. The baseline status and current INR are documented in the medical record.
3. Patients at WFH have their diet and/or drug therapy adjusted appropriately taking into account potential food-drug interactions. A list of drugs that have the potential for significant interaction with food is developed jointly by the Pharmacy Services Unit, Dietary Department, and the Medical Staff.
4. WFH has a policy that addresses baseline and ongoing laboratory tests that are required for anticoagulants.
5. The safety of medication management is monitored on an ongoing basis via the Adverse Drug Reaction and Medication Event Reporting processes. Additionally, a quality improvement indicator is included in the Pharmacy Department QI plan.

APPENDIX 1.

WARFARIN PROTOCOL

A. Warfarin Anticoagulation Management

1. The Appropriate Dose for Initiation of Warfarin

- a. The initiation of oral anticoagulation therapy with doses between 5 and 10mg for the first 1 or 2 days is suggested for most individuals.
- b. Subsequent dosing should be based on INR response.

Following the administration of warfarin, an initial effect on PT usually occurs within the first 2 or 3 days, depending on the dose administered, and an antithrombic effect occurs within the next several days.

A loading dose of warfarin (i.e. >20mg) is not recommended.

2. Anticoagulation in the Elderly

- a. In the elderly, for patients who are debilitated, malnourished, have congestive heart failure, or have liver disease a starting dose of 5mg or less is suggested.

3. Frequency of Monitoring Oral Anticoagulation Therapy

- a. A baseline INR should be available and INR monitoring should begin after the initial 2 or 3 doses of oral anticoagulation therapy.
- b. For patients who are receiving a stable dose of oral anticoagulants, monitoring at an interval of no longer than every 4 weeks is suggested.
- c. If INR is unstable and is determined to be the result of a vitamin K deficiency, patients may be supplemented with vitamin K orally.

4. Management of Dosing when the INR is Above the Therapeutic Range

- a. For patients with INRs above the therapeutic range but less than 5 who have no significant bleeding, lower the dose or omit the dose, monitor more frequently, and resume therapy at a lower dose when the INR is in the therapeutic range. If only minimally above the therapeutic range, no dose reduction may be required.
- b. For patients with INRs greater of equal to 5 but below 9 who have no significant bleeding, omit the next 1 or 2 doses, monitor more frequently, and resume therapy at a lower dose when the INR is in the therapeutic range. Alternatively, omit a dose and administer vitamin K1 (1-2.5mg *orally*), particularly if the patient is at increased risk of bleeding.
- c. For patients with INRs of greater than 9 who have no significant bleeding, discontinue warfarin therapy and administer vitamin K1 (5-10mg *orally*) with the expectation that the INR will be reduced in 24-48 hours. Monitor the patient more frequently and use additional vitamin K1 if necessary. Restart warfarin therapy at a lower dose when the INR is in the therapeutic range.
- d. In patient with serious bleeding and elevated INRs, discontinue warfarin therapy. Administration of vitamin K1 10mg by slow IV infusion supplemented with fresh plasma is recommended.
- e. In patients with life-threatening bleeding and elevated INRs, discontinue warfarin. Administration of prothrombin complex concentrate or recombinant factor VIIa supplemented with vitamin K1 by slow IV infusion is recommended.
- f. In patients with mild to moderately elevated INRs who have no major bleeding, it is suggested to administer vitamin K1 orally rather than subcutaneously.

5. Management of Dosing when an Invasive Procedure is Required

- a. For patients with a low risk of thromboembolism, stop warfarin therapy approximately 4 days before surgery, allow INR to return to near normal values, briefly use postoperative prophylaxis (if the intervention increases the risk of thrombosis) with a prophylactic dose of LMWH and simultaneously begin warfarin therapy.
- b. For patients with an intermediate risk of thromboembolism, stop warfarin therapy approximately 4 days before surgery, allow the INR to fall, cover the patient beginning 2 days preoperatively with a prophylactic dose of LMWH and then commence LMWH and warfarin postoperatively.

- c. For patients with a high risk of thromboembolism, stop warfarin therapy approximately 4 days before surgery, allow the INR to return to normal at the time of surgery and begin therapy with full dose of LMWH as the INR falls (approximately 2 days preoperatively); stop therapy 12-24 hours before surgery with the expectation that the anticoagulant effect will have worn off by the time of surgery. Then commence LMWH and warfarin postoperatively.
- d. For patients with a low risk of bleeding, continue warfarin therapy at a lower dose and operate at an INR of 1.3-1.5. The dose of warfarin can be lowered 4 or 5 days before surgery. Warfarin therapy then can be restarted postoperatively, supplemented with a prophylactic dose of LMWH if necessary.

B. Baseline and Ongoing Laboratory Studies

Baseline and periodic laboratory values include: PT/INR, and CBC.

C. Therapeutic Goals

Indication	Target INR (goal)	Duration
Prophylaxis for VTE	2.5 (2-3)	1 month
Arterial thrombosis and stroke prevention		
Atrial Fibrillation	2.5 (2-3)	Life
Acute Myocardial Infarction*	2.5 (2-3)	Variable
Valvular Heart Disease	2.5 (2-3)	Life
Prosthetic tissue heart valve	2.5 (2-3)	Variable
Prosthetic mechanical heart valve**	3 (2.5-3.5)	Life

* a target INR of 3 (2.5-3.6) is appropriate for patients following an acute MI to prevent recurrent cardiac events

** a target INR of 2.5 (2-3) is appropriated for patients who have a mechanical bileaflet valve in the aortic position, normal cardiac chamber size, and no other risk factors for stroke

D. Contraindications and Precautions

Contraindications

1. alcoholism; lack of patient cooperation
2. bacterial endocarditis
3. bleeding tendencies of the gastrointestinal, genitourinary, or respiratory tract
4. blood dyscrasias
5. gastrointestinal, genitourinary or respiratory tract ulcerations or overt bleeding
6. hemorrhagic tendencies
7. hypersensitivity to warfarin or any component of the product
8. pregnancy, known or suspected
9. psychosis; lack of patient cooperation
10. senility; lack of patient cooperation

Precautions

1. anemia; increased risk of bleeding
2. cerebrovascular disease; increased risk of bleeding
3. coronary disease, serious; increased risk of bleeding
4. CYP2C9 and VKORC1 genetic variation; influences patient response to initial and maintenance therapy and increase the risk of bleeding
5. duration of therapy, long; increased risk of bleeding
 - a. factors which influence response to warfarin including diet, medications (including herbal medications), environment and physical state
 - b. dietary vitamin K; may affect prothrombin time
 - c. poor nutritional state; may increase PT/INR response
 - d. vitamin K deficiency; may increase PT/INR response
 - e. hypertension, severe to moderate; increased risk of bleeding
 - f. malignancy; increased risk of bleeding
 - g. renal impairment, severe to moderate; increased risk of toxicity, and bleeding
 - h. trauma which may result in internal bleeding or in large exposed raw surfaces
 - i. cancer; may increase PT/INR response

- j. collagen vascular disease; may increase PT/INR response
- k. conditions that increase risk of hemorrhage, necrosis, and/or gangrene, pre-existing
- l. congestive heart failure; may exhibit increased PT/INR response to warfarin
- m. diabetes, severe
- n. diarrhea; may increase PT/INR response
- o. edema; may decrease PT/INR response
- p. elderly or debilitated; narrow therapeutic range may add to risk of hemorrhage in these patients
- q. febrile; may increase PT/INR response
- r. hemorrhage and necrosis, potentially life-threatening; have been reported
- s. hepatic impairment, severe to moderate; increased risk of toxicity
- t. hyperlipidemia; may increase PT/INR response
- u. hyperthyroidism; may increase PT/INR response
- v. hypothyroidism; may decrease PT/INR response
- w. indwelling catheters
- x. infectious diseases or disturbances of intestinal flora, such as sprue or antibiotic therapy
- y. nephrotic syndrome; may decrease PT/INR response
- z. polycythemia vera
- aa. protein C mediated anticoagulant response, known or suspected deficiency; increased risk of tissue necrosis
- bb. steatorrhea; may increase PT/INR response
- cc. thrombocytopenia, heparin-induced; potentially fatal venous limb ischemia, necrosis, and gangrene have been reported upon heparin discontinuation and warfarin initiation or continuance
- dd. thrombosis, deep venous; potentially fatal venous limb ischemia, necrosis, and gangrene have been reported upon heparin discontinuation and warfarin initiation or continuance
- ee. vasculitis
- ff. warfarin resistance, acquired or inherited; decreased therapeutic responses have been reported

APPENDIX 2.

ENOXAPARIN PROTOCOL

A. Enoxaparin Anticoagulation Management

1. The Appropriate Dose for Initiation of Enoxaparin

a. Abdominal surgery - Postoperative deep vein thrombosis; Prophylaxis

The recommended dosage for patients undergoing abdominal surgery who are at risk for thromboembolic complications is 40 milligrams subcutaneously once daily, with first dose given 2 hours prior to surgery, and continued for 7 to 10 days.

b. Arthroplasty of total knee - Postoperative deep vein thrombosis; Prophylaxis

The recommended dosage for patients undergoing knee replacement surgery is 30 milligrams every 12 hours beginning 12 to 24 hours after surgery and continued for 7 to 10 days.

c. Deep venous thrombosis, in combination with warfarin

Inpatient: The recommended dosage is 1 milligram/kilogram every 12 hours OR 1.5 milligrams/kilogram every 24 hours. Enoxaparin should be continued for at least 5 days and until INR of 2 to 3 has been achieved.

d. Deep venous thrombosis, in patients with restricted mobility from acute illness; Prophylaxis

The recommended dosage for medical patients who are at risk for thromboembolic complications due to severely restricted mobility during acute illness is 40 milligrams subcutaneously every 24 hours. The usual duration of administration is 6 to 11 days.

e. Total replacement of hip - Postoperative deep vein thrombosis; Prophylaxis

The recommended dosage for patients undergoing hip replacement surgery is 30 milligrams subcutaneously every 12 hours beginning 12 to 24 hours after surgery and continued for 7 to 10 days. Patients may begin therapy with 40 milligrams every 24 hours beginning 9 to 15 hours prior to surgery. Following the initial phase of thromboprophylaxis, extended prophylaxis with enoxaparin 40 mg subcutaneously once daily for 3 weeks is recommended for a total duration of therapy of approximately 4 weeks

2. Dosage in Renal Failure

a. Recommended Dosage Adjustments (CrCl less than 30 mL/min)

i. Prophylaxis in Abdominal Surgery

The recommended dosage is enoxaparin 30 milligrams subcutaneously once daily with the initial dose given 2 hours prior to surgery. The usual duration of administration is 7 to 10 days.

ii. Prophylaxis in Knee Replacement Surgery

The recommended dosage is enoxaparin 30 milligrams subcutaneously once daily with the initial dose given 12 to 24 hours after surgery. The usual duration of administration is approximately 7 to 10 days.

iii. Prophylaxis in Hip Replacement Surgery

The recommended dosage is enoxaparin 30 milligrams subcutaneously once daily with the initial dose given 12 to 24 hours after surgery. The usual duration of administration is 7 to 10 days.

iv. Prophylaxis In Medical Patients during Acute Illness

The recommended dosage is enoxaparin 30 milligrams subcutaneously once daily. The usual duration of administration is 6 to 11 day.

v. Treatment of Deep Vein Thrombosis

The recommended dosage is 1 milligram/kilogram subcutaneously once daily. Enoxaparin should be continued until a therapeutic INR has been reached. The average duration of administration is 7 days.

3. Dosage in Geriatric Patients

At dosages used for prophylaxis the incidence of bleeding complications is similar between elderly and younger patients. When use for treatment of venous thromboembolism, elderly experience a greater incidence of bleeding complications. Elderly patients weighing less than 45 kg or those predisposed to renal dysfunction should be closely monitored.

B. Baseline and Ongoing Laboratory Studies:

Baseline and periodic laboratory values include and CBC.

C. Therapeutic Goals

Unlike conventional unfractionated heparin, low-molecular-weight heparins (LMWH) cause only a slight increase in PTT and thrombin. Activated clotting time (ACT) of enoxaparin is also poorly correlated to the anti-Xa levels. When LMWHs are used for treatment, monitoring plasma anti-factor Xa concentrations may be useful in select populations.

These include:

Patients with renal insufficiency, Patients on long-term therapy with LMWH, Pregnant patients, Patients with extremes of body fat, Patients with a high risk of bleeding or recurrent thrombosis.

D. Contraindications and Precautions

Contraindications

1. active major bleeding (Prod Info LOVENOX(R) injection, 2004)
2. hypersensitivity to enoxaparin, heparin, pork products
3. hypersensitivity to benzyl alcohol (multi-dose formulation)
4. thrombocytopenia associated with a positive test for antiplatelet antibody in the presence of enoxaparin

Precautions

1. concurrent use of drugs which affect hemostasis (i.e., NSAIDs); increased risk of epidural or spinal hematoma
2. bacterial endocarditis; increased risk of hemorrhage
3. bleeding diathesis
4. concomitant platelet inhibitors; increased risk of hemorrhage
5. congenital or acquired bleeding disorders; increased risk of hemorrhage
6. diabetic retinopathy
7. elderly patients; potential for delayed elimination of enoxaparin
8. gastrointestinal disease, ulcerative and angiodysplastic, active or recent; Increased risk of hemorrhage
9. hemorrhagic stroke; increased risk of hemorrhage
10. heparin-induced thrombocytopenia, history of; use extreme caution
11. low-weight men (less than 57 kg) and women (less than 45 kg); increased exposure to enoxaparin and increased risk for bleeding

12. major hemorrhage (including intracranial and retroperitoneal) or bleeding at any site may occur; investigate any unexplained reduction in hematocrit or blood pressure
13. not adequately studied for thromboprophylaxis in patients (including pregnant women) with prosthetic heart valves
14. recent brain, spinal or ophthalmological surgery; increased risk of hemorrhage
15. renal impairment; increased exposure to enoxaparin and increased risk for bleeding, dosage adjustment recommended in patients with CrCl less than 30 mL/min
16. thrombocytopenia may occur; discontinue therapy if platelet count falls below 100,000/mm³
17. uncontrolled hypertension

WHITING FORENSIC HOSPITAL PHARMACY POLICY AND PROCEDURES MANUAL

SECTION XI: STATEMENT ADVISING OF SPECIAL CONSIDERATIONS IN DRUG USE. CHAPTER 11.3: IMPROVING THE SAFETY OF USING HIGH RISK MEDICATION.

POLICY: High risk medications are those drugs involved in a high percentage of medication errors and/or sentinel events and medications that carry a higher risk for abuse, errors, or other adverse outcomes.

Whiting Forensic Hospital understands the importance of identification, storage, ordering, distribution, and monitoring of high-risk medications. When appropriate, individualized policies and procedures will be implemented to insure the proper handling of these medications.

PROCEDURE:

1. Once high-risk medications are identified, common risk factors will be identified and a proactive planning process will be implemented.
2. Proactive planning may include the development and implementation of specific policies and procedures, and may address such things as storage, ordering, distributing, administering, and/or monitoring of the medication.
3. All formulary addition requests will be presented to the Pharmacy Nutrition and Therapeutics Committee and will have as an element of review the potential for being a high-risk medication.
4. The Pharmacy Nutrition and Therapeutics Committee will review all High Risk Medications on an annual basis for any necessary revision or additional proactive planning.
5. Medication Events will be reviewed to determine if the medication(s) involved should be considered for inclusion into the “High Risk Medication” Policy.
6. All medications available in more than one concentration in the hospital will be considered “High Risk Medications”.

When more than one concentration is necessary, the numbers of concentrations are limited to the minimum required to meet patient care needs.

COMMON RISK FACTORS AND PROACTIVE PLANNING FOR HIGH-ALERT MEDICATIONS

High-alert medication	Common Risk Factor	Proactive Planning
Fluphenazine injectable	Fluphenazine injectable is available as an immediate acting and decanoate preparation.	These medications are stored as far apart as possible in the pharmacy department. At WFH these medications are in separate drawers in the PYXIS medstation.
Insulin	No dose check system	Establish a check system in which one nurse prepares the dose and another reviews it. Refer to nursing Policy and Procedure.
	Mix-up due to insulin and heparin vials being kept in close proximity to each other on nursing units.	Heparin is only stocked in the pharmacy.
	"U" used as an abbreviation for	"U" was added to the DO NOT USE

	"units" in orders.	abbreviation list. See Pharmacy Policy and Procedure.
Haloperidol injectable	Haloperidol injectable is available as an immediate acting and decanoate preparation.	These medications are stored as far apart as possible in the pharmacy department. At WFH these medications are in separate drawers in the PYXIS medstation.
Heparin	Multidose containers. Mix-ups due to insulin and heparin vials being kept in close proximity to each other on nursing units. Greater than one concentration is available in the pharmacy.	The pharmacy does not stock multidose containers of heparin. Heparin vials are not stocked on the nursing units. Each different insulin is stored separately in vials. Warning labels are affixed to each vial.
Medroxy-	Greater than one	These medications

progesterone Injectable	concentration is available in the pharmacy.	are stored as far apart as possible in the pharmacy department. At WFH these medications are in separate drawers in the PYXIS medstation.
Opiates	Parenteral narcotics stored as floor stock in nursing areas.	Parenteral narcotics are not routinely stocked on the nursing units. Parenteral narcotics are non- formulary and obtained only for individual patients following the completion of the non-formulary approval process.

WHITING FORENSIC HOSPITAL PHARMACY POLICY AND PROCEDURES MANUAL

SECTION XI: STATEMENT ADVISING OF SPECIAL CONSIDERATION IN DRUG USE.

Chapter 11.4: USING MEDICATION WITH LOOK ALIKE-SOUND LIKE NAMES

Policy: There shall be a policy in the management of medication with look-alike or sound alike names.

Procedure: Strategies are developed to prevent the interchange of look-alike or sound alike medications as outline in the chart below.

Identify and, at a minimum, annually review a list of look–alike sound-alike (LASA) drugs used in the organization, and take action to prevent errors involving the interchange of these drugs.

All medication orders will be written using the generic name of the medication

Exception: combination medications (drugs having more than one ingredient) may be written using the *Brand Name* but the indication must be included in the order.

Pharmacists will verify that all medication orders are written according to the procedure before the order is accepted and dispensed; discrepancies will be brought to the attention of the prescriber so that the order can be re-written in the proper format.

Management of these medications is outlined in the chart below.

Look alike-sound-alike medication will be stored, packaged, and dispensed according to strategies listed in the chart below.

Bar coding is used when dispensing all medications to the Pyxis Medstations.

Non-formulary medications are stored in different colored bins or a separate section in the pharmacy inventory.

All LASA drug containers and/or bins/pockets used for storage of LASA medications are labeled “LOOK-ALIKE SOUND-ALIKE” via an auxiliary sticker.

National Patient Safety Goal: A list of Look-alike/sound-alike Drugs Used in the Organization: Strategies to Prevent the Interchange of these Drugs

Potential Problematic Drug Names	Generic Lower Case and Brand Names Upper Case	Potential Errors and Consequences	Specific Safety Strategies
Amiloride/Amlodipine	MIDAMOR (amiloride) NORVASC (amlodipine)	Generic names can be easily confused	“Tall Man” letters are used to differentiate these medications.
Bupropion/Buspirone	WELLBUTRIN (bupropion) BUSPAR (buspirone)	Generic names can be easily confused	Dosage must be clearly written to distinguish between drugs. “Tall Man” letters are used to differentiate these medications.
Carbamazepine/Oxcarbazepine	TEGRETOL (carbamazepine) TRILEPTAL (OXCARBAZEPINE)	Generic names can be easily confused	Drugs stored in pharmacy alphabetically by generic name. “Tall Man” letters are used to differentiate these medications.
Celebrex/Celexa	CELEBREX (celecoxib) CELEXA (citalopram)	Both brand and generic names can be easily confused	Orders to be written using the generic name of the drug. Dosage must be clearly written to distinguish between drugs. Celecoxib is a non-formulary drug stored accordingly.
Chlordiazepoxide/Chlorpromazine	LIBRIUM (chlordiazepoxide) THORAZINE (chlorpromazine)	Generic names can be easily confused	Chlordiazepoxide is a controlled drug and is stored in Pyxis CII safe in pharmacy.
Citalopram/Escitalopram	CELEXA (citalopram) LEXAPRO (escitalopram)	Generic names can be easily confused.	
Clonidine/Klonopin/	CATAPRES	The generic name for clonidine	Orders to be written using the generic name of the drug.

Clonazepam	(clonidine) KLONOPIN (clonazepam)	can be easily confused for the trade or generic name of clonazepam	Clonazepam is a controlled substance and is stored in Pharmacy in CII safe.
Gabapentin/ Gemfibrozil	NEURONTIN (gabapentin) LOPID (gemfibrozil)	Generic names can be easily confused, they have similar dosage strengths, these medications can be easily confused for each other.	Gemfibrozil is a non-formulary medication and stored accordingly.
Glyburide/Glipizide	MICRONASE (glyburide) GLUCOTROL (glipizide)	Generic names can easily be confused for each other; indication of use is similar as well	Glyburide placed in Pyxis Medstation with bar codes. "Tall Man" letters are used to differentiate these medications.
Guaifenesin/Guanfacine	VARIOUS BRAND NAMES (guaifenesin) TENEX/INTUNIV (Guanfacine)	Generic names can be easily confused	Guafacine is non-formulary and stored accordingly. "Tall Man" letters are used to differentiate these medications.
Hydroxyzine/ Hydralazine	Vistaril, Atarax (hydroxyzine) hydralazine	Because the first 4 letters of their generic names are identical and they have similar dosage strengths, these medications can easily be confused for each other	Storage in the Pharmacy separates the drugs as far from each other as possible. "Tall Man" letters are used to differentiate these medications.
Ibuprofen/Gabapentin/ Gemfibrozil	VARIOUS (ibuprofen) NEURONTIN (gabapentin) LOPID (gemfibrozil)	These medications can be easily confused for each other; They have similar dosage strengths, and appearances.	. Gemfibrozil is a non-formulary medication and stored accordingly.
Insulin Products	VARIOUS	Similar names, strengths, and concentrations may contribute to medication errors	Auxiliary labels are used to differentiate the different insulin products A check system in which one nurse prepares the dose and another reviews it. Refer to nursing Policy and Procedure.
Lamisil/Lamictal	LAMISIL	Similarity in brand names can	Orders to be written using the generic name of the drug

	(terbinafine) LAMICTAL (lamotrigine)	be easily confused	Drugs stored in pharmacy alphabetically by generic name
Metformin/ Methocarbamol	GLUCOPHAGE (metformin) ROBAXIN (methocarbamol)	Generic names can be easily confused for each other, and both drugs have similar strengths	Storage in the Pharmacy separates the drugs as far from each other as possible.
Metformin/ Metronidazole	FLAGYL (metronidazole) GLUCOPHAGE (metformin)	Generic names can easily be confused for each other, and medications are available in similar strengths	ONLY the 250mg tablets of metronidazole are on formulary, since metformin is not available in a 250mg tablet.
MS Contin/ Oxycontin	MS CONTIN (morphine) OXYCONTIN (oxycodone)	Brand names can be easily confused and medications are used for similar indications	Orders to be written using the generic name of the drug Drugs stored in the control drug vault/Pyxis CII safe in different compartments
Paroxetine/fFuoxetine	PAXIL (paroxetine) PROZAC (fluoxetine)	Generic names can be easily confused	Drugs stored in pharmacy alphabetically by generic name.
Paxil/Plavix	PAXIL (paroxetine) PLAVIX (clopidogrel)	Brand names can be easily confused	Orders to be written using the generic name of the drug. Drugs stored in pharmacy alphabetically by generic name.
Prilosec/Prozac	PRILOSEC (omeprazole) PROZAC (fluoxetine)	Brand names can be easily confused	Orders to be written using the generic name of the drug. Drugs stored in pharmacy alphabetically by generic name.
Retrovir/Ritonivir	RETROVIR (zidovudine) NORVIR (ritonavir)	Both drugs look and sound alike as well as indications are similar and strengths are the same	Orders to be written using the generic name of the drug Ritonavir is stored in the unit dose section
Sertraline/Cetirizine	ZOLOFT (sertraline)	Generic names can be easily confused	Dosage must be clearly written to distinguish between drugs.

	ZYRTEC (cetirizine)		Drugs stored in pharmacy alphabetically by generic name.
Terbinafine/Terbutaline	LAMISIL (terbinafine) BRETHINE (terbutaline)	Generic names can be easily confused	Orders to be written using the generic name of the drug In pharmacy drugs are stored in separate areas Terbutaline is not stocked
Topamax/Toprol XL	TOPAMX (topiramate) TOPROL XL (metoprolol)	Brand names can be easily confused, likely attributable to the similarity in the names with the “X” in the XL looking like the ending of Topamax, in addition the dosage strengths are identical	Orders to be written using the generic name of the drug Drugs stored in pharmacy alphabetically by generic name
Tramadol/Trazadone	ULTRAM (Tramadol) Trazadone	Generic names can be easily confused	Tramadol is now a controlled substance and placed in Pyxis Medstation with bar codes
Zantac/Xanax	ZANTAC (ranitidine) XANAX (alprazolam)	Both brand names sound a like	Orders to be written using the generic name of the drug Dosage must be clearly written to distinguish between drugs. Xanax is a controlled drug and is stored in Pyxis CII safe in pharmacy...
Zyprexa/Zyrtec	ZYPREXA (olanzapine) ZYRTEC (cetirizine)	Brand names can be easily confused	Orders to be written using the generic name of the drug. Drugs stored in pharmacy alphabetically by generic name.

WHITING FORENSIC HOSPITAL PHARMACY POLICY AND PROCEDURES MANUAL

SECTION XI: GUIDELINES FOR ORDERING MEDICATIONS AND STATEMENT ADVISING OF SPECIAL CONSIDERATIONS IN DRUG USE

CHAPTER 11.5: USE OF DIETARY SUPPLEMENTS

POLICY: Dietary supplements are defined in DSHEA (Dietary Supplement and Education Act of 1994) as products “intended to supplement the diet” that contains any of the following dietary ingredients: a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by humans to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, a constituent, extract, or combination of any ingredient mentioned above. They must be identified on the label as a dietary supplement.

Dietary supplement labels can bear health claims, nutrient content claims, and structure/function claims. Health claims can be used to characterize the relationship between a dietary ingredient and reducing the risk of a disease or health related condition. Both health claims and nutrient content claims must be approved by the FDA.

Structure/function claims are the most commonly use claims on dietary supplement labels. They can be sued to describe the effect a dietary supplement has on the structure or function of the body, the way a dietary ingredient acts to maintain a structure or function, general well-being from consumption, or a benefit related to a nutrient deficiency disease if the prevalence of the disease in the U.S. is also indicated. Structure/function claims are not pre-approved by the FDA.

DSHEA does not require FDA to review evidence or safety of dietary supplements, so manufacturers have no burden to prove that their products are effective or safe. Manufacturers that wish to carry the “USP approved” seal on their product labels have to subject their products to testing by USP. This only serves to establish GMPs (good manufacturing practices).

The decision to include any product in the WFH formulary is based on comparative data regarding efficacy, adverse effects, cost, and potential therapeutic advantages and deficiencies. The lack of definitive evidence of efficacy and safety and the demonstrated variability in product content make most dietary supplements unsuitable for inclusion on the formulary.

Dietary supplements are not routinely supplied by WFH pharmacy. WFH does not endorse the use of dietary supplements not recognized by well established medical evidence. The challenge to the hospital is to preserve patient autonomy and satisfaction without compromising high standards of care and evidence-based medicine.

The shortcomings that make most dietary supplements unsuitable for inclusion in formularies also argue

strongly against their use by patients during a hospital stay. The use of “patients own medications” for dietary supplements should be avoided to the extent possible.

PROCEDURE:

1. If a licensed independent practitioner determines that a supplement is appropriate for a patient, the LIP must complete a non-formulary request form for all products (even if patients wish to use their own supply) and follow procedures outlined in WFH Pharmacy Policy 17.3 Orders for Non-Formulary Medications.
2. If the non-formulary request is approved, the pharmacy will obtain the supplement; to the greatest extent possible obtain those supplements that are USP verified.
3. A patient’s own supply of supplements may only be taken with a physician’s order in accordance with WFH Pharmacy Policy 4.5, Patients’ Personal Medications brought to the Hospital, and after the non-formulary process has been carried out.
4. Orders for supplements will be reviewed by the pharmacist according to WFH Pharmacy Policies 4.1 Guidelines for Prescribing Medications, and 5.4 Physician Order Sheet.
5. If the order is for a nutrient supplement, the pharmacist will collaborate with the Supervising Dietician or designee.
6. Insufficient evidence to support the use of the requested supplement is considered grounds to not approve the non-formulary request.

SECTION XII

BULK PARENTERAL FLUIDS, INTRAVENOUS ADDITIVES AND COMPOUNDING

WHITING FORENSIC HOSPITAL PHARMACY POLICY AND PROCEDURE MANUAL

SECTION XII: BULK PARENTERAL FLUIDS AND INTRAVENOUS CHAPTER 12.1: ADDITIVES AND COMPOUNDING INTRAVENOUS FLUIDS

POLICY: Whiting Forensic Hospital uses intravenous administration of medications on an emergency response basis only. Intravenous fluids, additives, and devices are not routinely used at WFH.

PROCEDURE:

1. As the Pharmacy Services Unit does not have the Facility to prepare intravenous medications or fluids any patient requiring such therapy is referred to an outside vendor.
 - A. An exception is made when the medication can be provided in the Advantage system since this system does not require a strictly sterile preparation environment.
 - B. For bulk liquid concentrates, the manufacturer stated expiration date is the expiration date found on the bottle.
2. Patients requiring intravenous medications or fluids will have this processed via a private vendor that adheres to regulatory agency requirements. The intravenous medication or fluid from the vendor will be delivered to the pharmacy unless the pharmacy is closed.
 - A. All physician orders for the intravenous medication will be processed and then faxed to the vendor by the pharmacist. If the intravenous medication is an antibiotic, then the order will also be written on the WFH Antibiotic Form.
 - B. All prepared intravenous medications will be delivered directly to the pharmacy by the vendor during hours. In the event that the pharmacy is not open, the intravenous medication will be delivered to the respective unit to which the patient is assigned.

- C. Upon receipt of the intravenous medication in the pharmacy, a pharmacist will check it for accurate patient name, correct solution and label against the physician order, date, time, clarity and expiration date.
- D. The pharmacist will then initial the label and date it as evidence of the safety check.
- E. The intravenous medication will be stored in a separate refrigerator in the pharmacy.
- F. Pharmacy technicians will deliver the intravenous medication to the unit as needed. On Fridays or holiday weekends, the pharmacy technician will make sure enough is there to cover the intervening days until the next pharmacy work day. The pharmacy technician will place the intravenous medication in the unit medication refrigerator unless the IV medication needs to be hung immediately. In this case, the pharmacy technician can hand the intravenous medication to a Registered Nurse on the unit.

WHITING FORENSIC HOSPITAL PHARMACY POLICY AND PROCEDURE MANUAL

SECTION XII: TOTAL PARENTAL NUTRITION CHAPTER 12.2: NUTRITIONAL THERAPY

POLICY: Patients requiring total parental nutrition at WFH will have this processed via a private vendor that adheres to regulatory agency requirements. All TPN solution from the vendor will be delivered to the pharmacy unless they are closed.

PROCEDURE:

A. TPN orders

1. All physician orders for TPN will be processed and then faxed to the vendor by our pharmacist. TPN orders will be written every 30 days unless changes need to occur before the 30 days.
2. All prepared TPN solutions will be delivered directly to pharmacy by an outside vendor during pharmacy hours. In the event pharmacy is not open, the TPN solution will be delivered to the respective unit to which the patient is assigned.
3. Upon receipt of the TPN in the pharmacy, a pharmacist will check the TPN solution for accurate patient name, correct solution and label against the physician order, date, time, clarity and expiration date.
4. The pharmacist will then initial the label and date it as evidence of the safety check.
5. The TPN will be stored in a separate refrigerator in the pharmacy.
6. TPN's shall be delivered to the pharmacy at least twice a week.
7. Pharmacy Technicians will deliver the TPN solution on a daily basis, Monday through Friday, to the respective unit. On Fridays or holiday weekends, extra bags will be delivered to the respective unit in order to cover the intervening days until the next regularly scheduled delivery. The Pharmacy Technician will place these in the unit medication refrigerator unless the TPN needs to be hung immediately. In this case, the pharmacy technician can hand the TPN solution to a Registered Nurse on the unit. TPN solutions need to be at room temperature prior to the nurse connecting it.

B. Medication Orders added to the TPN

1. All medication orders that require addition to the TPN solution will be reviewed and processed by the Pharmacist. Any contraindications will be communicated to the physician immediately by the pharmacist for resolution
2. Medication orders shall be faxed to the vendor by our pharmacist as required.
3. A pharmacist will also review all medications prepared by our vendor at the time of delivery to the pharmacy. He/she will check the medication provided against the physician order sheet to ensure accuracy of the patient name, date, correct medication, correct label, expiration date and will verify the clarity of the solution.
4. The pharmacist will then initial the label and date it as evidence of the safety check.
5. If the medication requires refrigeration, the medication can be placed in the same refrigerator as the TPN solution. If not, then it can be stocked on a shelf and bar coded for use with the Pyxis ParX.
6. Pharmacy Technicians will deliver medications that must be added to the TPN solution along with the TPN solution itself to the respective unit on a daily basis if it is ordered daily. Otherwise it will be delivered as prescribed.

POLICY:

Whiting Forensic Hospital does not permit any sterile compounding of medications and does not allow the procurement of any sterile compounded medications from outside sources.

SECTION XIII

DISASTER PLAN

WHITING FORENSIC HOSPITAL PHARMACY POLICY AND PROCEDURE MANUAL

SECTION XIII: DISASTER PLAN

CHAPTER 13.1: DISASTER PLAN STATEMENT

POLICY:

The Pharmacy and its personnel are an integral part of the Disaster Plan of the hospital. They shall abide by the plan as written.

PROCEDURE:

1. As part of orientation each employee is made aware of the details of the WFH disaster plan.
2. Each employee will receive a disaster plan review in-service program periodically as per current WFH policy and procedure.
3. Records of the orientation and all reviews are maintained by Organizational Staff Development and by the Pharmacy Unit Supervisor.

WHITING FORENSIC HOSPITAL PHARMACY POLICY AND PROCEDURE MANUAL

SECTION XIII: DISASTER PLAN

CHAPTER 13.2: EVACUATION PLAN STATEMENT

POLICY:

Evacuation Plan for the Pharmacy.

PROCEDURE:

1. The Pharmacy Department is located in Dutcher on the basement level. Personnel follow the evacuation plans for that particular building and wing.
2. Pharmacy personnel who are in other buildings when evacuation is required follow the plans for that particular building/wing.

WHITING FORENSIC HOSPITAL PHARMACY POLICY AND PROCEDURE MANUAL

SECTION XIII: DISASTER PLAN CHAPTER 13.2.1: FIRE EVACUATION PLAN

POLICY: There is a plan for evacuating the Pharmacy Unit work area in case of fire or disaster.

PROCEDURE:

1. The Pharmacy Unit Supervisor shall be in charge until the arrival of the Fire Department, and then the Senior Fire Officer is in charge.
2. When a fire alarm or disaster is announced for Dutcher, basement level, personnel will evacuate to the nearest exit away from the fire and then to the outside of the building.
3. Listen to the voice message for further instructions.

SECTION XIV

SALES REPRESENTATIVES

WHITING FORENSIC HOSPITAL PHARMACY POLICY AND PROCEDURE MANUAL

SECTION XIV: SALES REPRESENTATIVES CHAPTER 14.1: VISITS OF PHARMACEUTICAL SALES REPRESENTATIVES

POLICY:

Although the relationship between the pharmaceutical industry and health care providers involves controversy, it is recognized that pharmaceutical representatives can provide information that would otherwise be inaccessible to some WFH staff. It is thus desirable to balance the need for education with the need to ensure the balance and validity of information presented. All visits by Pharmaceutical Sales Representatives shall be made by appointment with the staff members to be visited. Each representative shall wear a nametag with his/her name and the name of the company represented. Under no circumstances shall any representative be allowed in any clinical area.

PROCEDURE:

1. The sales representative makes an appointment with the staff member he or she wishes to visit. Prior to coming to campus, the representative must notify the Pharmacy of the visit. If the visit occurs during hours of Pharmacy operation, the representative must stop by the pharmacy and register. If the visit occurs when the Pharmacy is closed, the representative may proceed to the check in location of the building being visited and register with the nursing supervisor.
2. The sales representative must follow the procedures for visitors for each building visited, including signing in and wearing a name badge. The sales representative is authorized to visit only those persons with whom an appointment has been made.
3. If any staff person feels that information presented by a pharmaceutical representative is biased or otherwise misleading, this should be brought to the attention of the relevant discipline chief (e.g., the Chief Medical Officer, the Nursing Executive, or the Pharmacy Supervisor). If investigation supports any significant concern, an appointment to meet with the discipline chief will be requested of the representative in question. No visits to WFH by that representative can occur until that appointment has taken place. Concerns will be clearly expressed to the

representative, and it will be clearly stated that recurring concerns may result in the permanent suspension of visiting privileges.

4. If a discipline chief concludes that the visiting privileges of a pharmaceutical representative must be suspended, this matter will be submitted to the Chief Medical Officer and to the Chairmen of the Pharmacy, Nutrition and Therapeutics Committee for review by that committee.
5. While meals during an industry sponsored educational event; not in excess of \$50 per state employee, per company, per year is allowed by the Office of State Ethics; DMHAS no longer allows any giving to state employees. Individual staff, however, are reminded of their obligations to monitor their own adherence to such guidelines.

SECTION XV

PHARMACIST PARTICIPATION IN CLINICAL MONITORING PROGRAMS

FOOD DRUG INTERACTION MANAGEMENT

ADVERSE DRUG REACTION REPORTING

DOSAGE MONITORING OF RENALLY CLEARED MEDICATIONS

WHITING FORENSIC HOSPITAL PHARMACY POLICY AND PROCEDURE MANUAL

SECTION XV: CLINICAL PROGRAM PARTICIPATION CHAPTER 15.1: FOOD DRUG INTERACTIONS

POLICY: Patients at WFH have their diet and/or drug therapy adjusted appropriately taking into account potential food-drug interactions. A list of drugs that have the potential for significant interaction with food is developed jointly by the Pharmacy Services Unit, Dietary Department, and the Medical Staff. Patients are educated as deemed appropriate by the physician regarding food-drug interactions.

PROCEDURE:

1. A list of medications that has the potential to interact with foods is developed and maintained by the Pharmacy Nutrition and Therapeutics Committee (PNT).
2. The Food Drug Interaction List is maintained in the Drug Therapy Guidelines
3. The medications that have the potential for food-drug interactions are flagged in the pharmacy computer system in the clinical reporting portion of the drug database. This will cause the message Drug-Food Interaction to appear during the routine order entry process. The Pharmacy Unit Supervisor or designee is responsible for maintaining the computer message codes as the PNT modifies the list of drugs that interact with foods.
4. When the message Drug-Food Interaction appears during routine order entry of new/changed medication orders the pharmacist completes the Food Drug Interaction Communication Form and faxes it to the dietary department as instructed on the form.
5. Once received by dietary the clinical dietician follows the Dietary Department policy and procedure regarding food-drug interactions.

Whiting Forensic Hospital Food Drug Communication Form
Complete form and fax to the Clinical Dietician

Patient Name _____

Location _____

Date Therapy Started _____

Drug Name (Please check all that apply):

- ☐ Amiloride
- ☐ Antidiabetic agent: Drug Name _____
- ☐ Ciprofloxacin
- ☐ Isoniazid
- ☐ Lithium
- ☐ Lurasidone
- ☐ Lipid lowering drug: Drug Name _____
- ☐ Minocycline
- ☐ Monoamine-oxidase inhibitor
- ☐ Orlistat
- ☐ Phenytoin
- ☐ Potassium-depleting diuretics: Drug Name _____
- ☐ Tetracycline
- ☐ Verapamil
- ☐ Warfarin
- ☐ Ziprasidone
- Other: Drug Name _____

Drug Strength _____

Dosage Form _____

Regimen _____

Pharmacist _____

Date _____

WHITING FORENSIC HOSPITAL PHARMACY POLICY AND PROCEDURE MANUAL

SECTION XV: CLINICAL PROGRAM PARTICIPATION CHAPTER 15.3: SUSPECTED ADVERSE DRUG REACTION REPORTING PROGRAM

PURPOSE:

- 1) Provide a mechanism for the collection and evaluation of suspected adverse drug reaction (ADR) data in order to improve patient safety.
- 2) Review aggregate data for opportunities for improving patient safety.
- 3) Ensure proper reporting of ADRs to the FDA and manufacturer when indicated.

POLICY:

Definition (ASHP)¹: An ADR is “any, unintended, undesired, or excessive response to a medication.”

Adverse reactions due to administration of established drugs and diagnostics, investigational drugs and biological agents should be reported.

An ADR is not the same as a “medication error.”

All potential ADRs should be reported; there is no need for certainty of cause and effect.

Reactions observed in both inpatients and outpatients are reportable.

Adverse drug reactions should be reported if, in the view of the reporter, it will affect the patient's current and future medical therapy.

Minor temporary or reversible side effects normally associated with a drug in question need not be reported.

The definition of a non-reportable side effect is:

An expected, well known reaction resulting in little or no change in patient management (e.g.,

¹ American Society of Health System Pharmacists

drowsiness or dry mouth due to administration of certain antihistamines or nausea associated with the use of antineoplastics.)

The definition of a significant ADR is unintended, undesired, or excessive response to a medication that:

Requires discontinuing the drug (therapeutic or diagnostic),
Requires changing the drug therapy (adding a new agent to treat the ADR),
Requires modifying the dose (except for minor dosage adjustments),
Necessitates evaluation at an Emergency Department (ED),
Prolongs stay in at this hospital,
Necessitates supportive treatment,
Significantly complicates diagnosis,
Negatively affects prognosis, or
Results in temporary or permanent harm, disability, or death.”

ADRs at Whiting Forensic Hospital are ranked by severity as:

- | | |
|---------|---|
| LEVEL 1 | A reaction that resulted in the need for increased patient monitoring or observation but no other treatment or intervention was required. |
| LEVEL 2 | A reaction that resulted in the discontinuation of the medication or the need for treatment with another medication and/or intervention(s) in addition to monitoring, |
| LEVEL 3 | A reaction that resulted in the need for evaluation/treatment in a hospital emergency room or different level of care. |
| LEVEL 4 | A reaction that resulted in the need for acute care hospital admission but was not life threatening and resulted in no permanent patient harm. |
| LEVEL 5 | A reaction that was life threatening or resulted in permanent patient harm. |
| LEVEL 6 | A reaction that resulted in patient death. |

ADRs at Whiting Forensic Hospital are ranked by causal relationship as: Remote, Possible, Probable, or Highly Probable based upon completion of the ADR probability algorithm of the ADR reporting form

PROCEDURE:

1. Initiation of the ADR reporting process is the responsibility of the medical staff², nurses, and pharmacists. The person reporting the suspected ADR informs the prescribing and attending physician. All medical staff, nursing staff, and pharmacy staff are requested to report all observed ADRs by calling the ADR hotline (ADRS – x2377).
2. The unit pharmacist is responsible for completing the adverse drug reaction reporting form. The pharmacist will also complete the probability and severity ratings on the back of the form. Clinical activity is documented in the clinical section of the pharmacy computer system. The pharmacist will verify that the prescribing and/or attending physician have been notified.
3. After assessing the ADR, the attending physician should make an entry in the progress notes to document the occurrence of a possible ADR and to document patient counseling concerning the ADR as indicated. (This documentation is not needed for those ADRs classified as "remote").
4. Significant ADRs will be initially reviewed by the Pharmacy Supervisor, or designee, for submission to the FDA based on the criteria outlined in: ASHP Guidelines on Adverse Drug Reaction Monitoring and Reporting. See CHAPTER 15.3.1 of Pharmacy Policy and Procedure Manual.
5. All ADRs shall be reported to and reviewed by the PNT Committee. The PNT Committee will conduct an Intensive Case Analysis (ICA) on ADRs rated a level 3 or greater or when an ICA is otherwise indicated to improve care.
6. The PNT Committee receives from the Pharmacy Supervisor (or designee), a report of ADR trends and recommendations quarterly

WHITING FORENSIC HOSPITAL PHARMACY POLICY AND PROCEDURE MANUAL

SECTION XV: CLINICAL PROGRAM PARTICIPATION CHAPTER 15.3.1: INSTRUCTIONS FOR FDA FORM 3500

POLICY:

All ADRs will be reviewed by the Pharmacy Nutrition and Therapeutics Committee for possible submission to the FDA.

PROCEDURE:

Form FDA 3500 may be used by health professionals for voluntary reporting of adverse events, product use errors, product quality problems, and therapeutic failures for:

- drugs (prescription and over-the-counter)
- biologics, (including blood components, blood derivatives, allergenics, human cells, tissues, and cellular and tissue-based products (HCT/PS)
- medical devices (including in vitro diagnostic products)
- combination products
- special nutritional products (dietary supplements, infant formulas, medical foods)

Adverse events involving vaccines should be reported to the Vaccine Adverse Event Reporting System (VAERS), <http://vaers.hhs.gov/index>. For additional information or assistance with filing a VAERS report, call: 1-800-822-7967.

Adverse events involving investigational (study) drugs, such as those relating to Investigational New Drug (IND) applications, including those for cellular products administered under IND, should be reported as required in the study protocol and sent to the address and contact person listed in the study protocol. They should generally not be submitted to FDA MedWatch as voluntary reports.

WHITING FORENSIC HOSPITAL

PHARMACY POLICY AND PROCEDURE MANUAL

SECTION XV: CLINICAL PROGRAM PARTICIPATION

CHAPTER 15.4: DOSAGE ADJUSTMENT ASSESSMENT FOR RENALLY CLEARED MEDICATIONS

POLICY: All patients 65 years of age or older *and* patients who have a SrCr greater than the upper limit of normal are routinely monitored for appropriate dosing of renally cleared medications. The Pharmacy Services Unit and Medical Staff work collaboratively to identify drugs to be monitored, and implement and maintain a monitoring process.

PROCEDURE:

- 1) The Pharmacy Nutrition and Therapeutics Committee (PNT) formulate a list of drugs that require monitoring in renally impaired patients.
- 2) The list includes the usual dosage range for each medication and a recommended dosing adjustment based on calculated CrCl.
- 3) CrCl is calculated using SrCr and the formulas noted below.
 - a. MALES: $\text{CrCl (ml/min)} = (140 - \text{age in yrs})(\text{wgt in kg}) / \text{SrCr}(72)$
 - b. FEMALES: (Use above formula) X (0.85)
- 4) Patients' drug therapy is assessed using the dosing guidelines found in the Drug Therapy Guidelines.
- 5) Recommendations for dosing adjustments will be made as appropriate.
- 6) The estimated CrCl will be updated quarterly.
- 7) If a significant change has occurred in a patient's renal function, the procedure outlined above will be followed.

SECTION XVII

WFH FORMULARY

WHITING FORENSIC HOSPITAL PHARMACY POLICY AND PROCEDURE MANUAL

SECTION XVII: WFH FORMULARY CHAPTER 17.1: WFH FORMULARY SYSTEM

POLICY:

A formulary system is maintained to ensure medications used at WFH are safe and effective. The Whiting Forensic Hospital Formulary is a complete listing of drugs approved for use by the Pharmacy Nutrition and Therapeutics Committee and the Executive Committee of the Medical Staff in the treatment of patients under the care of WFH. Any member of the medical staff may request additions and/or deletions to the formulary. Formulary change requests are evaluated by the Pharmacy Nutrition and Therapeutics Committee for inclusion in the formulary. A copy of the formulary is available in all patient care areas via the “T” drive.

PROCEDURE:

1. The formulary list is sorted alphabetically by generic name and also by AHFS Therapeutic Class
2. The following information is listed for each formulary drug in the following order:
 - A. Pharmacy code
 - B. Usual name
 - C. Generic or chemical drug name
 - D. AHFS class
 - E. Dosage Form
 - F. Strength
 - G. Route of administration
3. As the formulary additions or deletions are approved, the revised formulary is available on the “T” drive.
4. Medications are reviewed for formulary addition as outlined in Policy 18.2.
5. When a non-formulary drug is prescribed the attending and/or prescriber will complete the approval

process outlined in Policy 18.3.

6. All non-formulary requests are reviewed quarterly to determine if any changes to the hospital formulary are appropriate.
7. The hospital formulary is reviewed on a continuing basis, and at least annually for any appropriate additions or deletions.

WHITING FORENSIC HOSPITAL PHARMACY POLICY AND PROCEDURE MANUAL

SECTION XVII: CHAPTER 17.2:

WFH FORMULARY ADMISSION OF NEW DRUGS TO THE FORMULARY

POLICY:

It is the policy of Whiting Forensic Hospital to maintain a formulary system in order to:

1. Insure the availability of specific medications within the hospital.
2. Promote rational drug therapy with safe and effective agents.
3. Minimize the possibility of confusion among staff.
4. Reduce pharmacy and nursing unit inventory.
5. Encourage economy in drug usage.

In order to achieve these goals, the Medical Staff and Pharmacy Services Unit via the Pharmacy, Nutrition and Therapeutics Committee maintain a formulary of approved drug products. It is the intent of the formulary system to serve as the basis of a cooperative agreement between Pharmacy and Medical Staff as to what pharmacologic agents should be available for use under routine circumstances.

PROCEDURE:

Requests for medications to be added to (or deleted) from the formulary may be made to the Chair of the Pharmacy, Nutrition and Therapeutics Committee, the Pharmacy Services Unit Supervisor, the Pharmacy Clinical Consultant, or by a member of the Medical staff. The request will then be placed on the agenda of the Pharmacy, Nutrition and Therapeutics Committee for consideration.

Upon request to the Pharmacy, Nutrition and Therapeutics Committee Chair, a member of the medical staff may introduce the merits of the

medication for formulary consideration to the members of the Pharmacy, Nutrition and Therapeutics Committee.

Criteria for Admission of Drugs to Formulary

1. Safety/toxicity - including known incidence of adverse drug reaction and perceived propensity to induce errors.
2. Efficacy.
3. Pharmaceutical and therapeutic equivalencies currently available on the Formulary.
4. Bio-Equivalencies.
5. Needs in relation to the diseases and conditions treated.
6. Pharmacokinetic properties.
7. Pharmacoeconomics.

Safety is a relative concept, given the complexity and strength of most of today's drugs. Risk/benefit considerations are compared in order to establish which drugs are safer than others having similar efficacy.

Efficacy is a clinical criterion, which casually is measured by comparing the chosen drug to other drugs within the same therapeutic class.

The safety and efficacy of a given drug, as well as projected needs for it in the foreseeable future, are important considerations in the inclusion of drugs to the Formulary.

The hospital formulary is found on the "T" drive.

Medication in pharmacy inventory has been approved as listed on the Hospital Formulary or using the Non-Formulary Request Policy and Procedure.

WHITING FORENSIC HOSPITAL PHARMACY POLICY AND PROCEDURE MANUAL

SECTION XVII: PRESCRIBING OF MEDICATION CHAPTER 17.3: ORDERS FOR NON-FORMULARY MEDICATIONS

POLICY: A formulary system is maintained to ensure medications used at WFH are safe, effective and cost effective. The Whiting Forensic Hospital Formulary is a complete listing of medications approved for use by the Medical Staff in the treatment of patients under their care. Any request/order for a non-formulary medication will be reviewed to determine if a therapeutically equivalent formulary alternative is available or if the medication must be dispensed as ordered.

PROCEDURE:

1. When a non-formulary medication that is not subject to therapeutic interchange is prescribed, the prescriber will be contacted by a pharmacist regarding therapeutic equivalents that are on formulary.
2. If the non-formulary medication is one in which there is an automatic therapeutic interchange policy (see Section IV, Chapter 4.1.3), the policy and procedure for such will be followed.
3. If the non-formulary medication is not subject to automatic therapeutic interchange and the prescriber does not change the medication to a therapeutic equivalent (either because one does not exist or there is clinical justification that the non-formulary medication must be dispensed as ordered), the prescriber will complete a Non-Formulary Medication Request Form. See Addendum A.
4. The prescriber will forward the Non-Formulary Medication Request Form to the Ambulatory Care Medical Director for medical requests, or to the WFH Medical Director for psychiatric requests. Criteria for ordering a non-formulary medication include: patient intolerance to formulary medication, allergy status, documentation of previous treatment failure to formulary medication, documentation of superior clinical effect of the non-formulary medication.
5. If criteria are not met and the prescriber maintains there is rationale for the non-formulary medication, the WFH Medical Director render a decision as to the necessity of the non-formulary medication.
6. After the decision to use a non-formulary medication, every effort will be made to procure the medication through the Pharmacy Services unit.
7. In the event a request is made outside of regular business hours, the medication will be procured if medically necessary, and the above process will be completed during regular business hours. This includes any non-formulary medications brought into the hospital by the patient and the prescriber requests that patient use their own.
8. The Pharmacy Services Unit will keep the completed form on file.

NON-FORMULARY MEDICATION REQUEST FORM

Patient Name _____ MPI # _____ Unit _____

Prescriber _____ Fax # _____ Date _____

Non-formulary medication requested
(Include dosage regimen) _____

Indication for non-formulary medication _____

What are the available formulary alternatives? _____

What is the clinical justification for obtaining the non-formulary medication?

Determination criteria include patient intolerance to formulary medication, allergy status, documented previous treatment failure to formulary medication, and documentation of superior clinical effect of the non-formulary medication.

Was this medication recommended by an outside consultant? _____

OFFICIAL USE ONLY

Criteria Met _____ Date _____
(signature/name of Medical Director)

Follow up needed _____ Date _____

Please fax signed form to the unit and to WFH Pharmacy.

SECTION XVI

IN - PHARMACY REGULATIONS

WHITING FORENSIC HOSPITAL PHARMACY POLICY AND PROCEDURES MANUAL

SECTION XVI: IN-PHARMACY REGULATIONS CHAPTER 16.1: CONFIDENTIALITY OF INFORMATION AND DATA

POLICY: Strict patient confidentiality is maintained. No information concerning any patient or their medication shall be given out except to authorized staff. Staff adheres to Health Insurance Portability and Accountability Act (HIPAA) requirements.

PROCEDURE:

1. Patient information may be requested from pharmacy staff for other health care professionals in the usual course of practice. This information is given out only after the requesting individual has been identified as a WFH employee and that the information request is reasonable as it relates to the patient care responsibilities of the requestor.
 - A. Identification is preferably done in person via the WFH security badge.
 - B. Identification may be made via phone if in the opinion of the pharmacy personnel the person requesting the information has adequately identified themselves and the voice is recognized.
2. Patient information may be requested as part of concurrent or retrospective research.
 - A. The research protocol is presented to the Chief Medical Officer for approval.
 - B. After approval, the pharmacy may provide the requested information to the individual(s) and/or agencies as approved by the Chief Medical Officer.

WHITING FORENSIC HOSPITAL PHARMACY POLICY AND PROCEDURE MANUAL

SECTION XVI: IN-PHARMACY REGULATIONS CHAPTER 16.2: SECURITY OF THE PHARMACY

POLICY: The Pharmacy area is considered a high security area, by the nature of its contents. Access to the Pharmacy is restricted to pharmacists, pharmacy support personnel, and contracted pharmacy employees. The pharmacy unit supervisor is responsible for the issuing of alarm codes, security badges and keys.

PROCEDURE:

1. The operations of the pharmacy are logistically located in the basement of Dutcher.
This area is locked and accessed by passing through
2 security doors via WFH security badge.
- A. The pharmacy is kept locked at all times. The security alarm is activated when the pharmacy is closed. The pharmacy unit supervisor is responsible for issuing alarm security codes to the pharmacists that are assigned opening and/or closing duties.
 1. Personnel ensure the door closes whenever entering or exiting the pharmacy.
 2. At closing time the pharmacist leaving the area sets the alarm.
2. Non pharmacy personnel that need to enter the pharmacy such as nurses, physicians, workmen, repairmen, inspectors, the housekeepers etc., are positively identified before being allowed in the pharmacy preferably via the WFH security badge. Non-pharmacy personnel are escorted at all times while in the Pharmacy by pharmacy personnel.

WHITING FORENSIC HOSPITAL PHARMACY POLICY AND PROCEDURE MANUAL

SECTION XVI: IN-PHARMACY REGULATIONS CHAPTER 16.3: MAINTENANCE AND STORAGE OF PHARMACY RECORDS

POLICY: All required records are maintained for the required length of time according to applicable laws, regulations, and/or WFH policy.

PROCEDURE:

1. It shall be the responsibility of the Pharmacy Supervisor or designee to maintain all pharmacy records.
2. The following records are maintained for a minimum of three years in an easily and readily retrievable form.
 - A. Controlled drug records of receipt, distribution, administration, and disposition.
 - B. Drug procurement records.
 - C. Adverse drug reaction reporting records.
 - D. Pharmacy quality assurance documentation and reports.
3. Storage of pharmacy records
 - A. Old pharmacy records are boxed and numbered and logged on an archive record and destroyed upon permission by the State of Connecticut Public Records administrators.

WHITING FORENSIC HOSPITAL PHARMACY POLICY AND PROCEDURE MANUAL

SECTION XVI: CHAPTER 16.4:

IN-PHARMACY REGULATIONS DESTRUCTION OF NON-CONTROLLED DRUGS

POLICY:

Outdated or otherwise unusable non-controlled drugs that do not meet the manufacturer's criteria for return for credit are destroyed or disposed of in a safe and effective manner. The financial impact on inventory is reported.

PROCEDURES:

1. Outdated or unusable non-controlled drugs are stored separate from all other drug inventory in a "Pending Destruction" bin or in the EXP Pharmaceutical Services box.
2. A pharmacist or technician determines if each item is returnable to the manufacturer for credit. The EXP Pharmaceutical Services Corp. visits the pharmacy routinely to sort through the medications returnable for credit. All returnable medications are processed for credit. Non-returnable medications are logged on the Inventory Adjustment for Drugs Wasted/Destroyed form and placed in the proper biohazard bucket.
3. There is a biohazard container used for storing medications to be destroyed or returned for credit.

These medications are processed/picked up by the currently contracted reverse wholesaler or Environmental Services when the container is $\frac{3}{4}$ full.

