[Insert Hospital Logo]	[INSERT MANUAL NAME]	No. CO-3.004
	Title: MEDICATIONS BROUGHT TO THE HOSPITAL BY THE PATIENT	Page: Page 1 of 8
		Origination Date: 02-27-09; 03-21-13
		Effective Date: xx-xx-xx
		Retires Policy Dated: xx-xx-xx
		Previous Versions Dated: xx-xx-xx
		Hospital Governing Board Approval Date: xx-xx-xx
		Medical Staff Approval Date: xx-xx-xx

I. SCOPE

This policy applies to _____("Hospital") and to all employees, Medical Staff members, contractors, patients and visitors regardless of service location or category of patient.

II. PURPOSE:

The purposes of this policy are (a) to provide for patient safety, continuity of care, and appropriate patient billing in circumstances when the patient brings his or her own medications to the Hospital; and (b) to provide safe and effective administration of, destruction of, and legal documentation of the use of investigational drugs brought into the hospital by a patient enrolled in a study at another facility.

III. POLICY:

If a patient is admitted as an inpatient to the Hospital and brings medications to the Hospital, the nurse should encourage the patient to send the medications home with a responsible family member or patient representative. If the medications cannot be sent home, the Hospital shall store the medications in accordance with this policy.

Further, medications brought into the Hospital by a patient will not be administered to the patient except in accordance with this policy.

For purposes of this policy, the term "medications" applies to all drugs, including prescription drugs, non-prescription drugs, homeopathic and herbal remedies, botanical products and any investigational drugs.

Use of a patient's own medications may only be approved for use if a medication or similar drug with same efficacy is not available through the pharmacy or the drugs are part of a clinical study that if not given would jeopardize the patient's medical care and/or his/her ability to continue to participate in his/her clinical research study. If a patient's medication can be procured by the pharmacy, it will procure the medication and once procured, the patient's medication shall be stored in accordance with this policy.

The pharmacy may not dispense, nor may a nurse or other Hospital employee be involved with the administration and storage of, any herbal or complementary medications or any other medication that is not approved by the FDA except in the case of investigational drugs that if not given would jeopardize the patient's medical care or the ability to continue to participate in their clinical research study. The lack of assurance that such drug meets FDA requirements for safety,

and has the identity, strength, quality and purity characteristics that it is represented to possess, and does not pose a risk of drug interactions among medications, herbals, and other complementary medications not approved by the FDA, makes administration of such drugs a true patient safety issue.

If an investigational drug is allowed, the "Investigational Drug Data Sheet" (see Attachment B) shall be completed and returned to the pharmacist. All investigational drugs brought in by the patient shall have the information required by this policy prior to their administration to the patient unless the omission of a dose would have deleterious consequences on the patient's status.

Medications brought in while being treated as an outpatient will remain in the custody of the patient or patient's family and will **NOT** be administered to the patient by Hospital staff while being treated as an outpatient.

IV. PROCEDURE:

A. Handling of Medications Brought to the Hospital by the Patient:

1. If a patient brings his or her own medications to the Hospital, the nurse shall request that a responsible family member or patient representative take the medications home. If the medications are unable to be removed from the Hospital, the admitting nurse shall be responsible for removing the medications from the patient's possession and taking the following steps :

   a. The nurse will place all medications into a clear plastic "security bag" (see Attachment A) in the patient's presence.

   b. The name of any medications placed into the bag shall be documented on the outside of the bag.

   c. The patient's name, unit, ID#, date and nurse's name are to be documented on the bag in the appropriate spaces. The patient and nurse shall initial the bag on the line titled "prepared by." If the patient is unable to initial, two nurses will initial the bag.

d. The patient's name, unit, ID#, date and nurse's name are to be documented on the "receipt" prior to removal. The "receipt" is to be removed and given to the patient. The green plastic (tamper-proof) tab shall be removed and the bag sealed.

e. The nurse shall be responsible for ensuring delivery of the sealed bag to the pharmacy. If any of the medications are controlled substances, delivery must be made by credentialed staff (i.e., nurse, pharmacist, pharmacy tech).

f. The nurse shall instruct the patient that upon discharge he or she will be required to present the receipt in order to obtain the medications. The patient will also be instructed that if he or she fails to request the medications within 30 days of discharge, the medications may be destroyed by the Hospital. The nurse shall document in the medical record that the medications have been removed from the patient and are being stored in the pharmacy.

2. The bag shall be stored in the pharmacy narcotic locker (or locking refrigerator, as applicable).

3. The following information shall be documented in a log entitled "Patient's Own Medication log" and maintained in the pharmacy in accordance with state pharmacy practice laws.

a. Patient Name

b. Date received

c. Receiving pharmacist's initials

d. Number of bottles in the bag

e. Whether medications are being used while in the Hospital

f. Temperature requirements

g. Date destroyed (if applicable) – separate log maintained for investigational drug accountability

h. Initials of two pharmacists witnessing destruction of controlled substances (if applicable) – separate log maintained for investigational drug accountability

i. Date returned to the patient

j. Signature

k. When the patient receives medication(s) or the medications have been destroyed, the pharmacist shall highlight (yellow marker) the entry in the log indicating that the process is complete.

B. Use of Medications Brought to the Hospital by the Patient:

1. If the pharmacy is unable to procure a prescribed medication prior to the patient's need for the medication, or if in the judgment of the patient's physician, the patient needs to use the FDA-approved medications he or she brought to the Hospital, the following steps shall be taken:

a. In circumstances where the Hospital is unable to procure the medication, the pharmacist shall notify the patient's physician, or Principal Investigator of the study if the study drug is investigational in nature, of the inability to procure the medication prior to ordered administration.

b. If the physician determines that there is no acceptable alternative to the prescribed medication, or if the physician determines other circumstances warrant the use of the patient's own medication, the physician may order the use of the medication brought to the Hospital by the patient. The physician's order shall include the following information: medication name or bottle ID, in the case of an investigational drug, source of medication being provided by patient, dose, frequency or schedule, route or device as required by the Medical Staff Bylaws and/or Rules and Regulations or Hospital policy.

c. Prior to the pharmacist dispensing medications brought to the Hospital by the patient, the pharmacist shall take the following steps:

(1) If the medication has been stored by Hospital personnel in a security bag as described in this policy, the pharmacist shall remove the medication in the patient's presence. If there are any remaining medications, the pharmacist shall either re-seal the bag (noting the removal of the medication on the bag) or place in a new security bag following the steps outlined in this policy.

(2) Examine the medication container to confirm the medication is clearly and properly labeled.

(3) Confirm the identity of the contents of the medication container and that such medication has not expired. Expired medication cannot be dispensed. The pharmacist will affix a sticker to the bottle that contents have been verified and include his/her initials and date.

(4) The pharmacist will also document the number of pills that were originally in the container on the label.

d. The medication(s) being used while in the Hospital will be stored in a secured work area within the pharmacy or secured with the automated dispensing cabinets. The medications received in the pharmacy will be individually packaged as per pharmacy process and dispensed as per "drug data sheet" guidelines.

2. If the patient's own medications are being used, the pharmacist will ensure that neither the patient nor any payer shall be billed for the medications.

3. Upon notice that a patient will be discharged, the pharmacist will coordinate the provision of medications to the patient or patient's representative and take the following steps:

a. Obtain the signature of the patient (or patient representative) indicating receipt of medications.

b. The pharmacist returning the medications to the patient shall highlight (in yellow or other color) on the discharge Medication

Reconciliation Form the lines(s) corresponding to the patient and his or her medication(s).

c. If the patient is discharged when the pharmacy is closed, he or she (or a representative) will be able to pick up the medication(s) the following day.

d. Medications may be disposed of 30 days after discharge. These medications shall be placed into the Pharmaceutical Waste Container and the date of destruction logged. The disposition of controlled substances will be co-signed by two pharmacists.

C. Patients Admitted on Investigational Drugs

1. When the order is written for a drug that needs to be administered to the patient as part of research protocol, the physician shall write the study name/protocol and the words "PATIENT'S OWN MED" on the order. The pharmacist needs to ensure the signed research informed consent has been received and has been placed in the medical record.

2. The nurse or pharmacist shall obtain the following information: prescribing physician's name and dispensing institution.

3. The pharmacist shall start a "Drug Accountability Log" documenting receipt date of the drug, quantity received from patient. The pharmacy shall record the date/time of each dose dispensed, along with the dispensing pharmacist's signature/initials. When the patient is discharged, the pharmacist shall document quantity of pills/vials returned to the patient and the number of empty vials or empty pill bottles returned to the patient.

4. Upon receipt of the medication, the pharmacist shall call the dispensing institution and ask to speak with the research pharmacist or investigator's coordinator. The pharmacist shall request the research pharmacist/ investigator's coordinator send/fax the "Investigational Drug Data Sheet" to the pharmacy for completion. The pharmacist shall make two copies of the sheet, with one placed on the patient chart and one stored in the pharmacy with the patient medication.

5. The medications will be packaged as per Hospital pharmacy procedures and stored/dispensed in the pharmacy in accordance with the Investigational Drug Data Sheet. Investigational drugs dispensed to patients will be entered into the patients' MAR. The investigational drug will be built into the CPOE or pharmacy system with a name starting with "Study – and then the study number."

6. Investigational drugs will not be disposed of for any reason and will be returned with all the original packing, copy of drug accountability log, and any empty bottle/ vials will be returned to the patient upon discharge in accordance with this policy. In the event of patient death, the study doctor will be contacted to pick up what would have been returned to the patient. If after 30 days the drug has failed to be picked up, the drug will be destroyed as per the hospital policy on drug destruction.

D. Responsible Person

The Pharmacy Director/Pharmacist in Charge is responsible for assuring that all individuals adhere to the requirements of this policy, that these procedures are implemented and followed at the Hospital, and that instances of noncompliance with this policy are reported to the Hospital's Chief Operating Officer.

E. Auditing and Monitoring

The Hospital must monitor compliance with this policy as part of its medication management process. Quality Management and Audit Services shall audit adherence to this policy during their routine audits processes.

F. Enforcement

All Hospital staff and Medical Staff members whose responsibilities are affected by this policy are expected to be familiar with the basic procedures and responsibilities created by this policy. Failure to comply with this policy will be subject to appropriate performance management pursuant to all applicable policies and procedures, including the Medical Staff Bylaws, Rules and Regulations.

V. REFERENCES:

- **[Hospital's Drug Destruction Policy]**

VI. ATTACHMENTS:

- Attachment A: Medication Security Bag

- Attachment B: Investigational Drug Data Sheet

Medication Security Bag

Patient's Medicine Inventory

Packaging Horizons Corp.

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DEPARTMENT OF PHARMACEUTICAL SERVICES
INVESTIGATIONAL DRUG DATA SHEET

1. Name of Drug:_____
2. Chemical Designation or other Name:_____
3. Dosage Forms:_____
    a. Routes of Administration: Oral_____ IV Push_____
    Intrathecal _____ Other_____

4. Sponsor or Source:_____
5. IND Number:_____
6. Principle Investigator:_____
7. Date Approved by Institutional Review Board:_____
8. Investigational Data:_____
    a. Pharmacologic Class:_____
    b. Pharmacologic Action:_____
    c. Pharmacokinetics: (Including administration, absorption, distribution, metabolism, elimination, serum levels (including therapeutic and toxic), etc.)_____
    _____
    _____
    _____
    d. Dosage: (usual & range)_____
    e. Contraindications:_____
    _____
    f. Side Effects / ToxicEffects:_____
    _____
    g. Recommendations for Limiting/Treatment Toxic Effects:_____

    h. Reconstitution Directions:_____
    i. Directions on Drug Administration:_____
    j. Special Administration Instructions:_____
    _____
    _____
    k. Special Handling Instructions (spill cleanup, special transportation, packaging, etc): _____
    l. Hazardous Waste Classification: _____

m. Stability and Storage Requirements:_____
Prior mixing: _____ Room Temperature_____ Refrigerate_____
Freeze_____
Protect from Light_____ Other _____
After mixing: Stable for _____ Days/Hours/Minutes in refrigerator.

n. Investigational /Experimental Drug Destruction
Hospital Vendor requirements for destruction: see hospital pharmacy policy for research study drugs.
Sponsor Requirements for destruction: contact study doctor for sponsor requirements.
Empty bottle/vial: _____
Partial bottle/vial: _____

9. Supplies available in Pharmacy: _____Yes _____No
Routine: _____Yes _____No Emergency: _____Yes _____No

10. All nurses, personnel given authority to administer this investigational drug must read and understand this document and other information provided on drug. Each person administering this drug must document below that they have read and understood the information and that they have documented competency in their nursing practice to administer this medication.

See last page for nursing signature verification/signature

Name (Please Print)	Date	Shift	Signature

Pharmacy Department
Investigational/Experimental Drug
Data Sheet