

**UNIVERSITY HOSPITAL**  
**DEPARTMENT OF PHARMACY POLICY AND PROCEDURE MANUAL**  
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# Stony Brook Medicine

## PHARMACY DEPARTMENT POLICIES & PROCEDURES MANUAL CODE: I-1

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: MISSION STATEMENT SCOPE OF SERVICES

EFFECTIVE DATE ORIGINAL  
POLICY: 09/1989

EFFECTIVE DATE REVISED  
POLICY: 02/2005

SUPERSEDES POLICY NUMBER:

LAST REVIEW DATE: 10/2017

### I. DEFINITION OF SERVICE

#### A. MISSION

The mission of the SBUH Department of Pharmacy is to guide the safe and appropriate use of medication in order to provide optimal pharmaceutical care to all patients of Stony Brook University Hospital.

#### B. PURPOSE/VISION/GOALS

The fundamental purpose of pharmaceutical services is to ensure the safe and appropriate use of medications. Our core philosophy is that pharmacists practicing in academic institutions such as SBUH are expected to make meaningful contributions to patient care, education, community service and research.

Optimal pharmaceutical care can be defined as the identification, resolution and prevention of drug-related problems that affect positive patient outcomes. We believe that this is best provided through a team approach that effectively integrates the knowledge and skills of the pharmacist with those of other health care professionals.

Our vision is to ensure the safe and optimal use of pharmaceuticals for all patients of Stony Brook Medicine by having pharmacists provide a central and visible role in all aspects of medication management.

To fulfill this responsibility Pharmacy is involved with decision making and actions relating to the procurement, storage, preparation, dispensing, distribution and administration of all drug products. Pharmacy also provides information to support judgments regarding medication selection, dosage,

method of administration and monitoring of therapy.

Our goals are:

- to establish the pharmacist as a crucial member of the patient care team whose presence is recognized as valuable and necessary for the achievement of Stony Brook Medicine's goal of best clinical practice and outcomes in at least 10 select disease states. This will involve pharmacist presence in both the inpatient and the outpatient community.
- to implement technology and processes that will ensure the safe preparation and dispensing of medication to our patients
- to make meaningful contributions to the fiscal viability of the institution by establishing specific revenue streams for Pharmacy
- to support SBM's quality initiative to be a top decile performer

### **C. FUNCTION**

The services provided by the Department of Pharmacy are divided into four categories:

1. Administrative
  - a. Formulary Management
  - b. Establishing Medication-related Policies and Procedures
  - c. Control of Pharmaceutical Expenditures
  - d. Procurement of Pharmaceuticals
  - e. Quality Management
  - f. Pharmacy Information Systems
2. Distributive
  - a. Operation of a Unit Dose Distribution System
  - b. Operation of a Unit-Based Dispensing System
  - c. Compounding of Sterile Products, including Antineoplastic and Parenteral Nutrition Admixtures
  - d. Investigational Drug Services
  - e. Satellite Pharmacy Services
    - i. Operating Room/Surgical Services
    - ii. Ambulatory Surgical Center
    - iii. Cancer Center/Infusion Services
3. Clinical
  - a. Decentralized Pharmacist Program
  - b. Pharmacy Specialist Program
  - c. Antimicrobial Stewardship Service
4. Educational
  - a. Pharmacy Residency Program
  - b. Pharmacy Continuing Education Program
  - c. Community Education Programs

### **D. CUSTOMERS**

The Department of Pharmacy serves patients of all ages, physicians, nurses, allied health professionals and hospital administration.

#### **E. STAFFING**

Services are provided by licensed pharmacists supported by pharmacy technicians and other members of the departmental staff.

The Department of Pharmacy ensures adequate staff to meet patient and other customer needs by requesting staff on a programmatic basis. Thus, once a program is approved, the staff required to support that program is an integral part of that approval. A sophisticated computerized scheduling system is used to ensure staff availability to support each area and program. Vacation or other time-off requests are not granted if the absence will compromise necessary service. Should an unanticipated staff shortage occur due to staff illness or emergency, members of the staff are cross trained to cover multiple areas. There is also a system for use of per diem staff and for coverage on a recall or overtime basis should the shortage occur on an off shift.

#### **F. DELIVERY OF CARE**

Pharmaceutical care is delivered from the Main Pharmacy, which includes the Sterile Compounding Area, Antineoplastic and Hazardous Drug Compounding Area, and the Investigational Drug Service; from the Satellite Pharmacies located in the Operating Room, Ambulatory Surgery Center, and Cancer Center; and by decentralized pharmacists assigned to patient care areas. Pharmacists consult with prescribers, check and fill medication orders and monitor patient medication therapy to ensure the safe and appropriate use of pharmaceuticals.

#### **G. AVAILABILITY OF SERVICE**

Pharmacy services are available 24 hours a day, 365 days a year.

### **II. NEEDS ASSESSMENT**

Customer need, as well as appropriateness, clinical necessity and timeliness of the services provided, are identified through interdisciplinary meetings and through the CQI/QAPI processes.

Individualized customer needs are considered through the Formulary process where practitioners can request the availability of those medications needed by their patients. The Department of Pharmacy provides informational resources to meet individual customer needs.

### **III. PRACTICE STANDARDS**

The Department of Pharmacy operates in accordance with Federal and State laws regulating the distribution of drugs and the practice of Pharmacy, as well as applicable standards as written in the Joint Commission Hospital Accreditation Standards Manual, CMS Conditions of Participation, and Practice Standards of ASHP. Institutional guidelines for the operation of the department are set forth in the Administrative Policy and Procedure Manual and the Departmental Policy and Procedure Manual.

#### **IV. PROTECTION OF HEALTHCARE INFORMATION**

- A. Patient information used by the Department of Pharmacy includes patient name, medical record number, admitting diagnosis, age, height and weight.
- B. Patient information sources include physician order sheets, lab information, and patient demographic data, as well as information obtained verbally from caregivers. Information is stored in patient profiles in the Cerner PharmNet<sup>TM</sup> pharmacy computer system and the Pyxis MedStation<sup>TM</sup> software. After processing, paper physician order sheets are boxed and stored in the Department of Pharmacy for a period of one month and then archived to a secure long-term storage center. Order sheets that have been electronically scanned are available in a retrievable archive. Orders entered electronically are stored in the EMR.
- C. Pharmacy data is available to hospital personnel with authorized access to this information via PowerChart<sup>TM</sup>.
- D. Patient information may be received via paper order, computer profile or by telephone, and is utilized in the preparation, distribution and monitoring of medication therapy. Patient information leaves the department on the computer-generated labels on both oral and parenteral medications delivered to the nursing units.

#### **V. CONTINUOUS QUALITY IMPROVEMENT ACTIVITIES**

- A. **MODEL USED**  
The Pharmacy primarily uses Focus PDCA as its CQI model and follows the CMS QAPI approach to quality improvement.
- B. **KEY CQI/QAPI ACTIVITIES**  
The key CQI/QAPI activities of the Department of Pharmacy address patient safety within the medication use process. This process includes medication procurement, storage, prescribing, preparation, distribution, administration and patient monitoring.
- C. **STAFF PARTICIPATION**  
The department supports staff involvement in Hospital Committees that play an active role in QA/CQI activities. These include but are not limited to the Patient Safety Committee, the Medication Safety Committee, the Pharmacy/Nursing Committee and the Pharmacy Departmental Process Teams.

#### **INDICATORS USED AND DATA MONITORED**

<u>INDICATOR</u>	<u>DATA</u>
1. Medication Errors	Type of error, unit, process, shift, severity, medication type
2. Adverse Drug Reactions	Drug(s), type of reaction, location, severity, probability, preventability
3. Pharmacist Interventions	Type of intervention, date, accepted outcome, significance, cost avoidance, pharmacist or area
4. Nursing area inspections	Unit, compliance with regulations, problems found, resolution
5. Non-Formulary drugs	Drug, frequency, cost
6. Drug Utilization Evaluations	Appropriateness of order (including dose, frequency, drug-drug interactions), dispensing (order entry accuracy, etc.), administering (potential drug-drug/food interactions, time of day (if relevant), rare, etc.) and monitoring (i.e., adverse drug reaction, outcome)
7. Workload Statistics	Number of IV preparations, chemo preparations, infusions, PNs, etc.
8. Controlled Drug Discrepancies	Nursing unit, date, drug, dosage form, quantity, corresponding sheet number (if applicable)

## **VI. ORIENTATION AND EDUCATION**

In addition to the hospital orientation, all Pharmacy personnel receive extensive training within the department before assuming their responsibilities. New staff must be signed off in each area before being allowed to practice. Periodic in-service educational programs are conducted and, when feasible, staff is encouraged to attend pertinent lectures and teaching rounds conducted in the Hospital or Health Sciences Center.

Continuing Education is a mandatory requirement for re-licensure of pharmacists. Each pharmacist must complete 45 hours of formal ACPE-accredited Continuing Education for each triennial registration period. The Pharmacy Department at Stony Brook University Hospital is an ACPE-approved provider of continuing education. Orientation and training are documented in each employee's departmental record.





# Stony Brook Medicine

## PHARMACY DEPARTMENT POLICIES & PROCEDURES MANUAL CODE: I-2

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: DEPARTMENTAL ORGANIZATION

EFFECTIVE DATE ORIGINAL POLICY: 11/2003	EFFECTIVE DATE REVISED POLICY: 11/2005	SUPERSEDES POLICY NUMBER:
	LAST REVIEW DATE: 10/2017	

**POLICY:** The manner in which the Department of Pharmacy is organized is established.

**SCOPE:** Pharmacy

**KEYWORDS:** Department, table of organization

**FORMS:**

**POLICY CROSS REFERENCE:**

**DEFINITIONS:**

**PROCEDURE:** The Department of Pharmacy shall be directed by a professionally competent and legally qualified pharmacist. It shall be staffed by a sufficient number of competent personnel, in keeping with the size and scope of services to the hospital.

The Department of Pharmacy is organized as shown in the following Table of [Organization](#).



# Stony Brook Medicine

## PHARMACY DEPARTMENT POLICIES & PROCEDURES MANUAL CODE: I-3

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: STAFFING AND SHIFT COVERAGE

EFFECTIVE DATE ORIGINAL  
POLICY: 11/2003

EFFECTIVE DATE REVISED  
POLICY: 11/2003

SUPERSEDES POLICY NUMBER:

LAST REVIEW DATE: 05/2017

**POLICY:** The Pharmacy is staffed to ensure that a full range of services for patients at Stony Brook University Hospital is provided.

**SCOPE:** Pharmacy

**KEYWORDS:** Staffing, coverage, schedule

**FORMS:** Daily schedule, off shift coverage list

**PROCEDURE:** Staffing levels will be maintained on all shifts to permit the Pharmacy to fulfill its mission 24 hours a day, 7 days a week.

### I. STAFFING

A. Work schedules are published 30 days in advance and daily assignments are posted weekly and further refined for particular areas as appropriate.

B. To fulfill the Pharmacy's mission and to ensure adequate provision of service it may be necessary to assign staff to any work area or on other shifts.

### II. OFF SHIFT PHARMACY COVERAGE

#### A. Off-shift Coverage List (OCL)

1. A dayshift pharmacist OCL list will be comprised of all senior and full-time and part-time staff pharmacists, as assigned by the Director. A current and updated copy of the OCL will be posted by Pharmacy Administration.

2. The AM shift pharmacist OCL will be comprised of all evening

shift senior and staff pharmacists.

3. A separate dayshift OCL will be comprised of all day shift pharmacy assistants. This list will exclude the OR technician.
4. The names on lists will rotate. Everyone must work an extra shift in order to get off the top of the OCL.
5. All new pharmacists and pharmacy assistants, once trained, will have their name added to the bottom of the appropriate OCL.

#### B. Implementation to Obtain Coverage

1. When it is known that a specific shift requires additional coverage, the staff member who is at the top of the appropriate OCL will be notified.
2. If the staff member at the top of the list is not present, the next staff member on the list who is present will be required to work the extra shift.
3. If this is a problem for the staff member, the pharmacy administrator in charge or his/her delegate will send a phone message to all pharmacy areas identifying that coverage is needed and soliciting volunteers.
4. If there are no volunteers available, it will be the responsibility of the staff member designated to work, to either work the extra shift or find coverage.
5. Once someone works an extra shift, that staff member's name goes to the bottom of the OCL.
6. If two staff members elect to split an eight shift, the staff member highest on the OCL goes to the bottom of the OCL.
7. If a staff member elects to volunteer to work an extra shift his or her name goes to the bottom of the OCL.
8. If it is known that a specific staff members schedule must be covered for an extended period of time, the following procedure will be enacted:
  - a. It will be determined by Pharmacy Administration what dates coverage will be needed, after review of the existing schedule and rescheduling as appropriate. This list of dates will be posted with an attached solicitation for volunteers.
  - b. Volunteers for this purpose shall be entitled to all benefits of anyone responsible for the extra coverage.
  - c. As a last resort if no volunteer coverage is available, then, on those dates, the appropriate OCL will be utilized

for coverage.

9. If a staff member is mandated to stay, for any reason, for greater than two hours beyond his or her normal shift, than that staff member's name will be placed on the bottom of the OCL.
10. A staff member who is working as a result of a switch with another staff member whose name is at the top of the OCL will not be the first designated to work an extra shift. The working staff member maintains his/her name position as listed on the current OCL.



# Stony Brook Medicine

## PHARMACY DEPARTMENT POLICIES & PROCEDURES MANUAL CODE: I-4

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: MEAL PERIODS AND BREAKS

EFFECTIVE DATE ORIGINAL  
POLICY: 11/2003

EFFECTIVE DATE REVISED  
POLICY: 06/2004

SUPERSEDES POLICY NUMBER:

LAST REVIEW DATE: 05/2017

**POLICY:** A procedure for allocating time for meals and breaks is established.

**SCOPE:** Pharmacy

**KEYWORDS:** meals, breaks

**FORMS:**

**POLICY CROSS REFERENCE:**

**DEFINITIONS:**

**PROCEDURE:** The Assistant Director or designated supervisor, on a daily basis, shall be responsible for assigning meal periods and breaks.

1. UUP personnel are entitled to 60 minutes per shift for meals. Meals are to be taken at times assigned by the Senior Pharmacist in consideration of workload.
2. CSEA personnel who work 40 hours per week are entitled to 30 minutes per shift for meals.
3. Up to two 15 minute breaks may be allowed if workload permits at the supervisor's discretion for both bargaining units.
4. Breaks are considered **"time worked"** and are not an entitlement. All staff must obtain permission from a supervisor prior to taking a break.



# Stony Brook Medicine

## PHARMACY DEPARTMENT POLICIES & PROCEDURES MANUAL CODE: I-5

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: MONTHLY WORK SCHEDULE

EFFECTIVE DATE ORIGINAL  
POLICY: 11/2003

EFFECTIVE DATE REVISED  
POLICY: 11/2005

SUPERSEDES POLICY NUMBER: I-5

LAST REVIEW DATE: 05/2017

**POLICY:** The Pharmacy provides patient care services every day of the year, 24 hours a day. Work schedules are established for the purpose of insuring such patient care is provided.

**SCOPE:** Pharmacy

**KEYWORDS:** schedule

**FORMS:** Monthly Schedule

**POLICY CROSS REFERENCE:** I-6 Request for Time Off

**DEFINITION:** The monthly work schedule indicates which staff persons will work during each shift on a given day over a four-week period.

**PROCEDURE:**

1. The monthly schedule will be prepared and distributed at least four weeks in advance by the Pharmacy supervisor assigned to do so.
2. Departmental needs will have priority when planning the schedule and additional shifts may have to be scheduled in periods of short staffing.
3. All Pharmacy personnel may be required to work any shift in a 24 hour period and on any day of the week consistent with union contracts and federal and state law to maintain adequate staffing to provide for patient medication needs at all times.
4. All changes in work schedules initiated by the staff must be approved by Pharmacy Administration in advance of the change.

- a. All parties involved in any schedule change must acknowledge their consent to the change to the proper Pharmacy administrator.
- 5. Should it become necessary for Pharmacy Administration to change an employee's work schedule, the employee will be notified of the change as required 4 weeks in advance.
- 6. Personnel are expected to be present at their assigned area at the scheduled time for the start of the shift.
- 7. Frequent tardiness is not acceptable and may subject the employee to corrective action.
- 8. Personnel may not leave before the end of their shift without the approval of Pharmacy Administration.
- 9. The Pharmacy Supervisors will be responsible to document all tardiness, and early departure in the department.



# Stony Brook Medicine

## PHARMACY DEPARTMENT POLICIES & PROCEDURES MANUAL CODE: I-6

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: REQUEST FOR TIME OFF

EFFECTIVE DATE ORIGINAL POLICY: 08/22/1984	EFFECTIVE DATE REVISED POLICY: 09/15/2003	SUPERSEDES POLICY NUMBER:
	LAST REVIEW DATE: 05/2017	

**POLICY:** The mechanism by which a member of the Pharmacy Department may request time off and the criteria to be used in granting such requests is established.

**DEFINITION:** Time off from a regularly scheduled working day will mean:  
a) Compensatory time for working holidays or extra shifts  
b) Annual days  
c) Personal days (where permitted under union contract)

**FORMS:** Time off Request/Access to Clarvia from Cerner

**SCOPE:** Pharmacy Staff

**PROCEDURE:**

1. A member of the Pharmacy Department requesting time off will do so by logging onto the Cerner web site Clarvia scheduling program.
2. A staff member requesting time off will enter the following information:
  - a. Date desired for time off
  - b. Type of day requested (i.e. vacation, compensatory, personal, etc.)
3. The Assistant Director or designee will review time off requests and either approve or deny the employee's request, and then notify the employee via AtStaff. Time off will be granted if it does not conflict with departmental staffing requirements or programmatic objectives.



## **VACATION REQUESTS**

1. When vacation requests are submitted by the deadlines in the table below, Pharmacy Administration will schedule vacations according to departmental seniority and staff availability. Exact dates will be posted in the message center in Clarvia.

<b>Date the request must be submitted</b>	<b>Time period covered by request</b>
On or before October 31th	Monday after New Year's Day to Monday before Memorial Day
On or before March 15th	Monday before Memorial Day to September 10th
On or before June 30th	September 11th to Sunday after New Year's Day

2. The exceptions to the above are Thanksgiving Week, Week prior to Christmas, Christmas Week, New Year's Week, July 4th Week, Spring Break Week, and Winter Break Week. Seniority will not be taken into consideration if the same week is requested for two consecutive years.
3. Vacation requests or requests for days off received after the dates specified above will be granted on a first come – first served basis as staffing permits.
4. When a vacation request includes a weekend that the employee normally works, it is preferred that the employee swap weekends with another employee. In this way, no employee will have to work more than 26 weekends in any given year. If an employee does not or cannot work out a swap, and the employee is granted the extra weekend off, that employee will be placed in a pool to cover another employee's weekend should the need arise.
5. Once a year staff may request a vacation of any duration prior to the normal period that requests are due and can expect to receive a reply within two weeks of the request. If said request is approved, the employee will not be eligible to use this process the following two years.
6. It is the responsibility of the employee to use annual days and holidays in a timely manner so as to avoid exceeding the maximum number of banked vacation days allowed by that employee's contract. Failure to do so may result in forfeiture of accrued annual time.
7. Staff who have exceeded maximum vacation accrual and will lose days will **not** be given special consideration if they have not requested time as stipulated in paragraph (1) of this section.
8. Summer (May – Sept) requests must include a note of which week may be a preference. The schedule-maker will try to maximize approvals based on seniority and preference for the first week requested. Second week of requests will be acted upon based on seniority after the first pass through of the staff requests.

9. Requests may be denied based on coinciding requests for the same work area(e.g. OR, Sterile Compounding, Clinical)
10. Requests can be entered in Clarvia up to 7 months in advance. Requests beyond that time period should be emailed to the schedule-maker.

#### **HOLIDAYS & OTHER DAYS OFF**

1. Personnel who have worked a holiday are entitled to a compensatory holiday day off.
2. Employees are to request compensatory days off as early as possible to assist in granting the requested day.
3. Every effort will be made to grant these requests, however, it may be necessary to select an alternate date if adequate coverage cannot be assured on the date requested.
4. Compensatory days must be taken within 12 months of accrual.
5. Personnel requesting a personal day off or elective "V" day are asked to request such days as early as possible.
6. These requests will be granted on a first come, first served basis and will take a lower priority to regular vacation time.
7. Staff is scheduled to work every other holiday.
8. Staff members may not switch holidays without prior approval by a supervisor.



# Stony Brook Medicine

## PHARMACY DEPARTMENT POLICIES & PROCEDURES MANUAL CODE: I-7

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: ORIENTATION PROGRAM

EFFECTIVE DATE ORIGINAL POLICY: 11/2003	EFFECTIVE DATE REVISED POLICY: 11/2005	SUPERSEDES POLICY NUMBER: I-13
	LAST REVIEW DATE: 10/2017	

**POLICY:** All new Pharmacy employees will undergo a departmental orientation. Each staff member will have a period of time for orientation and training in his or her role in the department and will not be allowed to perform specific tasks until evaluated as competent to perform those specific tasks. Additional orientation time will be granted for any employee that requests or requires additional area specific training.

**SCOPE:** Pharmacy

**KEYWORDS:** Orientation, training, competency

**FORMS:** Pharmacy Orientation Checklist

**POLICY CROSS REFERENCE:**

**PROCEDURE:**

### Hospital Orientation Program

1. The Human Resources Department is responsible for the content and scope of the Hospital Orientation Program.
2. The content and scope of this program deals primarily with Hospital safety, benefits and conditions of employment.
3. Employees will be required to complete a checklist prepared by the Human Resources Department which verifies their participation in the Orientation program.

4. This checklist must be signed by each employee and returned to the Human Resources Department.
5. The Orientation Checklist will become a permanent document in the employee's personnel file.

**Pharmacy Orientation Program**

1. The Pharmacy Orientation Program is conducted for all new employees of the Pharmacy Department.
2. The Assistant Director of Pharmacy will assign a new employee to receive mentorship from one of the Pharmacy Supervisors as the employee moves through each area in the Pharmacy.
3. Each new employee enters a scheduled rotation through each area of Pharmacy practice to receive orientation and training specific to that area.
4. The Pharmacy Supervisors will maintain the new employee's Pharmacy Orientation Checklist during the orientation process. Successful demonstration of orientation and training in each area is documented in PharmacyKeeper by a pharmacy supervisor.
5. The completed training is confirmed by a pharmacy manager.
6. The orientation program is updated as needed to reflect the current requirements and practices in Stony Brook University Hospital and the Pharmacy Department.



# Stony Brook Medicine

## PHARMACY DEPARTMENT POLICIES & PROCEDURES MANUAL CODE: I-8

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: SICK TIME

EFFECTIVE DATE ORIGINAL POLICY: 11/2003	EFFECTIVE DATE REVISED POLICY: 11/2005	SUPERSEDES POLICY NUMBER: I-8
	LAST REVIEW DATE: 05/2017	

**POLICY:** The procedure to be followed when calling in sick is defined.

**SCOPE:** Pharmacy

**KEYWORDS:** sick time, sick leave, medical leave

**FORMS:** Sick Call Log

**POLICY CROSS REFERENCE:**

**DEFINITION:** **Sick** – a temporary mental or physical impairment of health which disables an employee from full performance of duty.

**PROCEDURE:** **UUP PERSONNEL**

1. UUP personnel calling in sick will call and speak to a Pharmacy
2. Administrator during normal business hours.
3. Any UUP personnel calling in sick shall call no later than **one (1) hour** prior to the start of his/her scheduled shift.
  - a. **Day shift personnel** are to call the department and leave a message with the night pharmacist on duty and then call a second time and speak to a Pharmacy Administrator shortly after 8 AM.
  - b. **Evening personnel** are to call and speak to a Pharmacy Administrator.
  - c. **Night personnel** are to call and speak to an Evening Shift Supervisor while he or she is on duty or the Administrator on call after hours.

4. Abuse of sick leave will subject the employee to Medical Restriction and other disciplinary action.
5. All Sick calls must be documented on the **SICK CALL LOG** posted in the main dispensing area.

#### **CSEA PERSONNEL**

1. CSEA personnel are to call the Pharmacy Supervisor regarding sick leave absence no later than one hour prior to the beginning of his or her assigned work shift.
2. In the absence of an immediate supervisor, the sick employee may leave a message with any member of the departmental staff.
3. The staff member receiving such a message is then obligated to inform the appropriate supervisor or in his/her absence, the Pharmacy Administrator on call or an Assistant Director, whichever is appropriate.
4. Abuse of sick leave will subject the employee to Medical Restriction and other disciplinary action.
5. All Sick calls must be documented on the **SICK CALL LOG** posted in the main dispensing area.



# Stony Brook Medicine

## PHARMACY DEPARTMENT POLICIES & PROCEDURES MANUAL CODE: I-9

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: PHARMACY ACCESS

EFFECTIVE DATE ORIGINAL POLICY: 11/2003	EFFECTIVE DATE REVISED POLICY: 01/2009	SUPERSEDES POLICY NUMBER:
	LAST REVIEW DATE: 10/2017	

**POLICY:** Only pharmacy staff members will have access to the department.

**SCOPE:** Pharmacy

**KEYWORDS:**

**FORMS:**

**POLICY CROSS REFERENCE:**

**DEFINITION:**

**PROCEDURE:** I. Staff access

1. Access to the pharmacy department is controlled by prox card.
  - a) The level of access throughout the department is determined by the Pharmacy Director. Access levels range from 1 to 6.
  - b) Non-Pharmacist staff members will be assigned access level 1 or 2.
  - c) Pharmacists will have access level 3 or above.

Access levels are as follows:

Level 1: Outer entrance doors and staff entrance door

Level 2: Above access plus materials management delivery door.

Level 3: Above access plus controlled drug area and satellites

Level 4: Above access plus investigational drug area

Level 5: Above access plus all internal access doors

Level 6: All access doors, including adjacent rooms

## **II. Non-pharmacy Staff access**

1. Controlled access to the department by non-pharmacy staff will be granted by a pharmacy staff member.
2. Non-pharmacy staff allowed into the department must be accompanied by a pharmacy staff member at all times.





# Stony Brook Medicine

## PHARMACY DEPARTMENT POLICIES & PROCEDURES MANUAL CODE: I-10

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: COMPENSATORY TIME

EFFECTIVE DATE ORIGINAL POLICY: 09/01/1984	EFFECTIVE DATE REVISED POLICY: 01/2009	SUPERSEDES POLICY NUMBER:
	LAST REVIEW DATE: 05/2017	

**PURPOSE:** To clearly define the awarding and use of compensatory time off.

**DEFINITION:** Compensatory time off is time off given to an employee who is not eligible to receive overtime pay for all overtime shifts worked beyond his normal work week, at the request of Pharmacy Administration.

**POLICY:** Compensatory time off will be given to an employee who is not eligible to receive overtime pay and has been requested to work additional hours by Pharmacy Administration.

**PROCEDURE:**

1. If it becomes necessary to request that an employee work additional hours, that employee will be notified as much in advance as possible.
2. Compensatory time off will be awarded for working additional hours or shifts only if a member of Pharmacy management has requested the additional time be worked.
3. Documentation by the requesting Pharmacy manager of the date, time, duration, staff member and reason for the request must be submitted in writing to the Director of Pharmacy Services within 72 hours.
4. Compensatory time off will not be awarded for work that should have been performed during normal working hours as part of an employee's regular responsibilities.

5. Compensatory time for Pharmacists will be granted at the rate of one and one-half hours for each hour worked.
6. Compensatory time for Technicians will be granted at the rate of one and one-half hours for each hour of overtime worked. Compensatory time can be accrued to a maximum of 240 hours. After the maximum is reached, overtime will be paid in cash.
7. The use of compensatory time earned will be coordinated through the appropriate assistant director of pharmacy and will be granted as the department schedule allows.



# Stony Brook Medicine

PHARMACY DEPARTMENT POLICIES & PROCEDURES  
MANUAL CODE: I-11  
(FORMERLY 1-16)

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: EMPLOYEE EVALUATIONS-PHARMACY

EFFECTIVE DATE ORIGINAL POLICY: 07/1994	EFFECTIVE DATE REVISED POLICY: 09/2003	SUPERSEDES POLICY NUMBER:
	LAST REVIEW DATE: 10/2017	

**PURPOSE:** To assist employees to improve job performance and satisfaction.

**SCOPE:** All Pharmacy personnel

**POLICY:**

1. An employee's evaluation will be done by the immediate supervisor or designee of Director of Pharmacy.
2. Written evaluations of all Pharmacy personnel will be completed at least annually.
3. Evaluations will be based upon the employee's performance program.
4. The employee evaluation will objectively evaluate effectiveness of job performance, identifying areas of performance that can be improved upon, with suggested methods for improvement.
5. Evaluations will be reviewed by the supervisor and the employee and will be signed and dated by both. The original is placed in the employee's personnel file in Human Resources, a copy in the employee's departmental folder and a copy given to the employee.



# Stony Brook Medicine

PHARMACY DEPARTMENT POLICIES & PROCEDURES  
MANUAL CODE: I-12  
(FORMERLY I-17)

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: APPROPRIATE ATTIRE FOR PHARMACY STAFF

EFFECTIVE DATE ORIGINAL POLICY: 08/24/1984	EFFECTIVE DATE REVISED POLICY: 11/26/2010	SUPERSEDES POLICY NUMBER: I-10
	LAST REVIEW DATE: 10/2017	

**POLICY CROSS REFERENCE: HR0002 Hospital Uniforms  
HR0023 Identification Badges**

**POLICY:** Pharmacy employees shall be well groomed and dressed in appropriate attire to perform their normal duties. Attire should reflect a high level of service and professionalism.

**PROCEDURE:**

1. Pharmacy employees will be provided with two coats/jackets at the time of employment and one additional uniform each year thereafter.
2. Employees are required to wear the designated uniform and I.D. badge while on duty.
3. Uniform I.D. Badge must be displayed on the outer most garment above the employee's waist.
4. Personal protective clothing will be provided for employees who work with hazardous materials.
5. Employees who resign or are separated from the hospital must return all uniforms to the Linen Services.
6. Employees who return damaged or incomplete numbers of uniforms may be charged for those items.
7. Uniforms are not transferable from one individual to another.

**CODE:**

1. When the issued uniform is a lab coat or jacket, appropriate attire must also be worn.
2. Campaign buttons or any other **commercial** ornamentation is prohibited.
3. The departmental dress code policy must be followed in conjunction with the hospital-wide dress code policy.
4. Employees must wear identification badges at all times while on duty.



# Stony Brook Medicine

## PHARMACY DEPARTMENT POLICIES & PROCEDURES MANUAL CODE: I-13 (FORMERLY I-19)

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: DISASTER PLAN

EFFECTIVE DATE ORIGINAL POLICY: 11/2003	EFFECTIVE DATE REVISED POLICY: 11/2005	SUPERSEDES POLICY NUMBER: I-17
	LAST REVIEW DATE: 10/2017	

**POLICY:** A mechanism is established to ensure that necessary personnel is available and can be mobilized as needed, quickly and efficiently, in the event of a disaster. The Disaster Plan outlines the mechanics of alerting and mobilizing personnel and of allocating hospital resources, with a minimum of delay and confusion, at the time of disaster.

**SCOPE:** Pharmacy

**KEYWORDS:** Disaster, emergency

**FORMS:** The Hospital Emergency Preparedness Manual

**POLICY CROSS REFERENCE:** LD0036 Bomb/Terrorist Threat

**DEFINITION:** A disaster is any event which will generate patients in numbers greater than can be managed by normal patient care systems.

**PROCEDURE:**

1. The appropriate hospital administrator will notify the Director of Pharmacy during business hours. The Director will mobilize the Pharmacy staff. After hours the Administrative Pharmacist on call will be notified.
2. It is the responsibility of the Administrative Pharmacist on call

to mobilize the Pharmacy staff after normal business hours.

3. As additional pharmacy personnel become available, pharmacists may be deployed to areas in the hospital other than the main pharmacy to provide medications and to serve as front line communicators with the main pharmacy staff.



# Stony Brook Medicine

## PHARMACY DEPARTMENT POLICIES & PROCEDURES MANUAL CODE: II-1 (FORMERLY II-2)

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: CLINICAL INTERVENTIONS/CLARIFICATION OF ORDERS/REJECTED ORDERS

EFFECTIVE DATE ORIGINAL POLICY: 11/2003	EFFECTIVE DATE REVISED POLICY: 11/2005	SUPERSEDES POLICY NUMBER: II-21
	LAST REVIEW DATE: 10/2017	

**POLICY:** The procedure for documenting intervention, clarification or rejection of orders is described.

**SCOPE:** Pharmacy

**KEYWORDS:** Intervention, order clarification, rejected orders

**PROCEDURE:**

1. All order clarifications and clinical interventions will be documented using pharmacy intervention program.
2. No medication is to be dispensed if, in the professional judgment of the pharmacist, an order requires clarification.
3. CPOE orders that, in the judgment of the pharmacist, require clarification or revision will be rejected.
4. The Pharmacist who rejects an order will document reason for rejection in Cerner PharmNet, patient note section.
5. It is the responsibility of the pharmacist to contact the prescriber directly if the pharmacist has rejected an order, is seeking clarification, or offering therapeutic information.
6. When a response is delayed and, in the pharmacist's professional judgment, the patient could be harmed by further delay, the pharmacist will escalate with the patient care team



as required to resolve the issue.

7. If the prescriber is not immediately available, the nurse caring for the patient must be contacted and advised of the possible delay in filling the drug order.
8. Any rejected orders remaining at the end of the shift will be documented by the shift supervisor.
9. The shift supervisor will be responsible to contact the prescriber or patient care team to attempt resolution.
10. Any rejected orders that are not resolved by the shift supervisor will be handed off to the oncoming shift supervisor.
11. All discussions with the prescriber pertaining to the patient's drug therapy are recorded and documented in pharmacy intervention program.
12. Once a rejected order is corrected it is the responsibility of the prescriber to cancel the rejected order in Cerner.
13. Summaries on the intervention activity shall be prepared periodically for review by the Pharmacy and Therapeutics Committee and by other performance improvement groups within the organization.



# Stony Brook Medicine

## PHARMACY DEPARTMENT POLICIES & PROCEDURES MANUAL CODE: II-2 (FORMERLY II-3)

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: PHARMACY DISPENSING OF BLOOD DERIVATIVES

EFFECTIVE DATE ORIGINAL  
POLICY: 07/1994

EFFECTIVE DATE REVISED  
POLICY: 11/2005

SUPERSEDES POLICY NUMBER: II-  
55

LAST REVIEW DATE: 10/2017

**POLICY:** The procurement, storage, and distribution of blood derivatives is defined.

**SCOPE:** Pharmacy

**DEFINITIONS:** Blood derivative: A pharmaceutical product derived from human plasma.  
Examples of blood derivatives are human albumin, and human serum globulins.

**PROCEDURE:**

1. The lot number, manufacturer, and expiration date of all blood derivatives dispensed must be recorded in the appropriate dispensing log, along with the name and medical record number of the patient to whom the product was dispensed.
2. A sticker with the lot number, expiration date, and manufacturer will be included with each product dispensed for incorporation into the patient record as necessary.
3. In the event of product recall, procedures will be followed in accordance with the policy on Drug Recalls (MM: 0009).
4. The pharmacist will not routinely pool blood products to dispense.
5. Albumin and IVIG in premixed solution will be dispensed in the manufacturer's original container labeled for the individual patient.



# Stony Brook Medicine

## PHARMACY DEPARTMENT POLICIES & PROCEDURES MANUAL CODE: II-3 (FORMERLY II-4)

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: MANNITOL WARMING

EFFECTIVE DATE ORIGINAL POLICY: 11/2003	EFFECTIVE DATE REVISED POLICY: 11/2005	SUPERSEDES POLICY NUMBER: II-50
	LAST REVIEW DATE: 10/2017	

**POLICY:** Mannitol 20% solution 500mL IV bags and Mannitol 25% in glass vials have a tendency to crystallize at room temperature. In order to keep these solutions from crystallizing a small number of bags and vials are to be kept in a warmer so that they will be ready to use for patient care purposes.

**SCOPE:** Pharmacy

**POLICY CROSS REFERENCE:** MM: 0013, Storage and Handling of Medication.

**KEYWORDS:** Mannitol, Beyond Use Date (BUD)

**PROCEDURE:**

1. The warmer that is used for Mannitol will not exceed 104 degrees Fahrenheit or 40 degrees centigrade.
2. It is recommended that the temperature of the warmer be kept between 86 and 104 degrees Fahrenheit or 30 and 40 degrees centigrade.
3. A temperature log is attached to the door of the warmer and it will be the responsibility of the assigned staff members to check and record the temperature of the warmer on the log on a daily basis.
4. The beyond use date (BUD) of Mannitol bags or glass vials in the warmer is 14 days.

5. The BUD date must be placed on all items in the warmer.  
(BUD = Date of Placement + 14 days)
6. Any item in the warmer with date older than BUD must be removed and discarded.



# Stony Brook Medicine

## PHARMACY DEPARTMENT POLICIES & PROCEDURES MANUAL CODE: II-4 (FORMERLY II-5)

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: UNIT-DOSE DRUG DISTRIBUTION SYSTEM

EFFECTIVE DATE ORIGINAL POLICY: 08/24/1984	EFFECTIVE DATE REVISED POLICY: 08/31/1987	SUPERSEDES POLICY NUMBER: III-3
	LAST REVIEW DATE: 10/2017	

**POLICY:** The Pharmacy uses a Unit Dose method of distribution as a method for dispensing medications to in-patients. The objectives of the Unit Dose System of Distribution are to:

1. Minimize medication errors
2. Minimize dose preparation by nurses.
3. Increase drug use control
4. Minimize drug waste and pilferage
5. Enhance the billing accuracy
6. Enhance the overall quality of patient care

**SCOPE:** Pharmacy

**KEYWORDS:** Unit-dose, dispensing

**DEFINITIONS:** Unit-Dose System: Medication is dispensed to Patient Care Areas in single, individually labeled doses. Each dose provides the name and strength of the medication, along with both a manufacturer's lot number and expiration or a Pharmacy lot number and beyond-use date.

**PROCEDURE:**

1. For medications not dispensed via automated dispensing machines, the Pharmacy Department will distribute drugs using a centralized exchange system. Plastic bags containing patient medications will be exchanged on a daily basis
2. Medication exchange will occur at specified times throughout the day. The medication bag for each patient will be placed in the patient specific cassette drawer on the nursing unit.
3. Upon verification of a prescriber's order for medication, the Pharmacy Department will dispense an appropriate quantity of medication for

each patient to coincide with administration times until the next cart exchange.

4. Medication will continue to be provided daily until the order is discontinued, the automatic stop date is reached, or the patient is discharged.
5. All doses of medication intended for administration to patients at Stony Brook University Hospital will be individually packaged. Each packaged medication will be labeled as to name and strength of drug, lot number and beyond-use date.
6. Those drugs requested on new orders will be sent to the appropriate nursing unit in a zip-locked bag labeled with a computer-generated label. The quantity of medication contained in the bag will be sufficient to last until the next cart exchange time for each unit.
7. Cart fill drug orders will be automatically filled for the following 24-hour period. The medications required for cart fill will be placed into the patient's medication bag. The medication bag will be placed in a nursing unit bin.
8. A computer generated "cart fill list" of each medication profile will be generated daily. Each patient's medications will be listed along with the frequency, duration, and quantity necessary for the 24- hour period.
9. The pharmacy technician will fill the patient medications using the automated carousel and autopack technologies. Once the cart fill process for a particular patient care unit is completed, the technician will initial the cart fill list.
10. The pharmacist assigned to cart checking will perform the following:
  - a. Check the contents of each patient medication bag against the hard copy printout for correctness and accuracy.
  - b. Make any appropriate corrections or changes.
  - c. Communicate any errors to the filling technician
  - d. Sign off on the hard copy cart fill list.



# Stony Brook Medicine

## PHARMACY DEPARTMENT POLICIES & PROCEDURES MANUAL CODE: II-5 (FORMERLY II-6)

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: PROCESSING OF MEDICATION ORDERS

EFFECTIVE DATE ORIGINAL POLICY: 08/27/1983	EFFECTIVE DATE REVISED POLICY: 08/24/1987	SUPERSEDES POLICY NUMBER: III-18
	LAST REVIEW DATE: 10/2017	

**POLICY:** The methodology to be employed in processing new medication orders is defined.

**SCOPE:** Pharmacy

**PROCEDURES:**

1. Receipt of Orders
  - a. Orders are received via Cerner Power Chart system, digital imaging system, or pneumatic tube system.
  - b. Cerner and the digital image order system are setup to identify and prioritize STAT orders.
  - c. Order sheets brought to the pharmacy manually are scanned into the digital imaging system and processed accordingly.
2. Order Verification and Entry
  - a. All medication orders must be verified, or entered onto the patient's medication profile in Cerner PharmNet before medication can be dispensed.
    - Using ID and password sign on to the PharmNet System.
    - The CPOE queue will open up automatically.
    - Select the order based on priority
    - Select **view in profile** option
    - Review the order in the patient profile with all warning and alerts.
    - If order is correct the Pharmacist will choose the verify option and press apply button.
    - To complete verification process the pharmacist must press the

submit button to add the order to the profile.

3. Verified orders move through Cerner to the automated carousel and autopack machine to be filled or to a Pyxis ADC to be vended.
4. IV Orders are verified in the same manner as indicated above.
  - a. Large Volume (**LVP**) and Piggybacks (**IVPB**)
  - b. When the order is verified, labels for a 24-hour supply of the required drug will print in the IV bench area.
  - c. The labels will be split and attached to the IVPB bag for premixed medications by the Pharmacy technician. For compounded medications this is done by the pharmacist. Each individual initials the “fill” space on the label.
  - d. All IV orders are then checked by a second pharmacist and initialed as “checked” before any medication is dispensed.
5. Product Assignment: certain orders (depending on the prescriber method of entry) may require the pharmacist to perform the additional task of assigning a product. When required the pharmacist will use his/her professional judgment to assign the correct product to fill the order.
6. **STAT Orders:** the departmental goal for medication required stat is to have it available to the Nurse within 10 minutes.
7. Pharmacist performing order verification/entry will prioritize the work queue based on the order priority.
  - a. STAT will always come first
  - b. NOW will receive priority after STAT
  - c. Routine will receive priority after NOW.





# Stony Brook Medicine

PHARMACY DEPARTMENT POLICIES & PROCEDURES  
MANUAL CODE: II-6  
(FORMERLY II-8)

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: PYXIS ADS-CRITICAL OVERRIDE

EFFECTIVE DATE ORIGINAL POLICY: 11/2003	EFFECTIVE DATE REVISED POLICY: 11/2003	SUPERSEDES POLICY NUMBER: III-58
	LAST REVIEW DATE: 01/2015	

**POLICY:**

Pyxis Profile Stations will be set to critical override status in the event of failure of the Cerner pharmacy computer system or computer interface failure causing loss of communication between the Cerner and Pyxis systems. The purpose of this is to give Nursing personnel the ability to retrieve medication from the Pyxis MedStation during a time of computer system or communications failure. The Pharmacy IT Coordinator, Pharmacy Director, or Assistant Director must approve setting the Pyxis Profile Stations on critical override status. When full computer operations have been returned, the critical override will be turned off.

**SCOPE:**

Pharmacy

**KEYWORDS:**

Computer, downtime

**POLICY CROSS-REFERENCE:**

IM:0013 Computer Downtime  
II-7 Computer Downtime Procedures

**DEFINITIONS:**

**PROCEDURE:**

**A. Pyxis Profile Station Identification**

Pyxis Profile Stations capable of being set to override status are distinguished by the letters "RX" under the device type label on the machine. The following locations at Stony Brook University Hospital have Pyxis Profile Stations: 5L1, 8SP, 9NP, 9SP, 10NP, 11NP, 11SP, 12AP, 12NP, 12SP, 15NP, 15SP, 16NP, 16SP, 17SP, 18NP, 18SP, 19NP, 19SP, BURN, CTICU, and MRNP.

## **B. Enabling Critical Override**

If enabling critical override is assigned to a pharmacist that does not have Pyxis Manager status, the pharmacist may obtain temporary authorization to perform the task by utilizing the password kept in a sealed envelope in the Pyxis Operations Manual. The password for temporary authorization will be changed after this use and a new one created.

Enabling critical override should be performed from the main Pyxis console in the pharmacy. In the event that the main Pyxis console is unable to communicate with the Pyxis Profile Station(s), enabling critical override must be performed from the station.

1. From the console:
  - a. Log onto console.
  - b. Go to System set-up.
  - c. Go to Devices
  - d. Go to Edit.
  - e. Go to RX.
  - f. Choose Enable (under critical override).
  - g. Save (If you do not save, critical override will not be enabled and medications will not be accessible.)
2. From the station:
  - a. Log onto station.
  - b. Go to Main Menu.
  - c. Go to System Menu.
  - d. Go to Station Options.
  - e. Choose Enable (under critical override).
  - f. Save (If you do not save, critical override will not be enabled and medications will not be accessible.)

## **C. Communication to Nursing of Critical Override implementation**

When the above procedure is complete, the pharmacist who enabled the override will call the Nursing Office at extension **4-2960** to inform them that the Pyxis Profile Stations are set to critical override status. The Nursing Office will then notify each patient care unit of the critical override status, and have a nurse remove the Pyxis override sign from the narcotic drawer and place the sign on top of the Pyxis Profile Station as notification to the other nursing staff.

## **D. Disabling Critical Override**

1. From the console:
  - a. Log onto console.

- b. Go to System set-up.
- c. Go to Devices
- d. Go to Edit.
- e. Go to RX.
- f. Deselect Enable (click in box to remove check).
- g. Save (If you do not save, critical override will not be disabled and medications will still be accessible.)

2. From the station:

- a. Log onto station.
- b. Go to Main Menu.
- c. Go to System Menu.
- d. Go to Station Options.
- e. Deselect Enable (click in box to remove check).
- f. Save (If you do not save, critical override will not be disabled and medications will still be accessible.)

**E. Communication to Nursing of Normal Operations**

When the above procedure is complete, the pharmacist who disabled the override will call the Nursing Office at to inform them that the Pyxis Profile Stations are no longer at critical override status. The Nursing Office will then notify each patient care unit and have a nurse replace the Pyxis override sign to the narcotic drawer.



# Stony Brook Medicine

PHARMACY DEPARTMENT POLICIES & PROCEDURES  
MANUAL CODE: II-7  
(FORMERLY II-9)

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: OPERATING ROOM SATELLITE PHARMACY

EFFECTIVE DATE ORIGINAL POLICY: 08/24/1984	EFFECTIVE DATE REVISED POLICY: 08/31/1987	SUPERSEDES POLICY NUMBER: III-3
	LAST REVIEW DATE: 01/2015	

## I. General:

1. The satellite pharmacy will operate from 6:00 AM to 6:00 PM, Monday through Friday.
2. Scope of services will include order verification, preparation and dispensing of intra-operative medications, monitoring drug therapy, supplying anesthesia medication trays, dispensing and control of controlled substances kits.

## 2. Dispensing of Drugs – Non-Controlled:

1. Medications routinely required by Anesthesia will be dispensed in a tray, which will be placed in the Anesthesia Cart. The contents of trays will be decided jointly by Anesthesiology and Pharmacy.
2. The pharmacy technician will remove and replace the trays each morning
  - The tray will be restocked by the pharmacy technician and checked by the Pharmacist.
  - Anesthesia can request an additional supply of medication from the satellite.
3. Medications not contained in the trays will be dispensed pursuant to an order from a prescriber by the pharmacy on an "On Call" basis.
4. There are several kits maintained by the satellite pharmacy as required by anesthesia Eye Kit, Transplant Kit, Endoscopy Kit, and a Special Procedure Kit.
5. The main Pharmacy will review and verify all orders for those patients in OR, AICU, CTICU after 6:00 PM.
6. A supply of trays and other selected medications will be kept in the locked

anesthesia prep room and Pyxis for after-hours use. The keys for this box will be kept by the nurse anesthetist or anesthesiologist on duty.

**3. Controlled Substance Procedure During Hours of Operation**

- a. The OR Pharmacist will obtain supplies of controlled substances from the Central Pharmacy using an OR Pharmacy Narcotic Order form.
- b. The OR satellite pharmacy is responsible for the replenishment and reconciliation of the OR Pyxis machine, the L&D Pyxis machine, Endoscopy Pyxis machine, Pre-surgical Pyxis machine, and Pyxis Anesthesia System.
- c. Anesthesiologists and CRNAs will utilize the Pyxis Anesthesia System to remove medication in procedural areas that are equipped with the anesthesia system. Controlled substances removed from Pyxis anesthesia system will be reconciled against the Cerner anesthesia record and reports generated from Pyxis Knowledge Portal.
- d. For Procedural areas that do not have Pyxis Anesthesia system. Anesthesiologists will requisition controlled substance kits from the OR Pharmacy by signing out either a regular or open heart kit. One kit is issued per case.
- e. Required additional items are requisitioned and added to the kit by the pharmacist. Each addition is entered on the requisition along with the kit issued to the anesthesiologist.
- f. At the close of each case, the requisition, reconciliation form, a copy of the Anesthesia Record, and the kit containing any unused controlled substances are returned to the OR Pharmacy, including any waste (i.e. partial containers and drawn up syringes).
- g. The anesthesia record and the drugs returned are reconciled by the pharmacist. The Pharmacist checks that the record is complete and accurate when compared to the kit returned. When the kit is reconciled, the requisition is completed and stapled to the original and deductions from the narcotic log book are made.
- h. Any discrepancy found that cannot be resolved is reported to the Chairman of the Anesthesiology Department and the Director of Pharmacy.
- i. When reconciliation is complete the kit may then be restocked and resealed.
- j. Other reusable controlled substances are returned to inventory.
- k. A random sample of daily waste returned (i.e. partial containers and syringes) by the anesthesiologists is subject to light refraction with a refractometer by the pharmacist.

- l. The daily refractometer testing is logged into a daily record by the pharmacist.
- m. Any waste that returns a refraction reading outside the known normal value is reported to the Chairman of Anesthesia, and Director of Pharmacy, that the individual practitioner's narcotic waste is then subject to continued testing.



# Stony Brook Medicine

## PHARMACY DEPARTMENT POLICIES & PROCEDURES MANUAL CODE: III-1

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: PREPARATION OF LARGE VOLUME PARENTERAL SOLUTIONS

EFFECTIVE DATE ORIGINAL POLICY: 02/1986	EFFECTIVE DATE REVISED POLICY: 05/2003	SUPERSEDES POLICY NUMBER: IV-17
	LAST REVIEW DATE: 01/2015	

**POLICY:** Work-flow patterns, labeling and other procedures required to prepare a Large Volume Parenteral solutions (LVP) are defined and delineated.

**SCOPE:** Pharmacy

**PROCEDURE:** Large volume parenteral (LVP) solutions shall routinely be prepared and dispensed by Pharmacy personnel in accordance with departmental procedures for sterile compounding and manufacturing.

1. Verification or entry of an order for a LVP on the Pharmacy Information System will result in the generation of a label at the IV bench area.
  - a) Certain LVPs may be purchased as premixed solutions. If the order is for one of these items, the computer generated label is affixed directly to the bag/bottle.
  - b) If the order is for an admixture that must be prepared, the admixture is to be prepared in accordance with procedures for sterile manufacturing. The IV admixture label is affixed to the final container, without obscuring the name of the vehicle. The label is initialed by the preparing pharmacist.
  - c) Every large volume parenteral must be double checked by two pharmacists prior to dispensing. The checking pharmacist confirms that the solution, ingredients, and quantities are correct and places his/her initials on the LVP label.
  - d) When a pharmacist checker not available and a patient needs a pharmacist-prepared LVP, a nurse or physician may act as the checker of the solution.
2. The pharmacy is to dispense a 24 hour supply of LVP to the nursing unit.

3. Unopened premixed IVs that have been returned to the pharmacy may be re-dispensed in accordance with the manufacturer's expiration date or the Pharmacy's original beyond use date.
4. Solutions that are being titrated and replacement (with or without additives) for nasogastric effusion, urine output, etc. will be supplied on a one liter or one bag basis, with subsequent bags ordered as needed by the unit using the Cerner Medication Request function.
5. All LVPs prepared by the pharmacy will be prepared in the clean room under a horizontal laminar flow hood. (Exception: chemotherapy will be prepared under a biological safety cabinet.)
6. Labels are to be affixed to the container in such a way that the Nurse will be able to read the label when the LVP is hung on the patient.





# Stony Brook Medicine

## PHARMACY DEPARTMENT POLICIES & PROCEDURES MANUAL CODE: III-2

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: PERPARATION OF PIGGYBACK PARENTERAL SOLUTIONS

EFFECTIVE DATE ORIGINAL POLICY: 02/1986	EFFECTIVE DATE REVISED POLICY: 10/2003	SUPERSEDES POLICY NUMBER: IV-19
	LAST REVIEW DATE: 01/2015	

**POLICY:** 1. Standard operating procedures are used to prepare intravenous piggyback (IVPB) solutions.

2. A double check system is used to ensure accuracy.

**SCOPE:** Pharmacy

**PROCEDURE:**

- I. Order Verification or Entry of IVPBs:
  - A. Verification or Entry of an order for an IVPB preparation into the computer results in the generation of an IV label.
  - B. A pharmacist checks the IV label against the prescriber's order in Cerner PharmNet to ensure that the order is correct.
  - C. If an order is entered by pharmacist the second check is to verify transcription and entry are correct.
  - D. For hardcopy orders entered by a pharmacist, the pharmacist's initials and a check mark on the prescriber's order sheet or on a duplicate IV label placed on the prescriber's order sheet is evidence that correct order entry was confirmed.
- II. Preparation of IVPB bags or syringes:
  - A. Commercially-Prepared IVPBs:
    1. Whenever possible, commercially prepared IVPBs are purchased.
    2. When the order is for a commercially prepared IVPB, the computer-generated IV label is affixed to the bag without obscuring the manufacturer's descriptive information.
    3. The technician or pharmacist labeling the IVPB bags places

his/her initials in the "Filled By" space.

4. The pharmacist checking the bag places his/her initials in the "Checked By" space.

B. Pre-Packaged (In-House) IVPBs:

1. Certain IVPBs are prepared in bulk by a pharmacy technician and checked by a pharmacist.
2. Prior to manufacturing, the technician reviews the standard operating procedure (from the IV Manufacturing Log) and assembles the bags and IV components outside of the clean room.
3. A pharmacist reviews the bags and IV components prior to manufacturing.
4. Each batch is documented in the IV Manufacturing Log and signed by both the technician and pharmacist.
5. The computer generated IV label is affixed to the bag without obscuring the manufacturer's descriptive information.
6. The technician or pharmacist labeling the IVPBs places his/her initials in the "Filled By" space
7. The pharmacist checking the bag places his/her initials in the "Checked By" space.

C. Extemporaneously-Prepared IVPBs:

1. If the order is for an IVPB that must be prepared, the solution and additives are assembled outside of the clean room and brought to the laminar flow hood. The admixture is prepared in accordance with the procedures for sterile manufacturing.
2. The IVPB label is affixed to the container (without obscuring the name of the vehicle) and initialed by the preparing pharmacist.
3. The checking pharmacist confirms that the solution and ingredients used to prepare the solution are correct and places his/her initials on the IVPB label.
4. When a pharmacist is not available to perform the double-check and it is in the best interest of the patient to receive the medication prior to the availability of a second pharmacist, a nurse or physician may check the preparation by comparing the patient-specific label on the IV bag, as well as any manufacturer's labeling on the IV bag, to the order in the chart.



# Stony Brook Medicine

## PHARMACY DEPARTMENT POLICIES & PROCEDURES MANUAL CODE: III-3

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: BEYOND USE (STORAGE) DATING FOR COMPOUNDED STERILE PRODUCTS

EFFECTIVE DATE ORIGINAL POLICY: 01/2005	EFFECTIVE DATE REVISED POLICY: 08/2006	SUPERSEDES POLICY NUMBER:
	LAST REVIEW DATE: 01/2018	

**POLICY:** Storage conditions for sterile compounded products (CSPs) are in accordance with USP 797 guidelines.

**SCOPE:** Pharmacy

**KEYWORDS:** Beyond use date (BUD), expiration date, sterile

**DEFINITIONS:**

**CSP:** Sterile Compounded Product.

**BUD:** Beyond Use Date. Date or time after which a compounded sterile product (CSP) cannot be used and must be discarded because its required quality characteristics cannot be ensured.

**Expiration Date:** Identifying the time during which a conventionally manufactured drug product may be expected to maintain its labeled identity, strength, quality, and purity, provided it is kept under the labeled storage conditions

**In-use time:** Time before which a conventionally manufactured product or a CSP must be used after it has been opened or after a container closure has been penetrated.

**PROCEDURE:** The Pharmacist will assign a beyond use date to all *compounded* sterile products. This dating is based on the storage conditions (time and temperature), the risk level of the CSP. The shorter of the two dates will be used.

**Category 1 CSPs:** Made in a primary engineering control (PEC) in a non-classified area and in compliance with minimum quality controls for Category 1 CSPs

Assigned a **maximum Beyond Use Date (BUD)** of

- 12 hours or less at controlled room temperature.
- 24 hours or less if refrigerated.

**Category 2 CSPs:** Prepared in an ISO5 primary engineering control (PEC) in a ISO7 classified buffer area. Assigned BUD based on sterilization method, sterility testing, preservatives, and storage temperature

BUDs for CATEGORY 2 CSPs						
	Sterility achieved through	Sterility Testing?	Preservative	Room Temperature	Refrigerator	Freezer
				Sterile ingredients 6 DAYS	Sterile ingredients 9 DAYS	Sterile ingredients 45 DAYS
				Nonsterile ingredients 4 DAYS	Nonsterile ingredients 4 DAYS	Nonsterile ingredients 4 DAYS
			YES	28 DAYS	42 DAYS	45 DAYS
			NO	28 DAYS	42 DAYS	45 DAYS
			YES	42 DAYS	42 DAYS	45 DAYS
				NO	14 DAYS	28 DAYS
	YES			28 DAYS	42 DAYS	45 DAYS
			NO	28 DAYS	42 DAYS	45 DAYS
			YES	42 DAYS	42 DAYS	45 DAYS

Pharmaceutical Compounding—Sterile Preparations (Chapter 797). In: The United States Pharmacopeia, 39th rev., and the National Formulary, 34 ed. Rockville, MD: The United States Pharmacopeial Convention; 2016.

Medications dispensed using the Add-a-vial system or equivalent, are *not* considered compounded and will be excluded from these guidelines.

IN-USE TIMES	
AMPULES	Use immediately after opening and passing through a sterile particulate filter
PHARMACY BULK PACKAGE	As Specified by the manufacturer
SINGLE DOSE Container (bag, bottle, syringe)	6 HOURS
Multiple Dose Container	28 DAYS, unless otherwise specified by the original compounder
CSP: Compounded single-dose container	6 HOURS
CSP: Compounded stock Solutions	6 HOURS
CSP: Compounded Multiple dose container	28 DAYS, unless otherwise specified by the original compounder
Pharmaceutical Compounding—Sterile Preparations (Chapter 797). In: The United States Pharmacopeia, 39th rev., and the National Formulary, 34 ed. Rockville, MD: The United States Pharmacopeial Convention; 2016.	

#### **URGENT-USE CSPs:**

Prepared in worse than ISO Class 5 air quality due to urgent need only. Intended for a single patient. Compounding procedure is a continuous process not to exceed 1 hour. Administration begins upon completion of CSP preparation. Aseptic technique is followed.

#### **Procedures minimized:**

- Contact with non-sterile surfaces
- Introduction of particulate matter or biological fluids
- Mix-ups with other CSPs



# Stony Brook Medicine

PHARMACY DEPARTMENT POLICIES & PROCEDURES  
MANUAL CODE: III-4  
(FORMERLY III-5)

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: ENVIRONMENTAL PROCEDURES FOR THE STERILE COMPOUNDING AREA

EFFECTIVE DATE ORIGINAL POLICY: 01/2005	EFFECTIVE DATE REVISED POLICY: 01/2018	SUPERSEDES POLICY NUMBER:
	LAST REVIEW DATE: 01/2018	

- POLICY:** The sterile compounding area is kept in a state of general cleanliness at all times.
- Food and beverages will **never** be introduced into the ante room or clean room areas.
  - No shipping or other external cartons, cardboard, or paper towels are taken into the clean room.
  - Environmental controls are compliant with Pharmaceutical Compounding-Sterile Preparation (Chapter 797).

**SCOPE:** Pharmacy/Housekeeping

**KEYWORDS:** Environment, Clean room, Sterile compounding

**PROCEDURES:**

1. Floor is swept and mopped daily by the environmental services staff. Hospital approved sanitizing agents for floors will be utilized. When complete this is documented on the environmental cleaning log.
2. Cleaning tools such as wipers, buckets, sponges and mops shall be non-shedding and **used only in the clean room**. Separate cleaning supplies will be used for the general pharmacy. At the end of the work shift all equipment and supplies are cleaned and/or stored.
3. All counter areas, and easily reachable exposed flat surfaces will be cleaned daily using a 797 compliant disinfectant.
4. All shelves and exposed flat surfaces are cleaned and sanitized every month,

using a 797 compliant disinfectant.

5. In the anteroom all packing and boxes are removed as soon as incoming supplies are unpacked.
6. Unpackaged IV products shall have all loose cardboard and paper remnants removed before placing in storage.
7. Supplies are not left on the floor or stored on top of the laminar flow hoods at any time.
8. Waste containers should be emptied as necessary during the course of the work day.
  - a. Waste containers are removed from the clean room to be emptied.
  - b. Removal of the plastic bag liner will be done in the ante room away from laminar hoods to minimize airflow disruption in the clean room area.

#### Cleaning Requirements for Sterile Compounding Area

Minimum Frequency for Cleaning of Specific Sites	
ISO Class 5 PEC	Beginning of each shift Before each batch Every 30 minutes when compounding After spills When surface is contaminated
Counters and easily cleanable work surfaces	Daily
Floors	Daily
Walls	Monthly
Ceilings	Monthly
Storage shelving	Monthly

Environmental Monitoring Requirements (Adapted from USP Chapter 797)		
Parameter	Monitored by	Frequency
Temperature	Compounding personnel	Daily
Pressure differential or velocity across line demarcation	Compounding Personnel Qualified Certifier	Daily (at a minimum) Every 6 Months
Nonviable particles	Qualified Certifier	Every 6 months
Surface sampling	Compounding personnel / Qualified certifier	Every 6 months or after significant changes in procedures or cleaning practices
Electronic device sample of viable particles	Qualified certifier	Every 6 months

#### Recommended Action Levels for Microbial Contamination

(cfu per cubic meter [1000 liters] of air per plate adapted from USP <797>)

Classification	Air Sample
ISO Class 5	>1
ISO Class 7	>10
ISO Class 8 or worse	>100

- Any cfu count that exceeds its respective action level receives prompt re- evaluation of the adequacy of:
  - Personnel work practices.
  - Cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location.
- An investigation into the possible source of the contamination shall be conducted. Sources could include HVAC systems, damaged HEPA filters, and changes in personnel garbing or work practices.



3. The source of the problem shall be eliminated, the affected area cleaned, and resampling performed.
4. Action levels are determined on the basis of cfu data gathered at each sampling location.



# Stony Brook Medicine

PHARMACY DEPARTMENT POLICIES & PROCEDURES  
MANUAL CODE: III-5  
(FORMERLY III-6)

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: HAND HYGIENE

EFFECTIVE DATE ORIGINAL POLICY: 01/2005	EFFECTIVE DATE REVISED POLICY:	SUPERSEDES POLICY NUMBER:
	LAST REVIEW DATE: 01/2018	

**POLICY:**

Proper hand hygiene is used by personnel who compound sterile products. All personnel will wash their hands and up to the elbow of each arm every time prior to entering the clean room to begin compounding. Sterile gloves will be worn at all times while compounding sterile medications.

Artificial nail enhancements are not to be worn. Non-chipped polish is permitted, but anything applied to natural nails other than polish is considered an enhancement. This includes, but is not limited to: artificial nails, tips, wraps, appliques, acrylic, gels or other additional items applied to the nail surface.

Finger nails are to be neatly trimmed and maintained at a reasonable length. (No longer than ¼" beyond the finger tip).

**SCOPE:**

Pharmacy

**KEYWORDS:**

Handwashing, gloves, hand hygiene

**POLICY CROSS-REFERENCE: IC: 0003 Hand Hygiene Policy**

**PROCEDURES:**

1. All jewelry must be removed from hands, wrists, and arms prior to entering the clean area.
2. Commercial hand lotions should not be used when working in the clean area. Hand lotions have been shown to have a high microbial count.
3. Hand washing/sanitizing will reduce the microbial count, but the count will

begin to increase with time. Therefore, every two hours personnel must discard used gloves, sanitize hands and re-glove.

**Indications for Hand washing:**

Upon arriving at work

Before eating

After using a restroom

Upon completion of scheduled shift

**After 5 applications of alcohol based gel**

**HAND HYGIENE PROCEDURE**

- Remove debris from underneath fingernails using a nail cleaner under warm running water.
- Wash hands and forearms up to the elbows with unscented soap and water for at least 60 seconds.
- Dry hands and forearms completely with low-lint disposable towels or wipes.
- Immediately prior to donning sterile gloves, apply an alcohol-based hand rub with sustained antimicrobial activity.
- Allow hand rub to dry before donning sterile gloves.
- [Handwash.PDF](#)



# Stony Brook Medicine

PHARMACY DEPARTMENT POLICIES & PROCEDURES  
MANUAL CODE: III-6  
(FORMERLY III-7)

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: CLEANING LAMINAR FLOW HOODS AND BIOLOGICAL SAFETY CABINETS

EFFECTIVE DATE ORIGINAL POLICY: 01/2005	EFFECTIVE DATE REVISED POLICY: 11/2005	SUPERSEDES POLICY NUMBER:
	LAST REVIEW DATE: 01/2018	

**POLICY:** Laminar Flow Hoods and Biological Safety Cabinets are maintained free of extraneous materials and are cleaned prior to and immediately after each procedure to prevent contamination of compounded sterile products.

**SCOPE:** Pharmacy

**KEYWORDS:** Hoods, cleaning, BSC, clean bench, laminar flow hood

**DEFINITIONS:**

**BSC:** Biological Safety Cabinet

**PEC: Primary engineering control** refers to either a BSC or horizontal laminar flow hood

**Cleaning:** To make free from direct, organic matter, salts. First step of any disinfection process.

**Deactivation:** Treatment of a HD with another chemical, heat, ultraviolet light, or other agent to create a less hazardous agent.

**Decontamination:** Removal or neutralization of a contaminant. This can be microbiological or chemical.

**Disinfection:** Using specialized cleansing techniques and/or agents on inanimate objects that destroy or prevent growth of microorganisms capable of infection.

## PROCEDURES:

1. The hood will remain in continuous operation. If not in continuous operation, hood must be turned on and allowed to run for at least 60 minutes prior to compounding procedure.
2. The work area will be kept free of all extraneous materials.
3. All surfaces within hood workspace will be cleaned prior to and at the end of each work shift.
4. Cleaning the surface of the PEC first remove loose material and residue from spills using a suitable cleaning agent. With sterile wipes clean the PEC with sterile water for irrigation then disinfect with sterile 70% isopropyl / ethyl alcohol.
5. Cleaning will be performed immediately after compounding procedure, finished product and all related supplies will be removed from the hood.

### MINIMUM FREQUENCY OF CLEANING AND DISINFECTING SURFACES IN CLASSIFIED AND SEGREGATED COMPOUNDING AREAS

ISO Class 5 Primary Engineering Control (LAFW, BSC, CAI, CACI)	At the beginning of each shift, before each batch, not longer than 30 minutes following the previous surface disinfection when ongoing compounding activities are occurring, after spills, and when surface contamination is known or suspected
Work surfaces outside the PEC (in buffer area and/or segregated compounding area)	Daily
Floors	Daily
Walls	Monthly
Ceilings	Monthly
Storage Shelving	Monthly
Pharmaceutical Compounding – Sterile Preparations (Chapter 797). In: The United States Pharmacopeia, 39 <sup>th</sup> rev., and the National Formulary, 34 ed. Rockville, MD: The United States Pharmacopeial Convention; 2016.	

### Cleaning Technique:

- Clean “difficult to clean” areas first.
- Wiping motion moves from the cleanest area to the dirtiest, most critical to least critical.
  - top to bottom
  - back to front
- Use a clean wipe surface with every section of the PEC to avoid re-depositing

contaminants.

- Wipe in straight lines with overlapping strokes to avoid gaps.
- Never wipe in a circular motion.

#### **CLEANING the HORIZONTAL LAFW:**

Clean with sterile water, then disinfect with sterile 70% isopropyl alcohol on sterile wipes

Wiping movement:

- Start in a rear corner near HEPA filter grill and move along the filter grill
- Use overlapping strokes working toward the front of the LAFW
- Wipe side-to-side for ceiling and work surface
- Wipe top to bottom on the sides

Clean and disinfect in order of:

1. Ceiling
2. HEPA filter grill
3. Bar and hooks (if any)
4. Side panel
5. Work surface

#### **CLEANING C-PEC AND OTHER DEVICES USED FOR COMPOUNDING HAZARDOUS DRUGS**

##### **1. Deactivation**

- Treatment of HD to create less hazardous agent
- Chemical deactivation preferred, no single process will deactivate all HDs

##### **2. Decontamination**

- Inactivation, neutralization, removal of HDs
- Usually occurs by chemical means

##### **3. Cleaning**

- Removal of soil from objects and surfaces
- Water with detergents, enzymatic products, or germicidal agent

##### **4. Disinfecting**

- Chemical agent destroys or inhibits growth of microorganisms
- Frequency: beginning of workday, between batches, beginning of shift, routinely during compounding, anytime C-PEC has been powered off
- Sterile Water rinse

#### **CLEANING BIOLOGICAL SAFETY CABINET (BSC)**

**Clean with a sterile germicidal detergent, rinse with sterile water followed by a disinfecting agent, using sterile wipes.**

- Wiping movement:
- Starts in rear corner near HEPA filter grill and move along the filter grill
- Rear, side and front glass panels: use overlapping strokes working toward the bottom of the BSC/CACI

- Work surface: use overlapping strokes working rear to front of the BSC/CACI

**Clean and disinfect in order of:**

1. HEPA filter grill
2. Rear wall
3. Side panels
4. Bar and hooks (if any)
5. Glass shield
6. Work surface



# Stony Brook Medicine

PHARMACY DEPARTMENT POLICIES & PROCEDURES  
MANUAL CODE: III-7  
(FORMERLY III-8)

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: PERSONAL PROTECTIVE EQUIPMENT

EFFECTIVE DATE ORIGINAL POLICY: 01/2005	EFFECTIVE DATE REVISED POLICY:	SUPERSEDES POLICY NUMBER:
	LAST REVIEW DATE: 01/2015	

**POLICY:**

All personnel working within the sterile compounding area will be properly attired:

- Gowns must be worn at all times at all times while working in the clean room.
- Shoe Covers and Hair Covers shall be worn at all times.
- Gown shall be of non-shedding material with elastic cuffs.
- All jewelry shall be removed from the hands and wrists.
- Dressing shall be done the anteroom of the compounding area.
- A gowned individual is never to leave and then reenter the clean room without re-gowning.

**SCOPE:**

Pharmacy

**KEYWORDS:**

gown, personal protective equipment

**POLICY CROSS-REFERENCE:** III-9, III-7, JCAHO, IC 4.1, MM 4.2, NPSG #7

**PROCEDURES:**

1. Only properly trained pharmacy personnel will enter the dressing area/anteroom. The door should be closed upon entry.
2. Gloves will be put on after hands and wrists are washed.
3. Personnel about to prepare a product that contains a hazardous material and anyone preparing to enter the chemotherapy lab must wear specially designated latex-free nitrile gloves and specialty



chemotherapy gowns.

4. All staff must re-glove any time the gloves are damaged or a contaminated surface is touched. Hands must be sanitized prior to re-gloving.
5. Gowns and gloves must never leave and re-enter the clean room/anteroom area.



# Stony Brook Medicine

## PHARMACY DEPARTMENT POLICIES & PROCEDURES MANUAL CODE: III-8 (FORMERLY III-9)

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: ANTINEOPLASTIC AGENTS – USE PERSONAL PROTECTIVE EQUIPMENT FOR  
PREPARATION

EFFECTIVE DATE ORIGINAL POLICY: 08/1987	EFFECTIVE DATE REVISED POLICY: 11/2005	SUPERSEDES POLICY NUMBER: IV-11
	LAST REVIEW DATE: 01/2018	

**POLICY:** The safety of personnel who prepare antineoplastic agents is ensured.

**SCOPE:** Pharmacy

**KEYWORDS:** Personal protective equipment, PPE, gowning

**POLICY CROSS-REFERENCE:** III-1, III-2, III-3, III-8

**DEFINITIONS:** PPE: personal protective equipment

**PROCEDURES:**

1. All policies and procedures governing sterile compounding will be observed.
2. All parenteral antineoplastic agents will be prepared in the Pharmacy using either a class II type B2 biological safety cabinet.
3. The hood will be cleaned as per policy prior to use.
4. The glass shield must be in place before drug preparation begins.
5. Traffic in the preparation area will be limited to authorized personnel only. A sign must be posted stating such and warning of a hazard.
6. ChemoPlus Gowns (or hospital equivalent), hair cover and shoe covers are to be worn.
7. Hand Hygiene will be performed as part of the garbing process and as necessary throughout compounding period.
8. ASTM 6978 sterile latex-free (or hospital equivalent) double gloves must

- be worn during preparation of antineoplastic drugs
9. Latex-free nitrile (or hospital equivalent) gloves are to be changed every thirty minutes.
  10. Protective garments are **NOT** to be worn outside of the preparation area.
  11. A plastic-backed, absorbent mat will be used in the hood at all times to collect spills. It is to be replaced daily and after any significant accumulation.
  12. All liquids must be removed from the tips of ampules prior to opening. A sterile alcohol swab is to be wrapped around the amp before opening.
  13. In all cases, calculations of doses and volumes **MUST** be done before preparation begins.
  14. All drugs and equipment must be gathered and placed in hood before preparation begins.
  15. All antineoplastic infusions will be dispensed with primed infusion sets with Closed System Transfer Device (CSTD) attached. The set is primed by the Pharmacist prior to addition of chemotherapeutic agent(s).
  16. IV Push medication will have a CSTD attached to the syringe.
  17. Prepared chemotherapy will be transported to the Nursing unit in a Chemo-Safety Plastic Bag in a plastic bin to prevent a spill if broken during transport.
  18. All garments, excess drug or instruments used to prepare chemotherapy are contaminated. These will be handled and disposed of as hazardous waste.



# Stony Brook Medicine

## PHARMACY DEPARTMENT POLICIES & PROCEDURES MANUAL CODE: III-9 (FORMERLY III-10)

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: CHECKING PARENTERAL NUTRITION SOLUTIONS

EFFECTIVE DATE ORIGINAL POLICY: 09/05/1990	EFFECTIVE DATE REVISED POLICY: 03/1994	SUPERSEDES POLICY NUMBER:
	LAST REVIEW DATE: 01/2015	

**POLICY:** All parenteral nutrition (PN) solutions will be checked by a pharmacist prior to delivery to the nursing units.

**SCOPE:** Pharmacy

**POLICY CROSS-REFERENCE:** III-9, III-7, JCAHO, MM 4.2,

### PROCEDURES:

1. The system of checking PN is instituted before the final formulation is dispensed to the nursing unit.
2. The order for PN is entered into the Baxa "Abacus" computer system. The calculations used to determine the amount of each additive used are verified.
3. The PN label generated by the Baxa system is checked against the order for accuracy.
4. The order is verified in Cerner Autopharm which generates an order verification sheet that is used to check against the original order.
5. The pharmacist responsible for PN solution preparation performs the following checks:
  - a. A separate check of the prescribers order.
  - b. Checks the order to the label on the PN solution. The label generated is checked against the prescribers order for accuracy and completeness. (Include patient identity, drugs and solutions used and quantities added).

- c. The PN solution is visually checked for particulates.
  - d. The calculations used to determine the amounts of additives used are verified.
6. Delivery of Formulation
- a. After checking the completed Pediatric and Adult formulations will be delivered to the refrigerators on the nursing units by Pharmacy personnel by 8:00 PM daily.



# Stony Brook Medicine

PHARMACY DEPARTMENT POLICIES & PROCEDURES  
MANUAL CODE: III-10  
(FORMERLY III-11)

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: PREPARATION OF STERILE IRRIGATION SOLUTIONS WITH ADDITIVES

EFFECTIVE DATE ORIGINAL POLICY: 02/1986	EFFECTIVE DATE REVISED POLICY: 11/2005	SUPERSEDES POLICY NUMBER: IV-21
	LAST REVIEW DATE: 01/2015	

**POLICY:** The work flow patterns, labeling functions and responsibilities required in the preparation of an irrigating solution are defined.

**SCOPE:** Pharmacy

**KEYWORDS:** irrigation, sterile

**DEFINITIONS:** Irrigation solution with additives: a solution containing medication intended for the purpose of washing out a cavity or wound surface.

**PROCEDURES:**

1. All irrigation solutions with additives used in the hospital will be prepared aseptically by the Pharmacy Department.
2. The same aseptic technique that is used in preparing IV admixtures is used in the preparation of sterile irrigating solutions except that only bottles or bags of water or saline for irrigation are used. IV bags and sets are not to be used to prepare irrigations.
3. All irrigations will be made in bottles.
4. The notation "FOR IRRIGATION" must be entered in Special Directions during the order entry.
5. Irrigation solutions with one or more additive are given a 24 hour expiration date unless otherwise indicated by the drug.

6. Labeling:

- a. By selecting "IR" as the route, a white label will be generated identifying the Patient, Drug, and Route.
- b. An auxiliary Irrigation Label must be affixed to the container with the required information entered.
- c. Labels are to be affixed to irrigation containers in an upright position and initialed by the preparing pharmacist.
- d. The checking pharmacist confirms that the solution, ingredients, and quantities are correct and places his/her initials on the Irrigation label.



# Stony Brook Medicine

PHARMACY DEPARTMENT POLICIES & PROCEDURES  
MANUAL CODE: III-11  
(FORMERLY III-13)

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: PUMP CALIBRATION AND USASGE *PharmAssist*™

EFFECTIVE DATE ORIGINAL POLICY: 01/2005	EFFECTIVE DATE REVISED POLICY:	SUPERSEDES POLICY NUMBER:
	LAST REVIEW DATE: 04/2015	

**POLICY:** A volumetric pump, used to assist in reconstituting medication vials, will be maintained and calibrated appropriately to ensure sterility and accuracy of the equipment. The pump set will be labeled with an expiration date of 72 hours from time of change. Any pump tubing without an expiration labeled affixed will be discarded and replaced. The pump will be sanitized and calibrated once daily at the time of hood cleaning, using the same materials. A record for the set change and calibration will be kept in the QA logbook maintained in the clean room.

**SCOPE:** Pharmacy

**PROCEDURES:**

- Remove old tubing set and diluent and discard. Place used needle in sharps container.
- Insert new tubing set into pump, with arrow facing inward toward machine. Place tubing under pumps rollers, then replace blue cover.
- Attach set to a liter bag of sterile water, and to a 16g standard needle.
- Prime set by pumping approximately 30ml of sterile water.
- Calibrate pump as follows:
  1. Set volume to be pumped at 20ml
  2. Place needle into empty 30ml sterile syringe, with plunger pulled back.
  3. Run pump.
  4. Withdraw needle and remove excess air from syringe. Note volume of fluid in syringe.
  5. If different than 20ml, enter that syringe fluid volume into pump keypad and hit adjust.



6. Repeat as necessary to achieve exactly 20ml of sterile water delivered.
7. Replace 16g standard needle with a 16g vented needle. Vented needle must always be the same gauge as needle used during calibration.
8. Affix orange expiration sticker to tubing, noting date completed, date of expiration, and person conducting replacement.



# Stony Brook Medicine

PHARMACY DEPARTMENT POLICIES & PROCEDURES  
MANUAL CODE: III-12  
(FORMERLY III-44)

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: RETURN OF MEDICATION TO PHARMACY

EFFECTIVE DATE ORIGINAL POLICY: 09/1989	EFFECTIVE DATE REVISED POLICY: 07/1998	SUPERSEDES POLICY NUMBER: III-44
	LAST REVIEW DATE: 01/2015	

**PURPOSE:** To define the method for handling pharmaceuticals dispensed to a nursing unit for a patient but not administered and crediting the patient's account.

**SCOPE:** Nursing, Pharmacy

**POLICY:** All medications dispensed for a patient which are not administered to that patient must be returned to the Pharmacy within 24 hours. Once received in Pharmacy, all open, partially used or expired medications are to be discarded.

**PROCEDURE:**

I. For Oral Medications

1. When a patient is discharged or to be discharged, and a new patient is being admitted to that particular bed:
  - a) All unused oral medications are removed from the patient's medication cart bin by the nurse.  
(Note: The emptied bin can now be used for a newly admitted patient).
  - b) The unused oral medication is then bagged.
  - c) The bag is then placed in the bin designated for medication returns.
2. When a patient is not yet discharged or when a patient is discharged but the bed will not be occupied by a new patient until after the cart exchange:
  - a) All unused oral medications are left in the patient's

medication cart bin.

3. At the scheduled cart exchange during each day, all unused oral medications, those that were bagged and those left in the bins are brought back to Pharmacy by the assigned Pharmacy staff.
4. Unopened unit dose packaged with > 90 days remaining before expiration may be returned to dispensing area stock (they may not be returned to Materials Management).

## II. For IVs and Piggybacks

1. All unused refrigerated piggybacks are left in the refrigerator. They must not be removed from the refrigerator.
2. All unused non-refrigerated IVs are placed in the bin designated for medication returns.
3. Reports are generated at 12:00 PM and 3:00 PM to identify all IVs and piggybacks discontinued by order DC or patient discharge. These are removed from the IV cart delivery.
4. At the scheduled cart exchange during each day, all unused IVs and piggybacks are picked up and brought back to Pharmacy by the assigned Pharmacy staff.
5. I.V. piggybacks which have expired or are due to expire within 48 hours are to be discarded. I.V. piggybacks with expiration date more than 48 but less than 72 hours from the time of return will be labeled with date/time of return and may be used for STAT or on-call doses within the next 24 hours. I.V. piggybacks with more than 72 hour expiration remaining may be returned to stock and reissued within the expiration period. Information pertaining to the patient is obliterated with black marker. (Do not obliterate the expiration dates.) NOTE: Any piggyback requiring refrigeration where there is any doubt as to how it was once stored is to be discarded. Piggybacks may only be recycled once. If they are returned again, they are to be discarded even if there is still time remaining to expiration.
6. All controlled substances which were dispensed for a specific patient which were not administered are to be returned to the Pharmacy with the control records by the nurse within 24 hours after the order is discontinued or the patient is discharge.



# Stony Brook Medicine

## PHARMACY DEPARTMENT POLICIES & PROCEDURES MANUAL CODE: IV-1 (FORMERLY V-1)

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: INVENTORY CONTROL

EFFECTIVE DATE ORIGINAL POLICY: 09/1984	EFFECTIVE DATE REVISED POLICY:	SUPERSEDES POLICY NUMBER:
	LAST REVIEW DATE: 09/2016	

**POLICY:** The Pharmacy Department at Stony Brook University Hospital will procure and maintain an adequate stock of medications to be used for the treatment of patients at Stony Brook University Hospital.

**SCOPE:** Pharmacy

**KEYWORDS:** purchase, pharmaceutical, storage, inventory, procurement

**FORMS:** purchase requisition, internal requisition

**POLICY CROSS-REFERENCE:** MM:0003 Hospital Formulary System, MM:0009 Drug Recall Procedures, Pharmacy policy V-6, MM: 0013 Storage of Medication, MM:0002 Inspection of Medication Storage Areas

### PROCEDURES:

1. All drugs listed in the approved Hospital Formulary and those items which must be procured in support of departmental operations will be maintained at levels consistent with anticipated usage and allowing for the lead time inherent in the procurement process.
2. All documentation and records regarding procurement and return of pharmaceuticals and inventory control will be maintained as per policy.
3. In order to ensure adequate inventory stock levels, adequate records will be maintained regarding on hand inventory, reorder points, vendors, contract status, outstanding orders and other appropriate data.
4. A complete physical inventory will be done at least once a year for controlled substances. Inventory is comprised of all pharmaceuticals on hand in the Pharmacy.

5. All procurement receipts will be entered into the Lawson Inventory Management System by a staff member who has been trained to do so.
6. Working stock will be entered into the inventory system by the staff member that is assigned.
7. All Areas requiring stock from the Pharmacy inventory will be required to enter a requisition in the Lawson system. All dispersements are to be entered into the Inventory system to decrement physical inventory. Lawson Issue is done to transfer charges to receiving area.
8. All items will be stored as specified in the manufacturer's storage instructions.
9. Special storage requirements will be maintained for those agents that must be refrigerated or kept in light resistant containers, etc.
10. Controlled substances will be stored in accordance with State and Federal regulations.
11. Areas in which pharmaceutical inventories are maintained will be secured or manned at all times.
12. Doors to the Pharmacy storage area will be locked at all times and no unauthorized personnel will be allowed unsupervised entry.
13. The Department will review lot #s involved in the event of a recall, In the event of a recall, Hospital policy MM:0009, and Pharmacy Policy V-6 are to be followed.
14. Each month, the Pharmacy inventory will be inspected for expired medication (MM: 0002, Pharmacy Policy V-7).
15. Drugs approaching expiration (within 90days) will be removed from inventory and stored in a separate cabinet in the Pharmacy pending return to appropriate vendors or disposal.



# Stony Brook Medicine

PHARMACY DEPARTMENT POLICIES & PROCEDURES  
MANUAL CODE: IV-2  
(FORMERLY V-3)

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: EMERGENCY DRUG TRANSFER

EFFECTIVE DATE ORIGINAL POLICY: 11/1988	EFFECTIVE DATE REVISED POLICY:	SUPERSEDES POLICY NUMBER: VI-12
	LAST REVIEW DATE: 10/2017	

**POLICY:** A mechanism is identified whereby necessary pharmaceuticals are acquired expediently should the Pharmacy Department experience a temporary shortage when normal procurement methods do not allow for a timely delivery of required drugs or, if possible, to assist other institutions when they are confronted with an emergency shortage.

**SCOPE:** Pharmacy

**KEYWORDS:** Pharmaceuticals, drugs, KOW, borrow, lend.

**FORMS:** Emergency Medication Transfer Request

**PROCEDURES:** When medication is needed on an emergency basis, the Pharmacy Department will contact other institutions, pharmaceutical representatives, or retail pharmacies to make arrangements for emergency transfer of the required items. Stony Brook University Hospital Courier Services will be available (or on call) 24 hours a day to make the emergency pickup.

When another institution or retail pharmacy needs a drug on an emergency basis, Stony Brook University Hospital Pharmacy Department will transfer a sufficient quantity of the medication to the facility in need as long as there is an ample inventory on hand. The borrowing institution will pick up the requested drug which is to be returned when their normal stock is received.

## Borrowing

1. Local hospitals are contacted to ascertain which institution will lend the needed drug.

2. All transactions must be reduced to writing on the "Emergency Medication Transfer Request" which should be completed in duplicate and must be signed by both the issuing pharmacist and the person receiving the medication (each pharmacy department receives one copy).
3.
  - a) To arrange for transportation (pickup) from 8 AM to 5 PM the Pharmacy Department will call Courier Services (Extension 4-2640). A driver will report to the Pharmacy Department to obtain the "Emergency Drug Transfer Record" before leaving to pick up the required medication.
  - b) A vehicle is available from 5 PM to 8 AM daily to respond to emergency situations. The following procedure will be in effect during the above hours:
    1. A member of the Pharmacy staff will contact the operator and asks for the Courier Services driver on call to be paged to the pharmacy. The driver will then be provided with the following information:
      - a) The nature of transport – Pickup or Delivery
      - b) The destination
      - c) Any special instructions
    2. Operations will assign a driver to make the transport.
4. The driver will leave one copy of the "Emergency Drug Transfer Record" with the pharmacy loaning the medication to Stony Brook University Hospital.

### **Lending**

1. Authorization must be granted by Pharmacy Administration before loaning medication to another institution.
2. All transactions must be reduced to writing on the "Emergency Drug Transfer Record" which should be completed in duplicate (one copy to each Pharmacy Department).
3. SBUH Pharmacy does not loan controlled substances to other institutions.
4. The borrowing institution must make provisions for the pickup.
5. Any products that are compounded or repackaged at Stony Brook University Hospital Pharmacy are intended for use by Stony Brook University Hospital patients only and, therefore, should not be made available to other institutions. In the case of an urgent request, the matter should be directed to Pharmacy Administration before any exception to this policy is granted.

6. SBUH Pharmacy personnel will ask for identification of anyone picking up a drug for another institution.  
(identification should be an ID badge from the borrowing institution with name and photograph of the person)
7. SBUH pharmacy personnel will make sure the name written by the individual picking up the medication is legible and matches the ID furnished.

#### **Returning Borrowed Medications**

1. The institution borrowing the medication is responsible for replacing the borrowed drugs with the identified item (or acceptable equivalent) as soon as regular stock arrives.
2. When the drugs are returned, the lower portion of the “Emergency Drug Transfer Record” is completed and filed.

#### **Documentation**

1. Emergency medication transfer records are to be filed alphabetically by institution.
2. All transactions Loan or Borrow are documented in the loan borrow spreadsheet on the shared drive.
3. These records are to be reviewed monthly to ensure the items are returned.
4. All loans must be decremented from computerized inventory.
5. Loan returns must be added to computerized inventory.





# Stony Brook Medicine

## PHARMACY DEPARTMENT POLICIES & PROCEDURES MANUAL CODE: IV-3 (FORMERLY V-4)

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: ORDERING OF PHARMACEUTICALS

EFFECTIVE DATE ORIGINAL POLICY: 02/2010	EFFECTIVE DATE REVISED POLICY: NEW	SUPERSEDES POLICY NUMBER: NEW
	LAST REVIEW DATE: 09/2016	

**POLICY:** To define the process to be used for the purchasing of pharmaceuticals by the Pharmacy Department.

**SCOPE:** Pharmacy

**FORMS:** Pharmacy Area specific ordering forms

**POLICY CROSS-REFERENCE:**

**DEFINITIONS:**

**PROCEDURE:** The Pharmacy Supervisors and Purchase Agent/Tech are designated as responsible for the daily ordering of pharmaceuticals.

1. Only those drugs listed in the Stony Brook University Hospital Formulary Drug List shall be obtained on a routine basis and maintained in inventory.
2. A suggested order generated by the Autopharm inventory software will be imported into the Wholesaler ordering site. (currently Cardinal Health)
3. The designated person doing the ordering will print a copy of the suggested order from Autopharm before import into the wholesaler ordering site.
4. The imported order will be reviewed for contract compliance and availability.
5. The order will then be placed and confirmed with the wholesaler
6. Orders that are not generated by the Autopharm system will be placed using

specific area ordering form.

7. The area specific ordering forms are, ASC, ACP, Alcohol, Bulk Room, Chemotherapy, Frozen Antibiotics, Floor stock, Labels, Freezer, Blood Products, IV Supplies, Oral Syringe Area, Distribution, Non-medical Supplies, L&D trays, and TPN supplies.

8. The area specific forms are posted on the pharmacy share drive for printing. These forms require signature of the person initiating the order, supervisor approval of the order, and the individual placing the order.

9. Purchases made by the Pharmacy Department will be in accordance with the purchasing guidelines established by the State of New York. Segregation of duties with respect to ordering of pharmaceuticals and receipt of same will be strictly adhered to.

10. Sources of supply will be determined primarily on the basis of GPO or NYS contracts.

11. In the event of poor vendor performance (e.g. frequent back orders, incorrect billing, etc.) an alternative vendor will be selected.

12. In the event of an order being short of an item the material management staff will identify the product to the purchaser to be followed up with credit for item not received and reordering.

13. The Director of Pharmacy Services may authorize others to purchase pharmaceuticals if there is a valid reason that a product cannot be supplied by the Pharmacy.



# Stony Brook Medicine

## PHARMACY DEPARTMENT POLICIES & PROCEDURES MANUAL CODE: IV-4 (FORMERLY V-5)

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: RETURN OF MEDICATION TO PHARMACY

EFFECTIVE DATE ORIGINAL POLICY: 09/1989	EFFECTIVE DATE REVISED POLICY: 07/1998	SUPERSEDES POLICY NUMBER: III-44
	LAST REVIEW DATE: 09/2016	

**PURPOSE:** To define the method for handling return of pharmaceuticals dispensed to a patient but not administered.

**SCOPE:** Pharmacy

**POLICY:** All medications dispensed for a patient but not administered to that patient must be returned to the Pharmacy within 24 hours.

**PROCEDURE:** I. For Oral Medications

1. When a patient is discharged, and a new patient is being admitted to that particular bed:
  - a) All unused oral medications are removed from the patient's medication cart bin by the nurse.
  - b) The unused oral medication is then bagged.
  - c) The bag is then placed in the bin designated for medication returns.
2. Unopened unit dose packaged medications with > 90 days remaining before expiration may be returned to dispensing area stock
3. The Unit Based Pharmacy Technician will remove from the nursing unit all unused oral medications, continually throughout their daily rounds.
4. The Unit Based Pharmacy Technician will return the medications from the nursing unit to the Pharmacy.
5. The Unit Based Pharmacy Technician will sort the medication for return into the carousel inventory.
6. Unopened Unit dose medications will be placed back into inventory by

the Pharmacy Technicians. Processing returns is the responsibility of every Pharmacy Technician working on every shift.

7. Any medication not meeting criteria for return will be placed in the expired drug cabinet.
8. All medication returns must be completed before the Pharmacy Technicians leave for the day.
9. The Pharmacy Supervisors will monitor the returns daily and reassign staff to achieve completion.

## **II. For IVs and Piggybacks**

1. All unused refrigerated piggybacks left in the refrigerator are removed and returned to the Pharmacy.
2. All unused non-refrigerated IVs are placed in the bin designated for medication returns by nursing.
3. At the scheduled cart exchange during each day, all unused IVs and piggybacks are picked up and brought back to Pharmacy by the assigned Pharmacy staff.
4. I.V. piggybacks which have expired or are due to expire within 48 hours are to be discarded.
5. I.V. piggybacks with an expiration date more than 48 but less than 72 hours from the time of return will be labeled with date/time of return and may be used for STAT or on-call doses within the next 24 hours.
6. I.V. piggybacks with more than 72 hour expiration remaining may be returned to stock and reissued within the expiration period.
7. Information pertaining to the patient is obliterated with black marker. (Do not obliterate the expiration dates.)
8. If there is any question as to whether the medication being returned has been stored under required conditions it must be discarded.
9. All controlled substances dispensed for a specific patient, but not administered are to be returned to the Pharmacy along with the control records (CDAR) by the nurse within 24 hours after the order is discontinued or the patient is discharged.



# Stony Brook Medicine

## PHARMACY DEPARTMENT POLICIES & PROCEDURES MANUAL CODE: IV-5 (FORMERLY V-6)

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: MEDICATION RECALL

EFFECTIVE DATE ORIGINAL POLICY: 02/2014	EFFECTIVE DATE REVISED POLICY: NEW	SUPERSEDES POLICY NUMBER: NEW
	LAST REVIEW DATE: 09/2016	

**POLICY:** The Pharmacy Department will, upon notification of a recall by either the FDA, manufacturer, wholesaler or other source, immediately remove from circulation those medications identified as recalled. The Pharmacy will maintain appropriate records to track these recalls.

**SCOPE:** Pharmacy

**RECALL:** A process initiated by either the FDA or manufacturer that requires removal of a drug or device from circulation because of a clinical discovery or manufacturing problem that may place patients at risk.

### PROCEDURES:

1. Upon notification of a recall, the Pharmacy will ascertain whether or not the product in question has ever been purchased or is currently in stock in the Pharmacy.
2. If it can be determined that the recalled pharmaceutical has never been purchased by or used at Stony Brook University Hospital, the recall notice is filed and nothing further needs to be done.
3. If it is determined that the recalled pharmaceutical has been purchased and may be in stock at Stony Brook University Hospital, the following procedure will be followed:
  - a. All Nursing Units and Patient Care Areas will receive notification of the recall by the Pharmacy Department.
  - b. The documentation of notification will be saved and attached to the recall notice.
  - c. Pharmacy Department inventory will be checked and the drug in

question removed.

- d. Pharmacy staff will inspect all hospital areas where the drug may be stocked and will remove the drug from any area found.
  - e. Pharmacy manufacturing records will be checked to insure that the drug has not been repackaged or used in a manufactured formulation. The repackage record file and the Pharmacy/Med Keeper Program will be checked to determine if the particular drug lot(s) bearing the control number in question has been prepackaged. If the cited drug lot has been repackaged, the item is removed from storage and circulation. The Master Formula Manufacturing in the PK/MK program file will be checked to determine if the particular ingredient used in the manufacture of a Pharmacy product bears the control number in question. If the ingredient had been used in the manufacture of a Pharmacy product, the product is removed from storage and/or circulation.
4. In the event of a recall necessitating identification of the patients who received a recalled medication, the Pharmacy will run a computer report to obtain the needed information and will coordinate the patient notification process as per the manufacturer's specific instructions and in coordination with appropriate Administrative personnel.
  5. In the event of a recall of sample medication, the Pharmacy will notify all outpatient areas of the recall and ask that any recalled sample drugs be returned to the Pharmacy. It is the responsibility of the outpatient area to notify patients when necessary.
  6. Drug Recall Notices are logged and filed in the Pharmacy Department.
  7. Each log entry must contain date of receipt, the name of the product and manufacturer, and the quantity of the recalled drug if any, that was found in the hospital.
  8. Disposal or return of recalled items will be the responsibility of the Pharmacy Department. Disposal or return will be done in accordance with hospital policy and as directed by the specific recall notice.
  9. The Pharmacy Purchaser will follow up on any credit for merchandise returned to the manufacturer or wholesaler.
  10. A list of all recalls will be printed from the FDA each month to reconcile the recall notifications with appropriate action being taken.



# Stony Brook Medicine

PHARMACY DEPARTMENT POLICIES & PROCEDURES  
MANUAL CODE: IV-6  
(FORMERLY V-7)

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: INVENTORY REVIEW FOR EXPIRED MEDICATION

EFFECTIVE DATE ORIGINAL POLICY: 02/2010	EFFECTIVE DATE REVISED POLICY:	SUPERSEDES POLICY NUMBER: NEW
	LAST REVIEW DATE: 09/2016	

**POLICY:** To define the frequency and methods by which the Pharmacy Department reviews the inventory for expired medication.

**SCOPE:** Pharmacy

**KEYWORDS:** Expired, outdated

**FORMS:** None

**POLICY CROSS REFERENCE:**

**DEFINITION:**

**Expired medication:** A medication which has reached the expiration date assigned by the manufacturer or, for pharmacy-repackaged medications, the beyond use date assigned by the Pharmacy, beyond which potency or stability cannot be assured.

**Approaching expiration:** A medication will be removed from inventory when it is less than or equal to 90 days from its labeled expiration or beyond use date. For CSP that require significantly shorter beyond use dating under USP 797. These will be removed 48 hours prior to expiration.

**Procedure:**

1. Review of all inventory locations for medications approaching expiration will be completed every month.

2. As part of the daily assignment the pharmacy technician will have the responsibility to check the medication inventory for medications approaching expiration.
3. The technician will remove any medication found that has an expiration less than or equal to 90 days from the date of inspection.
4. If the Pharmacy technician removes part of a medication supply due to an approaching expiration date, the technician will perform a physical count of the remaining (non-outdated) medication inventory and update the AUTOPHARM inventory on hand (i.e. perform a cycle count).
5. The pharmacy technician will segregate the outdated inventory in the designated area. (i.e. expired medication cabinet)
6. The pharmacy technician will log into and document the completion of each designated area in Simplifi 797 as follows:
  - a. There is an ICON on each Autopharm computer that will take the technician directly to the Simplifi 797 program.
  - b. The pharmacy technician will choose the location that he or she has checked for outdates (i.e. VC1, VC2... Refrigerator 1...etc.)
  - c. Once the location is chosen the program opens up to all shelves in that carousel or refrigerator.
  - d. The pharmacy technician will document completion of each shelf that they have checked for outdates by checking the box.
  - e. When the technician has completed documentation for all sites reviewed, he or she will log off Simplifi797.
7. Materials management will follow the Guaranteed Returns process for tracking returned medications.
8. Pharmacy Supervisors will receive an overdue notice for any area that is not checked for outdates.





# Stony Brook Medicine

## PHARMACY DEPARTMENT POLICIES & PROCEDURES MANUAL CODE: IV-7 (FORMERLY V-8)

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: DISPOSAL OF EXPIRED MEDICATION

EFFECTIVE DATE ORIGINAL POLICY: 11/2003	EFFECTIVE DATE REVISED POLICY: 01/2009	SUPERSEDES POLICY NUMBER:
	LAST REVIEW DATE: 09/2016	

**POLICY:** To identify the mechanisms by which the Pharmacy Department disposes of expired medication.

**SCOPE:** Pharmacy

**KEYWORDS:** Expired, outdated

**FORMS:** None

### **POLICY CROSS REFERENCE:**

**DEFINITION:** Expired Medication: a medication that has reached the expiration date assigned by the manufacturer or, for pharmacy-repackaged medications, the beyond use date assigned by the Pharmacy, beyond which potency or stability cannot be assured.

### **PROCEDURES:**

A. For medications that can be returned to the manufacturer for credit:

1. Medications to be returned for credit will be removed from dispensing stock and segregated in the designated outdate cabinet until pick up by the Pharmacy's contracted Returned Goods Company.
2. Proper paperwork must accompany Controlled Substances returned via the Returned Goods Company, as delineated in the Administrative Controlled Drugs PolicyMM008.

3. Following the Carousel Outdate Process, medications that are within 90 days of expiration are to be segregated in the expired medication cabinet in the materials management area of the department.
  4. Returns are removed from segregated area and packaged for return to the Returned Goods Company. This is currently PharmaLogistics. (PLG)
  5. A return authorization form is produced by the Returned Goods Company.
  6. Packed returns are brought to shipping by a designated Pharmacy staff member.
  7. A Pharmacy staff member assigned to receiving tracks the packages until received by the Returned Goods Company.
  8. A Pharmacy staff member assigned to receiving signs off and gives received information to the Pharmacy Purchaser.
  9. The Pharmacy tracks the returns value until the entire value of returned goods is met.
- B. For RCRA listed hazardous waste.
1. Expired medications that are U-listed are disposed of in accordance with the EH&S policy on Hazardous Drugs Management.
  2. Expired medications that are P-listed may be returned for credit via the Pharmacy's contracted returned Goods Company. Expired medications awaiting pick-up by the Returned Goods Company must be stored in a box or similar container and kept segregated from the medications in the main dispensing area.
  3. Expired P-listed chemicals that are not deemed returnable must be disposed of in accordance with the EH&S policy on Hazardous Drugs Management.



# Stony Brook Medicine

## PHARMACY DEPARTMENT POLICIES & PROCEDURES MANUAL CODE: V-1 (FORMERLY VI-1)

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: REPACKAGING MEDICATIONS

EFFECTIVE DATE ORIGINAL POLICY: 09/1984	EFFECTIVE DATE REVISED POLICY: 11/2014	SUPERSEDES POLICY NUMBER: VII-1
	LAST REVIEW DATE: 11/2014	

**POLICY:** Medications purchased in bulk containers may need to be repackaged into unit dose packaging prior to dispensing. It will be the responsibility of the Pharmacy to repackage medication. Each unit of repackaged drug will be properly labeled with the name and strength of the drug, lot number, bar code, expiration date, repackaging technician initials, and manufacturer/distributor. All repackaged drugs will be checked by a Pharmacist prior to being placed in stock for dispensing. All information pertaining to the repackaging operation will be documented in the appropriate pharmacy repackaging record and signed off by a Pharmacist.

**SCOPE:** Pharmacy

**FORMS:** Pharmacy Repackaging Record

**PROCEDURE:**

1. The Pharmacy staff member assigned to repackage medication will assemble any equipment necessary for the repackaging operation and obtain the bulk container of drug to be repackaged.
2. The person performing the repackaging will make all required entries in the Repackaging record. The repackaging record entries are defined as follows:
  - A. Date: date of repackaging
  - B. Quantity: Amount packaged
  - C. Mfg. Name: Name of manufacturer/ distributor
  - D. Mfg. Lot #: Manufacturer's lot number
  - E. Mfg. Exp. Date: Manufacturer's expiration date
  - F. # Unit Per Pkg.: Amount per package (1 cap, 5ml).
  - G. Signature (not initials) of repackager

- H. Signature (not initials) of pharmacist
  - I. Lot #: Assigned SBUH sequential lot number or manufacturer's lot number
  - J. \*SBUH Exp. Date
3. The repackaging staff member will then prepare the label. The following information is to appear on each label:
- Name of Drug - generic name (and brand name where possible)
  - Strength or Concentration - in metric units (mg, mcg, ml) or other designated unit.
  - Lot Number
  - Manufacturer/Distributor
  - \*SBUH Exp. Date
  - Bar Code
  - Repackager ID
4. A designated pharmacist will complete the following checks before the actual repackaging begins:
- a. Ensure the correct drug is being packaged.
  - b. Check the label for correct content, format, spelling and legibility
  - c. Check entries on the repackaging record for accuracy.
  - d. Ensure the amount of drug to be packaged is not excessive for the expiration date or current inventory.
5. After the required checks have been completed, the repackager may package the number of doses indicated on the record.
- When repackaging oral antineoplastic agents, packager will wear a mask and surgical gloves throughout the procedure and after the procedure while cleaning apparatus that came into contact with the drug.
6. No repackaged drug may be dispensed until it has been checked by a pharmacist who has approved the package, label and bar code are correct and suitable for dispensing/ adding to inventory.
7. \*Expiration dates - Repackaged medications do not have the same expiration date as the original container.
- A. Pharmacy repackaged unit dose oral doses
- One-half the manufacturer's expiration date or 1 year, whichever is

less.

- B. Pharmacy repackaged oral syringes containing antibiotics
  - Refrigerated products one day in the cassette
  - 7 days for non-refrigerated products
- C. External use products
  - 3 months or 50% of the time remaining to manufacturer's expiration date, whichever is less.



# Stony Brook Medicine

PHARMACY DEPARTMENT POLICIES & PROCEDURES  
MANUAL CODE: V-2  
(FORMERLY VI-2)

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: AUTO-PACK REPACKAGING

EFFECTIVE DATE ORIGINAL POLICY:	EFFECTIVE DATE REVISED POLICY: 09/2014	SUPERSEDES POLICY NUMBER: VII-4
	LAST REVIEW DATE:	

**POLICY:** A mechanism is delineated for documentation of essential information pertaining to the operation of the Auto-Pack repackaging machine that is employed by the Pharmacy Department at Stony Brook University Hospital.

**SCOPE:** Pharmacy

**KEYWORDS:** unit-dose, repackaging

**FORMS:** Drugs that should not be repackaged in Auto-Pack, Auto-Pack Cleaning Log, Auto-Pack repackaging log.

**POLICY CROSS-REFERENCE:** MM:0009 Drug Recall Procedure

**PROCEDURE:**

1. The Auto-Pack machine will be used to repack medication into unit dose for the cart fill process at SBUH pharmacy.
2. Medications contained in an Auto-Pack Canister will be refilled by the technician assigned to Auto-Pack as required.
3. The technician will remove the bulk drug from the Autopharm system to refill the Auto-Pack.
4. The technician will barcode scan the drug and enter all required fields in the JV

server software for Auto-Pack.

5. A Pharmacist will be responsible to check all canister refills by barcode scanning the product and entering their user name and password into the JV server software which serves as their electronic signature on the checking of the Auto-Pack canister refill.
6. The technician and Pharmacist will complete the canister refill process by initialing the Auto-Pack repackaging canister refill log.
7. The Auto-Pack machine will be used to repack bulk medications into multiple unit doses for filling of Pyxis machines.
8. The Auto-Pack repackaging tray will be used for this purpose.
9. The technician will gather the medication to be repackaged from the Autopharm system.
10. The technician will choose the drug to be repackaged from The JV server drug file.
11. The technician will complete the information required by the software
12. Prior to initiating the repackaging a Pharmacist will be required to check what the technician has completed.
13. The technician will review the 'Drugs that should not be Repackaged in Auto-Pack" list (posted on the side of the machine) prior to the start of repackaging.
14. At the completion of the repackaging process a Pharmacist will check the repackaged final product prior to it being placed into inventory.
15. The Auto-Pack Machine will be cleaned daily by the technician assigned to operate the machine. Cleaning will include:
  - a. Clean hopper upper , middle, lower
  - b. Clean rollers
  - c. Wax rollers
  - d. Clean hopper cover and hopper
16. The technician completing the cleaning process will complete the Auto-Pack cleaning log.

The following information is recorded for each repackaging operation:

**Medication Name, Manufacturer and Lot # & Mfg. Exp. Date:**

These are obtained from the label on the bulk container.

**Quantity Packaged:**

This is the amount (number) of the bulk drug being repackaged. The technician will indicate if more than one bulk container was used, e.g., 4x30 tablets.

**# Units Packaged:**

This is the actual yield of the repackaging operation. For example, if 2x500 tablets are being repacked into units of 1, the theoretical yield is 1000 units. If for some reason, only 999 units are produced, it is imperative that this number (i.e., 999) be entered.

In the event of a recall, we must know the exact number of units produced.

**Remarks:**

Include such information as damage or destruction of drug or units during prepackaging operation, etc.

**Date:**

The date that repackaging was performed.

**Packaged By:**

Technician performing the repackaging.

**Checked By:**

To be initialed by pharmacist in charge.

**Generic Name:**

Always applicable.

**Trade Name:**

If more than one company's product is used, include each trade name and pharmacy repacks.

**Quantity/Unit:**

Fill in number, weight or volume repacked in each unit under the proper area heading.

**Expiration Date:**

Expiration date calculated and assigned to this lot.





# Stony Brook Medicine

PHARMACY DEPARTMENT POLICIES & PROCEDURES  
MANUAL CODE: V-3  
(FORMERLY VI-3)

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: LABELING OF REPACKAGED MEDICATION

EFFECTIVE DATE ORIGINAL POLICY: 09/1984	EFFECTIVE DATE REVISED POLICY: 11/2005	SUPERSEDES POLICY NUMBER: VII-7
	LAST REVIEW DATE: 10/2017	

**POLICY:** All medication that has been re-packaged by the Pharmacy must be properly labeled.

**SCOPE:** Pharmacy

**DEFINITIONS:** Repackaged medication: Any medication that has been removed from original manufacturer's packaging and place in a new package by the Pharmacy prior to dispensing.

Unit-dose package: A single dose of medication that is packaged in a container.

**PROCEDURES:** Each unit dose package of medication must be readily identifiable as to its contents. This will be accomplished by affixing a label to each dose lettered in such a way as to be legible and accurate.

The label on any container must contain all the information pertinent to the enclosed drug. Labels must be accurate, neat and complete.

The label is either typed (for small lots of individual units) or printed on a label printing machine. **Handwritten labels are unacceptable.**

If the repackaged drug label becomes damaged is incomplete or illegible it cannot be dispensed and must be discarded appropriately.

**Minimum information required on labels:**

- Repackaging machine, Fluid Dose and Auto-Pack:  
Generic name of medication (brand name if applicable)  
Strength of the medication  
Auto Generated Lot number  
Auto Generated Expiration date  
User Name of repackaging

Technician Auto generated bar-code  
Pharmacist checks products and signs the log

- Extemporaneous repackaged medications using the Medi-Dose Unit dose, Wheaton Vial, or oral syringe:

Generic name of the medication (brand if applicable)  
Strength of the medication  
Hospital Generated Lot number  
Expiration date (see V-1 Repackaging Medications)  
Initials of repackaging Technician/RPh.  
Name of manufacturer/distributor  
Medi-dose or other system generated bar-code  
Pharmacist checks products and signs the log



# Stony Brook Medicine

PHARMACY DEPARTMENT POLICIES & PROCEDURES  
MANUAL CODE: V-4  
(FORMERLY VI-4)

RESPONSIBLE DEPARTMENT, DIVISION, OR COMMITTEE: PHARMACY

SUBJECT: EXTEMPORANEOUS UNIT DOSE PACKAGING

EFFECTIVE DATE ORIGINAL POLICY: 09/1984	EFFECTIVE DATE REVISED POLICY: 11/2005	SUPERSEDES POLICY NUMBER: VII-8
	LAST REVIEW DATE: 09/2014	

**POLICY:** The procedure by which the Pharmacy will repackage unit dose medications on an as needed basis is delineated.

**SCOPE:** Pharmacy

**POLICY CROSS-REFERENCE:** VI-1 Repackaging medication, VI-3 Labeling of Repackaged Medication.

## DEFINITIONS:

## PROCEDURES:

- All medications dispensed to inpatients at Stony Brook University Hospital will be in unit of use packaging whenever possible.
- When an order is written for a drug not available in unit dose packaging or if the unit dose product is out of stock, the Pharmacy Department will prepare a short run of unit dose packages to meet the need until such time that a new supply of unit dose product arrives or until a new canister can be calibrated.
- For short run preparation of a few doses, the Pharmacy will be equipped with a supply of Med-Dose Blister, as well as a supply of bottles, Wheaton vials and oral liquid syringes doses. These extemporaneously packaged unit doses are to be properly labeled per Pharmacy policy VI-3.
- When receiving an order for a medication that is not, for whatever reason available in

unit dose packaging, the Pharmacy Department will repackage individual doses for dispensing. If an oral solid is needed, the dose will be placed in the appropriate section of the Auto-Pack packager and will be packaged in that manner. In the event that the automated repackaging systems cannot be used, the MILT system Med-Dose Blisters will be used and the process will be completed manually. A dose of oral liquid will be measured and placed into an appropriate sized glass container or oral liquid syringe, labeled and dispensed in the same fashion.

- The number of doses prepared on an extemporaneous basis will be determined by the frequency of administration. At least a 24 hour supply of medication will be sent up to the unit for regularly scheduled doses and an appropriate quantity of extemporaneously packaged drug will be sent on non-regularly scheduled drugs.
- All products repackaged will be logged into the repackaging logs maintained in the MILT system.