Pharmacy Department Policy
Chemotherapy Order Verification and Dose Preparation

A. EFFECTIVE DATE:
   August 17, 2021

B. PURPOSE:
   To ensure accuracy, quality, and safety of chemotherapy ordering and preparation at UConn Health.

C. POLICY:
   The pharmacy will prepare chemotherapy for patients of John Dempsey Hospital and UConn Medical Group. An authorized provider’s written or electronic order is sent to the pharmacy. All chemotherapy is checked by a pharmacist before dispensing. The Department of Pharmacy will prepare and dispense in ready-to-use form all antineoplastics, regardless of route, for all patients of UConn Health.

   All employees of the Department of Pharmacy will adhere to the procedure outlined below.

D. SCOPE:
   The procedure applies to the Department of Pharmacy which includes inpatient and outpatient care areas. The policy covers all antineoplastic drugs, regardless of route, that will be prepared and dispensed in ready-to-administered dosage forms at UConn Health.

E. DEFINITIONS:
   - **Closed System Transfer Device (CSTD)** – A drug transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of the hazardous drug or vapor concentrations outside the system.
   - **USP** – United States Pharmacopeia
   - **NCCN** – National Comprehensive Cancer Network
   - **BSA** – Body surface area

F. MATERIAL(S) NEEDED:
   - Electronic medical record and electronic orders (EPIC)
   - Electronic dose checking software (DoseEdge)
   - Antineoplastic medications
   - All necessary compounding equipment, including biological safety cabinets, closed-system transfer devices, etc.

G. PROCEDURE:
   Pharmacists and Technicians:
1. Preparation Procedures: The most recent version of the Hazardous Drug Handling Policy and the Cleanroom Standard Operating Policy and Procedure should be followed in preparing chemotherapy doses.

1.1. Biological Safety Hood
   1.1.1. All manipulation of parenteral antineoplastic drugs will be performed in a Class II biological safety cabinet. Personnel utilizing this equipment must undergo a separate orientation to the chemotherapy preparation area in order to become familiar with its proper operation, capabilities and limitations.
   1.1.1.1. Manipulations of solid dosage forms and oral solutions or suspensions will occur in a negative pressure hazardous drug storage area, within a powder hood when necessary.

   1.1.2. The hood blowers should operate continuously, 24 hours a day, 7 days a week, in order to prevent contamination of the surrounding work area.

   1.1.3. The work surfaces of the hood should be cleaned following Cleanroom Standard Operating Policy and Procedures

   1.1.4. Hood maintenance & performance should conform to accepted standards (e.g. USP <797>). Assurance of those standards shall be made through certification by a qualified certification technician every 6 months, or whenever the hood is moved or repaired.

1.2. Personnel
   1.2.1. Only adequately trained personnel should handle antineoplastic agents.

   1.2.2. All work must be done by or under the direct supervision of a licensed pharmacist.

1.3. General Techniques

   1.3.2. Closed system transfer devices will be used during preparation whenever possible.

   1.3.3. Aerosolization of drug should be minimized by observing the following techniques:

   o Introduce the minimum quantity of air into the vial which will facilitate withdrawal.

   o Pull drug back into barrel of syringe prior to expelling air bubbles. External surfaces of syringes and IV bottles should be free of spilled drug. Syringes and intravenous (IV) sets with Luer-lock fittings should be used for preparing antineoplastic agents.

1.4. Packaging Types
   1.4.1. Package Types

   o Intramuscular (IM), subcutaneous (SC) or intravenous (IV) bolus administered doses will be prepared in Luer-lock syringes. IV infusions will be prepared in the appropriate IV bags, depending upon stability of the drug.

   o Doses will be dispensed with closed system transfer devices whenever possible to minimize risk of exposure with administration. Intravenous infusions will be dispensed with primed tubing sets.

   1.4.2. Labeling
Labels should be attached directly on syringes or infusion bags as well as the outer plastic bags.

Labels should include the following information: patient name, room number (if inpatient), drug name, concentration, expiration date & time, special precautions, hazardous drug safe handling instructions, and storage requirements.

1.5. Reconstitution/Expiration Date Guidelines
In general, follow reconstitution guidelines outlined in the package insert, compendia listing, or the most recent edition of Trissel’s Handbook of Injectable Drugs. Preparation should be performed through the electronic dose checking software (DoseEdge) whenever possible.

Pharmacists:

2. Review of Physician Order

2.1. The pharmacist verifying chemotherapy orders must assure the doses are correct and appropriate. This is done by checking the treatment plan, monitoring and hold parameters, previous treatments, and any dose modifications, and referring to external references including the National Comprehensive Cancer Network (NCCN) Guidelines, tertiary drug information sources, or primary literature. The order review is documented in an intervention tied to the chemotherapy order within the electronic medical record (EPIC).

2.2. Any factor (e.g. BSA, creatinine clearance, etc.) that causes a resultant final dose to be outside of 10% of the provider ordered dose will require a dose adjustment. The dose calculations can and will be done by the Oncology Pharmacist but it will be the provider who will make the final determination and sign off on the change in dose. New orders will have to be written if the final dose is outside of 10% of the initial ordered dose. Any dose within the 10% variation from the provider ordered dose will be deemed appropriate and will be dispensed as written, subject to rounding by the pharmacist as necessary.

2.3. A second check of chemotherapy orders will be performed by a pharmacist following the process and references cited above (2.1). The second check will be captured in the electronic dose check system (DoseEdge) and documented in the intervention tied to the chemotherapy order within the electronic medical record (EPIC).

3. Preparation Check

3.1. All final anti-neoplastic preparations shall be checked by at least one registered pharmacist other than the preparer before dispensing to the patient care area. This procedure shall be followed regardless of whether the preparer is a pharmacy technician or pharmacist. The exception is when there is only one pharmacist on duty, during the night or weekend evenings. The credentials of the preparer and checking pharmacist(s) will be captured in the electronic dose checking system (DoseEdge), or recorded in a written compounding log as per department policy.

3.2. The checking pharmacist shall review the correctness of the drug, diluent, label, patient location, expiration date and compare the preparation directly with the provider’s order. A sole label check is not sufficient.

Pharmacists and Technicians:

4. Delivery

4.1. All antineoplastic agents will be transported in containers that will enclose any accidental spill or leakage during transport. Syringes and infusions will be double-bagged, with the outermost bag carrying chemotherapy warnings.
5. Accidental Exposure
   5.1. For direct skin or eye contact, refer to the *John Dempsey Hospital Administrative Manual on Safe Handling of Hazardous Drugs*.

   5.2. Spill kits are available in the Pharmacy and on each unit. Refer to the directions in the kit if a spill occurs. The *John Dempsey Hospital Administrative Manual on Safe Handling of Hazardous Drugs* describes the procedure for spills, and the Department of Environmental Safety supplies the kits.

6. Disposal
   6.1. Used syringes, vials, ampules, IV bags and partially-full containers of antineoplastics are considered pharmaceutical waste and should be segregated and disposed of properly, according to direction from the Environmental Safety Officer.

   6.2. Needles, syringes, and ampules either empty or partially-full are disposed of in designated sharps containers as defined by *Management of Pharmaceutical Waste Policy*.

   6.3. Follow waste stream management recommendations and work with the appropriate vendor for disposal.

H. ATTACHMENTS:
   None

I. REFERENCES:
   1. USP [2008]. USP General Chapter Pharmaceutical Compounding—Sterile Preparations
   2. USP [2016]. USP General Chapter Hazardous Drugs—Handling in Healthcare Settings

J. SEARCH WORDS:
   Chemotherapy, antineoplastic, oncology

K. ENFORCEMENT:
   Violations of this policy or associated procedures may result in appropriate disciplinary measures in accordance with University By-Laws, General Rules of Conduct for All University Employees, applicable collective bargaining agreements, the University of Connecticut Student Code, other applicable University Policies, or as outlined in any procedures document related to this policy.

L. STAKEHOLDER APPROVALS:
   On File

M. COMMITTEE APPROVALS:
   None
N. **FINAL APPROVAL:**

1. Andrew Agwunobi, MD (Signed) __________________________ 09/23/2021
   Andrew Agwunobi, MD, MBA
   **UConn Health Chief Executive Officer**

2. Anne D. Horbatuck, (Signed) __________________________ 09/23/2021
   Anne D. Horbatuck, RN, BSN, MBA
   **Clinical Policy Committee Co-Chair**

3. Scott Allen, MD (Signed) __________________________ 09/21/2021
   Scott Allen, MD
   **Clinical Policy Committee Co-Chair**

4. Caryl Ryan (Signed) __________________________ 09/15/2021
   Caryl Ryan, MS, BSN, RN
   **Interim Chief Operating Officer, JDH**
   **VP Quality and Patient Services & Chief Nursing Officer**

O. **REVISION HISTORY:**
   Date Issued: 8/29/12
   Date Revised: 10/16/17
   Date Reviewed: 8/29/12, 11/10/15, 10/16/17, 8/17/21