Pharmacy Department Policy
IV Infusion Service and Documentation Program

A. EFFECTIVE DATE:
   August 17, 2021

B. PURPOSE:
   To provide guidelines as set forth by USP Chapter <797> regarding ordering, labeling, and checking of compounding sterile preparations.

C. POLICY:
   The Pharmacy Department will prepare and distribute all intravenous (IV) admixtures, with the exception of certain cases (e.g. cardiopulmonary resuscitation procedure, emergent orders, unstable medications) which will necessitate the preparation of the initial solution on the nursing unit by either a nurse or a pharmacist in the designated IV preparation area.

D. SCOPE:
   This policy applies to the IV medication use at John Dempsey Hospital.

E. DEFINITIONS:
   None

F. MATERIAL(S) NEEDED:
   Epic®
   Dose Edge®

G. PROCEDURE:

1. Solutions Prepared by Pharmacy Consist of:
   a. All parenteral solutions with an added drug(s), including but not limited to large volume bags, syringes, mini-bags, and/or vials

2. Ordering IV Infusions
   a. Routine Orders
i. For nursing units with computerized prescriber order entry (CPOE) system, Pharmacists will check order for accuracy and validate orders in the EHR system (i.e. Epic®). The order will electronically be transmitted to the IV Infusion preparation software (i.e, Dose Edge®) to initiate preparation.

ii. The compounding software system (Dose Edge®) status monitor will indicate the need to compound an IV infusion prior to due time.

b. Emergency Orders
   i. When IV drug infusions are needed immediately, the Patient Unit Pharmacist or Pharmacist validating the order will notify central pharmacy to indicate the emergency need
   ii. Stat medications will automatically be prioritized by the IV compounding software (Dose Edge®).
   iii. These emergency infusion orders or STAT items are to be immediately prioritized from other orders and prepared.

c. Infusions Prepared on Nursing Unit
   i. As a general rule, all IV drug infusions will be prepared in the pharmacy
   ii. However, certain circumstances (e.g. cardiopulmonary resuscitation procedure, emergent orders, unstable medications, etc.) will necessitate the preparation of the initial solution on the nursing unit by either a nurse or a pharmacist in the designated IV preparation area. All subsequent solutions will be prepared in the central pharmacy.

3. Order Processing and Admixture Preparation
   a. Upon receipt of the admixture orders, records specific to compounding must match the original written or computerized order for accuracy.
   b. If an IV product is not prepared using DoseEdge® software, a manufacturing sheet (also known as an IV admixture profile) must be used in lieu of electronic record-keeping. Sufficient detail must be recorded on the worksheet so that manufacturing procedure can be replicated in the future. For certain drugs, it is optimal to have a second pharmacist check calculations and preparations [e.g. epoprostenol (e.g. Flolan®), treprostinil (Remodulin)].
   c. Routine orders for admixtures with at least 24 hour stability are prepared in two work periods.
      i. Solutions stable for 24 hours or greater are prepared on the 1st/2nd shift. Solutions that are stable for less than 24 hours may be admixed on 2nd or 3rd shift, based on time needed.
      ii. At the scheduled times, the profiles are reviewed electronically if using DoseEdge® or taken from the appropriate file slot. Materials needed (e.g. solutions, drugs, needles and syringes) are assembled in the sterile products area following cleanroom procedures. Only one admixture is prepared at a time.
   d. Technique
      i. IV admixtures are prepared using aseptic technique as prescribed by USP Chapter <797>. Operations and manipulations are performed in such a manner as to minimize the possibility of solutions contamination. Reference Cleanroom Standard Operating Policy and Procedure.
      ii. Work area is cleaned following appropriate cleanroom processes. Reference Cleanroom Standard Operating Policy and Procedure.
   e. Labeling
i. All labels of compounds and IV admixtures must have: correct names, amounts, or concentration of ingredients, total volume, date prepared, beyond use dating, proper barcode, storage conditions, and initials of preparer and checking pharmacist.

ii. Products being sent out of the pharmacy for patient use must contain all above items in addition to two (2) patient identifiers and also route and rate of administration.

4. Checking
   a. The compounding technician and the pharmacist must check the identity and ingredients of the compound for accuracy and also visually inspect product for container integrity, cloudiness, particulates, solution color, and any other irregularities.

   b. After preparation, pharmacist check is documented electronically (i.e. DoseEdge®) or via paper documentation. Admixture, transfer device and drug containers are viewable electronically or must be provided with the profile for pharmacist checking. Documentation includes: date and time of preparation, lot number and expiration date (and time if needed), and technician initials.

   c. Pharmacist check of compounds and IV admixtures includes:
      i. Order checked against the additives and amounts actually used (as evidenced by empty vials or ampules and syringes)

      ii. Visual inspection for particulate matter

      iii. Label compared to DoseEdge®/IV admixture profile for accuracy and completeness, with particular attention to:
           1. Drug name and amount of drug(s) or concentration of ingredients
           2. Total volume
           3. Date prepared
           4. Expiration date or beyond use dating
           5. Proper barcode
           6. Storage conditions, as applicable
           7. Initials of preparer and checking pharmacist
           8. Patient identifiers, for patient-specific products as applicable
           9. Infusion rate, as applicable
           10. Bottle number, as applicable

      iv. After checking, the pharmacist will document final check (e.g. electronically or on paper profile) and initial label on final product

H. ATTACHMENTS:
   None

I. REFERENCES:
   United States Pharmacopeia (USP); Chapter <797>
   Cleanroom Standard Operating Policy and Procedure Policy
   Medication Administration Policy

J. SEARCH WORDS:
   Compounding, IV infusion

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:
One File

M. COMMITTEE APPROVALS:
None

N. FINAL APPROVAL:

1. Andrew Agwunobi, MD (Signed) 09/29/2021
   Andrew Agwunobi, MD, MBA Date
   UConn Health Chief Executive Officer

2. Anne D. Horbatuck, (Signed) 09/29/2021
   Anne D. Horbatuck, RN, BSN, MBA Date
   Clinical Policy Committee Co-Chair

3. Scott Allen, MD (Signed) 09/24/2021
   Scott Allen, MD Date
   Clinical Policy Committee Co-Chair

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

O. REVISION HISTORY:
Date Issued: 10/16/12
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