Medication Labeling -- SAHS

I. Policy Statement: All drug containers shall be labeled and drug labels must be clear, consistent, legible and in compliance with state and federal requirements. There shall be a standard method for appropriately and safely labeling medications dispensed to both inpatients and outpatients.

II. Definitions: None.

III. Equipment: None.

IV. Procedure:
A. General Considerations
1. Medication containers are labeled whenever medications are prepared or transferred from the original packaging to another container but not immediately administered. If the medication leaves the hands of the person preparing it, it must be labeled.
2. For mass vaccination clinics, focusing solely on vaccinating with 1 type of vaccine the following apply:
   a. 1 multi dose vial can be drawn up ahead of time per vaccinator, if the vaccine is intended for immediate use, within the manufacturer storage recommendations
   b. If the vaccinator pre-draws up multiple doses from 1 vial, the syringes would not need to be labeled if:
      (1) the syringes do not leave the view of the vaccinator
      (2) the vaccinator is administering the same vaccine (ie the vaccinator is not in possession of multiple different vaccines at one time)
   c. If vaccine doses are pre-drawn up by someone who is not the one administering the vaccine, the syringes must be labeled with the vaccine name, lot, and expiration. Only 1 vial is pre-drawn and labeled at one time.
3. Do not pre-label medications, solution containers or empty syringes or containers. Label is to be prepared and attached at the time medication or solution is prepared.
4. Never give medications from an unlabeled /improperly labeled container unless the medication is being given immediately after preparation by the person who prepared the medication.
5. When the correct identity, purity, strength, and sterility of ingredients and components cannot be confirmed (in cases of, for example, unlabeled syringes, opened ampoules, punctured stoppers of vials and bags, and containers of ingredients with incomplete labeling) or when the ingredients and components do not possess the expected
appearance, aroma, and texture, they must be removed from stock and isolated for return, reclamation, or destruction.

6. At no time is it acceptable to attach a vial or amp from which the medication is drawn up, to the syringe to use as a label.

7. Saint Alphonsus Health System pharmacies will ensure bar codes are affixed to medications for point of care scanning at the bedside as part of our medication safety efforts.

8. Procedural areas:
   a. Label medications and solutions both on and off the sterile field even if there is only one medication being used.
   b. Keep all original containers from medications or solutions available for reference in the perioperative/procedural area until the conclusion of the procedure.
   c. Discard all labeled containers on the sterile field at the conclusion of the procedure.
   d. Entering and exiting personnel review all medications and solutions and their labels, both on and off the sterile field at shift change or break relief.
   e. In perioperative and other procedural settings both on and off the sterile field, medication or solution labels include the following:
      (1) Medication or solution name
      (2) Strength
      (3) Amount of medication or solution containing medication (if not apparent from the container)
      (4) Diluent name and volume (if not apparent from the container)
      (5) Expiration date when not used within 24 hours
      (6) Expiration time when expiration occurs in less than 24 hours
      (a) Note: The date and time are not necessary on the labeling when medications are removed from their original packaging for use within the procedural room. All medications removed from their original packaging in the procedural area are intended for immediate use and will be discarded at the end of that case.

9. See policy: Beyond-Use Dating, Deterioration and Expiration of Medications – SAHS for specific medication expiration dating

B. Intravenous admixture and parenteral nutrition solution

1. Labels shall include at a minimum:
   a. Name and location of the patient (if applicable)
   b. Generic drug name
   c. Name(s), quantity(s) and concentration(s) of drug(s) added and the primary solution
   d. Total volume
   e. Preparation date and time
   f. Expiration date
   g. Expiration time when expiration occurs in less than 24 hours
   h. Route of administration
   i. Infusion rate, when applicable
j. Directions for use and/or storage requirements when applicable
k. The initials of the compounding personnel and compounded in pharmacy includes the initials of the pharmacist or verification technician checking end product
l. Any applicable cautionary statements

2. Commercially manufactured IV fluids are labeled with all necessary information and do not require additional labeling unless manipulation of the manufactured product has occurred.

C. Repackaged unit-of-use medication labels shall include at a minimum:
   1. Generic drug name
   2. Dosage form (if special or other than oral)
   3. Strength of dose and total contents delivered (i.e., number of tablets and their total dose) if applicable
   4. Cautionary statements, storage requirements if applicable (i.e., refrigerate)
   5. Internally assigned control number and expiration date
   6. Beyond-Use date (one year from date of repackaging or manufacturer expiration date, whichever is sooner)

D. A drug that is to be sent home with a patient upon discharge must be labeled in accordance state and federal laws
   1. The following information must be included on such a prescription label, which will be our standard of practice when labeling medications for take home use:
      a. Prescription number or unique serial number
      b. Date the prescription if filled
      c. Drug name and strength
      d. Drug manufacturer
      e. Quantity
      f. Directions for use
      g. Name of practitioner prescribing drug
      h. Name and place of business of the pharmacist or the name and place of business of the pharmacy for which the pharmacist is acting (i.e., dispenser information)
      i. Patient name
      j. An expiration date after which the patient should not use the drug
      k. Cautionary Information when appropriate
      l. Warning: The warning: "Caution State or federal law, or both, prohibits the transfer of this drug to any person other than the patient for whom it was prescribed"

V. Related Policies/Forms:
   A. Beyond-Use Dating, Deterioration and Expiration of Medications -- SAHS
   B. Medication Administration and Scheduling -- SAHS

VI. References:
   A. Idaho State Board of Pharmacy: Omnibus Administrative Rules as of July 1, 2019
B. Oregon State Board of Pharmacy: Oregon Laws and Rules
   1. ORS 689.505(5)
   2. 855-041-6270

VII. Approval Committee(s):
    A. SAHS Pharmacy and Therapeutics Committee, August 2020