

UPDATED 2-2-1 RULE

The 2-2-1 rule is for safe & best practices when mixing IV bags **based** on Regulations that state RN's are not allowed to compound. For example, In CA- RN's cannot compound- what does that mean?

USP 797 defines *sterile compounding as combining, admixing, diluting, pooling, reconstituting, repackaging or otherwise altering a drug product or bulk drug substance to create a sterile preparation.*

Per the Nurse Practice Act, <https://www.rn.ca.gov/pdfs/regulations/npr-i-15.pdf>, in CA, *No registered nurse shall compound drugs.*

In section 1.4 of USP 797- *Compounding **does not** include mixing, reconstituting or other such acts that are performed in accordance with directions contained in approved labeling or supplemental materials provided by the products manufacturer. Preparing a conventionally manufactured sterile product in accordance with the directions in the manufacturer's approved labeling is out of scope of this chapter only if*

- 1. The product is prepared as a single dose for an individual patient and*
- 2. the approved labeling included information for the diluent, the resultant strength, the container closure system and storage time.*

This new menu is called the CA Piggyback Menu and is built based upon the directions contained in approved labeling/supplemental materials from the product manufacturers.

The guidelines include mixing up to 1 manufactured products in a bag and 2 entries into 1 sterile container.

The 2-2-1 rule is

- The bag (NS or LR) + 1 ingredients = 2
- 2 bag sticks (1 being the bag spike and the other being the addition of 2 ingredients)
- 1 hour to use the bag.

Steps

1. Clean your area with 70% isopropyl alcohol spray or wipes
2. Wash your hands with antibacterial soap and water for at least 1 minute
3. Don your gloves
4. Spray or clean your gloves with 70% isopropyl alcohol or wipes
5. Set out your ingredients, needles, syringes and bag
6. Wipe them down with 70% isopropyl alcohol
7. Draw up ingredients
 - a. Draw up the volume you need in air into your syringe for ingredient one
 - b. Insert the needle into the vial, turn upside down and push the air into the vial
 - c. Draw out the volume of ingredient you need
8. Add the ingredient to your IV Bag
9. Agitate the bag
10. Use the bag within 1 hour
11. Add ons for other piggybacks or IM injections should be drawn up following the same steps of preparation including hand hygiene, cleaning, needle changing, etc

Note- if you do not have a segregated area to spray down with 70% isopropyl alcohol or wipes, please use a blue paper sheet that you will dispose of and still use proper hand hygiene, mask, gloves, and cleaning of ingredients, needles, syringes, bag etc.

Sources:

<https://www.usp.org/>

<https://www.usp.org/sites/default/files/usp/document/our-work/compounding/proposed-revisions-gc-797.pdf>

DOI: https://doi.org/10.31003/USPNF_M99925_07_01