Non-Sterile Compounding Inspection Form

Simple compounding that does not precipitate the application of this form include:

1) Reconstituting or manipulating commercial products that may require the addition of one or more ingredients as directed by the manufacturer;
2) Making twenty or less compounds of an oral liquid or topical dosage form utilizing five or less non-hazardous APIs over any 30 day period (not exempt from 40-43-86(CC)(6), "Formulas and Logs Maintained").

CodeSection	Question
40-43-86(CC)(2)(c)	**Drugs meet CP, AR, ACS chemical grade or meets the accepted standard of the practice of pharmacy** ○ APIs**:** Certificates of analysis (COAs) obtained for all bulk APIs used for compounding ○ All substances and components have a complete label including a batch control or lot number, and an expiration date. ○ Where water is an ingredient, purified or distilled water is used. ○ There are not preparations made or ingredients used that appear on the FDA list of drug products withdrawn or removed from the market for safety reasons (facility has a copy of the list or other way to determine).
40-43-86(CC)(2)(d)	**History of valid prescriptions/ RPh./Patient/Practitioner relationship** ○ On hand inventory of compounded product may not exceed 3 months of dispensed prescriptions.
40-43-86(CC)(3)	**RPh. responsible for monitoring/training techs** ○ If technicians are compounding medications, pharmacist must be able to observe.
40-43-86(CC)(3)	**Continuing education in art and science of compounding** ○ There is documentation (6 hours initial; 4 hours annually) that all personnel that perform compounding are appropriately trained including policies and procedures, documentation, hazardous drug handling, and compounding technique and not

	allowed to compound or supervise compounding until training is successfully completed. (note: does not have to be ACPE or otherwise accredited continuing education) ○ If the pharmacy uses relief personnel from outside agencies to perform non-sterile compounding there is documentation that training is verified. ○ For animal compounding: 1) The pharmacist familiar with, or has a reference regarding drug residues in the food chain and withdrawal times if compounding for food-producing animals. 2) The facility has a list of drugs and components not allowed when compounding for food-producing animals.
40-43-86(CC)(3)	**Wear clean clothing appropriate to the operation being performed** ○ Compounding personnel maintain good hand hygiene and wear clean and appropriate clothing for the compounding being performed. ○ Personnel don protective garb (gowns, gloves, masks, hair covers, etc) as appropriate when performing compounding. ○ Appropriate protective attire (gowns, gloves, masks, etc.) is available including appropriate PPE for hazardous drug compounding, if hazardous drugs are used.
40-43-86(CC)(3)	**Only personnel authorized by pharmacist in immediate vicinity**
40-43-86(CC)(4)	**Specifically designated and adequate area for compounding** ○ The non-sterile area is a controlled environment. The area must be: 1) A room that is separated from the pharmacy area by a wall or curtain and allows for pharmacist observation; or 2) A low traffic area, within the pharmacy area, that has a powder containment hood. ○ There is sufficient space available for the type and amount of compounding performed and the space is orderly to prevent mix-ups between ingredients, containers, labels, in-process materials, and finished preparations.
40-43-86(CC)(4)	**Bulk drugs labeled in clean, dry and temperature controlled area** ○ For APIs without an expiration date assigned by the manufacturer or supplier, the pharmacy assigns a conservative expiration date that does not exceed three (3) years for ingredients used for non-sterile compounding. Note: purity and quality testing may be performed to extend. ○ **Temperature** in the compounding area is maintained to provide controlled

	room temperature storage of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements. Refrigerator temperature range is 36° to 46° F. ○ **Humidity** in the compounding area is maintained to provide humidity in the ranges warranted by specific drug product storage requirements. If drug products require storage in a "dry place", humidity is not to exceed 40%. Generally recommended range is 35-60%. ○ Must have logs that include, at a minimum, the following: 1) Time 2) Date 3) Initials 4) Refrigerator Temperature (Humidity inside refrigerator must be logged if it is located outside a controlled pharmacy environment) 5) Room Temperature 6) Room Humidity
40-43-86(CC)(4)	**Adequate lighting, ventilation and washing facilities** ○ The compounding area is well lit. ○ There is adequate space to wash equipment and utensils including access to water for rinsing.
40-43-86(CC)(4)	**Hot and cold water, detergent, air dryer or single use towels** ○ There is a sink in the compounding area with hot and cold potable water, soap or detergent, and air-driers or single-use towels.
40-43-86(CC)(4)	**Area clean and sanitary/free from infestation** ○ Floor of compounding area must be constructed of a material that can be easily cleaned. Carpeting is not permitted. ○ Cleaning must be documented and performed, at a minimum, according to the following schedule: 1) Daily – Countertops cleaned; floors swept; hoods cleaned; equipment wiped down; utensils cleaned; trash discarded 2) Weekly – Floors mopped 3) Monthly – Shelves cleaned/sanitized; drug product refrigerator cleaned/sanitized; drug product freezer cleaned/sanitized; cabinet exteriors cleaned sanitized ○ Must have policy and procedure for cleaning.
40-43-86(CC)(4)	**Trash disposed of in a timely and sanitary manner**

40-43-86(CC)(4)	**Special precautions used to prevent cross contamination**
40-43-86(CC)(5)	**Equipment and utensils protected from contamination** ○ When stored or not in use, equipment and utensils must be covered or in cabinets.
40-43-86(CC)(5)	**Equipment routinely inspected and calibrated** ○ Powder hoods used for nonsterile compounding are certified or tested periodically to ensure proper function. Hood filters are checked regularly and replaced when necessary. ○ Must document calibration of equipment, if required. ○ Must have a policy and procedure for routine cleaning of equipment.
40-43-86(CC)(6)	**Formulas and logs maintained** ○ The compounding record includes: 1. Official or assigned name, strength and dosage of the preparation 2. Master Formulation Record reference if available 3. Sources, lot numbers, and expiration dates of all components 4. Total quantity or number of dosage units compounded 5. Mixing instructions (order of mixing, temperatures, duration of mixing, and other pertinent factors) 6. Person compounding the preparation 7. Pharmacist who approved of completed procedures prior to dispensing 8. Date of compounding 9. Assigned internal identification number or prescription number 10. Storage requirements 11. Assigned Beyond Use Date (BUD) ○ BUDs are assigned from the day of preparation. ○ BUDs for nonaqueous formulations are not later than the remaining time until the earliest expiration date of any API and not later than six (6) months. ○ BUDs for water-containing oral formulations are not later than 14 days when stored at controlled cold temperatures (refrigerated). ○ BUDs for water-containing topical/dermal and mucosal liquid and semisolid formulations not later than 30 days. ○ BUDs are assigned based on dispensing in tight, light-resistant containers/overpacks. ○ Extended BUDs are supported by testing data and professional judgment. 12. If performed, results of quality control procedures (weight range of filled capsules, pH of aqueous liquids, etc.). 13. Documentation of any quality control issues and any adverse reactions or

	preparation problems reported by the patient or caregiver including investigation and recall, if appropriate. 40-43-86(I)(4) – **Labeling** (see retail inspection report) ○ BUD must be on patient specific label ○ All active ingredients in compound must be on label or affixed to the container
40-43-86(CC)(6)	**Components accurately weighed, measured, subdivided** ○ As appropriate, the final completed preparation assessed for weight, mixing, clarity, odor, color, consistency, pH, and strength and is documented.
40-43-86(CC)(6)	**Chemical transferred labeled as original and date of transfer**
40-43-86(CC)(6)	**Procedures to monitor output of compounded prescriptions** ○ Example: Using capsule quality assurance formula and document ○ Products that are made often should have a final analysis done to validate process ○ Documentation of adverse drug reactions per 40-43-88(A)(10)
40-43-86(CC)(7)	**Label excess product as to formula used/control # and beyond use date**
40-43-86(CC)(7)	**Excess product properly stored**
40-43-86(CC)(7)	**Records of compounding kept for two years**

40-43-86(DD)(5) **Standard Operating Polices and Procedures**

○ General compounding procedures
○ Procedures for types of products compounded
○ Maintenance and cleaning of area and equipment
○ Quality control procedures including analytical testing procedures