After filling out form, print, sign, and mail to: Iowa Board of Pharmacy
400 SW 8th Street, Suite E, Des Moines, Iowa 50309-4688. Deadline for inclusion on Board's agenda is three weeks prior to Board meeting.

Case No. or State ID No.
Rec'd:
(FOR PHARMACY BOARD USE ONLY)

IOWA BOARD OF PHARMACY
Petition for [☑] Waiver [☐] Variance
(check the appropriate box)

PLEASE PRINT OR TYPE ALL INFORMATION IN INK

A waiver excuses the petitioner from the requirements of a rule in its entirety or from a part of a rule; a variance does not. Instead, a variance is a modification to the requirements of a rule or a part of a rule. Example: A rule requires the fencing of certain property and further requires that the fence be at least 6 feet in height. A waiver of that rule would excuse the petitioner from the requirement for fencing the property. A variance would require the property be fenced but would allow the petitioner to maintain the current fencing configuration of 5 feet in height (perhaps the fence was constructed prior to the height requirement). When replacement of the current fence becomes necessary as a consequence of normal wear and tear, the variance would terminate and the petitioner would be required to comply with the 6-foot height requirement.

Note: Statutory requirements that have been repeated in administrative rules are not subject to consideration for a waiver or variance.

Is this petition an initial request or is it a request for renewal? [☑] Initial Request [☐] Request for Renewal
If a request for renewal, explain below why the renewal is necessary.

Petitioner Information (include licensee/registrant name and name of contact person, i.e. pharmacist in charge)

Name: UI Community Homecare Phone No.: 319-337-8522
(include area code)

Address: 2949 Sierra Ct SW

City: Iowa City State: IA Zip Code: 52240

Petition Information

1. Chapter Number and Title.

   Chapter 20

2. Rule Number(s) and Title(s).

   657-20.4

See Attached for Response to 1-5.

3. Describe in your own words the essence of each Rule Number(s) and Title(s) that pertains to this petition.

4. Describe the specific nature and scope of your petition. In your description, include the anticipated time period (beginning and ending) for which the petition would apply. A waiver or variance may not be requested or granted on a permanent basis; the petition must identify an end date.

After filling out form, print, sign, and mail to: Iowa Board of Pharmacy
400 SW 8th Street, Suite E, Des Moines, Iowa 50309-4688. Deadline for inclusion on Board's agenda is three weeks prior to Board meeting.

5. Describe the relevant facts and reasons that, in your opinion, justify and provide "clear and convincing evidence" as to why this petition merits consideration for waiver or variance. In your description, explain why the rule(s) poses an undue hardship. If there is a public health, safety and welfare issue associated with this rule(s), or if this rule(s) addresses security or confidentiality issues, also explain how equal protection will be maintained if this petition were granted.

6. Does anyone else (inside or outside state government) possess knowledge relevant to this petition?

   [☐] Yes [☐] No [☑] Do not know

   If yes, list their names, addresses and phone numbers below.

7. Would anyone (inside or outside state government) be adversely affected if this petition were granted?

   [☐] Yes [☑] No [☐] Do not know

   If yes, list their names, addresses and phone numbers below.

8. Do you know how the Board of Pharmacy has treated similar situations?

   [☐] Yes [☑] No

   If yes, describe below how similar situations were handled.

9. Have you had any past interaction with the Board of Pharmacy that might impact or relate to this petition?

   [☑] Yes [☐] No

   If yes, describe below the issue involved and the outcome.

   See attached

I authorize any person with knowledge of the relevant or important facts relating to this petition to release any pertinent information to the Iowa Board of Pharmacy. I hereby attest to the accuracy and truthfulness of the information contained herein.

Debra K Allison — Petitioner's Signature

4/5/16 — Date

UNIVERSITY OF IOWA
HEALTH VENTURES

University of Iowa Community HomeCare

2949 Sierra Court SW
Iowa City, Iowa 52240-8503
319-337-8522 Tel
888-262-6469 Tel
319-337-8524 Fax
www.uicommunityhomecare.org

April 5, 2016

To: Iowa Board of Pharmacy

From: Debra Killion, RPh, Pharmacist in Charge

Petition Information

1. Chapter Number and Title

   Chapter 20 Compounding Practices

2. Rule Number and Title

   657-20.4 Sterile Compounding

3. Describe essence of each Rule that pertains to this petition.

We are a home infusion pharmacy that compounds patient specific IV medications. We do not do Risk Level 3 compounding. We do not have a clean room. We have ISO 5 Primary Engineering Controls. We do not have an ISO 7 Buffer area. We do have a segregated Buffer area in which we use Compounding Aseptic Containment Isolators (CACI).

4. Describe specific nature of the petition:

Because we use CACI to compound, some of the current USP 797 guidelines are not applicable to our situation. This includes:

- Person Specific Gloved Fingertip Sampling: we do this for each CACI quarterly.
- Smoke Tests in PEC: We have contacted manufacturer and there is documentation on file that this is not applicable. A video is available that demonstrates the smoke pattern.
- Secondary Engineering Control: Full garbing (gowns) not required as we use CACI.
- Secondary Engineering Control ACPH: Our room is positive pressure, monitored with a gauge and is constructed with smooth/impervious materials.
- Ante Area, not applicable as we use CACI.

- Air sampling of the Buffer area is completed but not as delineated since we are not ISO 7 and therefore not applicable to complete as described.

5. Describe relevant facts and reasons why this petition merits consideration for waiver.

Our current sterile compounding conditions comply with current USP 797 guidelines for use of CACI. Our current conditions have passed previous Board of Pharmacy Inspections and accreditation Visits from ACHC (Accreditation Commission for Home Care).

Per the Sterile Compounding Inspection Checklist, we comply with all aspects related to

- Training and evaluation of staff in aseptic manipulations and hand hygiene
- Media Fill Testing
- Glove Fingertip Sampling (for the CACI)
- Cleaning and Disinfecting
- Primary Engineering Control operation, testing and maintenance
- Secondary Engineering Control segregation, operation and cleaning.
- Cleaning and Disinfecting Procedures
- Viable and Nonviable Environmental Sampling and Testing and documentation
- Quality Control
- Quality Assurance Program
- Verification of Automated Compounding Devices
- Policies and Procedures

We are aware of current USP 800 rules that go into effect July 1, 2018 and of the proposed revisions to USP 797 that most likely will be finally and effective on the same date.

We plan to construct a new facility with Primary and Secondary Engineering Controls that comply 100% with USP 797 and USP 800. Until then, we will phase in all requirements that are possible given our current facility (ISO 5 PEC in a non ISO 7 Buffer Area).

6. Does anyone else (inside or outside state government) possess knowledge relevant to this petition?

Do not know

7. Would anyone be adversely affected if this petition were granted?

   No

8. Do you know how the Board of Pharmacy has treated similar situations?

   No

9. Have you had any past interaction with the Board of Pharmacy that might impact or relate to this petition?

   Yes. I have discussed this petition with Curt Gerhold, Compliance Officer during his visit on April 1, 2016.

I authorize any person with knowledge of the relevant or important facts relating to this petition to release any pertinent information to the Iowa Board of Pharmacy. I hereby attest to the accuracy and truthfulness of the information contained herein.

Debra Killion
4/5/16

STERILE COMPOUNDING INSPECTION CHECKLIST

THIS CHECKLIST IS NOT INTENDED TO CONTRADICT OR REPLACE USP <797>. IT IS MEARLY A TOOL AND MAY NOT BE ALL INCLUSIVE

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TRAINING AND EVALUATION IN ASEPTIC MANIPULATION HAND HYGIENE AND GARBING CLEANING PROCEDURES

INITIAL

EACH PHARMACY EMPLOYEE WHO IS AUTHORIZED TO STERILE COMPOUND MUST HAVE COMPLETED TRAINING AND INITIAL COMPETENCIES ***PRIOR*** TO ENGAGING IN COMPOUNDING.

DOES THE PHARMACY HAVE DOCUMENTATION OF TRAINING AND SUCCESSFULLY PASSING THE FOLLOWING FOR EACH EMPLOYEE?		YES	NO
DID THE TRAINING INCLUDE:	• Didactic • Audio-Video • Professional Publications	YES	NO
HAND HYGIENE AND GARBING procedure on page 9-10 Appendix III—*Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel* Appendix III—*Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel*		YES	NO
MEDIA-FILL TESTING-(sterile fluid bacterial culture medium transfer using a single syringe and needle) procedure on page 5 Appendix IV—Sample Form for Assessing Aseptic Technique and Related Practices of Compounding Personnel		YES	NO
GLOVE FINGERTIP SAMPLING-3 times prior to compounding see procedure on page 5		YES	NO
CLEANING AND DISINFECTING schedule on page 8 AppendixV—Sample Form for Assessing Cleaning and Disinfection Procedures		YES	NO

ONGOING (ANNUALLY/SEMI-ANNUALLY FOR HIGH RISK)

Is Hand Hygiene assessed for each compounding employee annually? see procedure on page 9-10	YES	NO
Is Glove and Garbing assessed for each compounding employee annually? see procedure on page 9-10	YES	NO
Are Cleaning and Disinfecting procedures assessed annually? (includes any custodial or institutional environmental services) see schedule on page 8	YES	NO
Are Media-Fill tests completed for the highest level of compounding performed? procedure on page 5	YES	NO
Are Media-Fill tests for LOW RISK and MED-RISK LEVELS repeated EVERY YEAR?	YES	NO
Are Media-Fill tests for HIGH RISK repeated EVERY 6 MONTHS? Not Applicable	YES	NO
Are Media-Fill tests observed and documented??	YES	NO
Are Media-Fill tests documented?	YES	NO
Are Media-Fill tests performed under the most challenging conditions? i.e. at the end of day/shift	YES	NO
Are Glove Fingertip Sampling completed as follows? Low/Med Risk—annually High Risk—every 6 months See Waiver Petition	YES	NO
Are results of Glove Fingertip Sampling properly documented? by # of CFU per person/per hand	YES	NO
Are action levels based on # of CFUs per person? (not hand)	YES	NO
Do the evaluations occur in the following order? Hand Hygiene Garbing Fingertip Sampling-discard gloves hand Hygiene Garbing Media Fill Testing Cleaning and Disinfecting	YES	NO

MEDIA-FILL PROCEDURE
Commercially available Soybean-Casein Digest Medium
• able to promote exponential colonization of bacteria
INCUBATION—20°-25° or 30°-35° for minimum of 14 days
—7 days at each temp if using 2 temperatures
FAILURE—visible turbidity in any vial/bag on or before 14 days

GLOVE FINGERTIP SAMPLING PROCEDURE:	• sterile contact agar plates • neutralizing agents shall be in agar—lecithin and polysorbate 80 • all fingers AND THUMB shall be tested • one plate for each hand • test done after compounding has been completed • NO IMMEDIATE DISINFECTING OF GLOVES • observed and documented • Gloves must be discarded after Fingertip test and hand hygiene INCUBATION • Plates securely covered and inverted • 30°-35° for 48-72 hours

ACTION LEVELS—Table 4 in USP <797>

Classification	**Fingertip Sample**
ISO Class 5	>3
ISO Class 7	N/A
ISO Class 8 or worse	N/A

PRIMARY ENGINEERING CONTROL (PEC) ISOLATORS/HOODS-LAFW, CAI, CACI, BSC ≤ 3520 particles of 0.5µm and larger per cubic meter		
Does the PEC maintain an ISO CLASS 5?	YES	NO
Is the PEC free of debris and non-essential items for the specific compound?	YES	NO
Is FIRST AIR blocked? (air direct from filter to product)	YES	NO
Are critical sites swabbed with individually wrapped/single use sterile 70 IPA (isopropyl alcohol) immediately prior to penetration?	YES	NO
Are smoke tests performed? (determines airflow and should be unidirectional away from product) See Waiver	YES	NO
Is the PEC cleaned and disinfected top to bottom and back to front?	YES	NO

SECONDARY ENGINEERING CONTROL (CLEAN ROOM/BUFFER AREA) ≤ 352,000 particles of 0.5µm and larger per cubic meter)		
Is the secondary engineering control only accessible to personnel who are garbed? See Waiver	YES	NO
Is the equipment limited to necessary items for compounding? non permeable,non shedding, Cleanable,NO SINK OR FLOOR DRAIN, NO FOOD OR DRINK	YES	NO
Are items and equipment cleaned and disinfected when first brought into room?	YES	NO
Does the secondary engineering control maintain an ISO CLASS 7 OR 8? (7 if adjacent to a negative pfessure room; 8 if is not adjacent to a negative pressure room) See Waiver	YES	NO
Are work surfaces and shelving smooth, impervious materials that can be easily cleaned? (stainless steel/molded plastic)	YES	NO
Are ceilings, walls, floors, fixtures, shelving, counters and cabinets smooth, impervious, free from cracks and crevices and non-shedding? (ceiling/wall tiles impregnated with polymer or epoxy-coated gypsum board) test with alcohol swab	YES	NO
Are junctures caulked or covered so dirt cannot accumulate?	YES	NO
Are lights mounted flush to ceiling?	YES	NO
Are carts stainless steel wire, nonporous plastic or sheet metal with cleanable canisters?	YES	NO

SECONDARY ENGINEERING CONTROL (CLEAN ROOM/BUFFER AREA)
≤ 352,000 particles of 0.5µm and larger per cubic meter)

Are activities limited to necessary movements? (decreases shedding/bioburden)		YES	NO
Are sterile gloves donned in this area? (they should be)		YES	NO
Are smoke tests performed? • determines airflow • should be unidirectional away from product	See waiver	YES	NO
Are pressure differential monitors being used? pressure gauge or velocity monitor to measure airflow between • buffer area-ante area • ante area-general compounding area		YES	NO
Are the pressure differential monitors continuously monitoring pressure and documented on log every work shift?-minimum daily		YES	NO
Does the secondary engineering control provide HEPA filtered air to room with 30 air changes per hour (ACPH)? PEC cannot be the only source of filtered air	See waiver	YES	NO
Is the air received from the ceiling and returned on wall close to the floor?		YES	NO
If there is a physical barrier between ISO class areas (ISO CLASS 5 to 7 and ISO CLASS 7 or 8 to general pharmacy area) is there 0.02-0.05 inches of water column?		YES	NO
If there is no physical barrier between ISO Class areas is there a line of demarcation?	Not Applicable	YES	NO

ANTE-AREA-where garbing, hand hygiene occur

Does the ante-area contain a sink?		YES	NO
Does the ante-area have a line of demarcation? line that separates ante-area from buffer area	Not Applicable	YES	NO
Is the segregated compounding area free of food and drink?		YES	NO

CLEANING AND DISINFECTING

Does cleaning occur from cleanest to dirtiest? • ISO Class 5 — PEC => buffer Area => ante-area =>general supply area	YES	NO
Does cleaning and disinfecting of the PEC occur at appropriate times? • before each compounding shift • before each batch is started • at regular intervals-every 30 minutes • when spills occur or are visibly soiled • when contamination is suspected (procedural breaches)	YES	NO
Is residue free disinfectant –70% IPA-allowed to dry before compounding starts	YES	NO
When heavy soiling has occurred is a pre cleaning step completed before disinfecting?	YES	NO
Are materials used for cleaning appropriate? wipes, mops, sponges • low shedding • synthetic fibers • dedicated for use in specific compounding area • mops may be used in buffer/clean and ante-area—in that order **if discarded after one use**	YES	NO
Are cleaning materials discarded daily in plastic bags with minimal agitation?	YES	NO
If items are reused are they identified in PnP's and based on manufacturers recommendations that ensure effectiveness after repeated use and does not add to bioburden of area being cleaned? Not Applicable	YES	NO
Are cleaning agents appropriate and identified in PnP's? (agents selected for compatibilities, effectiveness and toxic residues)	YES	NO
Are areas cleaned according to schedule below? using approved agents by trained personnel?	YES	NO

CLEANING SCHEDULE REQUIREMENTS	
Daily: Counters Work surfaces Floors—mopped with cleaning and disinfecting agent once daily at a time when no aseptic operations are in process.	Monthly: Ceilings Walls Shelving

THIS CHECKLIST IS NOT INTENDED TO CONTRADICT OR REPLACE USP—797—IT IS MERELY A TOOL AND MAY NOT BE ALL-INCLUSIVE

PERSONNEL CLEANSING AND GARBING-Squamous Cells are laden with microorganisms and shed from the human body at a rate of 10^6 or more per hour

Do PnP's restrict from ISO Class 5 and 7 areas personnel who have the following? • rash • sunburn • weeping sore • conjunctivitis • active respiratory infection	YES	NO
Do compounding personnel in ISO Class 5 and 7 REMOVE make-up visible jewelry (including rings) and all outer clothing? (bandanas, scarves, vests) AND are unpolished nails neat and trimmed?	YES	NO
Is donning completed in the following order? • head covers • beard covers in addition to face masks • eye shields-optional unless working with hazardous drugs or germicidal disinfectants • shoe covers or dedicated shoes (1 at a time stepping over LOD) • hand cleansing—procedure on page 10 • non-shedding gown with sleeves —snug around wrists and enclosed around neck • hand antiseptic using waterless alcohol based surgical hand scrub with persistent activity • hands allowed to dry • sterile gloves—last item before compounding begins—gloves can be disinfected by wiping or rubbing with sterile 70% IPA if they touch any non-sterile surface	YES	NO
Are gowns discarded if removed from buffer area? See Waiver	YES	NO
If gowns are reused are the discarded after one shift?	YES	NO
Are shoe covers, head covers, face shields and gloves reused? (answer should be NO)	YES	NO
Have sterile gloves been tested by manufacturer for compatibility with alcohol disinfection?	YES	NO
Are gloves inspected for punctures and tears frequently throughout compounding?	YES	NO
If gloves need to be replaced, is hand cleansing and garbing repeated?	YES	NO
Are hand cleaning procedures appropriate? procedure on page 10	YES	NO

GARBING FOR ISOLATORS		
ARE PERSONNEL CLEANSING AND DONNING PROCEDURES BE FOLLOWED FOR COMPOUNDING IN AN ISOLATOR? (answer should be yes unless manufacturer provides written documentation that any component are not required) *	YES	NO

GARBING FOR HAZARDOUS DRUG PREPARATION			
Are personnel garbed while preparing non-sterile hazardous ingredients?	N/A	YES	NO
Do personnel **REGARB** prior to entering ISO Class 7 environment?	N/A	YES	NO

HAND HYGIENE PROCEDURE—Completed after donning shoe covers upon entry to ante-area

- Use anti or non-antimicrobial soap
- Remove debris from under nails using nail pick under warm water
- Wash hands to elbows vigorously for 30 seconds with soap (microbial or antimicrobial)
- hands to elbows—completely dried using non-shedding towels or electronic dryer

*use of brushes is not recommended as they cause skin irritation and damage

VIABLE AND NONVIABLE ENVIRONMENTAL SAMPLING (ES) TESTING (are PEC and Secondary engineering controls performing as designed)

Does the pharmacy have a comprehensive viable and nonviable Environmental Sampling plan? (required for all risk levels)	YES	NO
Is the equipment tested when new and repeated after servicing?	YES	NO
Does testing occur every 6 months by a qualified individual?	YES	NO
Is it certified using state-of-the-art electronic equipment?	YES	NO
Are records of certification maintained and reviewed for competency?	YES	NO
Is surface sampling completed in all ISO areas? (PEC, anti/buffer room and segregated compounding areas)	YES	NO
Does the surface sampling plan call for the the sampling of of areas where contamination is likely? (doors, counters, pass-through boxes)	YES	NO
Is the surface sampling procedure appropriate? (gently touching the surface with agar and rolling plate across surface)	YES	NO
Does the surface sampling plan include: • areas to be tested-same each time to show trending • frequency of testing • volume tested • day and time tested—should be done at end of compounding shift • action levels • size and type of plate (24-30cm^2)	YES	NO
Are areas of sampling wiped throughly with non-shedding wipe soaked in sterile 70% IPA after sample is taken? (a residue will be left by agar)	YES	NO
Are swabs used for irregular surfaces? (wheels on carts) Not Applicable	YES	NO
Are results reported as cfu per unit of surface area?	YES	NO

VIABLE AND NONVIABLE ENVIRONMENTAL SAMPLING (ES) TESTING (are PEC and Secondary engineering controls performing as designed)		
Is air sampling completed in locations that are prone to contamination? (zones of air backwash, turbulence, doorways) SETTLING PLATES ARE NOT RECOMMENDED	YES	NO
Is air sampling completed at all stages including staging, labeling, gowning, and cleaning? Not Applicable	YES	NO
Does air sampling test 400-1000 liters at each ISO Class area?	YES	NO
Is the device used to sample the air calibrated according to manufacturer's recommendations?	YES	NO
Is the air sampling results documented on Environmental Sampling (ES) form and periodically evaluated for trends?	YES	NO
Are all cfu identified by credited laboratory? Not Required	YES	NO
Are action levels followed? Table 4 in USP <797>	YES	NO
Are CFU's above action levels investigated and re-evaluated for the following • source of contamination identified • source eliminated • affected areas cleaned • re-sampled Re-evaluation of • Personnel work practices • Cleaning procedures Equipment Filtration HVAC/HEPPA filters	YES	NO

Actions Levels Table 4 USP <797> Surface Sampling and Fingertip Sampling

Classification	Surface Sample (contact plate) (cfu per plate)	Fingertip Sample
ISO Class 5	>3	>3
ISO Class 7	>5	n/a
ISO Class 8 or worse	>100	n/a

Procedure for surface sampling.

Swabs:

- placed in appropriate diluent
- aliquot is planted on or in specified nutrient agar

Agar plates:

Soybean-Casein Digest—bacteria
Malt extract agar or other —fungi—used in HIGH RISK
additive must be added to neutralize effects of disinfecting agents

Procedure for air sampling incubation and evaluation:

TCA (bacterial media)30-35 DEGREES FOR 48-72 HOURS
Malt Extract Agar or other fungal media—26-30 degrees for 5-7 days
# of Cfu's/cubic meter

STORAGE AND BEYOND USE DATING

Expiration Date-chemical and physical stability of manufactured sterile products under certain conditions—Assigned by manufacturer

Beyond Use Date-used when chemicals are removed from the manufacturers conditions—Assigned by compounders

Are BUDs appropriately assigned using chart below? YES NO

STORAGE AND BUDs	IMMEDIATE USE pg 17	LOW RISK WITH 12-BUD pg 18-19	LOW RISK pg 18-19	MEDIUM RISK (TPNs are MEDIUM RISK) pg 20-21	HIGH RISK pg 22-23	PROPRIETARY BAG AND VIAL SYSTEMS Add-Vantage® Mini Bag Plus® Add A Vial® Add Ease®
ROOM TEMPERATURE	1 HOUR	12 HOURS	48 HOURS	≤ 30 HOURS	24 HOURS	According to manufacturer
REFRIGERATED	N/A	12 HOURS	14 DAYS	9 DAYS	3 DAYS	According to manufacturer
FROZEN	NA/	N/A	45 DAYS	45 DAYS	45 DAYS	According to manufacturer

Single Dose and Multiple Dose Containers	
Single-Dose containers	must be used within 1 hour if opened in worse than ISO Class 5
If opened in < ISO Class	must be completely used within 1 hour of first puncture
Opened in ISO Class 5	must be completely used with in 6 hours of first puncture
Ampules	not stored for any period of time
Multiple-Dose containers	
BUD	28 days after first puncture (unless manufacturer specifies otherwise)

MONITORING STORAGE AREAS

Is the temperature logged daily and when product is placed in or removed from area?	YES	NO
Is Continuous Monitoring verified once daily?	YES	NO

QUALITY CONTROL

Is each unit of sterile commercially available products and ready to use containers inspected prior to use?	YES	NO
Is every piece of equipment calibrated after routine maintenance?	YES	NO
Is equipment monitored for proper function?	YES	NO
Are personnel trained on the proper use of equipment?	YES	NO
Is documentation kept on file for life of equipment?	YES	NO

QUALITY ASSURANCE PROGRAM

Is a formal, written QA program in place that includes the following? • CSP prep and dispensing • environmental testing & results • how to report and evaluate info • delineate by name or title of person responsible for each part of QA program	YES	NO

VERIFICATION OF AUTOMATED COMPOUNDING DEVICES (ACDs) OR PARENTERAL NUTRITION COMPOUNDING

TPNs ARE MEDIUM RISK

Are ACD's tested for weight and volume accuracy daily as outlined below?	YES	NO
Is the record maintained and reviewed weekly?	YES	NO

PROCEDURE FOR ACD VERIFICATION

VOLUME Procedure:

- suitable volume of Sterile Water for Injection that represents typical additive volume
  - 40 ml for small volume—1-100 ml
  - 300 ml for large volume—100-1000 ml
- programmed into ACD and delivered to volumetric container

WEIGHT Procedure:

- balance used in conjunction with ACD
- weights used to verify accuracy
- Sterile Water for Injection should be weighed (40 ml should weigh 40 grams)

HOME INFUSION PATIENT OR CAREGIVER TRAINING

Does the pharmacy have a training program for patients or caregivers?	YES	NO
Does it include the following? • hands-on demonstration and practice • aseptic and injection technique?	YES	NO
Is documentation of patient and caregiver training and understanding maintained?	YES	NO

PATIENT MONITORING & ADVERSE EVENT REPORTING

Do you have a P &P on addressing adverse events claimed to be associated with CSPs?	YES	NO
Does the P & P give instructions on the following? • Receipt of adverse event reports • Recording reports of adverse events • Reviewing and evaluating adverse event reports by compounding supervisor	YES	NO

POLICIES AND PROCEDURES			
Access to buffer area	restricted to qualified personnel with specific tasks	YES	NO
Storage	proper temperature and segregation of hazardous drugs	YES	NO
Supplies	decontaminated in area by removing them from shipping cartons and wiping or spraying them with non-residue-generating disinfecting agent while they are transferred to clean disinfected cart for introduction into buffer area	YES	NO
	supplies that are needed frequently can be decontaminated and stored in ante-area	YES	NO
	those for use in direct compounding areas shall be decontaminated prior to introduction into aseptic area arranged to decrease clutter and not block first air	YES	NO
	after use all are removed with the least amount of movement	YES	NO
Carts	for buffer area can not be rolled beyond line of demarcation unless cleaned and disinfected before returning	YES	NO
Non Essential shedding items	shall not be brought into buffer area including pencils cardboard paper towels cotton items (gauze pads)	YES	NO
Essential paper items	shall be put into protective plastic and wiped down prior to being brought into buffer area Not Applicable	YES	NO
Traffic Flow	in and out of buffer area shall be minimized	YES	NO
Personnel	must remove all outer garments, cosmetics, visible jewelry	YES	NO
	entering ante-area must don attire then perform hand washing	YES	NO

POLICIES AND PROCEDURES cont.			
Buffer area/ante-area	no food, gum or drinks	YES	NO
Cleaning and Disinfecting	Cleaning must be completed at beginning of compounding shift and when spills occur with purified water and then Disinfected with non-residue-generating agent using non-shedding wipe	YES	NO
PEC	shall be operated continuously. If turned off it must be turned on 30 minutes prior to cleaning and disinfecting before compounding can begin	YES	NO
Traffic	in designated compounding area shall be minimized and controlled	YES	NO
Gloves	disinfected frequently with Sterile 70 % IPA allowed to dry	YES	NO
Rubber stoppers and necks of vials	disinfected with sterile 70% IPA and allowed to dry (10 seconds) before they are used to prepare CSPs	YES	NO
Labels	contain correct names and amounts or concentrations of ingredients, total volume, BUD, route of administration, storage conditions, date prepared and any other information for safe use	YES	NO
Verification	correct identities, purities, amounts of ingredients by comparing original order with compounding record	YES	NO
	fill volume is correct and free of particulates,	YES	NO
Compliance with PnPs	for all aspects of compounding, storage, handling, transporting	YES	NO
Redispensing of CSPs	facility has sole authority		
Education and training			