National Home Infusion Association Comments on General Chapter <797> *Pharmaceutical Compounding—Sterile Preparations*

Revision proposed in *Pharmacopeial Forum* 44(5) Sept/Oct 2018

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General Comments:

Dear USP Compounding Expert Committee:

The National Home Infusion Association (NHIA) respectfully submits the comments outlined in the table below regarding the revision released September 4, 2018, to the General Chapter <797> *Pharmaceutical Compounding – Sterile Preparations*. NHIA is the trade association representing organizations that provide compounded sterile products and services to patients in the home setting. NHIA would like to express appreciation to the committee for their work to update and improve upon the existing standard to ensure patients consistently receive safe, high quality sterile medications. NHIA applauds the committee for incorporating many of the suggestions made in our comments submitted in response to the first revision published in 2015. Again, NHIA appreciates the opportunity to comment on the proposed revision and asks for consideration from the committee related to the presented suggestions and concerns. If you have questions regarding the comments submitted by NHIA, please contact Connie Sullivan, at connie.sullivan@nhia.org.

Specific Comments:

Section(s)	Line Number (s)	Existing text: (Provide the proposed text.)	Suggested change: (Provide the revised suggestion to replace the existing text.)	Comment
1	10 - 28	Preparing a conventionally manufactured sterile product in accordance with the directions contained in approved labeling provided by the product's manufacturer is not compounding as long as the product is prepared for an individual patient and follows the provisions for administration below. AND Preparation of non-hazardous CSPs for a single patient using only sterile starting ingredients when administration will begin within 1 hour of beginning the preparation (e.g.,	Preparing a single dose of a conventionally manufactured, non-hazardous, sterile product in accordance with the directions contained in approved labeling for an individual patient is exempt from the chapter if administration begins within one hour of initiating compounding.	This statement conflicts with the definition of compounding in lines 5 through 7. Performing the same acts as defined above as sterile compounding still qualify as compounding, but are being exempted from the chapter under certain circumstances, (i.e. preparation according to package insert for administration). The organization of these elements may create confusion as to when the chapter applies. The proposed language attempts to combine these elements to more clearly state the situation where the exemption applies without creating a conflicting definition of compounding.

		within 1 hour of initial entry into or puncture of a single-dose container) is not required to meet the standards in this chapter.		
1.1	67-69	Compounding using biological products requires special considerations because these products are particularly susceptible to microbiological growth and chemical and physical degradation.	Delete	This is a broader statement than what is required for the above reference to blood components.
3.1	312	Remove personal outer garments.	Provide examples, (e.g., hats, scarves, jackets,)	
3.1	320	Not bring electronic devices that are not necessary for compounding or other required tasks into the compounding area.	Limit electronic devices in the compounding area to those used to facilitate the compounding process.	Compounders may utilize cameras or other electronic devices to verify compounding procedures, perform calculations, communicate, etc. There may be some instances where these devices could be useful to limit the number of personnel in the compounding areas, or reduce the frequency of entry/exit into the area.
3.3	365-366	When personnel exit the compounding area, garb cannot be reused and must be discarded.	Personnel exiting the compounding area may re-use gowns for up to 12 hours as long as the gown is not visibly soiled or torn, and the gown is stored in the anteroom or SCA.	
4.2	479-502	All wording		Reorganize to connect with the Cleanroom Suite section starting on 454.
4.2	489-492	Airlocks and interlocking doors can be used to facilitate better control of air balance between areas of differing ISO classification (e.g., between the buffer room and ante-room), or between a classified area and an unclassified area (e.g., between the ante-room and an unclassified area such as a hallway).	Airlocks and interlocking doors **should** be used to facilitate better control of air balance between areas of differing ISO classification (e.g., between the buffer room and ante-room), or between a classified area and an unclassified area (e.g., between the ante-room and an unclassified area such as a hallway).	The current wording might be interpreted as a requirement.
4.2	692-693	Presterilization procedures must be performed in a containment ventilated enclosure (CVE), BSC, or CACI to minimize the risk of airborne contamination		Add definitions as appropriate as some sterile compounders are not familiar with CVE's or comparable enclosures. Harmonize with <795> in terms of requirements for pre-sterilization containment location and certification requirements.
4.3	717-718	Floors must include coving to the side-walls.	Floors should include coving to the side-walls.	Allow for alternatives to sealing the junction between the floor and walls.
4.4	740	In facilities with a cleanroom suite, the sink used for hand hygiene may be placed either inside or outside of the ante-room.		Retain the option to position the sink outside the ante-room; and clarify that if located in the anteroom, the sink must be placed on the clean side of the line of demarcation.
4.6	835-837	If levels measured during the nonviable air sampling program	If levels measured during the nonviable air sampling program exceed the criteria in Table 3	

		exceed the criteria in Table 3 for the ISO classification of the area sampled, the cause must be investigated and corrective action taken.	for the ISO classification of the area sampled, the cause must be investigated and corrective action taken, **including re-testing.**	
11	1521-1537	All wording	Combine the two separate sections with requirements for the immediate label.	
11	1529	Indication that the preparation is compounded.	Delete	Many software systems are limited in the number of characters available for the label placed on the immediate container. This information is not necessary, or could be included in supplemental labeling materials.
12.1	1552-1554	Each CSP label must state the date, or the hour and date, beyond which the preparation must not be used or administration must not begin, and after which time the preparation must be discarded.	Each CSP label must state the date (or in certain cases the hour and date) beyond which the preparation must be discarded to prevent the CSP from being administered or used in compounding.	The current wording is confusing and leading some to interpret CSPs as needing two separate dates on the label.
Table 12	1672	BUD for aseptically prepared CSPs from sterile starting components, not sterility tested.	Change 9 days to 12 days for refrigerated storage.	The current BUDs are not based on evidence. Extending the BUDs by a few more days would provide compounders who ship medications the ability to store CSPs for at least 24 hours, ensuring the CSP is sufficiently chilled prior to shipping.
Table 12	1672	BUD for aseptically prepared CSPs from sterile starting components, not sterility tested.	Change 4 days to 6 days for room temperature storage.	The current BUDs are not based on evidence. Extending the BUD for drugs that cannot be refrigerated, but are prepared from sterile starting components under the conditions outlined in the chapter would not propose a significant increase in risk. Currently, this short BUD promotes bed-side compounding of hazardous drugs such as 5-FU.
13.1	1716	If a single-dose vial is entered or punctured only in an ISO Class 5 or cleaner air, it may be used up to 6 hours after initial entry or puncture.	If a single-dose vial is entered or punctured only in an ISO Class 5 or cleaner air, it may be used for the duration of time specified in the manufacturer approved labeling so long as the storage requirements are met.	Extending the use of a single-dose vial punctured under ISO 5 conditions would alleviate shortages and reduce waste without introducing significant risk.
14.1	1742	A compounded single-dose container is intended for one-time administration (e.g., injection, infusion, case) for a single patient.	A compounded single-dose container is intended for one-time administration (e.g., injection, infusion, case) for a single patient. If a compounded single-dose container is entered or punctured outside of ISO 5 or cleaner air, it must be used within 1 hour or by the end of the case in which it will be used, and any remaining contents must be discarded.	Use consistent language as section 13.1 regarding puncturing in worse than ISO 5 air.
14.2	1751-1755	The compounded stock solution must be stored according to storage conditions for the BUD assigned. The compounded stock solution must	The compounded stock solution must be stored according to storage conditions for the BUD assigned, and may only be entered or punctured in an ISO Class 5 or cleaner air. The CSP must	Extending the use of compounded stock solutions punctured under ISO 5 conditions would alleviate shortages and reduce waste without introducing significant risk.

		only be entered or punctured in an ISO Class 5 or cleaner air. It may be used for up to 6 hours after initial entry or puncture. The remainder must be discarded.	be discarded according to BUD assigned.	