Washington
State
Hospital
Association

WSPA
WASHINGTON STATE PHARMACY ASSOCIATION

February 15, 2015

Peggy Crain (Peggy.Crain@doh.wa.gov)
Department of Health – Staff

Re: Pharmacy Quality Assurance Commission's draft compounding practice rule

Dear Ms. Crain,

The Washington State Pharmacy Association (WSPA) and the Washington State Hospital Association (WSHA) respectfully offer the following comments and recommendations on the Pharmacy Quality Assurance Commission's (PQAC) "draft compounding practice rules." Our comments and recommendations are provided on behalf of 1700 member pharmacists and pharmacist technicians and 99 hospitals across the state.

As an active participant in efforts to advance the practice of pharmacy we fully support work which aims to improve patient safety and quality across the health care landscape. We acknowledge the effort by PQAC in developing the draft compounding rule, which seeks to improve the practice of pharmacy and compounding in Washington State.

The public comment period affords interested stakeholders, specifically the two associations representing and dealing with the practice of pharmacy, the opportunity to provide input into the development of the new rule. While a number of WSPA and WSHA subject matter experts from both urban and rural settings met to discuss the draft rule, the compressed timeline from the release of the crosswalk to the close of the comment period did not afford a complete opportunity for an in-depth analysis. We look forward to providing additional comments during future commenting periods.

WSPA and WSHA have identified a number of strong concerns with the draft compounding rule and these are detailed in our enclosed comments. We have encouraged our members to submit comments directly, but some have expressed reservations about surfacing such concerns directly to the regulatory body which oversees them.

One of our major concerns with the proposed rules is making sure these recommendations align with national requirements. We have had an offer from a national consulting firm to offer pro bono assistance and can provide additional information if you are interested.

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We appreciate your attention to our joint comments and recommendations. WSPA, WSHA and our members invested a great deal of time and energy reviewing the draft rule and developing comments and recommendations. If a comment or recommendation is not accepted, we respectfully request that the Department of Health and PQAC provide a concise explanatory statement as to why changes were not considered.

We look forward to your response and any opportunity to work more directly with PQAC on this draft rule. Should you have any questions please contact, Jeff Rochon, Chief Executive Officer, (425) 207-3641 or Jrochon@wsparx.org and Ian Corbridge, Policy Director, Clinical Issues, Washington State Hospital Association at (206) 216-2514 or Ianc@wsha.org.

Sincerely,

Claudia Sanders

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Enclosure: 1

Enclosure

Comments and recommendations are organized by high-level concerns, followed by specific comments.

High-level Concerns:

1. **Creation of Rule Based on USP <797> Receiving Significant Update**

   While we agree that these rules are very important and recognize the work of the committee over the past 2 years, we are told that USP <797> is undergoing significant amendments and the draft is supposed to be released within the next month. Since this rule is based on USP <797> is would be appropriate to wait for the new version of USP <797> to be released before finalizing this rule. The rule making process is very onerous and the finalization of a rule based on an outdated chapter of USP would immediately create the need to start another labor-intensive and costly rule writing process. We have other important rules that also need to be written. Please delay finalization of the rule until the new USP <797> chapter is finalized.

2. **Overstepping Reasonable Authority:**

   While PQAC has the authority to promulgate rules, it should not cite or use standards in the rules that do not have national level consensus or that have not been formalized. The crosswalk provided by the Department of Health identifies USP <800> as the authoritative source approximately 32 separate times. USP <800> has not been officially adopted at a national level, and is currently in draft form under review. Any material or references to USP <800> should be stricken from the draft rule.

   Washington State has existing rules on the handling of hazardous drugs, specifically WAC 296-62. Section WAC 246-878-075 'Hazardous Drugs' of the draft rule attempts to add additional regulations on the handling of such material. This draft language is contradictory and duplicates existing rules, and will only serve to create more confusion in the marketplace. Rules governing a particular practice or issue should be concentrated in one location of the Washington Administrative Code. To reduce confusion, we respectfully ask PQAC to strike WAC 246-878-075 from the draft rule.

   Furthermore, stakeholders requested that PQAC consult with the Department of Labor & Industries on provisions pertaining to hazardous drugs. This draft rule does not reflect that any such collaboration took place. We strongly encourage PQAC to collaborate with Labor & Industries on issues pertaining to hazardous drugs.

3. **Definition Section:**

   Clear and succinct definitions are essential to properly understanding the scope of any regulation. With this in mind, WSPA and WSHA requested a crosswalk between the proposed draft and other authoritative sources to better understand how the definitions

were identified or developed. Unfortunately, the two-month delay in providing this crosswalk did not permit WSPA, WSHA and our members sufficient time to properly vet the definitions and evidentiary citations. We look forward to providing additional comments at a later date or during subsequent periods of public comments.

There are a number of discrepancies, inaccuracies, or potentially misleading citations throughout the definition section (WAC 246-878-010) of this proposed rule. In many instances, the proposed definitions do not align with USP <797>. Currently, USP <797> provides pharmacies across the nation a standard of practice by which to follow. Definitions in WAC 246-787 should align with USP <797> in an effort to establish clarity across the state. Definitions that do not align with USP <797> should be augmented or stricken.

Furthermore, the crosswalk document explicitly states that some definitions were taken, "in part from USP <797>." It is unclear to stakeholders what "in part" truly means. It is imperative for PQAC to be transparent and clear when a definition has been augmented. If a situation necessitates the need to vary from a USP <797> definition, an explanation should be provided and stakeholders should be permitted the opportunity to comment.

The gold standard for safely preparing and operating a sterile compounding practice is USP <797>, and we respectfully request that any rules imposing stricter standards are supported by additional evidence to support new requirements.

4. Endorsement Requirements:

WAC 246-878-015 of this draft rule denotes that all "pharmacists and pharmacy technicians must obtain a sterile compounding endorsement...in order to perform sterile compounding activities." This section raises a number of concerns and questions including, but not limited to:

I. What is the purpose or intent?;
II. What does the endorsement include?;
III. Is such an endorsement required in other states?;
IV. Will it be displayed on the pharmacists or technicians license?; and
V. Will there be an associated cost?

WSPA and WSHA request clarification on the above questions.

Access to health care services, especially in rural areas, is a priority for WSHA, WSPA, and the Department of Health. As currently written, we have concerns access may be compromised for rural entities who rely upon nurses to perform compounding during times when a pharmacist is not available. We request clarification about whether a registered nurse can perform compounding, and if the registered nurse would also need a compounding endorsement.

Furthermore, the extra endorsement will not only place a burden on licensed pharmacists and technicians, but will also require additional Department of Health personnel. This burden and increased cost is not justified.

Given the above noted concerns regarding the compounding endorsement, we recommend PQAC consider an alternate path, allowing facilities to conduct structured training programs for appropriate staff and third parties who may compound drugs. Allowing designated individuals who have received the proper training to compound drugs will ensure access to such services, especially for rural areas.

We also question the placement of this WAC and the endorsement requirement in the draft rule. If a compounding endorsement will be required, it would seem logical to place such a requirement in 18.64 RCW, which pertains to licensing for pharmacists and pharmacy technicians. Accordingly, we respectfully encourage PQAC to reconsider the placement of this potential requirement.

Lastly, USP uses a risk model to determine the appropriate training and protective steps necessary for personnel conducting drug compounding. This draft rule does not take into account such risk models and instead, views all compounding activities under one umbrella. We strongly encourage PAQC consider adding a risk model into any endorsement requirements for compounding activities.

5. **Training Program Requirements:**

It is the conclusion of WSPA, WSHA, and our members that WAC 246-878-035 of this draft rule is overly prescriptive and will eventually create the need for additional rulemaking as evidence or best practices evolve. We recommend revising this section to provide more guidance on the direction and objectives of training programs, as opposed to only outlining the specific requirements.

Section 246-878-035 WAC states, "All personnel involved in...compounding sterile preparations shall receive a minimum of thirty (30) hours of didactic instruction and forty (40) hours of experiential training." While we agree training for personnel is essential, the hourly requirements listed in this rule are unjustified when content should be the focus of training. In addition, these requirements excessively add costs and take staff out of the clinical setting, ultimately creating barriers to providing patient care.

We respectfully recommend that PQAC reconsider the hour requirements for training. It is our recommendation that training requirements focus on objectives instead of time requirements. We ask PQAC to revise this section by detailing objectives that should be part of any training program.

We were told that Critical Points Compounding (CPC) was consulted in the development of this draft rule. This is unprecedented and outlandish. We also understand CPC offers a training program with 30 hours of didactic training at a cost of $699. While it may be unintentional, the appearance of a conflict of interest exists for profit-driven entities to manipulate Washington State rules for financial gain. We therefore request you please provide us with the evidentiary citation for the hour requirements listed in the draft rule.

PQAC provides three options for training programs. The draft rule states that on-the-job didactic and experiential training must be preapproved by PQAC. As stakeholders, we fear that PQAC will not have sufficient time and resources to review and make informed

decisions regarding the approval of training programs. A delay in approval may compromise patient care and access, and we urge you to consider these potential issues.

6. **Pharmacist In Charge Requirements:**

As associations representing pharmacists, pharmacy technicians, and hospitals, we have strong concerns with the draft rule language pertaining to the "pharmacist-in-charge" (PIC). Please provide the rationale and evidentiary citation for the requirement that a PIC be "on site... for a minimum of thirty-two hours per week."

While a PIC may be ultimately responsible for these duties, we do not believe it should be required for the PIC to be the individual who actually conducts all the duties outlined in this proposed provision. We have found, in practice, many of these duties may be competently completed by another member of the pharmacy staff (i.e., designated technician trainer or coordinator, or pharmacist manager). It is unclear whether the intention was for the PIC to be responsible to actually conduct these requirements or whether they may delegate to another competent member of the pharmacy staff, and oversee completion of the requirements.

Additionally, we object to the language stipulating that a PIC can "not be in charge of more than one licensed pharmacy at a time." We believe a PIC should be permitted to oversee multiple pharmacies. Delegating the duties outlined in WAC 246-878-030 to a pharmacy manager aligns more appropriately with the job description of a pharmacy manager. Therefore, we respectfully request you strike this limitation.

7. **Prescription vs. Setting a Vision:**

As previously noted, the draft rule is very prescriptive in nature. We respectfully request PQAC consider revising the draft rule to provide more guidance and direction, as opposed to specific granular requirements. This type of guidance will better assist the practice of pharmacy as evidence and practices evolve.

8. **Potential Negative Impacts on Access to Pharmacy Services in Rural Areas:**

WSPA and WSHA have a strong commitment to ensuring access to pharmacy services across the state. It is important that this draft rule not place undo barriers or requirements, such as excessive training or document retention policies on facilities, especially rural facilities that may have existing resource or workforce barriers. Such barriers or requirements may jeopardize patient's access to care.

Also, please provide an implementation plan with timeframes in future drafts of this rule. We anticipate that many facilities, especially small facilities, will have to update structural components, workflow, and policies. It is essential for stakeholders to be afforded the appropriate amount of time to make such changes.

Specific Comments:

Definitions:

Anteroom – "where personnel hand hygiene" should read where personnel perform hand hygiene."
American Society of Hospital Pharmacists- should be "American Society of Health-System Pharmacists."
Compounding – the definition of compounding is overly proscriptive and narrow. We recommend the compounding definition aligns with USP <797> or the FDA definition, and should not include "packaging" and "labeling".
Batch – Defining "batch" as "more than one" is far too restrictive and will cause technicians to spend a lot of their time on documentation. We recommend revising the batch definition to be less restrictive.
Manufacturer – The definition of "manufacturer" as proposed is overly broad. For instance, the proposed definition infers labeling or packing a product is manufacturing. Depending on the type of practice, the act of repackaging for resale is very different than repackaging for internal use and this definition does not make that distinction. Additionally, the proposed definition goes well beyond the WAC 246-878-020 and RCW 18-64-011, cited in the crosswalk document as the foundation for the definition. Finally, we believe this proposed definition contradicts WAC 246-895-010 (definition of "manufacture") and may potentially lead to confusion and inconsistencies, especially with regards to commercial containers
Segregated Compounding Area – A second look at the proposed definition of "segregated compounding area" is needed to maintain consistency with the current USP 797 standard.

We have found unnecessary duplication, inconsistencies, and contradictions between these proposed rules and USP 797, federal requirements from the FDA, as well as state level requirements, including Washington's hazardous drug rules (WAC 296-62-500). With this in mind, and to guarantee proper implementation and compliance, we recommend cross referencing rules and making appropriate revisions to ensure the rules supplement each other accurately.

WAC 246-878-015 Licensure requirements – We request further guidance by specifically defining "non-resident pharmacy" and clarifying whether this means a pharmacy is out of state, or something else. Moreover, what are the requirements in the case of a satellite pharmacy, and would satellite pharmacies be considered non-resident pharmacies? As currently written in the draft language, this may be subject to multiple interpretations.

Additionally, this section should be drafted with the FDA's Section 503B requirements in mind. Why is it not enough for manufacturers to be inspected by the FDA but to also add the extra costs associated with added state requirements? We have concerns this may be a disincentive for working with facilities located in Washington State.

WAC 246-878-030 Personnel compounding sterile preparations -

Section 1(c)(viii) - We request the "release test" be clarified or defined, as we find it unclear as currently proposed. For example, what does the release test entail? Also, is the release test in this rule referring specifically to high-risk compounds?

Section 1(c)(xviii) - We request you provide further guidance in this section related to the instruction requirements. For example, does this provision require instructions to be sent to the outpatient infusion center for every compounded sterile preparation (CSP), including CSPs prepared for operating or surgical areas and products that are administered by a clinician in a health care facility? Moreover, is this requirement referring only to home infusion products?

Section 1(c)(xix) - We have strong concerns this requirement would go far beyond the standard practice, and be extremely time consuming. Specifically, the resources required to comply with this provision would be unreasonable, and outweigh the value when standard recipes and compounding logs are in place for most items. We request you provide us with further information and your rationale for supporting this requirement.

Section 2(d) - Although it may be preferred, performing in-process checks is not always feasible due to personal protective equipment (PPE) and garbing requirements required by USP 797. Additionally, the setup of the clean rooms in reference to the layout of the pharmacist workstations may hinder the ability to perform the in-process checks. In order to be compliant, this provision would require significant investment in added technology, such as camera equipment and software to support these in-process checks. Finally, this provision goes beyond the requirements of USP <797>, and we respectfully request more information supporting rationale behind enacting a more stringent rule.

WAC 246-878-035 Personnel education, training, and testing - Speaking generally, we have a number of concerns regarding the new requirements for personnel who participate in producing CSPs.

Section 2 - Training and program development does not typically need to be performed by a pharmacist. Pharmacy technicians are the experts in the sterile compounding field and can provide training and program execution. For instance, an IV coordinator can serve as a USP <797> expert and trainer, and be a pharmacy technician. In most hospitals, pharmacists do not do the actual sterile compounding. Technicians do the compounding and pharmacists do the checking.

Section 7 - USP requires twice-yearly competency testing for high risk compounding and once yearly for low and medium risk compounding. The time and financial resources necessary to certify all compounding staff twice yearly would create a hardship. Also, please reconcile with proposed sections three and four to WAC 246-878-100, to resolve contradictory language stating "once yearly".

Section 8 - Five hours of continuing education (CE) pertaining to sterile compounding is overly burdensome representing 1/3 of the total continuing education requirements. This seems excessive when techniques to not change from year to year and amount of actual time on the job compounding will vary greatly between individuals and settings. From our experience, we have found very few training programs available related to CSPs. This lack of available and accessible trainings may ultimately pose challenges for infusion pharmacists and technicians to meet the requirements. We respectfully ask PQAC to lessen the continuing education requirements for compounding.

WAC 246-878-045 Operational standards -

Section 1(a)(ii) – It is unclear whether this section is referring to all in-facility administered CSPs, and whether this provision applies to batched compounds, medications for the operating room, and infusion centers. Additionally, current practice at infusion centers and hospitals require in-facility medication orders to be signed by a physician. With this practice in mind, we believe sufficient protections are already in place, making the prescription requirement overly duplicative.

Section 1(b) – We have concerns the language of this provision is overly limiting, and precludes pharmacies from making the business decision to compound. Currently, rather than using commercially available products, pharmacies may choose to compound, giving the pharmacies control to guarantee high quality products and ensure compliance with all requirements. In practice, specific examples include: (1) drawing up and labeling CSPs for use in operating rooms to ensure products are properly labeled for providers, (2) insourcing compounding of products to manage costs, (3) preparing Avastin for ophthalmology clinic areas, and (4) buffering lidocaine. From our perspective, the ability to buy larger volumes of medications and put them into smaller containers for patient use is imperative and analogous to buying a 1000 count bottle of tablets which are placed into vials for each patient. We do not want to be required to always use commercially available products like unit dose. Furthermore, we have strong concerns the requirement from section 1(b)(iv)(A) impedes provider prescribing practices and clinical decision making processes.

Section 2 -Why do the reference materials need to be listed in the rule? They should fall under the existing WAC 246-869-180.

Sections 3(a) and (b) – Section 3 has a number of areas of uncertainty, and we request further clarification. For instance, in section 3(a) we are uncertain how the designation of a physician in these instances relates to compounding practices and ultimately within the scope of this rule. Specifically, is this record in addition to documentation in the EMR or progress notes by physician? Further, although the language requires documentation of this physician designation in the patient medication record system, how will this provision be enforced? Additionally, in Section 3(b) we are unclear whether this section refers to home infusion CSPs?

Section 3(c) – We respectfully request that PQAC strike this section. It is unreasonable to expect that "an appropriate health care provider" will be able to monitor every new drug therapy for a patient. Currently, the compounding pharmacy is not always involved in patient response at home, and we believe this provision is unnecessarily specific. Accordingly, we believe it is unnecessary for the PIC to always be responsible for conveying drug therapy response to the provider. We have found the provider or person administering the drug is typically most appropriate. In our practice, some patients may be better served by an infusion RN or visiting/home RN who is caring for and monitoring the patient response.

Section 3(f) – Please clarify whether this section applies only for home IV dispensed prescriptions.

Section 3(g) – Please clarify "multi-use" or "bulk" preparation, as this could potentially impact patients in rural settings. For instance, "bulk" could refer to multiple doses of antibiotics prepared in advance, labeled, and dispensed to a patient for a one week supply of administrations. Alternately, this definition could also refer to insulin injections, MTX injections, testosterone

vials, and pituitary injections. Therefore, we strongly encourage this definition to be clearly stated as to avoid multiple interpretations.

Section 4(c) – These are not needed as they are redundant to FDA labeling criteria. Please strike this section.

We are hoping to be provided with the rationale behind this requirement, and seek further guidance. For example, please provide more details whether this the labeling while compounding in hood from a pool?

Section 5(a)(i) and 5(a)(ii) – We have a number of concerns relating to this section, and request further guidance. In particular, we would like clarification as to why two documentation sheets are required, and recommend removing the words "and on which all documentation for that batch occurs" from section 5(a)(i). The work sheet described in section 5(a)(i) should not be a documentation sheet because this is a recipe sheet for reference by the compounder or checking pharmacist. Furthermore, a pharmacist does not necessarily need to develop the work sheets, but perhaps only approve the work sheets. In practice, the compounding technician or coordinator typically develops the standardized records and recipes, which is then reviewed by a pharmacist. Also, we have questions why this has to be a PIC, when we believe it could be any trained and qualified infusion pharmacist.

Also, we believe section 5(a)(i)(D) should ultimately be removed. We believe the PIC should not be required to sign off on the recipe, but only be required to sign off on the preparation reference worksheet. Please keep in mind that no paper should be in clean rooms and minimal paper should be in anterooms for safety purposes. Finally, in accordance with Section 5(a)(ii)(L), an adverse event would not be known to have occurred when completing the preparation work sheet. Since it would be impossible to document an event that has yet to occur, is this language proposing to return to the preparation work sheet after the adverse even has occurred? Please elaborate further on the value of this requirement.

Section 5(b)(ii)(G)(I) – Please clarify whether this section requires documentation of the BUD from the package insert or USP on every compounded item. If this is the case, please elaborate the value in documenting the BUD on every CSP prepared, because this activity would be overly burdensome, and should instead be a part of the master formula requirements section 5(a)(i), not requiring documentation with every preparation.

WAC 246-878-055 Microbial contamination risk levels and beyond-use-dates

Section 2(a)(v) - Please provide a definition of what is meant by "bacteriostatic substance". Although there is an example ("externally worn infusion device"), this could be misinterpreted or be applied inconsistently across different providers.

Section 4(a)(v) – This sentence is an editorial note and should not be in the draft rule. Please strike.

WAC 246-878-060 Compounding Sterile Radiopharmaceuticals

We strongly advise PQAC to reach out to nuclear pharmacy stakeholders to get comments on this section. We do not have that expertise in our membership.

WAC 246-878-065 Environment

Section 3(b)(i) – We believe "at least 0.2 inches of water" should read "at least 0.02 inches of water" to be consistent with USP <797>. Please update.

Section 5(e) –The BUD table for medium risk level under refrigeration lists 7 days. We believe it should be listed as 9 days to be consistent with USP <797>. Please update.

We have strong concerns these proposed revisions are often contradictory or go well beyond the current requirements under USP <797>. Is there documented evidence demonstrating a need for these additional requirements? We are providing a number of questions for clarification related to these apparent inconsistencies with USP <797>.

For instance, in section 3(b)(iv), this proposed requirement goes beyond USP <797>, and we are curious why this is necessary when facilities are meeting USP <797> air exchange and pressure requirements? Additionally, in section 3(c), why require ceilings caulked in all IV room areas when USP <797> requires only ceilings in the buffer area to be caulked? We interpret USP <797> to define the line of demarcation as a physical separator or line between the buffer room and anteroom. However, the proposed language in sections 4(c)(iv) and 4(c)(v) as dirty to clean areas in the anteroom. Please clarify what is meant in the proposed language. Also, in section 4(c)(viii), please explain the justification behind specifically requiring "marine grade epoxy paint" or an "approved equivalent", when USP <797> does not specify such a paint requirement. From section 5(b), please clarify which tests are required for the clean room suites, and if we have colony forming unit (CFU) on a surface, do we need to shut down the room under this proposed revision?

Finally, we have concerns sections 5(e)(i) and 5(e)(iii) are contradictory statements. Specifically, one statement directs "must do" testing and the other states documentation of criteria used to determine BUD. We request further explanation of this potential contradiction.

WAC 246-878-075 Hazardous drugs

As stated above, this rule is duplicative to WAC 296-62 and we ask that it be removed.

Section 5(g)(i) –We have concerns with this provision because the mask is not only for employee protection, and we believe this language is misguided. The PEC is protecting the staff member. The mask is providing product protection and is not solely for employee protection. The respirators are not easily cleaned and could introduce contamination potential to clean rooms and CSPs. This could pose a safety risk to personnel if placing a hazardous drug exposed respirator on the face. In our experience, a disposable product would be preferred in a hazardous drug environment. We would not want to use negative pressure respirators in positive pressure rooms, because this would require the costly purchase of two respirators and yearly fit testing for each compounding staff member.

Section 6(c)(ii)(A) – We are requesting further guidance on how to decontaminate under the proposed rules. Specifically, what type of agent should be used to decontaminate? For instance, it would be necessary to use bleach to remove any chemo residue. Bleach, however, will be caustic to the outer bag or syringe and could infect or have other effects the final product. Accordingly, we suggest additional guidance is provided.

Section 7 – In circumstances where spill control cleanup and containment is contracted with an outside vendor, is it possible to defer training, polices, and procedures to a third party? At some facilities, an outside agency is called to clean up hazardous spills.

Section 10 – We have strong concerns with the new medical surveillance requirements, and believe a thorough questionnaire and baseline complete blood count should be sufficient. The requirements in this section are time consuming, costly, unrealistic, and do not include evidence that the requirements will actually benefit employees. This is not a requirement under the Labor and Industries WAC, which should be the guiding regulation for safety requirements in Washington unless more stringent requirements are added to USP<797>.

Section 11(c) – We request further guidance clarifying which emergency protocols are being referenced in this section. Specifically, does this section refer to organizational, national, or other guidelines? Additionally, investigating a medical surveillance finding will be challenging because the effects of exposure occur over time, making it difficult to pinpoint exactly where a breach in protocol or PPE occurred. Further complicating the matter, it is possible the symptoms may also be from an event that occurred outside of the work place.

WAC 246-878-080 Equipment and supplies

Section 1(b) – Again, we request for you to define "bulk" chemicals. For example, is this provision referring to non-sterile chemicals to make sterile parenteral products, such as in high risk compounding? Under current law, we are not required to continuously monitor the temperature in a pharmacy. Please explain why this rule is proposing different standards for parenteral products used in compounding.

WAC 246-878-090 Drug components and materials used in sterile compounding

Section 3 – It is unclear whether this provision refers to compounding vendors?

Section 10 – the WAC lists that the BUD for multi-dose vials cannot exceed 28 days. The Joint Commission and the Centers for Disease Control and Prevention exempt vaccines from this requirement. Please update to exempt vaccines.

Section 11 – We have concerns about changing this standard practice. The FDA approved this practice, and it is done in other states nationally. Why are we deciding to deny this practice in Washington State if it has been FDA approved? Furthermore, what is the evidence to show that products using CSTDs allow microbial ingress?

WAC 246-878-093 Compounding process requirements

Section 9 – Labeling the final product outside of the hood after preparation in the hood poses safety concerns, including the potential risk of mislabeling a product. We have strong concerns this new requirement goes against standard practice. Moreover, the majority of product labels have no more shedding that product vial boxes in these areas. Why are we focusing specifically on the labeling?

Section 11(i) – Please provide us with the rationale behind random testing every three months. Furthermore, the purpose of the glove fingertip test is to evaluate the compounder's ability to gown and to don sterile gloves without contaminating them. In these circumstances, random testing during compounding would always have growth since the compounder is not staying

perfectly sterile during the compounding process. Per USP <797> glove fingertip samples are taken immediately after donning sterile gloves, before disinfection or performing other activities, not while compounding is occurring. We respectfully recommend that fingertip testing is done every year for low and medium risk and every 6 months for high-risk.

WAC 246-878-097 Operational standards – sanitation

We have a number of concerns related to this section, and want to ensure the reporting requirements are not overly burdensome. For example, in the introductory language of section 1, we believe the PIC does not have to be responsible, and should have the option to designate qualified personnel. In our practice, we have found technicians generally do this work in the community and in many cases, are better qualified. Also, in section 1(c), we recommend dividing the list for pharmacy personnel and non-pharmacy personnel because the requirements for each are different.

We also have concerns that section 3(a) improperly combines environmental services (janitorial) and pharmacy duties. There are separate duties for each, and in the proposed language it is not clear who is doing each cleaning activity. For example, the primary engineering control cleaning is pharmacy only. Additionally, we request clarification for section 3(c). If using reusable microfibers and rinsing and sanitizing prior to storage, it is unnecessary to hang to dry. In section 3(d), we have concerns Section 3(d), that sprayers may not be preferred due to aerosolization of cleaning agents and respiratory issues. For instance, infection control discourages the use of sprays due to the problem of occupationally acquired asthma and reactive airway disease in environmental services staff.

Section 5 – What is the evidence indicating a germicidal agent is required for cleaning all PECs including in positive pressure compounding PECs?

Section 9(d) – USP is not prescriptive about what agent to use on what equipment. Sporicidal agents are high level disinfectants that can be damaging to products and can cause harm if ingested. It would not be safe to use this type of product for disinfecting supplies used in the PEC, and therefore, we have strong concerns with the use of this proposed language.

WAC 246-878-100 Operational standards - quality assurance and control

Section 2(iv) – Where did the requirement for a specific black and white background come from? Please explain why both would be required?

Section 5(d) – We have very strong concerns with this provision because it will be hugely impactful to operations and the cost of multisystem infusion centers, especially those that have centralized infusion services. Why wouldn't you do this for home infusion products also if it were an important quality check when transferring from one site to another? Further, why is this requirement for compounded items transported to another pharmacy, but not for compounded items prepared and delivered to a hospital unit five floors from the pharmacy? Please revisit the rationale for this new requirement and consider its potential impact.

Section 6 – We request to change PIC to designee or compounding coordinator.