Commission SBAR Communication

Agenda Item/Title: Discussion and possible approval of the 2020 Self-Inspection Worksheets

Date SBAR Communication Prepared: January 28, 2020

Reviewer: Tracy West, Deputy Director

Link to Action Plan:

☒ **Action** ☐ **Information** ☐ **Follow-up** ☐ **Report only**

Situation:

The Commission needs to discuss and approve self-inspection worksheets for 2020. Inspection staff and Commission management are meeting on January 29, 2020 to discuss staff suggestions on changes for 2020 self-inspection worksheets. This may include developing recommendations for the Commission to consider in terms of removing, adding, or switching questions around.

Background:

The Commission adopted a new inspection process in September 2017 changing from a point based system to a notice of deficiency/plan of correction model. As part of the rule change, licensees are now required to conduct annual self-inspections in the month of March. The Commission needs to update the worksheet and addendums for 2019 for licensees to use this March.

The Commission needs to review, edit, and approve the following worksheets.

1. General Self-Inspection Worksheet
2. Long-Term Care Addendum Worksheet
3. Hospital Self-Inspection Addendum Worksheet
4. USP 795 Non-Sterile Compounding Addendum Worksheet
5. USP 797 Sterile Compounding Addendum Worksheet
6. Nuclear Pharmacy Self-Inspection Addendum Worksheet

Assessment:

Staff will send out the recommendations for Commission consideration on Thursday, January 30, 2020. The 2019 self-inspection worksheets are attached in box.com for your review and Commission recommendations for changes.

Recommendation:

Make suggested edits and approval all worksheets.

Follow-up Action: Staff will make changes and work with the Department's webpage team to get the documents posted before February 10th.

Washington State Department of Health

WA Pharmacy Quality Assurance Commission
2019 Responsible Manager
Pharmacy Self-Inspection Worksheet
USP 797 – Sterile Compounding Addendum

ATTENTION: Responsible Manager

Washington law holds the responsible manager and all pharmacists on duty responsible for ensuring pharmacy compliance with all state and federal laws governing the practice of pharmacy. Failure to complete this addendum within the month of March or within 30 days of becoming responsible manager (as required by WAC 246-869-190) may result in disciplinary action. **The following addendum is required to be filled out and kept on file with the General Pharmacy Self-Inspection Worksheet. Do not send to the Commission office.**

The primary objective of this report, and your self-inspection, is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. This worksheet does not replace *U.S. Pharmacopeia (USP) <797> Pharmaceutical Compounding – Sterile Preparations*. (NOTE: Neither the self-inspection nor a Commission inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.)

By answering the questions and referencing the appropriate laws/rules/CFR provided, you can determine whether you are compliant with many of the rules and regulations. If you have corrected any deficiencies, please write corrected and the date of correction by the appropriate question.

General Rule Reference - Applies to all questions through worksheet.
RCW 18.64.270(2) "Any medicinal products that are compounded for patient administration or distribution to a licensed practitioner for patient use or administration shall, at a minimum, meet the standards of the official United States pharmacopeia as it applies to nonsterile products and sterile administered products."

If you are an early adopter of USP chapter 800 under PQAC Policy Statement #60 - Regulation of the Handling of Hazardous Drugs, Questions 43, 56, and 72 you may answer N/A to the USP <797> requirement. However, a requirement statement from USP <800> has been added in blue.

Questions highlighted in blue are questions that will be focused on during routine pharmacy inspections.

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
Standard Operating Procedures						
			1	The permitted pharmacy listed above shall have a written, properly approved, Standard Operating Procedures Manual (or Policy and Procedure Manual) with detailed instructions that describe how, when (frequency), and by whom all requirements in USP <797> are to be met.	**USP Chapter 797 - Suggested Standard Operating Procedures.** "The compounding facility shall have written, properly approved SOPs designed to ensure the quality of the environment in which a CSP is prepared."	
Compounding Personnel						
				Documentation is on file for EACH person who compounds sterile products that they are adequately skilled, educated, instructed, and trained to correctly perform and document the following activities:	**USP Chapter 797 - "**The dispenser shall, when appropriate and practicable, obtain and evaluate results of testing for identity, strength, purity, and sterility before a CSP is dispensed. Qualified licensed healthcare professionals who supervise compounding and dispensing of CSPs shall ensure that the following objectives are achieved: 1. Compounding personnel are adequately skilled, educated, instructed, and trained to correctly perform and document the following activities in their sterile compounding duties. **a.** perform antiseptic hand cleansing and disinfection of nonsterile compounding surfaces; **b.** select and appropriately don protective garb; **c.** maintain or achieve sterility of CSPs in ISO 5 PEC devices and protect personnel and compounding environments from contamination by radioactive, cytotoxic, and chemotoxic drugs (see Hazardous Drugs as CSPs and Radiopharmaceuticals as CSPs); **d.** identify, weigh, and measure ingredients; **e.** manipulate sterile products aseptically, sterilize high-risk level CSPs, and label and quality inspect CSPs."	
			2	Perform aseptic hand cleansing;		
			3	Perform disinfection of compounding surfaces;		
			4	Select and appropriately don protective garb;		
			5	Maintain or achieve sterility of CSPs;		
			6	Identify, weigh and measure ingredients;		
			7	Manipulate sterile products aseptically;		
			8	Label and quality inspect CSPs.		
Personnel Training and Competency						
			9	Before beginning to prepare CSPs, personnel are trained by expert personnel, audio-video instructional sources, professional publications in the theoretical principles, practical skills of aseptic manipulations.	**USP Chapter - 797 Personnel Training and Evaluation in Aseptic Manipulation Skills -** "Personnel who prepare CSPs shall be trained conscientiously and skillfully by expert personnel and through audio–video instructional sources and professional publications in the theoretical principles and practical skills of aseptic manipulations and in achieving and maintaining ISO Class 5 (see Table 1) environmental conditions before they begin to prepare CSPs."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			10	Prior to compounding, personnel are trained in garbing procedures, aseptic work practices, achieving and maintaining ISO Class 5 conditions and cleaning and disinfections procedures.	**USP Chapter 797 Environmental Quality and Control - Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures -** "Personnel who prepare CSPs shall be trained conscientiously and skillfully by expert personnel and through multimedia instructional sources and professional publications in the theoretical principles and practical skills of garbing procedures, aseptic work practices, achieving and maintaining ISO Class 5 (see Table 1) environmental conditions, and cleaning and disinfection procedures. USP Chapter - 797 Personnel Training and Evaluation in Aseptic Manipulation Skills - "Personnel who prepare CSPs shall be trained conscientiously and skillfully by expert personnel and through audio–video instructional sources and professional publications in the theoretical principles and practical skills of aseptic manipulations and in achieving and maintaining ISO Class 5 (see Table 1) environmental conditions before they begin to prepare CSPs."	
			11	Personnel perform didactic review, pass written and media-fill testing of aseptic work skills initially before beginning to prepare CSPs and at least annually thereafter for low- and medium-risk level; and semi-annually for high-risk level.	**USP Chapter 797 - Personnel Training and Evaluation in Aseptic Manipulation Skills -** "Compounding personnel shall perform didactic review and pass written and media-fill testing of aseptic manipulative skills initially, at least annually thereafter for low- and medium-risk level compounding, and semiannually for high-risk level compounding."	
			12	Personnel who fail written tests, observational audits, or whose media-fill test vials have one or more units showing contamination are re-instructed and re-evaluated to ensure correction of all aseptic work practice deficiencies; personnel pass all evaluations prior to resuming compounding.	**USP Chapter 797 - Personnel Training and Evaluation in Aseptic Manipulation Skills -** "Compounding personnel who fail written tests or whose media-fill test vials result in gross microbial colonization shall be immediately reinstructed and reevaluated by expert compounding personnel to ensure correction of all aseptic practice deficiencies."	
			13	Personnel demonstrate proficiency of proper hand hygiene, garbing and consistent cleaning procedures in addition to didactic evaluation of aseptic media fill and glove tip testing.	**USP Chapter 797 Environmental Quality and Control - Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures -** "In addition to didactic evaluation and aseptic media fill, compounding personnel must demonstrate proficiency of proper hand hygiene, garbing, and consistent cleaning procedures."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			14	Personnel are visually observed during the process of performing hand hygiene and garbing procedures and appropriately documented and maintained to provide a permanent record.	**USP Chapter 797- Environmental Quality and Control - Competency Evaluation of Garbing and Aseptic Work Practice - Garbing and Gloving Competency Evaluation -** "Compounding personnel shall be visually observed during the process of performing hand hygiene and garbing procedures (see Personnel Cleansing and Garbing under Personnel Training and Evaluation in Aseptic Manipulation Skills above). The visual observation shall be documented on a form such as the Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel (see Appendix III) and maintained to provide a permanent record and long-term assessment of personnel competency."	
			15	Personnel successfully complete an initial competency evaluation and gloved fingertip/thumb sampling procedure no less than 3 times before initially being allowed to compound CSPs; which must be repeated at least annually for low- and medium-risk, and twice annually for high-risk compounding.	**USP Chapter 797 - Environmental Quality and Control - Competency Evaluation of Garbing and Aseptic Work Practice - Gloved Fingertip Sampling -** "All compounding personnel shall successfully complete an initial competency evaluation and gloved fingertip/thumb sampling procedure (zero cfu) no less than three times before initially being allowed to compound CSPs for human use."	
			16	All compounding personnel have technique and competency evaluated initially during the Media-Fill Test Procedure and subsequent annual or semi-annual Media-Fill Test Procedures.	**USP Chapter 797 - Environmental Quality and Control - Competency Evaluation of Garbing and Aseptic Work Practice - Aseptic Manipulation Competency Evaluation - "**After successful completion of an initial Hand Hygiene and Garbing Competency Evaluation, all compounding personnel shall have their aseptic technique and related practice competency evaluated initially during the Media-Fill Test Procedure and subsequent annual or semi-annual Media-Fill Test Procedures."	
CSP Microbial Contamination: Low-Risk Level CSPs						
			17	The CSPs are compounded with aseptic manipulations entirely within ISO Class 5 or better quality air using only sterile ingredients, products, components and devices.	**USP Chapter 797 - CSP Microbial Contamination Risk Levels - Low-Risk Conditions -** "CSPs compounded under the following conditions are at a low risk of contamination. 1. The CSPs are compounded with aseptic manipulations entirely within ISO Class 5 or better air quality using only sterile ingredients, products, components, and devices."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			18	Compounding involves only transfer, measuring and mixing manipulations using not more than 3 commercially manufactured sterile products and not more than 2 entries into any container.	**USP Chapter 797 - CSP Microbial Contamination Risk Levels - Low-Risk Conditions -** "CSPs compounded under the following conditions are at a low risk of contamination. 2. The compounding involves only transfer, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile products and not more than two entries into any one sterile container or package (e.g., bag, vial) of sterile product or administration container/device to prepare the CSP."	
			19	Manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and containers for storage and dispensing.	**USP Chapter 797 - CSP Microbial Contamination Risk Levels - Low-Risk Conditions -** "CSPs compounded under the following conditions are at a low risk of contamination. 3. Manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers or other sterile products, and containers for storage and dispensing."	
			20	In the absence of sterility tests, storage is not more than 48 hours at controlled room temperature, 14 days at cold temperature, and 45 days in a solid frozen state of -25° to -10°, or per manufacturer guidelines.	**USP Chapter 797 - CSP Microbial Contamination Risk Levels - Low-Risk Conditions -** "CSPs compounded under the following conditions are at a low risk of contamination. 4. For a low-risk level preparation, in the absence of passing a sterility test (see Sterility Tests <71>), the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and are exposed for not more than 48 hours at controlled room temperature (see General Notices and Requirements), for not more than 14 days at a cold temperature (see General Notices and Requirements), and for 45 days in solid frozen state between -25° and -10°."	
CSP Microbial Contamination: Low-Risk Level CSPs with 12-Hour or Less Beyond-Use Date (BUD)						
			21	PECs are certified, maintained ISO Class 5 and located in a segregated compounding area restricted to sterile compounding activities.	**USP Chapter 797 - CSP Microbial Contamination Risk Levels - Low-Risk Level CSPs with 12-Hour or Less BUD -** "1. PECs (LAFWs, BSCs, CAIs, CACIs) shall be certified and maintain ISO Class 5 as described in Facility Design and Environmental Controls for exposure of critical sites and shall be in a segregated compounding area restricted to sterile compounding activities that minimize the risk of CSP contamination."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			22	The segregated compounding area is not in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or in a location that is adjacent to construction sites, warehouse or food preparation.	**USP Chapter 797 - CSP Microbial Contamination Risk Levels - Low-Risk Level CSPs with 12-Hour or Less BUD -** "2. The segregated compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or that is adjacent to construction sites, warehouses, or food preparation. Note that this list is not intended to be all inclusive."	
			23	Sinks are not located within one meter of the ISO Class 5 PEC.	**USP Chapter 797 - CSP Microbial Contamination Risk Levels - Low-Risk Level CSPs with 12-Hour or Less BUD - "**3. Personnel shall follow the procedures described in Personnel Cleansing and Garbing and Additional Personnel Requirements prior to compounding. Sinks should not be located adjacent to the ISO Class 5 PEC. Sinks should be separated from the immediate area of the ISO Class 5 PEC device."	
CSP Microbial Contamination: Medium-Risk Level CSPs						
			24	Product considered medium risk if multiple individual or small doses of sterile products are combined or pooled to prepare a CSP that will be administered either to multiple patients or to one patient on multiple occasions.	**USP Chapter 797 - CSP Microbial Contamination Risk Levels - Medium Risk Conditions - "**When CSPs are compounded aseptically under Low-Risk Conditions and one or more of the following conditions exists, such CSPs are at a medium risk of contamination. 1. Multiple individual or small doses of sterile products are combined or pooled to prepare a CSP that will be administered either to multiple patients or to one patient on multiple occasions."	
			25	Products considered medium-risk if the compounding process includes complex aseptic manipulations or unusually long duration.	**USP Chapter 797 - CSP Microbial Contamination Risk Levels - Medium Risk Conditions - "**When CSPs are compounded aseptically under Low-Risk Conditions and one or more of the following conditions exists, such CSPs are at a medium risk of contamination. 2. The compounding process includes complex aseptic manipulations other than the single-volume transfer."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			26	In the absence of sterility tests, storage is not more than 30 hours at controlled room temperature, 9 days at cold temperature, and 45 days in a frozen state of -25° to -10°, or per manufacturer guidelines.	**USP Chapter 797 - CSP Microbial Contamination Risk Levels - Medium Risk Conditions -** "When CSPs are compounded aseptically under Low-Risk Conditions and one or more of the following conditions exists, such CSPs are at a medium risk of contamination. 4. In the absence of passing a sterility test (see Sterility Tests USP Chapter 71), the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and are exposed for not more than 30 hours at controlled room temperature (see General Notices and Requirements), for not more than 9 days at a cold temperature (see General Notices and Requirements), and for 45 days in sold frozen state between -25° and -10°."	
			27	Products considered medium-risk if aseptic manipulations within an ISO Class 5 environment use prolonged and complex mixing and transfer, more than 3 sterile products and two entries into any container, and pooling ingredients from multiple sterile products to prepare multiple CSPs.	**USP Chapter 797 Appendices - CSP Microbial Contamination Risk Levels - Medium-Risk Level CSPs -** "Aseptic manipulations within an ISO Class 5 environment using prolonged and complex mixing and transfer, more than three sterile products and entries into any container, and pooling ingredients from multiple sterile products to prepare multiple CSPs."	
Immediate Use CSPs						
			28	Immediate-use CSPs are used only when there is a need for emergency or immediate patient administration of a CSP, where administration can begin with 1 hour of compounding.	**USP Chapter 797 Immediate-Use CSPs -** "The immediate-use provision is intended only for those situations where there is a need for emergency or immediate patient administration of a CSP. … 4. Administration begins not later than 1 hour following the start of the preparation of the CSP."	
			29	Product considered immediate-use only if the compounding process involves simple transfer of not more than 3 commercially manufactured packages of sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers and not more than 2 entries into any one container or package of sterile infusion solution or administration container/device.	**USP Chapter 797 Immediate-Use CSPs - "**Immediate-use CSPs are exempt from the requirements described for Low-Risk Level CSPs only when all of the following criteria are met: 1. The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile-nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers and not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration con-trainer/device. For example, anti-neoplastics shall not be prepared as immediate-use CSPs because they are hazardous drugs."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			30	Aseptic technique is followed and if not immediately administered, CSP is continually supervised.	**USP Chapter 797 Immediate-Use CSPs -** "Immediate-use CSPs are exempt from the requirements described for Low-Risk Level CSPs only when all of the following criteria are met: 3. During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces."	
			31	Unless the person who prepares the CSP immediately witnesses or completely administers it, the CSP is labeled with patient identifier, names and amounts of all ingredients, initials of the compounder, and the exact 1-hour BUD and time.	**USP Chapter 797 Immediate-Use CSPs -** "Immediate-use CSPs are exempt from the requirements described for Low-Risk Level CSPs only when all of the following criteria are met: 5. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time."	
			32	Administration begins not later than 1 hour following the start of the preparation of the CSP; If administration has not begun within 1 hour of being compounded, CSP is discarded.	**USP Chapter 797 Immediate-Use CSPs -** "Immediate-use CSPs are exempt from the requirements described for Low-Risk Level CSPs only when all of the following criteria are met: 5. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1 hour BUD and time."	
Single-Dose and Multiple-Dose Containers						
			33	Single-dose containers are used within 1 hour of entry when opened or removed in worse than ISO Class 5 air quality.	**USP Chapter 797 - Single-Dose and Multiple-Does Containers -** "Opened or needle-punctured single-dose containers, such as bags, bottles, syringes, and vials of sterile products and CSPs shall be used within 1 hour if opened in worse than ISO Class 5 (see Table 1) air quality (see Immediate-Use CSPs), and any remaining contents must be discarded."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			34	Single-dose containers entered in ISO Class 5 or cleaner air are used within 6 hours of entry, if vial is kept inside the PEC.	**USP Chapter 797 - Single-Dose and Multiple-Does Containers - "**Single-dose vials exposed to ISO Class 5 (see Table 1) or cleaner air may be used up to 6 hours after initial needle puncture."	
			35	Opened single-dose ampules are not stored.	**USP Chapter 797 - Single-Dose and Multiple-Does Containers - "**Opened single-dose ampules shall not be stored for any time period."	
			36	Closure sealed multiple-dose containers are used within 28 days after initial opening or entry, or as specified by the manufacturer, whichever is less.	**USP Chapter 797 - Single-Dose and Multiple-Does Containers - "**Multiple-dose containers (e.g., vials) are formulated for removal of portions on multiple occasions because they usually contain antimicrobial preservatives. The BUD after initially entering or opening (e.g., needle-punctured) multiple-dose containers is 28 days (see Antimicrobial Effectiveness Testing USP Chapter 51) unless otherwise specified by the manufacturer."	
Hazardous Drugs as CSPs						
			37	Hazardous drugs are prepared for administration only under conditions that protect the healthcare workers and other personnel in the preparation and storage areas.	**USP Chapter 797 - Hazardous Drugs as CSPs -** "Hazardous drugs shall be prepared for administration only under conditions that protect the healthcare workers and other personnel in the preparation and storage areas."	
			38	Hazardous drugs are stored separately from other inventory.	**USP Chapter 797 - Hazardous Drugs as CSPs -** "Hazardous drugs shall be stored separately from other inventory in a manner to prevent contamination and personnel exposure."	
			39	Hazardous drugs are handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparation for administration and disposal.	**USP Chapter 797 - Hazardous Drugs as CSPs -** "Hazardous drugs shall be handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparation for administration, and disposal."	
			40	Hazardous drugs are prepared in an ISO Class 5 environment with protective engineering controls in place and follows aseptic practices specified for the appropriate contamination risk levels.	**USP Chapter 797 - Hazardous Drugs as CSPs -** "Hazardous drugs shall be prepared in an ISO Class 5 (see Table 1) environment with protective engineering controls in place and following aseptic practices specified for the appropriate contamination risk levels defined in this chapter."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			41	Access is limited to areas where hazardous drugs are stored and prepared.	**USP Chapter 797 - Hazardous Drugs as CSPs -** "Access shall be limited to areas where drugs are stored and prepared to protect persons not involved in drug preparation."	
			42	All hazardous drugs are prepared in a BSC or a CACI that meets or exceeds standards.	**USP Chapter 797 - Hazardous Drugs as CSPs -** "All hazardous drugs shall be prepared in a BSC3 or a CACI that meets or exceeds the standards for CACI in this chapter."	
			43	The ISO Class 5 BSC or CACI is placed in an ISO Class 7 area, physically separated and optimally has not less than 0.01-inch water column negative pressure to adjacent positive pressure ISO Class 7 or better ante-areas.	**USP Chapter 797 - Hazardous Drugs as CSPs -** "The ISO Class 5 (see Table 1) BSC or CACI shall be placed in an ISO Class 7 (see Table 1) area that is physically separated (i.e., a different area from other preparation areas) and optimally has not less than 0.01-inch water column negative pressure to adjacent positive pressure ISO Class 7 (see Table 1) or better ante-areas, thus providing inward airflow to contain any airborne drug."	
				Early adopters of USP 800 pursuant to PQAC Policy #60: The ISO Class 5 C-PEC is placed in either an ISO Class 7 ante-room or an unclassified containment segregated compounding area (C-SCA). If using a C-SCA, the C-PEC and C-SCA must be externally vented, maintain at least 12 ACPH with negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas, and BUDs must be adjusted accordingly.		
			44	A pressure indicator is installed that can be readily monitored for correct room pressurization.	**USP Chapter 797 - Hazardous Drugs as CSPs -** "A pressure indicator shall be installed that can be readily monitored for correct room pressurization."	
			45	If closed-system vial-transfer devices are used, they are used within the ISO Class 5 environment of a BSC or CACI.	**USP Chapter 797 - Hazardous Drugs as CSPs -** "When closed-system vial-transfer devices (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment) are used, they shall be used within the ISO Class 5 (see Table 1) environment of a BSC or CACI."	
			46	Personal protective equipment is worn when compounding.	**USP Chapter 797 - Hazardous Drugs as CSPs -** "Appropriate personnel protective equipment (PPE) shall be worn when compounding in a BSC or CACI and when using CSTD devices."	
			47	Personnel who compound hazardous drugs are trained in storage, handling and disposal of drugs prior to preparing or handling hazardous CSPs.	**USP Chapter 797 - Hazardous Drugs as CSPs -** "All personnel who compound hazardous drugs shall be fully trained in the storage, handling, and disposal of these drugs."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			48	Effectiveness of training is verified by testing specific hazardous drug preparations techniques and is documented for each person at least annually.	**USP Chapter 797 - Hazardous Drugs as CSPs -** "This training shall occur prior to preparing or handling hazardous CSPs, and its effectiveness shall be verified by testing specific hazardous drugs preparation techniques. Such verification shall be documented for each person at least annually."	
			49	Compounding personnel of reproductive capability confirm in writing that they understand the risks of hazardous drug handling.	**USP Chapter 797 - Hazardous Drugs as CSPs -** "Compounding personnel of reproductive capability shall confirm in writing that they understand the risks of handling hazardous drugs."	
			50	Disposal of hazardous waste complies with all applicable federal and state regulations.	**USP Chapter 797 - Hazardous Drugs as CSPs -** "Disposal of all hazardous drug wastes shall comply with all applicable federal and state regulations."	
			51	Personnel who perform routine custodial waste removal and cleaning activities for hazardous drugs are trained in appropriate procedures to protect themselves and prevent contamination.	**USP Chapter 797 - Hazardous Drugs as CSPs -** "All personnel who per-form routine custodial waste removal and cleaning activities in storage and preparation areas for hazardous drugs shall be trained in appropriate procedures to protect themselves and prevent contamination."	
Environmental Quality and Control						
Facility Design and Environmental Controls						
			52	Critical sites are only exposed to ISO Class 5 or cleaner air.	**USP Chapter 797 - Environmental Quality and Control - Exposure of Critical Sites -** "Protection of critical sites by precluding physical contact and airborne contamination shall be given the highest priority in sterile compounding practice. Airborne contaminants, especially those generated by sterile compounding personnel, are much more likely to reach critical sites than are contaminants that are adhering to the floor or other surfaces below the work level. Furthermore, large and high-density particles that are generated and introduced by compounding manipulations and personnel have the potential to settle on critical sites even when those critical sites are exposed within ISO Class 5 (see Table 1) air."	
			53	Compounding facility provides a comfortable and well-lighted working environment.	**USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls -** "Compounding facilities are physically designed and environmentally controlled to minimize airborne contamination from contacting critical sites. These facilities shall also provide a comfortable and well-lighted working environment, …"	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			54	Facility has current certification documenting that PECs maintain ISO Class 5 and meet airflow requirements.	**USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - Engineering Control Performance Verification -** "Certification procedures such as those outlined in Certification Guide for Sterile Compounding Facilities (CAG-003-2006)[7] shall be performed by a qualified individual no less than every 6 months and whenever the device or room is relocated or altered or major service to the facility is performed."	
			55	Policies and procedures for PEC area are written and followed; determined by the scope and risk levels of aseptic compounding activities utilized during the preparation of the CSPs.	**USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls -** "Policies and procedures for maintaining and working within the PEC area shall be written and followed. The policies and procedures will be determined by the scope and risk levels of the aseptic compounding activities utilized during the preparation of the CSPs."	
				Facility has current certification documenting that the buffer area maintains ISO Class 7 conditions with an ACPH of not less than 30.	**USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls -** "An ISO Class 7 (see Table 1) buffer area and ante-area supplied with HEPA-filtered air shall receive an ACPH of not less than 30."	
			56	**Early adopters of USP 800 pursuant to PQAC Policy #60:** If using an unclassified containment segregated compounding area (C-SCA), the C-PEC and C-SCA must be externally vented, maintain at least 12 ACPH with negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas, and BUDs must be adjusted accordingly.		
			57	A minimum differential positive pressure of 0.02- to 0.05-inch water column is used for rooms providing a physical separation through the use of walls, doors and pass-through.	**USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls -** "For rooms providing a physical separation through the use of walls, doors, and pass-through, a minimum differential positive pressure of 0.02- to 0.05-inch water column is required."	
			58	Displacement airflow is employed for buffer areas not physically separated from the ante-areas.	**USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls -** "For buffer areas not physically separated from the ante-areas, the principle of displacement air-flow shall be employed."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			59	Adequate HEPA-filtered airflow is supplied to the buffer area and ante-area.	**USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - "**Adequate HEPA-filtered airflow supplied to the buffer area and ante-area is required to maintain cleanliness classification during operational activity through the number of ACPHs."	
			60	Facility has current certification documenting that ante-area maintains ISO Class 8 conditions with an ACPH of not less than 30.	**USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls -** "Buffer areas are designed to maintain at least ISO Class 7 (see Table 1) conditions for 0.5-mm particles under dynamic conditions and ISO Class 8 (see Table 1) conditions for 0.5-mm and larger particles under dynamic conditions for the ante-areas." **USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - Engineering Control Performance Verification -** "Certification procedures such as those outlined in Certification Guide for Sterile Compounding Facilities (CAG-003-2006)[7] shall be performed by a qualified individual no less than every 6 months and whenever the device or room is relocated or altered or major service to the facility is performed." **USP Chapter 797 - Environmental Quality and Control - Viable and Nonviable Environmental Sampling (ES) Testing - Environmental Quality and Control - Environmental Nonviable Airborne Particle Testing Program - Total Particle Counts -** "ISO Class 8: not more than 3,520,000 particles or 0.5 mm size and larger per cubic meter of air for any ante-area."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			61	For nuclear buffer areas, facility has current certification documenting that the buffer area maintains ISO Class 8 conditions.	**USP Chapter 797 - Radiopharmaceuticals as CSPs -** "These radiopharmaceuticals shall be compounded using appropriately shielded vials and syringes in a properly functioning and certified ISO Class 5 (see Table 1) PEC located in an ISO Class 8 (see Table 1) or cleaner air environment to permit compliance with special handling, shielding, and negative air flow requirements." **USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - Engineering Control Performance Verification -** "Certification procedures such as those outlined in Certification Guide for Sterile Compounding Facilities (CAG-003-2006)[7] shall be performed by a qualified individual no less than every 6 months and whenever the device or room is relocated or altered or major service to the facility is performed."	
			62	If the area has an ISO Class 5 recirculating device, a minimum of 15 ACPHs through the area supply HEPA filters is adequate, providing the combined ACPH not less than 30.	**USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls -** "If the area has an ISO Class 5 (see Table 1) recirculating device, a minimum of 15 ACPHs through the area supply HEPA filters is adequate, providing the combined ACPH is not less than 30."	
			63	Only the furniture, equipment, supplies and other material required for the compounding activities are brought into the area and they are nonpermeable, nonshedding, cleanable, and resistant to disinfectants; before such items are brought into the area, they are cleaned and disinfected.	**USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls -** Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed shall be brought into the area, and they shall be nonpermeable, nonshedding, cleanable, and resistant to disinfectants.	
			64	The surfaces of ceilings, walls, floors, fixtures, shelving, counters and cabinets in the buffer area are smooth, impervious, free from cracks and crevices and nonshedding; the surfaces are resistant to damage by disinfectant agents.	**USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls -** "The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area shall be smooth, impervious, free from cracks and crevices, and nonshedding, thereby promoting cleanability and minimizing spaces in which microorganisms and other contaminants may accumulate. The surfaces shall be resistant to damage by disinfectant agents."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			65	Junctures of ceilings to walls are coved or caulked.	**USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls -** "Junctures of ceilings to walls shall be coved or caulked to avoid cracks and crevices where dirt can accumulate."	
			66	If ceilings consist of inlaid panels, the panels are impregnated with a polymer to render them impervious and hydrophobic; they are caulked around each perimeter.	**USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls -** "If ceilings consist of inlaid panels, the panels shall be impregnated with a polymer to render them impervious and hydrophobic, and they shall be caulked around each perimeter to seal them to the support frame."	
			67	The exterior lens surface of the ceiling lighting fixtures are smooth, mounted flush and sealed; any other penetrations through the ceiling or walls are sealed.	**USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls -** "The exterior lens surface of ceiling lighting fixtures should be smooth, mounted flush, and sealed. Any other penetrations through the ceiling or walls shall be sealed."	
			68	The buffer area does not contain sources of water (sinks) or floor drains.	**USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls -** The buffer area shall not contain sources of water (sinks) or floor drains.	
			69	Works surfaces are constructed of smooth, impervious materials	**USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls -** "Work surfaces shall be constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected."	
			70	Carts are stainless steel wire, nonporous plastic or sheet metal with cleanable casters.	**USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls -** "Carts should be of stainless steel wire, nonporous plastic, or sheet metal construction with good quality, cleanable casters to promote mobility."	
			71	Storage shelving, counters and cabinets are smooth, impervious, free from cracks and crevices, nonshedding, cleanable and disinfectable; their number, design and manner of installation promotes effective cleaning and disinfection.	**USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls -** "Storage shelving, counters, and cabinets shall be smooth, impervious, free from cracks and crevices, nonshedding, cleanable, and disinfectable; their number, design, and manner of installation shall promote effective cleaning and disinfection."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
Placement of Primary Engineering Controls						
			72	PECs are located within a restricted access ISO Class 7 buffer area unless an exception met Exceptions: • Only authorized personnel and materials required for compounding and cleaning shall be permitted in buffer area • Presterilization procedures for high-risk level CSPs, such as weighing and mixing, shall be completed in no worse than Class 8 environment. • PECS shall be located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns.	**USP Chapter 797 - Environmental Quality and Control - Placement of Primary Engineering Controls -** "PECs (LAFWs, BSCs, CAIs, and CACIs) shall be located within a restricted access ISO Class 7 (see Table 1) buffer area (see Figure 1), with the following CAI/CACI exceptions below: • Only authorized personnel and materials required for compounding and cleaning shall be permitted in the buffer area. • Presterilization procedures for high-risk level CSPs, such as weighing and mixing, shall be completed in no worse than an ISO Class 8 (see Table 1) environment. • PECs shall be located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns."	
				Early adopters of USP 800 pursuant to PQAC Policy #60: If using an unclassified containment segregated compounding area that complies with USP 800.		
			73	When isolators are used for sterile compounding, the recovery time to achieve ISO Class 5 air quality is documented and internal procedures are developed.	**USP Chapter 797 - Environmental Quality and Control - Placement of Primary Engineering Controls -** "When isolators are used for sterile compounding, the recovery time to achieve ISO Class 5 (see Table 1) air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations."	
			74	A pressure gauge or velocity meter is installed to monitor the pressure differential or air-flow between the buffer area and the ante-area and between the ante-area and the general environment outside the compounding area; results are reviewed and documented in a log at least every work shift (minimum daily) or by a continuous recording device.	**USP Chapter 797 - Environmental Quality and Control - Pressure Differential Monitoring - "**A pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the buffer area and the ante-area and between the ante-area and the general environment outside the compounding area. The results shall be reviewed and documented on a log at least every work shift (minimum frequency shall be at least daily) or by a continuous recording device."	
			75	The pressure between the ISO Class 7 and the general pharmacy area is not less than 5 Pa -0.02 inch water column.	**USP Chapter 797 - Environmental Quality and Control - Pressure Differential Monitoring -** "The pressure between the ISO Class 7 (see Table 1) and the general pharmacy area shall not be less than 5 Pa (0.02 inch water column)."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			76	In facilities where low- and medium-risk level CSPs are prepared, differential airflow is maintained at a minimum velocity of 0.2 meters/second (40 feet per minute) between buffer area and ante-area.	**USP Chapter 797 - Environmental Quality and Control - Pressure Differential Monitoring -** In facilities where low- and medium-risk level CSPs are prepared, differential airflow shall maintain a minimum velocity of 0.2 meters per second (40 feet per minute) between buffer area and ante-area.	
Additional Personnel Requirements						
			77	Foods, drinks and materials exposed in patient care and treatment areas do not enter ante-areas, buffer areas or segregated compounding areas.	**USP Chapter 797 - Environmental Quality and Control - Additional Personnel Requirements -** "Food, drinks, and materials exposed in patient care and treatment areas shall not enter ante-areas, buffer areas, or segregated compounding areas where components and ingredients of CSPs are present."	
Cleaning and Disinfecting the Compounding Area						
			78	When compounding activities require the manipulation of patient's blood-derived or other biological material, the manipulations are clearly separated from routine material-handling procedures and equipment used in CSP preparation and are controlled by specific SOPs to avoid any cross-contamination.	**USP Chapter 797 - Environmental Quality and Control - Additional Personnel Requirements -** "When compounding activities require the manipulation of a patient's blood-derived or other biological material (e.g., radiolabeling a patient's or donor's white blood cells), the manipulations shall be clearly separated from routine material-handling procedures and equipment used in CSP preparation activities, and they shall be controlled by specific SOPs in order to avoid any cross-contamination."	
			79	When possible, packaged compounding supplies and components are uncartoned and wiped down with a disinfectant that does not leave a residue in an ante-area ISO Class 8 air quality, before being passed into buffer areas; Supplies are allowed to dry before compounding.	**USP Chapter 797 - Environmental Quality and Control - Additional Personnel Requirements -** "Packaged compounding supplies and components, such as needles, syringes, tubing sets, and small- and large-volume parenterals, should be uncartoned and wiped down with a disinfectant that does not leave a residue (e.g., sterile 70% IPA), when possible in an ante-area of ISO Class 8 (see Table 1) air quality, before being passed into the buffer areas."	
			80	For ISO Class 5, all cleaning and disinfecting practices and policies for the compounding of CSPs are included in written SOPs and are followed by all compounding personnel.	**USP Chapter 797 - Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area -** The cleaning and disinfecting practices and frequencies in this section apply to ISO Class 5 (see Table 1) compounding areas for exposure of critical sites as well as buffer areas, ante-areas, and segregated compounding areas. ... All cleaning and disinfecting practices and policies for the compounding of CSPs shall be included in written SOPs and shall be followed by all compounding personnel.	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			81	LAFWs, BSCs, CAIs, and/or CACIs are cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods, when spills occur and when surface contamination is known or suspected.	**USP Chapter 797 - Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area -** "Cleaning and disinfecting surfaces in the LAFWs, BSCs, CAIs, and CACIs are the most critical practices before the preparation of CSPs. Consequently, such surfaces shall be cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches."	
			82	Work surfaces in ISO Class 7 buffer areas, ISO Class 8 ante-areas and segregated compounding areas are cleaned and disinfected at least daily, and dust and debris are removed when necessary from storage sites.	**USP Chapter 797 - Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area -** "Work surfaces in the ISO Class 7 (see Table 1) buffer areas and ISO Class 8 (see Table 1) ante-areas as well as segregated compounding areas shall be cleaned and disinfected at least daily, and dust and debris shall be removed when necessary from storage sites for compounding ingredients and supplies using a method that does not degrade the ISO Class 7 or 8 (see Table 1) air quality."	
			83	Floors in ISO Class 7 and 8 areas are cleaned daily while you are not actively compounding; mopping is performed by trained personnel using approved agents and written procedures.	**USP Chapter 797 - Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area -** "Floors in the buffer or clean area, ante-area, and segregated compounding area are cleaned by mopping with a cleaning and disinfecting agent once daily at a time when no aseptic operations are in progress. Mopping shall be performed by trained personnel using approved agents and procedures described in the written SOPs."	
			84	In the buffer or clean area, ante-area and segregated compounding area, walls, ceilings, and shelving are cleaned and disinfected monthly.	**USP Chapter 797 - Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area -** "In the buffer or clean area, ante-area, and segregated compounding area, walls, ceilings, and shelving shall be cleaned and disinfected monthly."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			85	All cleaning materials are nonshedding and dedicated to use in the buffer or clean area, ante-area, and segregated areas and are not removed from these areas except for disposal.	**USP Chapter 797 - Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area -** "All cleaning materials, such as wipers, sponges, and mops, shall be nonshedding, preferably composed of synthetic micro fibers, and dedicated to use in the buffer or clean area, ante-area, and segregated compounding areas and shall not be removed from these areas except for disposal."	
			86	If cleaning materials are reused, SOPs ensure that the effectiveness of the cleaning device is maintained and repeated use does not add to the bioburden of the area being cleaned.	**USP Chapter 797 - Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area -** "If cleaning materials (e.g., mops) are reused, procedures shall be developed (based on manufacturers' recommendations) that ensure that the effectiveness of the cleaning device is maintained and that repeated use does not add to the bioburden of the area being cleaned."	
			87	Sterile 70% IPA swabs do not contact any object before contacting the site to be cleaned.	**USP Chapter 797 - Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area -** "The surface of the sterile 70% IPA swabs used for disinfecting entry points of sterile packages and devices shall not contact any other object before contacting the surface of the entry point."	
			88	No particle-generating material is used to disinfect the sterile entry points of packages and devices.	**USP Chapter 797 - Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area -** "Sterile 70% IPA wetted gauze pads or other particle-generating material shall not be used to disinfect the sterile entry points of packages and devices."	
			89	No shipping cartons are taken into the buffer area, clean area or segregated compounding area.	**USP Chapter 797 - Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area -** "No shipping or other external cartons may be taken into the buffer or clean area or segregated compounding area."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
Personnel Cleansing and Garbing						
			90	Personal hand hygiene and garb procedures are performed in ante-areas.	**USP Chapter 797 - Environmental Quality and Control - Personnel Cleansing and Garbing -** "The careful cleansing of hands and arms and the correct donning of PPE by compounding personnel constitute the first major step in preventing microbial contamination in CSPs. … Before entering the buffer area or segregated compounding area (see Low-Risk Level CSPs with 12-Hour or Less BUD), compounding personnel shall remove personal outer garments (e.g., bandannas, coats, hats, jackets, scarves, sweaters, vests); all cosmetics, because they shed flakes and particles; and all hand, wrist, and other visible jewelry or piercings (e.g., earrings, lip or eyebrow piercings) that can interfere with the effectiveness of PPE (e.g., fit of gloves and cuffs of sleeves). The wearing of artificial nails or extenders is prohibited while working in the sterile compounding environment. Natural nails shall be kept neat and trimmed."	
			91	Personnel with rashes, sunburn, weeping sores, conjunctivitis, active respiratory infection or cosmetics are prohibited from preparing CSPs.	**USP Chapter 797 - Environmental Quality and Control - Personnel Cleansing and Garbing -** "When individuals are experiencing rashes, sunburn, weeping sores, conjunctivitis, active respiratory infection, as well as when they wear cosmetics, they shed these particles at even higher rates. Particles shed from compounding personnel pose an increased risk of microbial contamination of critical sites of CSPs. Therefore, compounding personnel with such conditions as mentioned above shall be excluded from working in ISO Class 5 (see Table 1) and ISO Class 7 (see Table 1) compounding areas until their conditions are remedied."	
			92	Don shoe covers one at a time placing covered shoe on clean side line of demarcation. ***This is considered a best practice.***		
			93	PPE is donned in an order that proceeds from activities considered dirtiest to cleanest: Garb and cleansing in ante-area as follows: Dirty garb (shoes or shoe covers, head and facial hair covers, face mask) Hand hygiene (fingernail cleansing, hand and forearm washing and drying), Clean garb nonshedding gown.	**USP Chapter 797 - Environmental Quality and Control - Personnel Cleansing and Garbing -** "Personnel shall don the following PPE in an order that proceeds from those activities considered the dirtiest to those considered the cleanest. Garbing activities considered the dirtiest include donning of dedicated shoes or shoe covers, head and facial hair covers (e.g., beard covers in addition to face masks), and face masks/eye shields."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			94	Cleansing and gloving in buffer room or area as follows: hand cleansing with a surgical alcohol-based product with persistent activity, allow hands to dry, don sterile gloves and apply sterile 70% IPA.	**USP Chapter 797 - Environmental Quality and Control - Personnel Cleansing and Garbing -** "Once inside the buffer area or segregated compounding area (see Low-Risk Level CSPs with 12-Hour or Less BUD), and prior to donning sterile powder-free gloves, antiseptic hand cleansing shall be performed using a waterless alcohol-based surgical hand scrub with persistent activity following manufacturers' recommendations."	
			95	Gloves are routinely disinfected with sterile 70% IPA after contacting nonsterile objects.	**USP Chapter 797 - Environmental Quality and Control - Personnel Cleansing and Garbing -** "Routine application of sterile 70%IPA shall occur throughout the compounding process and whenever nonsterile surfaces (e.g. vials, counter tops, chairs, carts) are touched."	
			96	Gloves are inspected for holes and replaced when breaches are detected.	**USP Chapter 797 - Environmental Quality and Control - Personnel Cleansing and Garbing -** "Gloves on hands shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected."	
			97	Only exterior gown used for non-hazardous compounding maybe removed and redonned in the ante area during the work shift if not visibly soiled. It is suggested that gowns be redonned only if they are removed and retained on the clean side of the line of demarcation in the ante area.	**USP Chapter 797 - Environmental Quality and Control - Personnel Cleansing and Garbing -** "When compounding personnel exit the compounding area during a work shift, the exterior gown may be removed and retained in the compounding area if not visibly soiled, to be redonned during that same work shift only."	
Elements of Quality Control						
			98	A written description of specific training and performance evaluations for compounding personnel is developed for each site.	**USP Chapter 797 - Environmental Quality and Control -** "A written description of specific training and performance evaluation program for individuals involved in the use of aseptic techniques for the preparation of sterile products shall be developed for each site."	
			99	Facility follows procedures for physical inspection of all sterile drugs and devices		
			100	If any nonsterile components, including containers and ingredients, are used to make a CSP, such CSPs must be high risk.	**USP Chapter 797 - Environmental Quality and Control - Ingredients and Devices - Nonsterile Ingredients and Devices -** "If any nonsterile components, including containers and ingredients, are used to make a CSP, such CSPs must be high risk."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			101	Bulk or unformulated drug substances and added substances or excipients are stored in tightly closed containers under temperature, humidity and lighting conditions that are either indicated in the official monographs or approved by suppliers.	**USP Chapter 797 - Environmental Quality and Control - Ingredients and Devices - Nonsterile Ingredients and Devices -** "Bulk or unformulated drug substances and added substances or excipients shall be stored in tightly closed containers under temperature, humidity, and lighting conditions that are either indicated in official monographs or approved by suppliers."	
			102	All devices used to compound a CSP operate properly within acceptable tolerance limits, as determined by the device's manufacturer or any regulations that govern the use of that device.	**USP Chapter 797 - Environmental Quality and Control - Equipment -** "It is necessary that equipment, apparatus, and devices used to compound a CSP be consistently capable of operating properly and within acceptable tolerance limits."	
			103	For all equipment, SOPs exist and are followed that state routine maintenance required and frequency of calibration, annual maintenance, monitoring for proper function, and procedures for use.	**USP Chapter 797 - Environmental Quality and Control - Equipment -** "Written procedures outlining required equipment calibration, annual maintenance, monitoring for proper function, and controlled procedures for use of the equipment and specified time frames for these activities are established and followed. Routine maintenance and frequencies shall be outlined in these SOPs."	
			104	Personnel are appropriately trained to operate any equipment they use while compounding and are trained to determine if the device is operating properly or is malfunctioning.	**USP Chapter 797 - Environmental Quality and Control - Equipment -** "Personnel are prepared through an appropriate combination of specific training and experience to operate or manipulate any piece of equipment, apparatus, or device they may use when preparing CSPs. Training includes gaining the ability to determine whether any item of equipment is operating properly or is malfunctioning."	
			105	Results from equipment maintenance and calibration are kept for the lifetime of the equipment.	**USP Chapter 797 - Environmental Quality and Control - Equipment -** "Results from the equipment calibration, annual maintenance reports, and routine maintenance are kept on file for the lifetime of the equipment."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
Viable and Non-Viable Environmental Sampling						
			106	For low-risk level CSPs with 12-hour or less BUD prepared in a PEC that maintains an ISO Class 5 sampling, air sampling is performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO Class 5.	**USP Chapter 797 - Environmental Quality and Control - Environmental Viable Airborne Particle Testing Program - Viable Air Sampling -** "For low-risk level CSPs with 12-hour or less BUD prepared in a PEC (LAFWs, BSCs, CAIs) that maintains an ISO Class 5 (see Table 1), air sampling shall be performed at locations inside the ISO Class 5 (see Table 1) environment and other areas that are in close proximity to the ISO Class 5 (see Table 1) environment during the certification of the PEC."	
			107	A sufficient volume of air (400 to 1000 liters) is tested at each location where compounding takes place, performed at least semi-annually.	**USP Chapter 797 - Environmental Quality and Control - Environmental Viable Airborne Particle Testing Program - Air Sampling Devices -** "Sufficient volume of air (400 to 1000 liters) shall be tested at each location in order to maximize sensitivity."	
			108	Engineering control performance verification is performed by a qualified individual no less than every 6 months and whenever the device or room is relocated, altered or major service to the facility is performed. (Nonviable)	**USP Chapter 797 - Environmental Quality and Control - Viable and Nonviable Environmental Sampling (ES) Testing - Environmental Nonviable Airborne Particle Testing Program - Engineering Control Performance Verification -** "PECs (LAFWs, BSCs, CAIs, and CACIs) and secondary engineering controls (buffer and ante-areas) are essential components of the overall contamination control strategy for aseptic compounding. As such, it is imperative that they perform as designed and that the resulting levels of contamination be within acceptable limits. Certification procedures such as those outlined in Certification Guide for Sterile Compounding Facilities (CAG-003-2006)[7] shall be performed by a qualified individual no less than every 6 months and whenever the device or room is relocated or altered or major service to the facility is performed."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			109	Total particle counts are performed by a qualified operator using state-of-the-art electronic equipment and are within established guidelines in each ISO classified area no less than every 6 months and whenever the LAFW, BSC, CAI, or CACI is relocated or the physical structure of the buffer area or ante-area has been altered. (Nonviable)	**USP Chapter 797 - Environmental Quality and Control - Viable and Nonviable Environmental Sampling (ES) Testing - Environmental Nonviable Airborne Particle Testing Program - Total Particle Counts -** "Certification that each ISO classified area, for example, ISO Class 5, 7, and 8 (see Table 1), is within established guidelines shall be performed no less than every 6 months and whenever the LAFW, BSC, CAI, or CACI is relocated or the physical structure of the buffer area or ante-area has been altered."	
			110	An appropriate environmental sampling plan is in place for airborne viable particles, is performed at least every 6 months, and includes locations within each ISO class 5 environments and in the ISO class 7 and 8 areas.	**USP Chapter 797 - Environmental Quality and Control - Viable and Nonviable Environmental Sampling (ES) Testing - Environmental Viable Airborne Particle Testing Program - Sampling Plan -** "An appropriate environmental sampling plan shall be developed for airborne viable particles based on a risk assessment of compounding activities performed. Selected sampling sites shall include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas and in the segregated compounding areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 environment, counters near doors, pass-through boxes)."	
			111	The sampling plan for airborne particles includes sample location, method of collection, frequency of sampling, volume of air sampled, time of day as related to activity in the compounding area and action levels.	**USP Chapter 797 - Environmental Quality and Control - Viable and Nonviable Environmental Sampling (ES) Testing - Environmental Viable Airborne Particle Testing Program - Sampling Plan -** "The plan shall include sample location, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels."	
			112	A general microbiological growth medium supplemented with additives to neutralize the effects of disinfecting agents is used to support the growth of bacteria.	**USP Chapter 797 - Environmental Quality and Control - Viable and Nonviable Environmental Sampling (ES) Testing - Environmental Viable Airborne Particle Testing Program - Growth Medium -** "A general microbiological growth medium such as Soybean–Casein Digest Medium shall be used to support the growth of bacteria."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			113	Surface sampling is performed in all ISO classified areas on a periodic basis to evaluate cleaning and disinfecting procedures and employee competency in work practices.	**USP Chapter 797 - Environmental Quality and Control - Surface Cleaning and Disinfection Sampling and Assessment -** "Surface sampling shall be performed in all ISO classified areas on a periodic basis."	
			114	Sampling data is collected and reviewed on a routine basis as a means of evaluating overall control of the compounding environment.	**USP Chapter 797 - Environmental Quality and Control - Action Levels, Documentation, and Data Evaluation -** "Sampling data shall be collected and reviewed on a routine basis as a means of evaluating the overall control of the compounding environment."	
			115	When microbial sampling exceeds action levels, procedures and practices are reviewed.	**USP Chapter 797 - Environmental Quality and Control - Action Levels, Documentation, and Data Evaluation -** "Any cfu count that exceeds its respective action level (see Table 4) should prompt a reevaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location. An investigation into the source of the contamination shall be conducted."	
			116	Regardless of the number of cfu identified in each sample, microorganisms recovered must be identified at least by genus level by an appropriate credentialed laboratory.	**USP Chapter 797 - Environmental Quality and Control - Viable and Nonviable Environmental Sampling (ES) Testing - Environmental Viable Airborne Particle Testing Program - Action Levels, Documentation, and Data Evaluation -** "Counts of cfu are to be used as an approximate measure of the environmental microbial bioburden. Action levels are deter-mined on the basis of cfu data gathered at each sampling location and trended over time. The numbers in Table 2 should be used only as guidelines. Regardless of the number of cfu identified in the pharmacy, further corrective actions will be dictated by the identification of microorganisms recovered (at least the genus level) by an appropriate credentialed laboratory of any microbial bioburden captured as a cfu using an impaction air sampler."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			117	In high risk environments, growth media also supports the growth of fungi.	**USP Chapter 797 - Environmental Quality and Control - Viable and Nonviable Environmental Sampling (ES) Testing - Environmental Viable Airborne Particle Testing Program - Growth Medium - "**Malt extractagar or some other media that supports the growth of fungi shall be used in high-risk level compounding environments."	
Verification of Automated Compounding Devices for Parenteral Nutrition						
			118	Testing procedures for accuracy are verified to meet the USP requirements stated in the individual monograph for the component being tested.	**USP Chapter 797 - Verification of Automated Compounding Devices (ACDs) for Parenteral Nutrition Compounding - Accuracy -** "Thus, their testing procedures shall be verified to meet the USP requirements stated in the individual monograph for the component being tested."	
			119	Compounding personnel keep a daily record of the accuracy assessments and the results are reviewed at least in weekly intervals.	**USP Chapter 797 - Verification of Automated Compounding Devices (ACDs) for Parenteral Nutrition Compounding - Precision -** "Thus, compounding personnel shall keep a daily record of the above-described accuracy assessments and review the results over time. This review shall occur at least at weekly intervals to avoid potentially clinically significant cumulative errors over time."	
Finished Preparation Release Checks and Tests						
			120	All CSPs are visually inspected for being intact with no abnormal particulate matter, and prescriptions and written compounding procedures are reviewed to verify accuracy of correct ingredients and amounts, aseptic mixing, high-risk sterilization, packaging, labeling, and expected physical appearance before they are administered or dispensed.	**USP Chapter 797 - Finished Preparation Release Checks and Tests - Inspection of Solution Dosage Forms and Review of Compounding Procedures -** "All CSPs that are intended to be solutions shall be visually examined for the presence of particulate matter and not administered or dispensed when such matter is observed. The prescription orders, written compounding procedure, preparation records, and expended materials used to make CSPs at all contamination risk levels are inspected for accuracy of correct identities and amounts of ingredients, aseptic mixing and sterilization, packaging, labeling, and expected physical appearance before they are administered or dispensed."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			121	A double-check system is in place that meets state regulations that includes label accuracy and accuracy of the addition of all ingredients used.	**USP Chapter 797 - Finished Preparation Release Checks and Tests - Compounding Accuracy Checks -** "Written procedures for double-checking compounding accuracy shall be followed for every CSP during preparation and immediately prior to release."	
Storage and Beyond-Use Dating						
			122	Personnel who prepare, dispense and administer CSPs store them strictly in accordance with the conditions stated on the label of ingredient products and finished CSPs.	**USP Chapter 797 Storage and Beyond-Use Dating -** "Personnel who prepare, dispense, and administer CSPs shall store them strictly in accordance with the conditions stated on the label of ingredient products and finished CSPs."	
			123	If CSPs are distributed to and administered in other than healthcare facilities, the effect of potentially uncontrolled and unmonitored temperature conditions is considered when assigning BUDs.	**USP Chapter 797 Storage and Beyond-Use Dating - Determining Beyond-Use Dates -** "When CSPs will be distributed to and administered in residential locations other than healthcare facilities, the effect of potentially uncontrolled and unmonitored temperature conditions shall be considered when assigning BUDs."	
			124	The controlled temperature areas are monitored at least once daily and results are documented.	**USP Chapter 797 Storage and Beyond-Use Dating - Monitoring Controlled Storage Areas -** "A controlled temperature area shall be monitored at least once daily and the results documented on a temperature log."	
			125	Facilities have policies and procedures governing the determination of BUDs.	**USP Chapter 797 Storage and Beyond-Use Dating - Determining Beyond-Use Dates -** "To ensure consistent practices in determining and assigning BUDs, the compounding facility should have written policies and procedures governing the determination of the BUDs for all compounded products."	
			126	Compounding personnel verify the storage temperature when placing a product into or removing a product from the storage unit.	**USP Chapter 797 Storage and Beyond-Use Dating - Monitoring Controlled Storage Areas -** "Additionally, compounding personnel shall note the storage temperature when placing the product into or removing the product from the storage unit in order to monitor any temperature aberrations."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			127	Temperature-sensitive mechanisms are placed to reflect true temperature in the controlled space and are not subject to significantly prolonged temperature fluctuations.	**USP Chapter 797 Storage and Beyond-Use Dating - Monitoring Controlled Storage Areas -** "The temperature-sensing mechanisms shall be suitably placed in the controlled temperature storage space to reflect accurately its true temperature. In addition, the compounding facility shall adhere to appropriate procedures of all controlled storage spaces to ensure that such spaces are not subject to significantly prolonged temperature fluctuations as may occur, for example, by leaving a refrigerator door open too long."	
Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs						
			128	The facilities have written procedures for proper packaging, storage, and transportation conditions to maintain sterility, quality, purity and strength of CSPs.	**USP Chapter 797 Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs -** "Establishing, maintaining, and ensuring compliance with comprehensive written policies and procedures encompassing these responsibilities is a further responsibility of the compounding facility."	
			129	Chemotoxic and other hazardous CSPs have safeguards to maintain the integrity of the CSP and minimize the exposure potential of these products to the environment and personnel.	**USP Chapter 797 Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs - Packaging, Handling, and Transport -** "Chemotoxic and other hazardous CSPs require safeguards to maintain the integrity of the CSP and to minimize the exposure potential of these products to the environment and to personnel who may come in contact with them."	
			130	Delivery and patient-care-setting personnel are properly trained to deliver the CSP to the appropriate storage location.	**USP Chapter 797 Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs - Use and Storage -** "Delivery and patient-care-setting personnel shall be properly trained to deliver the CSP to the appropriate storage location."	
			131	Outdated and unused CSPs are appropriately disposed.	**USP Chapter 797 Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs - Use and Storage -** "Outdated and unused CSPs shall be returned to the compounding facility for disposition."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			132	SOPs exist to ensure that the storage conditions in the patient-care setting are suitable for the CSP-specific storage requirements.	**USP Chapter 797 Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs - Use and Storage -** "SOPs must exist to ensure that storage conditions in the patient care setting are suitable for the CSP specific storage requirements."	
			133	Returned CSPs are only redispensed if sterility, acceptable purity, strength and quality can be assured.	**USP Chapter 797 Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs - Redispensed CSPs -** "The compounding facility shall have the sole authority to determine when unopened, returned CSPs may be redispensed. Returned CSPs may be redispensed only when personnel responsible for sterile compounding can ensure that such CSPs are sterile, pure, and stable (contain labeled strength of ingredients)."	
			134	If redispensed CSPs are given a later BUD, sterility testing and quantitative assay of ingredients occur to support the extended BUD.	**USP Chapter 797 Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs - Redispensed CSPs -** "Assignment of new storage times and BUDs that exceed the original dates for returned CSPs is permitted only when there is supporting evidence from sterility testing and quantitative assay of ingredients."	
Patient or Caregiver Training						
			135	A multiple component formal training program is in place to ensure that patients and caregivers understand proper storage, handling, use and disposal of CSPs.	**USP Chapter 797 - Patient or Caregiver Training -** "A formal training program is provided as a means to ensure understanding and compliance with the many special and complex responsibilities placed on the patient or caregiver for the storage, handling, and administration of CSPs."	
Patient Monitoring and Adverse Events Reporting						
			136	SOPs are available that describe the means for patients or other recipients to ask questions, report concerns and adverse events with CSPs, and for compounding supervisors to correct and prevent future problems.	**USP Chapter 797 - Patient Monitoring and Adverse Events Reporting -** "The SOP manuals of compounding facilities shall describe specific instructions for receiving, acknowledging, and dating receipts, and for recording, or filing, and evaluating reports of adverse events and of the quality of preparation claimed to be associated with CSPs."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			137	Reports of CSP adverse events are reviewed promptly and thoroughly by compounding supervisors.	**USP Chapter 797 - Patient Monitoring and Adverse Events Reporting -** "Reports of adverse events with CSPs shall be reviewed promptly and thoroughly by compounding supervisors to correct and prevent future occurrences."	
Quality Assurance Program						
			138	Media-fill test procedure with appropriate risk level prepared or equivalent test is performed at least annually by personnel.	**USP Chapter 797 Environmental Quality and Control - Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures -** "Media-fill testing of aseptic work skills shall be performed initially before beginning to prepare CSPs and at least annually thereafter for low- and medium-risk level compounding and semiannually for high-risk level compounding."	
			139	Quality assurance practices include routine disinfection and air quality testing, visual confirmation that personnel are appropriately garbed, review of all orders for correct identity and strength, visual inspection of CSPs, as well as a more challenging media-fill test performed annually.	**USP Chapter 797 - CSP Microbial Contamination Risk Levels - Low-Risk Level CSPS - Quality Assurance -** "Quality assurance practices include, but are not limited to the following: 1. Routine disinfection and air quality testing of the direct compounding environment to minimize microbial surface contamination and maintain ISO Class 5 air quality. 2. Visual confirmation that compounding personnel are properly donning and wearing appropriate items and types of protective garments, including eye protection and face masks. 3. Review of all orders and packages of ingredients to ensure that the correct identity and amounts of ingredients were compounded. 4. Visual inspection of CSPs to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, and the accuracy and thoroughness of labeling."	
			140	A formal quality assurance program is in place that monitors, evaluates, corrects and improves activities and processes.	**USP Chapter 797 - Quality Assurance (QA) Program -** "A provider of CSPs shall have in place a formal QA program intended to provide a mechanism for monitoring, evaluating, correcting, and improving the activities and processes described in this chapter."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
CSP Microbial Contamination: High-Risk Level CSPs						
			141	Sterilize high-risk CSPs.	**USP Chapter 797 - CSP Microbial Contamination Risk Levels -** "High-risk level CSPs must be sterilized before being administered to patients."	
			142	If compounding personnel are improperly garbed and gloved, CSP treated as a high-risk compound.	**USP Chapter 797 CSP Microbial Contamination Risk Levels - High Risk Conditions -** "CSPs compounded under any of the following conditions are either contaminated or at a high risk to become contaminated. 3. Compounding personnel are improperly garbed and gloved (see Personnel Cleansing and Use of Barrier Protective Equipment)."	
			143	Product considered high-risk if any nonsterile ingredients or devices are used.	**USP Chapter 797 - CSP Microbial Contamination Risk Levels - High Risk Conditions -** "CSPs compounded under any of the following conditions are either contaminated or at a high risk to become contaminated. 1. Nonsterile ingredients, including manufactured products not intended for sterile routes of administration (e.g., oral), are incorporated or a nonsterile device is employed before terminal sterilization."	
			144	Product considered high-risk if CSP is exposed to air quality worse than ISO Class 5 for > 1 hour.	**USP Chapter 797 - CSP Microbial Contamination Risk Levels - High Risk Conditions -** "CSPs compounded under any of the following conditions are either contaminated or at a high risk to become contaminated. 2. Any of the following are exposed to air quality worse than ISO Class 5 for more than 1 hour (see Immediate-Use CSPs): - sterile contents of commercially manufactured products, - CSPs that lack effective antimicrobial preservatives, and - sterile surfaces of devices and containers for the preparation, transfer, sterilization, and packaging of CSPs."	
			145	Product considered high-risk if Nonsterile water-containing preparations are stored for more than 6 hours before being sterilized.	**USP Chapter 797 - CSP Microbial Contamination Risk Levels - High Risk Conditions -** "CSPs compounded under any of the following conditions are either contaminated or at a high risk to become contaminated. 4. Nonsterile water-containing preparations are stored for more than 6 hours before being sterilized."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			146	The date of receipt of nonsterile components is clearly and indelibly marked on each package.	**USP Chapter 797 - Elements of Quality Control - Ingredients and Devices - Nonsterile Ingredients and Devices -** "The date of receipt by the compounding facility shall be clearly and indelibly marked on each package of ingredient."	
			147	Sterilization methods are verified to achieve sterility for the quantity and type of containers.	**USP Chapter 797 - Responsibility of Compounding Personnel -** "The dispenser shall, when appropriate and practicable, obtain and evaluate results of testing for identity, strength, purity, and sterility before a CSP is dispensed. Qualified licensed healthcare professionals who supervise compounding and dispensing of CSPs shall ensure that the following objectives are achieved: 5. Sterilization methods achieve sterility of CSPs while maintaining the labeled strength of active ingredients and the physical integrity of packaging."	
			148	Media-fill test procedure or equivalent test is performed at least semi-annually by personnel.	**USP Chapter 797 - CSP Microbial Contamination Risk Levels - High Risk Level CSPs - Quality Assurance -** "In addition, a media-fill test that represents high-risk level compounding is performed semiannually by each person authorized to compound high-risk level CSPs."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			149	Quality assurance practices include routine disinfection, air quality testing, visual confirmation of appropriate personnel garbing, review of all orders for correct identity and strength, and visual inspection of CSPs.	**USP Chapter 797 - CSP Microbial Contamination Risk Levels - High Risk Level CSPs - Quality Assurance -** "Quality Assurance procedures for high-risk level CSPs include all those for low-risk level CSPs." **USP Chapter 797 - CSP Microbial Contamination Risk Levels - Low-Risk Level CSPs - Quality Assurance -** "Quality assurance practices include, but are not limited to the following: 1. Routine disinfection and air quality testing of the direct compounding environment to minimize microbial surface contamination and maintain ISO Class 5 air quality. 2. Visual confirmation that compounding personnel are properly donning and wearing appropriate items and types of protective garments, including eye protection and face masks. 3. Review of all orders and packages of ingredients to ensure that the correct identity and amounts of ingredients were compounded. 4. Visual inspection of CSPs to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, and the accuracy and thoroughness of labeling."	
			150	Allowable limits for bacterial endotoxins are met.	**USP Chapter 797 - Finished Preparation Release Checks and Tests - Bacterial Endotoxin (Pyrogen) Testing -** "In the absence of a bacterial endotoxins limit in the official monograph or other CSP formula source, the CSP shall not exceed the amount of USP Endotoxin Units (per hour per kilogram of body weight or square meters of body surface area) specified in Bacterial Endotoxins Test <85> referenced above for the appropriate route of administration."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			151	High-risk level CSPs must be sterility tested if they are prepared in batches of > 25 identical containers, or exposed longer than 12 hours at 2 to 8 degrees and 6 hours at warmer than 8 degrees before being sterilized.	**USP Chapter 797 - Finished Preparation Release Checks and Tests - Sterility Testing -** "All high-risk level CSPs that are prepared in groups of more than 25 identical individual single-dose packages (e.g., ampules, bags, syringes, vials) or in multiple-dose vials (MDVs) for administration to multiple patients or that are exposed longer than 12 hours at 2° to 8° and longer than 6 hours at warmer than 8° before they are sterilized shall meet the sterility test (see Sterility Tests <71>) before they are dispensed or administered."	
			152	If high-risk level CSPs are dispensed before receiving the results of their sterility tests, there is a written procedure requiring daily observation of incubating test specimens.	**USP Chapter 797 - Finished Preparation Release Checks and Tests - Sterility Testing -** "When high-risk level CSPs are dispensed before receiving the results of their sterility tests, there shall be a written procedure requiring daily observation of the incubating test specimens and immediate recall of the dispensed CSPs when there is any evidence of microbial growth in the test specimens."	
			153	High-risk level CSPs must be pyrogen tested, excluding those for inhalation or ophthalmic administration, if prepared in batches of > 25 identical containers, or exposed longer than 12 hours at 2 to 8 degrees and 6 hours at warmer than 8 degrees before being sterilized.	**USP Chapter 797 - Finished Preparation Release Checks and Tests - Bacterial Endotoxin (Pyrogen) Testing -** "All high-risk level CSPs, except those for inhalation and ophthalmic administration, that are prepared in groups of more than 25 identical individual single-dose packages (e.g., ampules, bags, syringes, vials) or in MDVs for administration to multiple patients or that are exposed longer than 12 hours at 2° to 8° and longer than 6 hours at warmer than 8° before they are sterilized shall be tested to ensure that they do not contain excessive bacterial endotoxins (see USP Chapter 85 - Bacterial Endotoxins Test and USP Chapter 151 - Pyrogen Test)."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			154	All high-risk CSP solutions subjected to terminal sterilization by filtration are appropriately prefiltered and terminally filtered in ISO Class 5 air.	**USP Chapter 797 - CSP Microbial Contamination Risk Levels - High Risk Level CSPs -** "All high-risk level CSP solutions subjected to terminal sterilization are prefiltered by passing through a filter with a nominal pore size not larger than 1.2. µm preceding or during filing into their final containers to remove particulate matter. Sterilization of high-risk level CSPs by filtration shall be performed with a sterile 0.2-µm or 0.22-µm nominal pore size filter entirely within an ISO Class 5 or superior air quality environment."	
			155	CSP maintains acceptable strength, purity and integrity of containers after sterilization.	**USP Chapter 797 Appendices - CSP Microbial Contamination Risk Levels - High Risk Level CSPs -** "Maintain acceptable strength and purity of ingredients and integrity of containers after sterilization."	
			156	In the absence of sterility tests, storage is not more than 24 hours at controlled room temperature, 3 days at cold temperature, and 45 days in a solid frozen state of -25° to -10°.	**USP Chapter 797 - CSP Microbial Contamination Risk Levels - High Risk Level CSPs -** "For sterilized high-risk level preparation, in the absence of passing a sterility test, the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and are exposed for not more than 24 hours at controlled room temperature (see General Notices and Requirements), for not more than 3 days at a cold temperature (see General Notices and Requirements), and for 45 days in sold frozen state between -25° and -10°."	
			157	Sterility tests are performed for autoclaved CSPs if they are prepared in batches > 25 units.	**USP Chapter 797 - CSP Microbial Contamination Risk Levels - High Risk Level CSPs -** "[NOTE—Sterility tests for autoclaved CSPs are not required unless they are prepared in batches of more than 25 units.]"	
Verification of Compounding Accuracy and Sterility (High-Risk Compounding)						
			158	Packaged and labeled CSPs are visually inspected for physical integrity and expected appearance.	**USP Chapter 797 - Verification of Compounding Accuracy and Sterility -** "Packaged and labeled CSPs shall be visually inspected for physical integrity and expected appearance, including final fill amount."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			159	The accuracy of identities, concentrations, amounts and purities of ingredients in CSPs are confirmed by reviewing labels on packages, observing and documenting correct measurements with approved and correctly standardized devices, and reviewing information in labeling with certificates of analysis provided by suppliers.	**USP Chapter 797 - Verification of Compounding Accuracy and Sterility -** "The accuracy of identities, concentrations, amounts, and purities of ingredients in CSPs shall be confirmed by reviewing labels on packages, observing and documenting correct measurements with approved and correctly standardized devices, and reviewing information in labeling and certificates of analysis provided by suppliers."	
			160	The licensed healthcare professional is responsible for determining that the selected sterilization method both sterilizes and maintains the strength, purity, quality and packaging integrity of CSPs.	**USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods -** "The licensed healthcare professionals who supervise compounding shall be responsible for determining that the selected sterilization method (see Methods of Sterilization under USP Chapter 1211 - Sterilization and Sterility Assurance of Compendial Articles) both sterilizes and maintains the strength, purity, quality, and packaging integrity of CSPs."	
			161	Commercially available sterile filters are approved for human-use applications in sterilizing pharmaceutical fluids.	**USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Filtration -** "Commercially available sterile filters shall be approved for human-use applications in sterilizing pharmaceutical fluids."	
			162	Sterile filters used to sterilize CSPs are pyrogen free with a nominal porosity of 0.2 or 0.22 micrometers.	**USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Filtration -** "Sterile filters used to sterilize CSPs shall be pyrogen free and have a nominal pore size of 0.2 or 0.22 µm."	
			163	Sterile filters used are certified by the manufacturer to retain at least 10^7 microorganisms of a strain of Brevundimonas diminuta on each square centimeter of upstream filter surface area.	**USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Filtration -** "They shall be certified by the manufacturer to retain at least 10^7 microorganisms of a strain of Brevundimonas (Pseudomonas) diminuta on each square centimeter of upstream filter surface area under conditions similar to those in which the CSPs will be sterilized (see High-Risk Conditions in High-Risk Level CSPs)."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			164	The compounding supervisor ensures that the filters are chemically and physically stable at the pressure and temperature conditions to be used, that they have enough capacity to filter the required volumes, and that they will achieve sterility and maintain prefiltration pharmaceutical quality.	**USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Filtration -** "The compounding supervisor shall ensure, directly or from appropriate documentation, that the filters are chemically and physically stable at the pressure and temperature conditions to be used, that they have enough capacity to filter the required volumes, and that they will achieve sterility and maintain prefiltration pharmaceutical quality, including strength of ingredients of the specific CSP."	
			165	The filter dimensions and liquid material to be sterile-filtered permit the sterilization process to be completed rapidly, without replacement of the filter during the process.	**USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Filtration -** "The filter dimensions and liquid material to be sterile-filtered shall permit the sterilization process to be completed rapidly, without the replacement of the filter during the process."	
			166	When CSPs are known to contain excessive particulate matter, a prefilter of larger-porosity membrane is placed upstream from the sterilizing filter to remove gross particulate contaminants.	**USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Filtration -** "When CSPs are known to contain excessive particulate matter, a prefilter of larger nominal pore size membrane is placed upstream from the sterilizing filter to remove gross particulate contaminants in order to maximize the efficiency of the sterilizing filter."	
			167	Filter units used are subjected to manufacturers' recommended integrity test.	**USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Filtration -** "Filter units used to sterilize CSPs shall also be subjected to manufacturers' recommended integrity test, such as the bubble point test."	
			168	Personnel must know that filters will achieve sterilization of the particular CSPs being sterilized.	**USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Filtration -** "Compounding personnel shall ascertain that selected filters will achieve sterilization of the particular CSPs being sterilized."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			169	The description of steam sterilization conditions and duration for specific CSPs are included in written documentation in the compounding facility.	**USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Steam -** "The description of steam sterilization conditions and duration for specific CSPs shall be included in written documentation in the compounding facility."	
			170	The effectiveness of steam sterilization is verified using appropriate Bis of Bacillus stearothermophilus and other confirmation methods.	**USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Steam -** "The effectiveness of steam sterilization shall be verified using appropriate BIs of Bacillus stearothermophilus (see USP Chapter 1229.5 - Biological Indicators for Sterilization) and other confirmation methods such as temperature-sensing devices (see USP Chapter 1211 - Sterilization and Sterility Assurance of Compendial Articles and USP Chapter 71 - Sterility Tests)."	
			171	Heated filtered air is evenly distributed throughout the chamber by a blower device; the oven is equipped with a system for controlling temperature and exposure period.	**USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Heat -** "Heated filtered air shall be evenly distributed throughout the chamber by a blower device."	
			172	Dry heat is used only for those materials that cannot be sterilized by steam.	**USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Heat -** "Dry heat shall be used only for those materials that cannot be sterilized by steam, when either the moisture would damage the material or the material is impermeable."	
			173	During sterilization, sufficient space is left between materials to allow for good air circulation.	**USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Heat -** "During sterilization, sufficient space shall be left between materials to allow for good circulation of the hot air."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			174	The description of dry heat sterilization conditions and duration for specific CSPs are included in written documentation in the compounding facility.	**USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Heat -** "The description of dry heat sterilization conditions and duration for specific CSPs shall be included in written documentation in the compounding facility."	
			175	The effectiveness of dry heat sterilization is verified using appropriate BIs of Bacillus subtilis and other confirmation methods.	**USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Heat -** "The effectiveness of dry heat sterilization shall be verified using appropriate BIs of Bacillus subtilis (see USP Chapter 1229.5 - Biological Indicators for Sterilization) and other confirmation methods such as temperature-sensing devices (see USP Chapter 1211 - Sterilization and Sterility Assurance of Compendial Articles and USP Chapter 71 - Sterility Tests)."	
			176	The description of dry heat depyrogenation cycle conditions and duration for specific CSPs are included in written documentation in the compounding facility.	**USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Depyrogenation by Dry Heat -** "The description of the dry heat depyrogenation cycle and duration for specific load items shall be included in written documentation in the compounding facility."	
			177	The effectiveness of the dry heat depyrogenation cycle is verified using endotoxin challenge vials (ECVs); the bacterial endotoxin test is performed on the ECVs to verify that the cycle is capable of achieving a 3- log reduction in endotoxin.	**USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Depyrogenation by Dry Heat -** "The effectiveness of the dry heat depyrogenation cycle shall be verified using endotoxin challenge vials (ECVs). The bacterial endotoxin test should be performed on the ECVs to verify that the cycle is capable of achieving a 3-log reduction in endotoxin (see USP Chapter 1211 - Sterilization and Sterility Assurance of Compendial Articles and USP Chapter 85 - Bacterial Endotoxins Test)."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
Radiopharmaceuticals as CSPs						
			178	Radiopharmaceuticals are compounded using appropriately shielded vials and syringes in a properly functioning and certified ISO Class 5 PEC located in the ISO Class 8 or cleaner air environment.	**USP Chapter 797 - Radiopharmaceuticals as CSPs -** "These radiopharmaceuticals shall be compounded using appropriately shielded vials and syringes in a properly functioning and certified ISO Class 5 (see Table 1) PEC located in an ISO Class 8 (see Table 1) or cleaner air environment to permit compliance with special handling, shielding, and negative air flow requirements."	
			179	Radiopharmaceutical vials designed for multi-use, compounded with technetium-99m, exposed to ISO Class 5 environment, and punctured by needles with no direct contact contamination are used by the time indicated by the manufacturers' recommendations.	**USP Chapter 797 - Radiopharmaceuticals as CSPs -** "Radiopharmaceutical vials designed for multi-use, compounded with technetium-99m, exposed to ISO Class 5 (see Table 1) environment, and punctured by needles with no direct contact contamination may be used up to the time indicated by manufacturers' recommendations."	
			180	Technetium-99m/molybdenum-99 generator systems are stored and operated under conditions recommended by manufacturers and applicable state and federal regulations; such generator systems are operated in an ISO Class 8 or cleaner air environment.	**USP Chapter 797 - Radiopharmaceuticals as CSPs -** "Technetium-99m/molybdenum-99 generator systems shall be stored and eluted (operated) under conditions recommended by manufacturers and applicable state and federal regulations. Such generator systems shall be eluted in an ISO Class 8 (see Table 1) or cleaner air environment to permit special handling, shielding, and air flow requirements."	
			181	Direct visual inspection of radiopharmaceutical CSPs containing high concentrations of doses of radioactivity are conducted in accordance with ALARA.	**USP Chapter 797 - Radiopharmaceuticals as CSPs -** "To limit acute and chronic radiation exposure of inspecting personnel to a level that is as low as reasonably achievable (ALARA), direct visual inspection of radiopharmaceutical CSPs containing high concentrations of doses of radioactivity shall be conducted in accordance with ALARA."	
			182	Radiopharmaceuticals prepared as low-risk level CSPs with 12-hour or less BUD are prepared in a segregated compounding area; a line of demarcation is established.	**USP Chapter 797 - Radiopharmaceuticals as CSPs -** "Radiopharmaceuticals prepared as Low-Risk Level CSPs with 12-Hour or Less BUD shall be prepared in a segregated compounding area. A line of demarcation defining the segregated compounding area shall be established."	
			183	Materials and garb exposed in patient care and treatment do not cross the line of demarcation.	**USP Chapter 797 - Radiopharmaceuticals as CSPs -** "Materials and garb exposed in a patient care and treatment area shall not cross a line of demarcation into the segregated compounding area."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
Allergen Extracts as CSPs						
			184	Compounding is performed only with simple transfers using sterile ingredients and supplies.	**USP Chapter 797 - Allergen Extracts as CSPs -** "Allergen extracts as CSPs are single-dose and multiple-dose intradermal or subcutaneous injections that are prepared by specially trained physicians and personnel under their direct supervision. Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all CSP Microbial Contamination Risk Levels in this chapter only when all of the following criteria are met: 1. The compounding process involves simple transfer via sterile needles and syringes of commercial sterile allergen products and appropriate sterile added substances (e.g., glycerin, phenol in sodium chloride injection)."	
			185	Allergen extracts contain appropriate concentrations of preservatives.	**USP Chapter 797 - Allergen Extracts as CSPs -** Allergen extracts as CSPs are single-dose and multiple-dose intradermal or subcutaneous injections that are prepared by specially trained physicians and personnel under their direct supervision. Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all CSP Microbial Contamination Risk Levels in this chapter only when all of the following criteria are met: 2. All allergen extracts as CSPs shall contain appropriate substances in effective concentrations to prevent the growth of microorganisms. Nonpreserved allergen extracts shall comply with the appropriate CSP risk level requirements in the chapter.	
			186	Before compounding, personnel appropriately wash hands with soap and water, apply alcohol-based scrub with persistent activity, don hair covers, facial hair covers, gowns, face masks and gloves.	**USP Chapter 797 - Allergen Extracts as CSPs -** "Allergen extracts as CSPs are single-dose and multiple-dose intradermal or subcutaneous injections that are prepared by specially trained physicians and personnel under their direct supervision. Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all CSP Microbial Contamination Risk Levels in this chapter only when all of the following criteria are met: 3. Before beginning compounding activities, personnel perform a thorough hand-cleansing procedure by removing debris from under fingernails using a nail cleaner under running warm water followed by vigorous hand and arm washing to the elbows for at least 30 seconds with either nonantimicrobial or antimicrobial soap and water."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			187	Sterile gloves are intermittently disinfected with sterile 70% IPA.	**USP Chapter 797 - Allergen Extracts as CSPs -** "Allergen extracts as CSPs are single-dose and multiple-dose intradermal or subcutaneous injections that are prepared by specially trained physicians and personnel under their direct supervision. Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all CSP Microbial Contamination Risk Levels in this chapter only when all of the following criteria are met: 7. Compounding personnel disinfect their gloves intermittently with sterile 70% IPA when preparing multiple allergen ex-tracts as CSPs."	
			188	Vial/ampule critical sites are wet with 70% IPA for 10 seconds and allowed to dry before use.	**USP Chapter 797 - Allergen Extracts as CSPs -** "Allergen extracts as CSPs are single-dose and multiple-dose intradermal or subcutaneous injections that are prepared by specially trained physicians and personnel under their direct supervision. Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all CSP Microbial Contamination Risk Levels in this chapter only when all of the following criteria are met: 8. Ampule necks and vial stoppers on packages of manufactured sterile ingredients are disinfected by careful wiping with sterile 70% IPA swabs to ensure that the critical sites are wet for at least 10 seconds and allowed to dry before they are used to compound allergen extracts as CSPs."	
			189	Compounding manipulations are performed to minimize contact contamination of critical sites.	**USP Chapter 797 - Allergen Extracts as CSPs -** "Allergen extracts as CSPs are single-dose and multiple-dose intradermal or subcutaneous injections that are prepared by specially trained physicians and personnel under their direct supervision. Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all CSP Microbial Contamination Risk Levels in this chapter only when all of the following criteria are met: 9. The aseptic compounding manipulations minimize direct contact contamination (e.g., from glove fingertips, blood, nasal and oral secretions, shed skin and cosmetics, other nonsterile materials) of critical sites (e.g., needles, opened ampules, vial stoppers)."	

Compliant					USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			190	Vials are labeled with patient's name, BUD and storage information based on manufacturers' recommendations or peer-reviewed literature.	**USP Chapter 797 - Allergen Extracts as CSPs -** "Allergen extracts as CSPs are single-dose and multiple-dose intradermal or subcutaneous injections that are prepared by specially trained physicians and personnel under their direct supervision. Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all CSP Microbial Contamination Risk Levels in this chapter only when all of the following criteria are met: 10. The label of each multiple-dose vial (MDV) of allergen extracts as CSPs lists the name of one specific patient and a BUD and storage temperature range that is assigned based on manufacturers' recommendations or peer-reviewed publications."	

WA Pharmacy Quality Assurance Commission
2019 Responsible Manager
Pharmacy Self-Inspection Worksheet
Hospital and HPAC Addendum

Attention: Responsible Manager

Washington law holds the responsible manager and all pharmacists on duty responsible for ensuring pharmacy compliance with all state and federal laws governing the practice of pharmacy. Failure to complete this self-inspection worksheet addendum within the month of March or within 30 days of becoming responsible manager (as required by WAC 246-869-190) may result in disciplinary action. **The following addendum is required to be filled out and kept on file with the General Pharmacy Self-Inspection Worksheet. Do not send to the Commission office.**

The primary objective of this worksheet addendum, and the self-inspection, is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. (NOTE: Neither the self-inspection nor a Commission inspection evaluates complete compliance with all laws and rules of the practice of pharmacy.)

By answering the questions and referencing the appropriate laws/rules/CFR provided, you can determine whether the pharmacy is compliant with many of the rules and regulations. If any deficiencies have been corrected, please write corrected and the date of correction by the appropriate question.

Document and Record Review Document Review

Where are the following items located inside the pharmacy (be as specific as possible, there can be many filing cabinets and binders)? The rule references require the documentation printed below, by listing the location of these documents **you are also confirming your compliance with the referenced rule.**

	Rule Reference
Pilot Project Documentation, if applicable: Location:	**WAC 246-901-100(4)** "The board may give conditional approval for pilot projects for innovative applications in the utilization of pharmacy ancillary personnel."
Nursing Unit Inspection Reports for the last 12 months. Location:	**WAC 246-873-080(1)(b)** A monthly inspection of all nursing care units or other areas of the hospital where medications are dispensed, administered or stored. Inspection reports shall be maintained for one year.
Pharmacy - Controlled Substance Distribution Records for the last 2 years. Location:	**WAC 246-873-080(7)(a)** Complete, accurate, and current records shall be kept of receipt of all controlled substances and in addition, a Schedule II perpetual inventory shall be maintained. **(b)** The pharmacy shall maintain records of Schedule II drugs issued from the pharmacy to other hospital units which include: **(i)** Date **(ii)** Name of the drug **(iii)** Amount of drug issued **(iv)** Name and/or initials of the pharmacist who issued the drug **(v)** Name of the patient and/or unit to which the drug was issued."
Hospital Unit - Controlled Substance Utilization Records. If electronic, be prepared to demonstrate retrieval of records and data. Location:	**WAC 246-873-080(7)(c)** "Records shall be maintained by any unit of the hospital which utilizes Schedule II drugs indicating: **(i)** Date **(ii)** Time of administration **(iii)** Name of the drug (if not already indicated on the records **(iv)** Dosage of the drug which was used which shall include both the amount administered and any amount destroyed. **(v)** Name of the patient to whom the drug was administered **(vi)** Name of the practitioner who authorized the drug **(vii)** Signature of the licensed individual who administered the drug.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
General Requirements						
			1	Is the pharmacy managed by a licensed pharmacist appropriately qualified by education, training, and experience to manage a hospital pharmacy?	**WAC 246-873-040(1)** "Director of pharmacy. The pharmacy, organized as a separate department or service, shall be directed by a licensed pharmacist appropriately qualified by education, training, and experience to manage a hospital pharmacy. …"	
			2	Do the responsible pharmacy manager's (e.g. director of pharmacy) responsibilities include the following?	**WAC 246-873-040(1)** "Director of pharmacy...The responsibilities shall include the establishment and maintenance of policies and procedures, ongoing monitoring and evaluation of pharmaceutical service, use and control of drugs, and participation in relevant planning, policy and decision-making activities..."	
				a Establishing and maintaining policies and procedures;		
				b Ongoing monitoring and evaluation of pharmacy services;		
				c Utilization and control of drugs;		
				d Participation in planning, policy, and decision-making activities.		
			3	If the pharmacy does not have fulltime services of a director, does your pharmacy have an ongoing arrangement with a qualified pharmacist?	**WAC 246-873-040(1)** "Director of pharmacy... Hospitals which do not require, or are unable to obtain the services of a fulltime director shall be held responsible for the principles contained herein and shall establish an ongoing arrangement in writing with an appropriately qualified pharmacist to provide the services. Where the director of pharmacy is not employed fulltime, then the hospital shall establish an ongoing arrangement in writing with an appropriately qualified pharmacist to provide the services described herein... "	
			4	Are <u>all</u> pharmacists working in this facility licensed by the Commission?	**WAC 246-873-030** "Hospital pharmacists shall be licensed by the board of pharmacy in accordance with chapter 18.64 RCW."	

Compliant			#			Rule Reference	Notes/Corrective Actions
Yes	No	N/A					
Policies & Procedures							
			5	Does the pharmacy have policies and procedures?		**WAC 246-873-080(4)** "The director shall establish, annually review and update when necessary comprehensive written policies and procedures governing the responsibilities and functions of the pharmaceutical service...."	
			6	Do your policies and procedures include the following?			
				a	Patient care and treatment involving drug use	**WAC 246-873-080(4)** "… Policies affecting patient care and treatment involving drug use shall be established by the director of pharmacy with the cooperation and input of the medical staff, nursing service and the administration."	
				b	Self-Administered Medications	**WAC 246-873-090(4)** "Self-administration. Self-administration of drugs shall occur only within approved protocols in accordance with a program of self-care or rehabilitation. Policy and specific written procedures, approved by the appropriate medical staff, nursing service and administration shall be established by the director of pharmacy."	
				c	Administration of Patient Owned Medications	**WAC 246-873-090(3)** "Patient's drugs. The hospital shall develop written policies and procedures for the administration of drugs brought into the hospital by or for patients."	
				d	Inspections of nursing units	**WAC 246-873-080** "**(1)** General. Pharmaceutical service shall include: **(b)** A monthly inspection of all nursing care units or other areas of the hospital where medications are dispensed, administered or stored. Inspection reports shall be maintained for one year."	

Compliant			#			Rule Reference	Notes/Corrective Actions
Yes	No	N/A					
			6	e	Monitoring of Drug Therapy **See also WAC 246-863-110 for what policy must address.**	**WAC 246-873-080** "**(1)** General. Pharmaceutical service shall include: **(c)** Monitoring the drug therapy."	
				f	Provision of Drug Information	**WAC 246-873-080** "**(1)** General. Pharmaceutical service shall include: **(d)** Provisions for drug information to patients, physicians and others."	
				g	Adverse Drug Reactions	**WAC 246-873-080** "**(1)** General. Pharmaceutical service shall include: **(e)** Surveillance and reporting of adverse drug reactions and drug product defect(s). **WAC 246-873-080(10)** "Adverse drugs reactions. All adverse drug reactions shall be appropriately recorded in the patient's record and reported to the prescribing practitioner and to the pharmacy."	
				h	Drug Error Reporting	**WAC 246-873-080(11)** "Drug errors. All drug errors shall upon discovery be recorded in an incident report and reported to the prescribing practitioner and to the pharmacy."	
				i	Drug Recall Procedures	**WAC 246-873-080(8) "**Drug recall. The director shall develop and implement a recall procedure to assure that potential harm to patients within the hospital is prevented and that all drugs included on the recall are returned to the pharmacy for proper disposition."	
				j	Quality Assurance Program	**WAC 246-873-110(2)** "Quality assurance. The pharmaceutical service shall establish a pharmacy quality assurance program."	
Absence of Pharmacist							

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			7	Does the pharmacy provide 24 hour pharmaceutical services on-site? ***If yes, please skip to question 10***	**WAC 246-873-050(1)** "General. Pharmaceutical services shall be available on a 24-hour basis. If round-the-clock services of a pharmacist are not feasible, arrangements shall be made in advance by the director of pharmacy to provide reasonable assurance of pharmaceutical services."	
			8	Is access to the pharmacy restricted to a designated nurse in the absence of a pharmacist?	**WAC 246-873-050(2)** "Access to the pharmacy. Whenever a drug is required to treat an immediate need and not available from floor stock when the pharmacy is closed, the drug may be obtained from the pharmacy by a designated registered nurse, who shall be accountable for his/her actions. One registered nurse shall be designated in each hospital shift for removing drugs from the pharmacy."	
			9	Are there policies and procedures to assist a designated registered nurse removing drugs from the pharmacy when it is closed? ***See all of WAC 246-873-050(2) for what policy must address.***	**WAC 246-873-050(2)(a)** "The director of pharmacy shall establish written policy and recording procedures to assist the registered nurse who may be designated to remove drugs from the pharmacy, when a pharmacist is not present, in accordance with Washington State Pharmacy Practice Act, RCW 18.64.255(2), which states that the director of pharmacy and the hospital be involved in designating the nurse."	
Emergency Outpatient Dispensing						

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			10	Does the pharmacy dispense emergency outpatient prepackaged medications? ***If no, skip to question 14.***	**RCW 70.41.480(1)** "... It is the intent of the legislature to accomplish this objective by allowing practitioners with prescriptive authority to prescribe limited amounts of prepackaged emergency medications to patients being discharged from hospital emergency departments when access to community or outpatient hospital pharmacy services is not otherwise available."	
			11	Does the pharmacy have policies and procedures regarding prepacking medications?	**RCW 70.41.480(2)(b) "**… The director of pharmacy, in collaboration with appropriate hospital medical staff, develops policies and procedures regarding the following: … **(b)** Assurances that emergency medications to be prepackaged pursuant to this section are prepared by a pharmacist or under the supervision of a pharmacist licensed under chapter 18.64 RCW."	
				Do those policies and procedures include the following?		
				a List of types of emergency medications that can be prepackaged	**RCW 70.41.480(2)(a) "**… The director of pharmacy, in collaboration with appropriate hospital medical staff, develops policies and procedures regarding the following: … **(a)** Development of a list, preapproved by the pharmacy director, of the types of emergency medications to be prepackaged and distributed."	

Compliant			#			Rule Reference	Notes/Corrective Actions
Yes	No	N/A					
			12	b	Criteria for when emergency prepackaged medications can be prescribed and distributed	**RCW 70.41.480(2)(c)** "… The director of pharmacy, in collaboration with appropriate hospital medical staff, develops policies and procedures regarding the following: … **(c)** Development of specific criteria under which emergency prepackaged medications may be prescribed and distributed consistent with the limitations of this section;"	
				c	Supply limitations	**RCW 70.41.480(2)(f)** "… The director of pharmacy, in collaboration with appropriate hospital medical staff, develops policies and procedures regarding the following: … **(d)** Establishment of a limit of no more than a forty-eight hour supply of emergency medication as the maximum to be dispensed to a patient, except when community or hospital pharmacy services will not be available within forty-eight hours. In no case may the policy allow a supply exceeding ninety-six hours be dispensed;"	
				d	Pharmacy receipt of order for verification	**WAC 246-873-060(6)** "The original hard copy or electronically transmitted order by the practitioner is retained for verification by the pharmacist after completion by the practitioner or registered nurse and shall contain: **(a)** Name and address of patient if not already listed in the medical record; **(b)** Date of issuance; **(c)** Units issued; **(d)** Initials of practitioner or registered nurse."	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			13	Is there a policy for practitioners to counsel patients prior to the dispensing of emergency prepackaged medications?	**RCW 70.41.480(2)(h) "**… The director of pharmacy, in collaboration with appropriate hospital medical staff, develops policies and procedures regarding the following: … **(h)** Assurances that nurses or practitioners will distribute prepackaged emergency medications to patients only after a practitioner has counseled the patient on the medication."	
			14	Do prepackaged medications contain the following information on their labels: - Name, address, and telephone number of the hospital; - Name of Drug, strength and number of units; - Cautionary information as required for patient safety and information of use - Expiration Date - Direction for use	**WAC 246-873-060(2)** "A department credentialed pharmacy technician or a licensed pharmacist shall prepackage the medication. Medication prepackaged by a department credentialed pharmacy technician must be checked by a licensed pharmacist. The prepackaged medication must contain any supplemental material provided and an affixed label that contains: **(a)** Name, address, and telephone number of the hospital. **(b)** The name of the drug (as required by chapter 246-899 WAC), strength and number of units. **(c)** Cautionary information as required for patient safety and information on use is provided. **(d)** An expiration date after which the patient should not use the medication. **(e)** Directions for use."	
Automated Drug Dispensing Devices (ADDDs)						

Compliant			#			Rule Reference	Notes/Corrective Actions
Yes	No	N/A					
			15		Does the pharmacy maintain policies and procedures for the use of ADDDs throughout the hospital and do they include the following?	**WAC 246-874-030(1) "**The pharmacy and any facility using an ADDD shall have written policies and procedures in place prior to any use of an ADDD. ... **(2)** The pharmacy or facility must maintain a current copy of all policies and procedures related to the use of the ADDD and make them available within the pharmacy or facility where the ADDD is located and make available upon request to the commission or its designee. Electronic documents made available on a computer at the facility or pharmacy are permissible."	
				a	User types and privileges	**WAC 246-874-030(3) "**The policies and procedures must include, but are not limited to: **(b)** User privileges based upon user type;"	
				b	Override medication criteria	**WAC 246-874-030(3) "**The policies and procedures must include, but are not limited to: **(c)** Criteria for selection of medications subject to override and an override list approved by the pharmacy or facility's pharmacy and therapeutics committee or equivalent committee;"	
				c	Diversion prevention procedures	**WAC 246-874-030(3)** "The policies and procedures must include, but are not limited to: **(d)** Diversion prevention procedures;"	
				d	Record retention and retrieval	**WAC 246-874-030(3)** "The policies and procedures must include, but are not limited to: **(e)** Record retention and retrieval requirements that adhere to all state and federal laws and regulations. Records must be retained for a minimum of two years."	

Compliant			#			Rule Reference	Notes/Corrective Actions
Yes	No	N/A					
				e	Inventory control	**WAC 246-874-030 (3)** "The policies and procedures must include, but are not limited to: **(a)** All sections of part 1; **(5)** Inventory control. **(a)** Authorized personnel must place drugs into the ADDD in the manufacturer's original sealed unit dose or unit-of-use packaging, in repackaged unit-dose containers, or in other suitable containers to support patient care and safety, and in accordance with federal and state laws and regulations; **(b)** When applicable, patient owned medications that have been properly identified and approved for use per the facility's policies, may be stored in accordance with policies for safe and secure handling of medication practices."	

Compliant			#			Rule Reference	Notes/Corrective Actions
Yes	No	N/A					
			15	f	Securing and accounting for wasted, discarded, expired or unused medications	**WAC 246-874-050(1)** "The facility shall have a mechanism for securing and accounting for wasted, discarded, expired, or unused medication removal from the ADDD according to policies and procedures and existing state and federal laws and regulations." **WAC 246-874-050(3)** "Wasted controlled substances. All controlled substances wasted shall have a witness, who is a Washington state credentialed health care professional, acting within their scope of practice; the record of waste shall be authenticated by both persons. A waste record must be readily retrievable in the ADDD, electronic health record, or as a hard copy report in accordance with the facility's policies and procedures. The report of waste shall include patient name, drug name, drug strength, date and time of waste, the amount wasted, and the identity of the person wasting and the witness. Waste records must be maintained for a minimum of two years."	
			15	g	Maintenance of adequate records regarding use and accountability of legend drugs including controlled substances ***See all of WAC 246-874-050(2) for policy and procedure requirments.***	**WAC 246-874-050(2)** "The responsible manager shall implement procedures and maintain adequate records regarding use and accountability of legend drugs, including controlled substances, in compliance with state and federal laws and regulations including, but not limited to: ..."	

Compliant			#			Rule Reference	Notes/Corrective Actions
Yes	No	N/A					
				h	Quality Assurance Process ***See all of WAC 246-874-060 for policy and procedure requirments.****	**WAC 246-874-060** "Each pharmacy and facility shall establish and maintain a quality assurance and performance program that monitors performance of the ADDD, which is evidenced by written policies and procedures that are made readily available on request to the commission or its designee. ..."	
			16		Does the policy limit access, by secure means, to ADDD(s) to Washington State credentialed health care professionals acting within their scope of practice? **See also WAC 246-874-070 regarding nursing student access to ADDDs.**	**WAC 246-874-040(1)** "The responsible manager shall ensure adequate security systems and procedures for the ADDD, addressing access …" **WAC 246-874-040(2)** The responsible manager or designee shall assign, discontinue, or change user access and types of drug privileges for accessing an ADDD. Access to the ADDD must be limited to those Washington state credentialed health care professionals acting within their scope of practice. Access to the ADDD by facility information technology employees or employees of similar title must be properly restricted and addressed in policies and procedures.	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			17	Unless an exception applies, do pharmacists perform prospective review and approve each medication order?	**WAC 246-874-040(3)** "A pharmacist shall perform prospective drug utilization review and approve each medication order, except if: **(a)** The drug is a subsequent dose from a previously reviewed drug order; **(b)** The prescriber is in the immediate vicinity and controls the drug dispensing process; **(c)** The system is being used to provide access to medications on override and only a quantity sufficient to meet the immediate need of the patient is removed; or **(d)** When twenty-four hour pharmacy services are not available. **(4)** When twenty-four hour pharmacy services are not available, a pharmacist shall perform retrospective drug utilization review within six hours of the pharmacy being open, except when a dispensed override medication is a one-time dose or order for discharged patients."	
			18	When 24 hour services are not available does the pharmacist perform retrospective drug utilization review of orders within six hours of being open?	**WAC 246-874-040(4)** "When twenty-four hour pharmacy services are not available, a pharmacist shall perform retrospective drug utilization review within six hours of the pharmacy being open, except when a dispensed override medication is a one-time dose or order for discharged patients."	
			19	Does the pharmacist reconcile and review all medication orders issued outside normal pharmacy hours no later than the next business day?	**WAC 246-874-040(5)** "The pharmacist shall reconcile and review all medication orders added to a patient's profile outside of the facility's normal admission discharge transfer process and procedures, no later than the next business day."	
Hospital Drug Procurement, Distribution, and Control						

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			20	Does the pharmacy receive and distribute drug samples?	**RCW 69.45.050** "**(1)** Drug samples may be distributed by a manufacturer or a manufacturer's representative only to practitioners legally authorized to prescribe such drugs or, at the request of such practitioner, to pharmacies of hospitals or other health care entities. The recipient of the drug sample must execute a written receipt upon delivery that is returned to the manufacturer or the manufacturer's representative. **(2)** Drug samples may be distributed by a manufacturer or a manufacturer's representative only to a practitioner legally authorized to prescribe such drugs pursuant to a written request for such samples. The request shall contain: **(a)** The recipient's name, address, and professional designation; **(b)** The name, strength, and quantity of the drug samples delivered; **(c)** The name or identification of the manufacturer and of the individual distributing the drug sample; and **(d)** The dated signature of the practitioner requesting the drug sample. **(3)** No fee or charge may be imposed for sample drugs distributed in this state. **(4)** A manufacturer's representative shall not possess legend drugs or controlled substances other than those distributed by the manufacturer they represent. Nothing in this section prevents a manufacturer's representative from possessing a legally prescribed and dispensed legend drug or controlled substance."	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			21	Is the pharmacy responsible for all procurement, preparation, storage, distribution, and control of all drugs throughout the hospital?	**WAC 246-873-080** "**(1)** General. Pharmaceutical service shall include: **(a)** Procurement, preparation, storage, distribution and control of all drugs throughout the hospital."	
			22	Are all drug containers in the hospital labeled clearly and adequately to show the drug name, strength, and expiration/BUD?	**WAC 246-873-080** "**(5)** Labeling **(a)** "Inpatient. All drug containers in the hospital shall be labeled clearly, legibly and adequately to show the drug's name (generic and/or trade) and strength when applicable. Accessory or cautionary statements and the expiration date shall be applied to containers as appropriate."	
			23	Do medication labels for discharge medications contain: - Name and address of dispensing pharmacy (may also be recorded in the pharmacy's record system) - Prescription number - Name of the prescriber - Prescriber's directions	**RCW 18.64.246** "**(1)** To every box, bottle, jar, tube or other container of a prescription which is dispensed there shall be fixed a label bearing the name and address of the dispensing pharmacy, the prescription number, the name of the prescriber, the prescriber's directions, the name and strength of the medication, the name of the patient, the date, and the expiration date. The security of the cover or cap on every bottle or jar shall meet safety standards adopted by the commission. At the prescriber's request, the name and strength of the medication need not be shown. If the prescription is for a combination medication product, the generic names of the medications combined or the	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
				- Prescriber's directions - Name and strength of medication - Patient name - Date and expiration date	names of the medications combined or the trade name used by the manufacturer or distributor for the product shall be noted on the label. The identification of the licensed pharmacist responsible for each dispensing of medication must either be recorded in the pharmacy's record system or on the prescription label. This section shall not apply to the dispensing of medications to in-patients in hospitals.	
			24	Do all parenteral and irrigation solutions meet labeling requirements?	**WAC 246-873-080** "**(5)** Labeling: **(c)** Parenteral and irrigation solutions. When drugs are added to intravenous solutions, a suitable label shall be affixed to the container. As a minimum the label shall indicate name and location of the patient, name and amount of drug(s) added, appropriate dating, initials of the personnel who prepared and checked the solution."	
			25	Do pharmacists review the original order or copy of the order prior to dispensing any drug except for emergency use, or as authorized in WAC 246-873-050? ****Does not apply to medications dispensed from an ADDD, see WAC 246-874-030(3).****	**WAC 246-873-080(6)** "Medication orders. Drugs are to be dispensed and administered only upon orders of authorized practitioners. A pharmacist shall review the original order or direct copy thereof, prior to dispensing any drug, except for emergency use or as authorized in WAC 246-873-050."	
Drug Administration						

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			26	Are all drugs administered only upon the order of a practitioner who has been granted clinical privileges to write such orders?	**WAC 246-873-090(1)** "General. Drugs shall be administered only upon the order of a practitioner who has been granted clinical privileges to write such orders. Verbal orders for drugs shall only be issued in emergency or unusual circumstances and shall be accepted only by a licensed nurse, pharmacist, or physician, and shall be immediately recorded and signed by the person receiving the order. Such orders shall be authenticated by the prescribing practitioner within 48 hours."	
			27	Are all drugs administered only by appropriately licensed personnel as specified in policy? **Nursing students acting within their scope of practice can administer medications.**	**WAC 246-873-090(2)** "Administration. Drugs shall be administered only by appropriately licensed personnel in accordance with state and federal laws and regulations governing such acts and in accordance with medical staff approved hospital policy."	
			28	Does the pharmacy dispense investigational drugs? ****If no, skip to question 31.****	**WAC 246-873-100(1)** "Distribution. Storage, distribution, and control of approved investigational drugs used in the institution shall be the responsibility of the director of pharmacy or his designee. The pharmacy shall be responsible for maintaining and providing information on approved investigational drugs."	
			29	Are investigational drugs properly labeled and stored only for use under explicit directions from principal investigators?	**WAC 246-873-100(2)** "General. Investigational drugs shall be properly labeled and stored for use only under the explicit direction of the authorized principal investigator or coinvestigator(s). Such drugs shall be approved by an appropriate medical staff committee."	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			30	Are investigational drugs administered in accordance with approved written protocols?	**WAC 246-873-100(3) "**Administration. On approval of the principal investigator or coinvestigator(s), those authorized to administer drugs may administer these drugs after they have been given basic pharmacological information about the drug. Investigational drugs shall be administered in accordance with approved written protocol that includes any requirements for the patient's appropriate informed consent."	
Control Substance Accountability						
			31	Are procedures established for effective accountability of controlled substances?	**WAC 246-873-080(7)** "The director of pharmacy shall establish effective procedures and maintain adequate records regarding use and accountability of controlled substances, and such other drugs as appropriate, in compliance with state and federal laws and regulations."	
			32	Does the pharmacy maintain a perpetual inventory for Schedule II controlled substances?	**WAC 246-873-080(7)(a)** "Complete, accurate, and current records shall be kept of receipt of all controlled substances and in addition, **a Schedule II perpetual inventory shall be maintained.**"	
			33	Does a second nurse, or licensed health professional acting within their scope, witness destroying/wasting of small amounts of controlled substances after administration of a dose?	**WAC 246-873-080(7)(d) "**When it is necessary to destroy small amounts of controlled substances following the administration of a dose by a nurse, the destruction shall be witnessed by a second nurse who shall countersign the records of destruction."	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			34	Are procedures established for the proper destruction of controlled substances? ***See all of WAC 246-873-080(7)(e) for what procedures must contain.***	**WAC 246-873-080(7)(e)** "The director of the pharmacy shall develop written procedures for the proper destruction of controlled substances not covered by (d) above conforming with federal and state statutes."	
			35	Are controlled substance records periodically verified by a pharmacist or nurse?	**WAC 246-873-080(7)(f)** "Periodic monitoring of controlled substances records shall be performed by a nurse or a pharmacist to determine whether the drugs recorded on usage records have also been recorded on the patient's chart."	
			36	If ADDDs are not being used, are actual physical counts of all floor stock Schedule II and III controlled substances performed at each shift change?	**WAC 246-873-080(7)(h)** "Controlled substances, Schedule II and III, which are floor stocked, in any hospital patient or nursing service area shall be checked by actual count at the change of each shift by two authorized persons licensed to administer drugs."	
			37	Are significant losses or disappearances of controlled substances reported to PQAC, the DEA, the CEO of the hospital, and other appropriate authorities?	**WAC 246-873-080(7)(k)** "Significant losses or disappearances of controlled substances and the facts surrounding the discrepancy shall be reported to the board of pharmacy, the drug enforcement agency, the chief executive officer of the hospital and other appropriate authorities."	
Facilities						
			38	Does the pharmacy have sufficient space and equipment for secure, environmentally controlled storage of drugs and other pharmaceutical supplies?	**WAC 246-873-070** "**(1)** Area. The pharmacy facilities shall include: **(b)** Sufficient space and equipment for secure, environmentally controlled storage of drugs and other pharmaceutical supplies."	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			39	Are all pharmacy areas locked and secured to prevent unauthorized access?	**WAC 246-873-070(3)** "Access to unattended areas. All areas occupied by the hospital pharmacy shall be locked by key or combination in order to prevent access by unauthorized personnel. The director of pharmacy shall designate in writing, by title and/or position those individuals who shall be authorized access to particular areas within the pharmacy, including authorization of access to keys and/or combinations."	
			40	Are medications secured in nursing service areas or units?	**WAC 246-873-070(4)** "Drug storage areas. Drugs shall be stored under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security. … **(b)** Locked storage or locked medication carts shall be provided for use on each nursing service area or unit."	
			41	Are all drugs stored under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security?	**WAC 246-873-070 (4)** "Drug storage areas. Drugs shall be stored under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security."	

Please continue onto the next page if you have Hospital Pharmacy Associated Clinics.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
Hospital Pharmacy Associated Clinics (HPACs)						
			1	Are there clinics owned, operated, or under common control of the hospital listed as HPACs on the hospital pharmacy license? ***If no, you DO NOT need to answer the remaining questions.****	**WAC 246-873A-020(2)** "Current hospital pharmacy license holders. The parent hospital pharmacy must notify the commission in writing of any change of HPAC ownership, location of HPACs, and addition or removal of HPACs from the parent hospital pharmacy license."	
HPAC Responsible Manager Requirements Rule Reference for HPAC Questions 44 - 52.						
WAC 246-873A-030 "**Responsible Manager.** The responsible manager shall comply with the requirements of WAC 246-873-080 (3), (4), (7), and (8)." ***Policies and procedures, required below, regarding HPACs may be incorporated into the overarching hospital pharmacy required policies and procedures.****						
			2	Are procedures established for the procurement, distribution, and maintenance of a system of accountability for dugs, IV solutions, chemicals, and biologicals related to the practice of pharmacy for identified HPACs?	**WAC 246-873-080(3) "**The director shall be responsible for establishing specifications for procurement, distribution and the maintenance of a system of accountability for drugs, IV solutions, chemicals, and biologicals related to the practice of pharmacy."	
			3	Are drugs located in HPACs properly stored and secured?	**WAC 246-873-070 (4)** "Drug storage areas. Drugs shall be stored under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security."	
			4	Has the responsible pharmacy manager (e.g. director of pharmacy) established procedures for effective accountability of controlled substances in your HPACs?	**WAC 246-873-080(7)** "The director of pharmacy shall establish effective procedures and maintain adequate records regarding use and accountability of controlled substances, and such other drugs as appropriate, in compliance with state and federal laws and regulations."	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			5	Is a perpetual inventory for Schedule II controlled substances maintained in all the HPACs?	**WAC 246-873-080(7)(a)** "Complete, accurate, and current records shall be kept of receipt of all controlled substances and in addition, **a Schedule II perpetual inventory shall be maintained.**"	
			6	Does a second nurse, or licensed health professional acting within their scope, witness the destroying/wasting of small amounts of controlled substances after administration of a dose?	**WAC 246-873-080(7)(d) "**When it is necessary to destroy small amounts of controlled substances following the administration of a dose by a nurse, the destruction shall be witnessed by a second nurse who shall countersign the records of destruction."	
			7	Are controlled substance records periodically verified by a pharmacist or nurse?	**WAC 246-873-080(7)(f)** "Periodic monitoring of controlled substances records shall be performed by a nurse or a pharmacist to determine whether the drugs recorded on usage records have also been recorded on the patient's chart."	
			8	If ADDDs are not being used, are actual physical counts of all floor stock Schedule II and III controlled substances performed at each shift change?	**WAC 246-873-080(7)(h)** "Controlled substances, Schedule II and III, which are floor stocked, in any hospital patient or nursing service area shall be checked by actual count at the change of each shift by two authorized persons licensed to administer drugs."	
			9	Are significant losses or disappearances of controlled substances reported to PQAC, the DEA, the CEO of the hospital, and other appropriate authorities?	**WAC 246-873-080(7)(k)** "Significant losses or disappearances of controlled substances and the facts surrounding the discrepancy shall be reported to the board of pharmacy, the drug enforcement agency, the chief executive officer of the hospital and other appropriate authorities."	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			10	Does the pharmacy have drug recall procedures to prevent potential harm to patients within the HPAC?	**WAC 246-873-080(8) "**Drug recall. The director shall develop and implement a recall procedure to assure that potential harm to patients within the hospital is prevented and that all drugs included on the recall are returned to the pharmacy for proper disposition."	
General Rule Reference for HPAC Questions 53 - 54.						
WAC 246-873A-040 Physical Requirements of a HPAC. Physical Requirements must be consistent with the applicable subsections of WAC 246-873-070 according to the HPAC category type."						
			11	Do the HPACs have sufficient space and equipment for secure, environmentally controlled storage of drugs and other pharmaceutical supplies?	**WAC 246-873-070** "**(1)** Area. The pharmacy facilities shall include: **(b)** Sufficient space and equipment for secure, environmentally controlled storage of drugs and other pharmaceutical supplies."	
			12	Are all medication areas in the HPAC locked and secured to prevent unauthorized access?	**WAC 246-873-070(3)** "Access to unattended areas. All areas occupied by the hospital pharmacy shall be locked by key or combination in order to prevent access by unauthorized personnel. The director of pharmacy shall designate in writing, by title and/or position those individuals who shall be authorized access to particular areas within the pharmacy, including authorization of access to keys and/or combinations." **WAC 246-873-070(4)** "Drug storage areas. Drugs shall be stored under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security. … **(b)** Locked storage or locked medication carts shall be provided for use on each nursing service area or unit."	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
HPAC Drug Transfer and Control						
			13	Do labels for medications dispensed to HPAC patients include: - Name of prescriber - Directions for use - Brand or Generic Drug name and strength per dose - Name of patient, and - Date	**WAC 246-873A-060 Labeling.** "**(1)** Labels on medications dispensed to HPAC patients, including drug samples, must meet the requirements of RCW 69.41.050. This does not apply to HPAC administered medications."	
			14	Do parenteral and irrigation solution labels include: - Patient's name - Name and amount of drugs added - Beyond use date; and - Initials of personnel who prepared solution?	**WAC 246-873A-060 Labeling.** "**(2)** Parenteral and irrigation solutions in Category 2 HPACs. When drugs are added to intravenous solutions, a suitable label shall be affixed to the container and at a minimum should include the following: **(a)** The name of the patient; **(b)** Name and amount of drug(s) added; **(c)** Beyond use date; and Initials of the personnel who prepared and checked the solution."	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
Records						
WAC 246-873A-070 Records. "All transaction and inventory records must be maintained in compliance with applicable sections in Chapter 246-875 WAC according to HPAC category type."						
			15	For MANUAL patient record systems: Do patient records include all required information? - Patient full name and address - Serial number assigned to each new prescription - Date of all instances of dispensing a drug - The identification of the dispenser who filled the prescription - Name, strength, dosage form, and quantity of drug dispensed - Prescriber's name address, and DEA number where required.	**WAC 246-875-030** "A manual patient medication record system consists of the hard copy of the original prescription and a card or filing procedure that contains all data on new and refill prescriptions for a patient. This data must be organized in such a fashion that information relating to all prescription drugs used by a patient will be reviewed each time a prescription is filled. **(1)** All manual patient medication record systems must maintain the following information with regard to ambulatory patients: **(a)** Patient's full name and address. **(b)** A serial number assigned to each new prescription. **(c)** The date of all instances of dispensing a drug. **(d)** The identification of the dispenser who filled the prescription. **(e)** The name, strength, dosage form and quantity of the drug dispensed. **(f)** The prescriber's name, address and DEA number where appropriate."	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			16	For AUTOMATED patient record systems: Do patient records include all required information? - Patient full name and address - Serial number assigned to each new prescription - Date of all instances of dispensing a drug - The identification of the dispenser who filled the prescription - Name, strength, dosage form, and quantity of drug dispensed - Prescriber's name address, and DEA number where required. - Any refill instructions by the prescriber - Complete directions for use of the drug, which prohibits use of "as directed". - Authorization for other than child-resistant containers, if applicable.	**WAC 246-875-020** "An automated patient medication record system is an electronic system that must have the capability of capturing any data removed on a hard copy of microfiche copy. The hard copy of the original prescription and all documents in the audit trail shall be considered a part of this system. **(1)** All automated patient medication record systems must maintain the following information with regard to ambulatory patients: **(a)** Patient's full name and address. **(b)** A serial number assigned to each new prescription. **(c)** The date of all instances of dispensing a drug. **(d)** The identification of the dispenser who filled the prescription. **(e)** The name, strength, dosage form and quantity of the drug dispensed. **(f)** Any refill instructions by the prescriber. **(g)** The prescriber's name, address, and DEA number where required. **(h)** The complete directions for use of the drug. The term "as directed" is prohibited pursuant to RCW 18.64.246 and 69.41.050."	.
			17	For automated patient record systems, is an auxiliary recordkeeping system in place for new or refill prescription tracking if automated systems are down?	**WAC 246-875-050** "If an automated data processing system is used to maintain a patient's medication record, an auxiliary recordkeeping procedure must be available for use when the automated data system is temporarily inoperative due to scheduled or unscheduled system interruption. The auxiliary recordkeeping procedure shall provide for the maintenance of all patient recordkeeping information as required by this chapter."	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			18	Are allergies and chronic conditions identified in patient records?	**WAC 246-875-020(1)(i) and WAC 246-875-030(1)(g)** "Any patient allergies, idiosyncrasies, or chronic condition which may relate to drug utilization. If there is no patient allergy data the pharmacist should indicate none or "NKA" (no known allergy) on the patient medication record."	
DRUG ADMINISTRATION						
			19	Are all drugs in an HPAC administered only by WA credentialed personnel acting within their scope of practice? *Nursing students acting within their scope of practice can administer medications.*	**WAC 246-873A-080(1)** "Drugs administered in a HPAC shall only be administered by Washington state credentialed personnel, acting within their scope of practice, in accordance with state and federal laws and regulations governing such acts."	
			20	Are all drugs in an HPAC administered only upon a valid order or a practitioner?	**WAC 246-873A-080(2)** "Drugs must be administered only upon the valid order of a practitioner, as defined in RCW 69.50.101, who is licensed to prescribe legend drugs or controlled substances and who has been granted clinical privileges to write such orders."	
			21	Are all drugs administered to patients in an HPAC recorded in the patient's medical record?	**WAC 246-873A-080(3)** "All medications administered to HPAC patients must be recorded in the patient's medical record."	

WA Pharmacy Quality Assurance Commission
2019 Responsible Manager
Pharmacy Self-Inspection Worksheet
Nuclear Pharmacy Addendum

Attention: Responsible Manager

Washington law holds the responsible manager and all pharmacists on duty responsible for ensuring pharmacy compliance with all state and federal laws governing the practice of pharmacy. Failure to complete this report within the month of March or within 30 days of becoming responsible manager (as required by WAC 246-869-190) may result in disciplinary action. **The following addendum is required to be filled out and kept on file with the General Pharmacy Self-Inspection Worksheet. Do not send to the Commission office.**

The primary objective of this report, and your self-inspection, is to provide an opportunity to identify and correct areas of non-compliance with state and federal law**. All radiopharmaceuticals must be compounded in accordance with RCW 18.64.270(2) which requires compliance with the U.S. Pharmacopeia (USP) standards for sterile and non-sterile compounding. You must also complete those self-inspection addendums.** (NOTE: Neither the self-inspection nor a Commission inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.)

By answering the questions and referencing the appropriate laws/rules/CFR provided, you can determine whether you are compliant with many of the rules and regulations. If you have corrected any deficiencies, please write corrected and the date of correction by the appropriate question.

Questions highlighted in blue are questions that will be focused on during routine pharmacy inspections.

Compliant Yes	Compliant No	#		Rule Reference	Notes/Corrective Actions
General Requirements					
		1	Does the pharmacy have a permit to operate as a nuclear pharmacy?	**WAC 246-903-020(1)** "A permit to operate a nuclear pharmacy providing radiopharmaceutical services shall only be issued to a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals shall be under the supervision of a nuclear pharmacist. The nuclear pharmacist shall be responsible for all operations of the licensed area. In emergency situations, in the nuclear pharmacist's absence, he or she may designate one or more qualified, registered or certified health care personnel to have access to the licensed area. These individuals may obtain radiopharmaceuticals for the immediate emergency and must document such withdrawals in the control system."	
		2	Are all pharmacists working in the nuclear pharmacy qualified nuclear pharmacists or working under the supervision of a qualified nuclear pharmacists?	**WAC 246-903-001(1)** "No person may lawfully provide radiopharmaceutical services unless he or she is a nuclear pharmacist, or is performing radiopharmaceutical services under the supervision of a nuclear pharmacist, and is acting in accordance with the state board of pharmacy and state radiation control agency regulations." ***See WAC 246-903-030 for specific qualifications.***	

Compliant Yes	Compliant No	#		Rule Reference	Notes/Corrective Actions
Facilities					
		3	Are areas where radiopharmaceuticals are prepared separate from nonradiopharmaceutical preparation areas?	**WAC 246-903-020(2)** "Nuclear pharmacies shall have adequate space, commensurate with the scope of services to be provided. **The nuclear pharmacy area shall be separate from the pharmacy areas for nonradiopharmaceuticals** and shall be secured from access by unauthorized personnel...."	
		4	Are areas where radiopharmaceuticals are prepared secured from unauthorized personnel access?	**WAC 246-903-020(2)** "Nuclear pharmacies shall have adequate space, commensurate with the scope of services to be provided. The nuclear pharmacy area shall be separate from the pharmacy areas for nonradiopharmaceuticals and **shall be secured from access by unauthorized personne**l...."	
		5	Do you have acquisition and deposition records of all your radiopharmaceuticals?	**WAC 246-903-020(5)** "Nuclear pharmacies shall maintain records of acquisition and disposition of all radiopharmaceuticals in accordance with applicable regulations of the state board of pharmacy, the state radiation control agency and other state and federal agencies."	
		6	Are radiopharmaceuticals dispensed based on valid prescriptions or orders from practitioners authorized to possess and administer them?	**WAC 246-903-020(7)** "Radiopharmaceuticals are to be dispensed only upon a prescription from a practitioner authorized to possess, use and administer radiopharmaceuticals. A nuclear pharmacy may also furnish radiopharmaceuticals for office use to these practitioners."	

Compliant Yes	Compliant No	#			Rule Reference	Notes/Corrective Actions
		7	In addition to labeling requirements in RCW 18.64.246, are the immediate outer containers and immediate containers of the radiopharmaceuticals dispensed labeled with the following?		**WAC 246-903-020(9)** "In addition to any labeling requirements of the state board of pharmacy for nonradiopharmaceuticals, the immediate outer container of the radiopharmaceutical to be dispensed shall also be labeled with: **(a)** Standard radiation symbol; **(b)** the words "caution-radioactive material"; **(c)** the name of the radiopharmaceutical; **(d)** the amount of radioactive material contained, in millicuries or microcuries; **(e)** if a liquid, the volume in milliliters; **(f)** the requested calibration time for the amount of radioactivity contained; **(g)** expiration data, if applicable; and **(h)** specific concentration of radioactivity." **WAC 246-903-020(10)** "The immediate container shall be labeled with: **(a)** The standard radiation symbol; **(b)** the words "caution-radioactive material"; **(c)** the name of the nuclear pharmacy; **(d)** the prescription number; **(e)** the name of the radiopharmaceutical; **(f)** the date; and **(g)** the amount of radioactive material contained in millicuries or microcuries."	
			a	Standard radiation symbol		
			b	"Caution-radioactive material"		
			c	Name of radiopharmaceutical		
			d	Amount of radioactive material contained, in millicuries or microcuries		
			e	If applicable, amount of liquid contained in milliliters		
			f	Calibration time		
			g	Expiration data		
			h	If applicable, specific concentration of radioactivity.		
		8	Is there a radiometric method used for determining the amount of radioactivity for each radiopharmaceutical preparation?		**WAC 246-903-020(11)** "The amount of radioactivity shall be determined by radiometric methods for each individual preparation immediately prior to dispensing."	
		9	Are current state radiation control laws and regulations readily available?		**WAC 246-903-020(13)** "The nuclear pharmacy shall have the current revisions of state laws and regulations of the state board of pharmacy and state radiation control agency."	

Compliant		#		Rule Reference	Notes/Corrective Actions
Yes	No				
		10	Are research resources for the radiopharmaceutical services provided by the pharmacy available?	**WAC 246-903-020(14)** "The nuclear pharmacy shall maintain a library commensurate with the level of radiopharmaceutical service to be provided. A detailed library listing shall be submitted to the state board of pharmacy and state radiation control agency before approval of the license."	

Read this Page Carefully

WA Pharmacy Quality Assurance Commission
2019 Responsible Manager
General Pharmacy Self-Inspection Worksheet

Attention: Responsible Manager

Washington law holds the responsible manager and all pharmacists on duty responsible for ensuring pharmacy compliance with all state and federal laws governing the practice of pharmacy. Failure to complete this annual worksheet and applicable self-inspection worksheet addendums within the month of March or within 30 days of becoming responsible manager (as required by WAC 246-869-190) may result in disciplinary action.

Following your self-inspection and completion of the worksheet(s), please review it with your staff pharmacists, ancillary staff and interns, correct any deficiencies noted, sign and date the worksheet(s), and file it so it will be readily available to Commission inspectors. DO NOT SEND to the Commission office. You are responsible for ensuring your completed worksheet(s) is available at the time of inspection.

The primary objective of this worksheet(s), and your self-inspection, is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. (NOTE: Neither the self-inspection nor a Commission inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.) The inspection worksheet also serves as a necessary document used by Commission inspectors during an inspection to evaluate a pharmacy's level of compliance.

When a Commission inspector discovers an area(s) of non-compliance, they will issue an **Inspection Report with Noted Deficiencies**. The responsible manager must provide a written response (plan of correction) addressing all areas of non-compliance. Identifying and correcting an area of non-compliance prior to a Commission inspection, or during an inspection, may eliminate that item from being included as a deficiency on an Inspection Report. Do not *assume* that you are in compliance with any statement; take the time to personally verify that compliance exists. If you have any questions, please contact your inspector.

A common reason for issuing an Inspection Report with Noted Deficiencies is either not having or not being able to readily retrieve required documents and records. Because Commission inspections are unscheduled, it is common for the responsible manager to be absent or unavailable. For this reason, you are asked to provide a list of the locations of required documents. Having all required documents and records maintained in a well-organized and readily retrievable manner (a binder is recommended) reduces the chance that you will receive an Inspection Report with Noted Deficiencies.

By answering the questions and referencing the appropriate laws/rules/CFR provided, you can determine whether you are compliant with many of the rules and regulations. If you have corrected any deficiencies, please write corrected and the date of correction by the appropriate question.

Questions highlighted in blue are questions that will be focused on during routine pharmacy inspections.

Washington State Department of Health

2019 Responsible Manager
General Pharmacy Self-Inspection Worksheet

All responsible managers of pharmacies MUST complete and sign this self-inspection worksheet within the month of March or within 30 days of becoming responsible manager and have it available for inspection (as required by WAC 246-869-190). This worksheet focuses on **community/retail practice**, but includes regulations applicable across all areas of pharmacy. **Do not send to the Commission office.**

In addition to this worksheet, if you engage in more than one type of pharmacy, identified below, you must complete all addendum worksheets associated with that practice.

Type of Pharmacy: ☐ Hospital ☐ Nuclear ☐ Sterile-Compounding ☐ Non-Sterile Compounding

☐ Long-term Care (Closed door, or supply drugs for residents of long-term care facilities or hospice programs.)

Date responsible manager inspection was performed: _____

Form completed after 3/31/2019. ☐ Change in responsible manager ☐ Other, please explain: _____

Signature of responsible manager: _____

Print Name & License #: _____

Responsible Manager Work E-mail *(optional)*: _____

Pharmacy: _____ Telephone: _____ Fax: _____

Address: _____ DEA #: _____ Expiration: _____

Pharmacy License #: _____

Endorsements: ☐ Use of Ancillary Personnel ☐ Differential Hours ☐ Dispense Controlled Substances

Document and Record Review

Where are the following items located inside the pharmacy (be as specific as possible, there can be many filing cabinets and binders)? The rule references require the documentation printed below, by listing the location of these documents **you are also confirming your compliance with the referenced rule.**

	Rule Reference
Responsible Manager Self-Inspection Worksheet for last 2 years Location:	**WAC 246-869-190(1)** "The completed self-inspection forms must be signed and dated by the responsible manager and maintained for two years from the date of completion;"
Current Biennial Controlled Substance Inventory Location:	**WAC 246-887-020(3)** "Every registrant shall be required to keep inventory records required by section 1304.04 (of the federal rules which have been adopted by reference by Rule 1) and must maintain said inventory records for a period of two years from the date of inventory." **21 CFR 1304.04(h)(1)** "Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant; and **(2)** Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant.
Schedule II Invoices for the last 2 years Location:	**WAC 246-887-020(3)** "Every registrant shall be required to keep inventory records required by section 1304.04 (of the federal rules which have been adopted by reference by Rule 1) and must maintain said inventory records for a period of two years from the date of inventory. Such registrants are further required to keep a record of receipt and distribution of controlled substances. Such record shall include: **(a)** Invoices, orders, receipts, etc. showing the date, supplier and quantity of drug received, and the name of the drug;" **WAC 246-887-020(4)** "The records must be maintained separately for Schedule II drugs."

Document and Record Review Where are the following items located inside the pharmacy (be as specific as possible, there can be many filing cabinets and binders)? The rule references require the documentation printed below, by listing the location of these documents **you are also confirming your compliance with the referenced rule.**	
Schedule III-V Invoices for the last 2 years Location:	**WAC 246-887-020(3)** "Every registrant shall be required to keep inventory records required by section 1304.04 (of the federal rules which have been adopted by reference by Rule 1) and must maintain said inventory records for a period of two years from the date of inventory. Such registrants are further required to keep a record of receipt and distribution of controlled substances. Such record shall include: **(a)** Invoices, orders, receipts, etc. showing the date, supplier and quantity of drug received, and the name of the drug;" **WAC 246-887-020(4)** "The records for Schedule III, IV and V drugs may be maintained either separately or in a form that is readily retrievable from the business records of the registrant."
Completed CII order forms (DEA Form 222) and/or finalized CSOS documentation for the last 2 years Location:	**WAC 246-887-020** "Consistent with the concept of uniformity where possible with the federal regulations for controlled substances (21 C.F.R.), the federal regulations are specifically made applicable to registrants in this state by virtue of RCW 69.50.306." **21 CFR 1305.13(e)** "The purchaser must record on Copy 3 of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser." **21 CFR 1305.22(g)** "When a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived."
Completed loss by theft or destruction forms (DEA Form 106) for the last 2 years Location:	**WAC 246-887-020(3)(c)** "In the event of a loss by theft or destruction, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission;" **21 CFR 1301.76(b)** "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete, and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft."

Document and Record Review Where are the following items located inside the pharmacy (be as specific as possible, there can be many filing cabinets and binders)? The rule references require the documentation printed below, by listing the location of these documents **you are also confirming your compliance with the referenced rule.**	
Power of Attorney for staff authorized to order controlled substances Location:	**WAC 246-887-020** "Consistent with the concept of uniformity where possible with the federal regulations for controlled substances (21 C.F.R.), the federal regulations are specifically made applicable to registrants in this state by virtue of RCW 69.50.306." **21 CFR 1305.05(a)** "A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records."
Ancillary Utilization Plan Location:	**RCW 18.64A.060** "No pharmacy licensed in this state shall utilize the services of pharmacy ancillary personnel without approval of the commission. Any pharmacy licensed in this state may apply to the commission for permission to use the services of pharmacy ancillary personnel." **WAC 246-901-100(2)(a)** "A copy of the utilization plan must be maintained in the pharmacy."
Technician training documents, if applicable Location:	**WAC 246-901-030(1)** "Applicants must obtain education and training from one of the following: **(a)** Formal academic pharmacy technician training program approved by the board. **(b)** On-the-job pharmacy technician training program approved by the board." **WAC 246-901-050** "In order for a program for training pharmacy technicians to be considered for approval by the board, the director of the program, who shall be a pharmacist, shall submit to the board a description of the course of training offered, including subjects taught, method of teaching, and practical experience provided. The director of the program shall also advise the board concerning the skills and knowledge which are obtained in the course, and the method by which the proficiency of the pharmacy technician in those skills and knowledge is tested or ascertained. The board may require such additional information from program sponsors."

Document and Record Review Where are the following items located inside the pharmacy (be as specific as possible, there can be many filing cabinets and binders)? The rule references require the documentation printed below, by listing the location of these documents **you are also confirming your compliance with the referenced rule.**	
Collaborative Drug Therapy Agreement(s) (CDTA), including Immunization CDTAs, if applicable Location:	**WAC 246-863-100** "A pharmacist planning to exercise prescriptive authority in his or her practice (see RCW 18.64.011(11)) by initiating or modifying drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs must have on file at his/her place of practice a properly prepared written guideline or protocol indicating approval has been granted by a practitioner authorized to prescribe. A copy of the written guideline or protocol must also be on file with the board of pharmacy."
Location:	**WAC 246-869-100(1)** "Records for the original prescription and refill records shall be maintained on the filled prescription or in a separate record book or patient medication record. Such records must be maintained for a period of at least two years and shall be made available for inspection to representatives of the board of pharmacy."

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
General Requirements						
			1	Is the current pharmacy license posted?	**RCW 18.64.043(3)** "It shall be the duty of the owner to immediately notify the commission of any change of location, ownership, or licensure and to keep the license of location or the renewal thereof properly exhibited in said pharmacy."	
			2	Are the pharmacist license(s) posted and up to date?	**RCW 18.64.140** "The current license shall be conspicuously displayed to the public in the pharmacy to which it applies."	
			3	Does the pharmacy have a DEA registration number, is it listed on page 2 of this document?	**WAC 246-887-020(2)** "A separate registration is required for each place of business (as defined in section 1301.23) where controlled substances are manufactured, distributed or dispensed."	
Ancillary Personnel						
			4	Are ancillary personnel certification(s) and registration(s) up to date? *Please provide documentation of a regular staff roster with credential and expiration date.*	**WAC 246-901-060** "To become certified as a pharmacy technician, an individual must apply to the board for certification." **WAC 246-901-080** "Any person desiring registration as a pharmacy assistant shall apply to the board for registration on forms to be supplied by the board."	
			5	Are pharmacy assistants adhering to the Commission approved ancillary utilization plan?	**WAC 246-901-070** "Pharmacy assistants may perform, under the general supervision of a licensed pharmacist, all duties except those reserved to the pharmacist and the pharmacy technician."	
			6	Are pharmacy technicians adhering to the Commission approved ancillary utilization plan?	**WAC 246-901-020(1)** "Pharmacy technicians may perform certain nondiscretionary and specialized functions consistent with their training in pharmacy practice while under the immediate supervision of a licensed pharmacist." **WAC 246-901-100(2)(a)** "The application for approval must describe the manner in which the pharmacy technicians will be utilized and supervised, including job descriptions, task analysis or similar type documents that define the duties performed and the conditions under which they are performed, number of positions in each category, as well as other information as may be required by the board."	

Questions highlighted in green are questions that will be focused on during a routine pharmacy inspection.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			7	Is the pharmacy approved for pharmacy technicians to perform specialized functions?	**WAC 246-901-100(2)(b)** "Specialized function. The utilization plan for pharmacy technicians performing specialized functions. The utilization plan must include: **(i)** The criteria for selection of pharmacy technicians to perform specialized functions; **(ii)** A description of the methods of training and of initial demonstration of proficiency; **(iii)** A copy of the part of the section of the pharmacy's quality assurance plan related to pharmacy technician specialized functions; **(iv)** Other information that may be required by the board."	
			8	Is the pharmacy within the required pharmacist to technician ratio, or as otherwise authorized? ***The ratio includes pharmacy assistants currently enrolled in a technicians in training.***	**WAC 246-901-130(1)** "A standard ratio of one pharmacist to a maximum of three technicians is established for each licensed pharmacy." **RCW 18.64A.040(3)** The commission may by rule modify the standard ratios set out in subsection (2) of this section governing the utilization of pharmacy technicians by pharmacies and pharmacists. Should a pharmacy desire to use more pharmacy technicians than the standard ratios, the pharmacy must submit to the commission a pharmacy services plan for approval.	
			9	Are all ancillary personnel wearing proper identification as required?	**WAC 246-901-090** "All pharmacy ancillary personnel working within the pharmacy and having contact with patients or the general public shall wear badges or tags clearly identifying them as pharmacy assistants or technicians."	
Prescription Record Requirements **Please perform appropriate audits on pages 20-21**						
				A patient medical record system is required, it may be automated, manual or a combination. **** If a system is part automated and part manual, each part of the system must meet the respective requirements outlined in questions 10-13. ****	**WAC 246-875-001** "The purpose of this chapter shall be to insure that a patient medical record system is maintained by all pharmacies and other sites where the dispensing of drugs takes place, in order to insure the health and welfare of the patients served. … It may be either a manual system or an automated data processing system for the storage and retrieval of prescription and patient information."	

Questions highlighted in green are questions that will be focused on during a routine pharmacy inspection.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			10	For **manual** patient record system: Do patient records include all required information? - Patient full name and address - Serial number assigned to each new prescription - Date of all instances of dispensing a drug - The identification of the dispenser who filled the prescription - Name, strength, dose, and quantity of drug dispensed - Prescriber's name address, and DEA number where required.	**WAC 246-875-030** "A manual patient medication record system consists of the hard copy of the original prescription and a card or filing procedure that contains all data on new and refill prescriptions for a patient. This data must be organized in such a fashion that information relating to all prescription drugs used by a patient will be reviewed each time a prescription is filled. **(1)** All manual patient medication record systems must maintain the following information with regard to ambulatory patients: **(a)** Patient's full name and address. **(b)** A serial number assigned to each new prescription. **(c)** The date of all instances of dispensing a drug. **(d)** The identification of the dispenser who filled the prescription. **(e)** The name, strength, dosage form and quantity of the drug dispensed. **(f)** The prescriber's name, address and DEA number where appropriate."	
			11	For **automated** patient record system: Do patient records include all required information? - Patient full name and address - Serial number assigned to each new prescription - Date of all instances of dispensing a drug - The identification of the dispenser who filled the prescription - Name, strength, dosage form, and quantity of drug dispensed - Prescriber's name address, and DEA number where required. - Any refill instructions by the prescriber - Complete directions for use of the drug, which prohibits use of "as directed". - Authorization for other than child-resistant containers, if applicable.	**WAC 246-875-020** "An automated patient medication record system is an electronic system that must have the capability of capturing any data removed on a hard copy of microfiche copy. The hard copy of the original prescription and all documents in the audit trail shall be considered a part of this system. **(1)** All automated patient medication record systems must maintain the following information with regard to ambulatory patients: **(a)** Patient's full name and address. **(b)** A serial number assigned to each new prescription. **(c)** The date of all instances of dispensing a drug. **(d)** The identification of the dispenser who filled the prescription. **(e)** The name, strength, dosage form and quantity of the drug dispensed. **(f)** Any refill instructions by the prescriber. **(g)** The prescriber's name, address, and DEA number where required. **(h)** The complete directions for use of the drug. The term "as directed" is prohibited pursuant to RCW 18.64.246 and 69.41.050."	

Questions highlighted in green are questions that will be focused on during a routine pharmacy inspection.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			12	For automated patient record systems, is an auxiliary recordkeeping system in place for new or refill prescription tracking if automated systems are down?	**WAC 246-875-050** "If an automated data processing system is used to maintain a patient's medication record, an auxiliary recordkeeping procedure must be available for use when the automated data system is temporarily inoperative due to scheduled or unscheduled system interruption. The auxiliary recordkeeping procedure shall provide for the maintenance of all patient recordkeeping information as required by this chapter."	
			13	Does your record system identify allergies and chronic conditions on all patient records?	**WAC 246-875-020(1)(i) and WAC 246-875-030(1)(g)** "Any patient allergies, idiosyncrasies, or chronic condition which may relate to drug utilization. If there is no patient allergy data the pharmacist should indicate none or "NKA" (no known allergy) on the patient medication record."	
			14	Do you fill prescriptions for residents of a long term care facility or hospice program based on chart orders?	**RCW 18.64.550 "(1)** A chart order must be considered a prescription if it contains…"	
			15	If yes to question 14, do the chart orders include: - Patient's full name - Date order was issued - Name, strength, and dosage form of drug - Directions for use; and - Authorized Signature **Quantity is not required, and authorized signature may be the practitioner's agent, if order is for a non-controlled legend drug or over-the counter medication.**	**RCW 18.64.550 (1)** A chart order must be considered a prescription if it contains: **(a)** The full name of the patient; **(b)** The date of issuance; **(c)** The name, strength, and dosage form of the drug prescribed; **(d)** Directions for use; and **(e)** An authorized signature: **(i)** For written orders, the order must contain the prescribing practitioner's signature or the signature of the practitioner's authorized agent, including the name of the prescribing practitioner; or **(ii)** For electronic or digital orders, the order must contain the prescribing practitioner's electronic or digital signature, or the electronic or digital signature of the practitioner's authorized agent, including the name of the prescribing practitioner.	

Questions highlighted in green are questions that will be focused on during a routine pharmacy inspection.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			16	Do pharmacists perform drug utilization reviews for each new prescription? This includes review of patient record to determine the possibility of a clinically significant drug interaction, reaction, or therapeutic duplication.	**WAC 246-875-040** "Upon receipt of a prescription or drug order, a dispenser must examine visually or via an automated data processing system, the patient's medication record to determine the possibility of a clinically significant drug interaction, reaction or therapeutic duplication, and to determine improper utilization of the drug and to consult with the prescriber if needed." **WAC 246-863-095** "**(1)** A pharmacist's primary responsibility is to ensure patients receive safe and appropriate medication therapy. (2)(e) Interpretation of data in a patient medication record system."	
			17	Do pharmacists perform patient counseling: - New prescriptions - Refill prescriptions	**WAC 246-869-220** "The pharmacist shall directly counsel the patient or patient's agent on the use of drugs or devices." ***See PQAC Policy #52 Patient Counseling****	
			18	Is there a system in place for ancillary staff to know when counseling should take place?	**WAC 246-863-095 (2)(b)** "Consultation with the patient regarding the prescription, both prior to and after the prescription filling and/or regarding any information contained in a patient medication record system provided that this shall not prohibit pharmacy ancillary personnel from providing to the patient or the patient's health care giver certain information where no professional judgment is required such as dates of refills or prescription price information."	

Questions highlighted in green are questions that will be focused on during a routine pharmacy inspection.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			19	Are all legend drugs dispensed in child-resistant containers? *(This includes special packaging used such as customized patient medication packages; blister packs, med-minders, etc.)* If not, does the pharmacy have valid patient signed authorizations? _____ Where are these located? _____ *** Best practice recommendation: It is recommended that these authorizations are updated annually. *****	**WAC 246-869-230** "**(1)** All legend drugs shall be dispensed in a child-resistant container as required by federal law or regulation, including C.F.R. Part 1700 of Title 16, unless: **(a)** Authorization is received from the prescriber to dispense in a container that is not child-resistant. **(b)** Authorization is obtained from the patient or a representative of the patient to dispense in a container that is not child-resistant. **(2)** Authorization from the patient to the pharmacist to use a regular container (nonchild-resistant) shall be verified in one of the following ways: **(a)** The patient or his agent may sign a statement on the back of the prescription requesting a container that is not child-resistant. **(b)** The patient or his agent may sign a statement on a patient medication record requesting containers that are not child-resistant. **(c)** The patient or his agent may sign a statement on any other permanent record requesting containers that are not child-resistant. **(3)** No pharmacist or pharmacy employee may designate himself or herself as the patient's agent. **WAC 246-869-255** The board approves the use of medpack containers in the dispensing of prescription drugs within the same pharmacy, provided that: **(1)** The pharmacy must maintain custody of the original prescription container at the pharmacy; **(2)** No more than a thirty-one day supply of drugs is packaged; **(3)** The signature of the patient or the patient's agent is obtained for dispensing in a nonchild resistant container; **(4)** The container's label bear the following information: **(a)** Pharmacy name and address; **(b)** Patient's name; **(c)** Drug name, strength, quantity; **(d)** Directions; **(e)** Serial prescription numbers; date **(f)** Prescriber's name, and pharmacist's initials."	

Questions highlighted in green are questions that will be focused on during a routine pharmacy inspection.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			20	Is a sign posted in view of patients informing them of generic substitution requirements?	**RCW 69.41.160** "Every pharmacy shall post a sign in a location at the prescription counter that is readily visible to patrons stating, 'Under Washington law, a less expensive interchangeable biological product or equivalent drug may in some cases be substituted for the drug prescribed by your doctor. Such substitution, however, may only be made with the consent of your doctor. Please consult your pharmacist or physician for more information.'"	
			21	Is the telephone number to the nearest poison control center readily available, either posted or available online?	**WAC 246-869-200** "The telephone number of the nearest poison control center shall be readily available."	
			22	Is all merchandise in date?	**WAC 246-869-150(2)** "Dated items—All merchandise which has exceeded its expiration date must be removed from stock." *Including OTC medications anywhere within the store, not solely behind the counter.*	
			23	Is there a process in place to check and properly dispose of expired medications? **It's advised to perform an inventory check for expired medications while filling out this self-inspection report.**	**WAC 246-869-150(2)** "Dated items—All merchandise which has exceeded its expiration date must be removed from stock." *Including OTC medications anywhere within the store, not solely behind the counter.*	
			24	Does the pharmacy participate in a drug take back program? *Please review WAC 246-869-130 for the allowances of return and exchange of drugs, and the commission's guidance document located on their webpage.*	**WAC 246-869-130** "Except as provided in this rule, prescriptions, drugs, medicines, sick room supplies and items of personal hygiene shall not be accepted for return or exchange by any pharmacist or pharmacy after such prescriptions, drugs, medicines, sick room supplies or items of personal hygiene have been taken from the premises where sold, distributed or dispensed.	
			25	Does the pharmacy possess, distribute, or dispense legend drug samples?	**WAC 246-877-020** "The possession, distribution or dispensing of legend drug samples by a pharmacy is hereby **prohibited**."	

Questions highlighted in green are questions that will be focused on during a routine pharmacy inspection.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
Professional Requirements						
			26	Is there access to up-to-date copies of the state of Washington statutes and rules governing the practice of pharmacy? (Electronic or online access is acceptable.)	**WAC 246-869-180(2)** "All pharmacies will have in their possession one up-to-date copy of the state of Washington statutes and rules governing the practice of pharmacy, the sale and dispensing of drugs, poisons, controlled substances, and medicines. Electronic or online versions are acceptable."	
			27	Does the pharmacy have up-to-date reference sources available, electronic resources are acceptable? Give Examples:_____	**WAC 246-869-180(3)** "All pharmacies shall have up-to-date references in order for the pharmacist(s) to furnish patients and practitioners with information concerning drugs."	
			28	Does the pharmacy fill prescriptions for animals? What are your up-to-date reference resources for these prescriptions? _____ ** Best practice recommendation: It is recommended you have species specific reference resources when filling prescriptions for animals. It is also recommended if you perform compounding to have USP reference resources.**	**WAC 246-869-180(3)** "All pharmacies shall have up-to-date references in order for the pharmacist(s) to furnish patients and practitioners with information concerning drugs."	
			29	Are all drugs properly labeled and stored including prepackaged medications, in accordance with federal and state statutes, rules and regulations?	**WAC 246-869-150 (3)** "All stock and materials on shelves or display for sale must be free from contamination, deterioration and adulteration. **(4)** All stock and materials must be properly labeled according to federal and state statutes, rules and regulations. **(5)** Devices that are not fit or approved by the FDA for use by the ultimate consumer shall not be offered for sale and must be removed from stock. **(6)** All drugs shall be stored in accordance with USP standards and shall be protected from excessive heat or freezing except as those drugs that must be frozen in accordance with the requirements of the label. If drugs are exposed to excessive heat or frozen when not allowed by the requirements of the label, they must be destroyed."	

Questions highlighted in green are questions that will be focused on during a routine pharmacy inspection.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			30	Are components for compounding that do not have an expiration date from the manufacturer or supplier labeled with: - The date of receipt - Assigned a conservative expiration date, that does not exceed 3 years after the receipt This date should take into consideration the nature of the component, its degradation mechanism, the packaging/container, and storage conditions.	**RCW 18.64.270(2)** "Any medicinal products that are compounded for patient administration or distribution to a licensed practitioner for patient use or administration shall, at a minimum, meet the standards of the official United States pharmacopeia as it applies to nonsterile products and sterile administered products." **USP 795 Component Selection, Handling, and Storage** "For components that do not have expiration dates assigned by the manufacturer or supplier, the compounder shall label the container with the date of receipt and assign a conservative expiration date, not to exceed three years after receipt, to the component based on the nature of the component and its degradation mechanism, the container in which it is packaged, and the storage conditions."	
			31	Are suitable beyond use date or discard by date placed on patient prescriptions? - Quantity dispensed - Warnings regarding transfer of drugs *Check will call areas for prescriptions in original packaging to confirm that prescription label expiration date does not exceed actual manufacturer expiration date.*	**WAC 246-869-210** "To every prescription container, there shall be fixed a label or labels bearing the following information: **(1)** All information as required by RCW 18.64.246, provided that in determining an appropriate period of time for which a prescription drug may be retained by a patient after its dispensing, the dispenser shall take the following factors into account: **(a)** The nature of the drug; **(b)** The container in which it was packaged by the manufacturer and the expiration date thereon; **(c)** The characteristics of the patient's container, if the drug is repackaged for dispensing; **(d)** The expected conditions to which the article may be exposed; **(e)** The expected length of time of the course of therapy; and **(f)** Any other relevant factors. *(Citation continues on next page).*	

Questions highlighted in green are questions that will be focused on during a routine pharmacy inspection.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			Question 31 Citation Continued		The dispenser shall, on taking into account the foregoing, place on the label of a multiple unit container a suitable beyond-use-date or discard by date to limit the patient's use of the drug. In no case may this date be later than the original expiration date determined by the manufacturer. (2) The quantity of drug dispensed, for example the volume or number of dosage units. (3) The following statement, "Warning: State or federal law prohibits transfer of this drug to any person other than the person for whom it was prescribed. (4) The information contained on the label shall be supplemented by oral or written information as required by WAC 246-869-220."	
			32	Do original prescription records contain: - Serial number - Date of Dispensing - Initials of the responsible pharmacist on the prescription - Patient's address is readily available to the pharmacist	**WAC 246-869-100 (2)** "The pharmacist shall be required to insure that the following information be recorded: **(a)** Original prescription—At the time of dispensing, a serial number, date of dispensing, and the initials of the responsible pharmacist shall be placed on the face of the prescription. The patient's address must be readily available to the pharmacist, either from the face of the prescription, a record book, patient medication record, or hospital or clinic record." ***NOTE: this information can be on the face or back of the presription.***	
			33	Does the pharmacy have refill prescription authorizations?	**WAC 246-869-100(2)(b)** "Refill prescription authorization—Refills for prescription for legend drugs must be authorized by the prescriber prior to the dispensing of the refill prescription."	
			34	Do refill prescription records contain: - Date of refilling - Quantity of the drug (if other than original) - Name of authorizing person (if other than original) - Initials of the responsible pharmacist is on the back of prescription or in a separate record book or patient medication record	**WAC 246-869-100(2)(c)** "Refill prescription—At the time of dispensing, the date of refilling, quantity of the drug (if other than original), the name of authorizing person (if other than original), and the initials of the responsible pharmacist shall be recorded on the back side of the prescription, or in a separate record book or patient medication record."	

Questions highlighted in green are questions that will be focused on during a routine pharmacy inspection.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			35	TRANSFERRING PRESCRIPTION: When transferring original prescription information for a non-controlled legend drug for the purpose of refill dispensing, does a pharmacist: - Communicate directly with the pharmacist receiving the transfer. - Record in the patient medication record system that a copy has been issued. - Record in the patient medication record system the name and address of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information.	**WAC 246-869-090(1)** "The transfer is communicated directly between two licensed pharmacists and the transferring pharmacist records the following information: **(a)** Record in the patient medication record system that a copy has been issued. **(b)** Record in the patient medication record system the name and address of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information."	
			36	RECEIVING A TRANSFERRED PRESCRIPTION: When a pharmacist receives a transferred prescription for a noncontrolled legend drug, do they: - Write "TRANSFER" on the transferred prescription - Provide all information required to be on the prescription: o Patient Name and Address o Prescriber's name and address o Date of issuance of original prescription o Number of refills remaining and date of last refill o Pharmacy's name, address, and original prescription number of the transferring pharmacy o Name of the transferor pharmacy	**WAC 246-869-090(2)** "The pharmacist receiving the transferred prescription information shall reduce to writing the following: **(a)** Write the word "TRANSFER" on the face of the transferred prescription. **(b)** Provide all information required to be on the prescription - patient's name and address; prescriber's name and address, and also include: **(i)** Date of issuance of original prescription. **(ii)** Number of valid refills remaining and date of last refill. **(iii)** The pharmacy's name, address, and original prescription number from which the prescription information was transferred. **(iv)** Name of transferor pharmacist. **(c)** Both the original and transferred prescription must be maintained as if they were original prescriptions. **(d)** A transferred prescription may not be refilled after one year from the date the original was issued. **(e)** The above subsections apply to the transfer of prescription information for noncontrolled substances. The transfer of controlled substance prescription information must conform to the requirements of 21 C.F.R. 1306.25."	

Questions highlighted in green are questions that will be focused on during a routine pharmacy inspection.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			37	Do all of prescriptions contain two lines clearly identified for a practitioners signature, one that denote "dispense as written" and the other "substitution permitted"? *This is not necessary if substitution is permitted by a prior consent authorization.*	**RCW 69.41.120(1)** "Every drug prescription shall contain an instruction on whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted in its place, unless substitution is permitted under a prior consent authorization. If a written prescription is involved, the prescription must be legible and the form shall have two signature lines at opposite ends on the bottom of the form. Under the line at the right side shall be clearly printed the words "DISPENSE AS WRITTEN." Under the line at the left side shall be clearly printed the words "SUBSTITUTION PERMITTED." The practitioner shall communicate the instructions to the pharmacist by signing the appropriate line. No prescription shall be valid without the signature of the practitioner on one of these lines. In the case of a prescription issued by a practitioner in another state that uses a one-line prescription form or variation thereof, the pharmacist may substitute a therapeutically equivalent generic drug or interchangeable biological product unless otherwise instructed by the practitioner through the use of the words "dispense as written," words of similar meaning, or some other indication."	
Facilities						
			38	If the pharmacy is located in a larger mercantile building, are the pharmacy hours permanently displayed at the pharmacy **and** permanently outside at all entrances?	**WAC 246-869-020(8)** "If a pharmacy is located within a larger mercantile establishment having hours of operation different from the pharmacy then the pharmacy times of being open for business shall be prominently displayed in a permanent manner at the pharmacy area and on or adjacent to the entrance to the mercantile establishment."	
			39	If the pharmacy is located in a larger mercantile building, is there a separate phone line for the pharmacy?	**WAC 246-869-020(6)** "Any pharmacy having hours differing from the remainder of an establishment shall have a separate and distinct telephone number from that business establishment. The phone shall not be answerable in the remainder of the establishment unless all conversations, when the pharmacist is absent, are recorded and played back by the pharmacist."	
			40	Is the pharmacy area where drugs are secured and stored restricted from access from the public? Are deliveries stored within the secured pharmacy area?	**WAC 246-869-160(7)** "The prescription department shall be situated so that the public shall not have free access to the area where legend drugs, controlled substances, poisons, or other restricted items are stored, compounded or dispensed."	

Questions highlighted in green are questions that will be focused on during a routine pharmacy inspection.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			41	Does the pharmacy meet the following facility requirements: - Have proper lighting - Well ventilated, with a constant flow of air throughout the work area - Minimum of 3 linear feet by 18 inch deep counter working space, with space for each person filling prescriptions - Prescription counter is not cluttered	**WAC 246-869-160 "(1)** The prescription department shall be well lighted (adequately to allow any person with normal vision to read a label without strain, 30-50 foot candles). **(2)** The prescription department shall be well ventilated. There shall be a constant flow of air through the area. **(3)** There shall be a minimum of three linear feet by a minimum of 18 inches in depth of counter working space for each pharmacist or intern compounding or filling prescriptions at the same time. **(4)** The prescription counter shall be uncluttered and clean at all times. Only those items necessary to the filling of prescriptions shall be thereon. (Profile systems are excepted.)"	
			42	Does the pharmacy have a properly operating sink, with both hot and cold running water?	**WAC 246-869-160(5)** "There shall be a sink with hot and cold running water in the prescription compounding area."	
			43	Are refrigerators temperatures maintained between 2-8°C (36-46°F)? ** *Electronic monitoring is acceptable.* **	**WAC 246-869-160(6)** "There shall be refrigeration facilities with a thermometer in the prescription compounding area for the storage of pharmaceutical items requiring refrigeration. USP standards of refrigeration require that the temperature be maintained between two degrees and eight degrees Centigrade (36 degrees and 46 degrees Fahrenheit). A locked refrigerator in the immediate vicinity of the prescription department will meet the requirements of this paragraph."	
			44	Are freezers between -25°& -10°C (-13° & 14°F)?	**RCW 18.64.270(2) "**Any medicinal products that are compounded for patient administration or distribution to a licensed practitioner for patient use or administration shall, at a minimum, meet the standards of the official United States pharmacopeia as it applies to nonsterile products and sterile administered products." **USP Chapter 32 10.30.10** "Freezer indicates a place where the temperature is maintained thermostatically between -25°C and -10°C (-13°F and 14°F)"	
			45	Are there adequate trash receptacles?	**WAC 246-869-170(2)** "Adequate trash receptacles shall be available, both in the prescription compounding and in the retail areas."	

Questions highlighted in green are questions that will be focused on during a routine pharmacy inspection.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			46	If there is a restroom located in the pharmacy, does it have an operating sink, with hot and cold running water, is clean and sanitary?	**WAC 246-869-170(3) "**If a restroom is provided, there must be a sink with hot and cold running water, soap and towels, and the toilet must be clean and sanitary."	
			47	Are the walls, ceilings, floors, and windows clean, free from cracked and peeling paint or plaster, and in general good repair and order?	**WAC 246-869-170(1) "**The walls, ceilings, floors and windows shall be clean, free from cracked and peeling paint or plaster, and in general good repair and order."	
			48	Does the pharmacy have all the necessary equipment and supplies necessary for the practice of pharmacy? *All equipment must be in good repair.*	**WAC 246-869-180(1) "**All pharmacies shall have in their possession the equipment and supplies necessary to compound, dispense, label, administer and distribute drugs and devices. The equipment shall be in good repair and shall be available in sufficient quantity to meet the needs of the practice of pharmacy conducted therein."	

Other Areas of Non-Compliance

The Commission and its investigators reserve the right to note areas of non-compliance not specifically identified above on this self-inspection form. If an investigator identifies an issue of non-compliance they will note it in the section below and it will be included on the inspection report.

Questions highlighted in green are questions that will be focused on during a routine pharmacy inspection.

Audits

Question 10 through 13 – Patient Medical Records – Compliance

Please audit 10 patient profiles to confirm compliance, and document below.

	Rx#	Allergy	Conditions
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

Question 16 – Drug Utilization Reviews – Include
(1) Drug-Drug; (2) Duplicate Prescription; (3) Drug-Allergy; & (4) DUR Chronic Conditions (x2)
Please audit 5 different patient profiles to confirm compliance and document below.

	Type of DUR	Audit Criteria Used	DUR Notification
1	Drug-Drug		
2	Duplicate Prescription		
3	Drug-Allergy		
4	DUR Chronic Condition		
5	DUR Chronic Condition		

Question 19 – Non-Child Resistant Container Authorizations
Please audit 5 different patients in the will call section packaged in non-child resistant containers and confirm you have valid authorization records, and document below.

	Rx# with non-CRC	Authorized Signature	
		Yes	No
1			
2			
3			
4			
5			

WA Pharmacy Quality Assurance Commission
2019 Responsible Manager
Pharmacy Self-Inspection Worksheet

Long-Term Care Pharmacy Addendum

Attention: Responsible Manager

Washington law holds the responsible manager and all pharmacists on duty responsible for ensuring pharmacy compliance with all state and federal laws governing the practice of pharmacy. Failure to complete this self-inspection worksheet addendum within the month of March or within 30 days of becoming responsible manager (as required by WAC 246-869-190) may result in disciplinary action. **The following addendum is required to be filled out and kept on file with the General Pharmacy Self-Inspection Worksheet. Do not send to the Commission office.**

The primary objective of this worksheet addendum, and your self-inspection, is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. (NOTE: Neither the self-inspection nor a Commission inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.) The inspection worksheet addendum also serves as a necessary document used by Commission inspectors during an inspection to evaluate a pharmacy's level of compliance.

By answering the questions and referencing the appropriate laws/rules/CFR provided, you can determine whether your pharmacy is compliant with many of the rules and regulations. If any deficiencies have been corrected, please write corrected and the date of correction by the appropriate question.

Questions highlighted in blue are questions that will be focused on during routine pharmacy inspections.

Definitions - Below are terms used in this document you should keep in mind as regulations around pharmaceutical services have different standards based on the type of facility your pharmacy services.

RCW 18.64.011(4) "'Closed door long-term care pharmacy' means a pharmacy that provides pharmaceutical care to a defined and exclusive group of patients who have access to the services of the pharmacy because they are treated by or have an affiliation with a long-term care facility or hospice program, and that is not a retailer of goods to the general public."

RCW 18.64.011(16) "'Hospice program' means a hospice program certified or paid by Medicare under Title XVIII of the federal social security act, or a hospice program licensed under chapter 70.127 RCW.

RCW 18.64.011(20) "'Long-term care facility' means a nursing home licensed under chapter 18.51 RCW, an assisted living facility licensed under chapter 18.20 RCW, or an adult family home licensed under chapter 70.128 RCW."

RCW 18.51.010(3) "Nursing home" means any home, place or institution which operates or maintains facilities providing convalescent or chronic care, or both, for a period in excess of twenty-four consecutive hours for three or more patients not related by blood or marriage to the operator, who by reason of illness or infirmity, are unable properly to care for themselves. Convalescent and chronic care may include but not be limited to any or all procedures commonly employed in waiting on the sick, such as administration of medicines, preparation of special diets, giving of bedside nursing care, application of dressings and bandages, and carrying out of treatment prescribed by a duly licensed practitioner of the healing arts. It may also include care of mentally incompetent persons. It may also include community-based care. Nothing in this definition shall be construed to include general hospitals or other places which provide care and treatment for the acutely ill and maintain and operate facilities for major surgery or obstetrics, or both. Nothing in this definition shall be construed to include any *assisted living facility, guest home, hotel or related institution which is held forth to the public as providing, and which is operated to give only board, room and laundry to persons not in need of medical or nursing treatment or supervision except in the case of temporary acute illness. The mere designation by the operator of any place or institution as a hospital, sanitarium, or any other similar name, which does not provide care for the acutely ill and maintain and operate facilities for major surgery or obstetrics, or both, shall not exclude such place or institution from the provisions of this chapter: PROVIDED, That any nursing home providing psychiatric treatment shall, with respect to patients receiving such treatment, comply with the provisions of RCW 71.12.560 and 71.12.570.

Document and Record Review

Where are the following items located inside the pharmacy (be as specific as possible, there can be many filing cabinets and binders)? The rule references require the documentation printed below, by listing the location of these documents **you are also confirming your compliance with the referenced rule.**

	Rule Reference
Ancillary Utilization Plan Location: **If you are a **closed door long-term care pharmacy** and pharmacy technicians are performing administrative tasks, your plan should address that.**	**RCW 18.64A.060** "No pharmacy licensed in this state shall utilize the services of pharmacy ancillary personnel without approval of the commission. Any pharmacy licensed in this state may apply to the commission for permission to use the services of pharmacy ancillary personnel." **RCW 18.64.580** "For the purpose of such standards, a pharmacy technician licensed under chapter 18.64A RCW may not be considered to be practicing as a pharmacy technician while performing administrative tasks not associated with immediate dispensing of drugs that may lawfully be performed by a registered pharmacy assistant. Administrative tasks not associated with immediate dispensing of drugs include but are not necessarily limited to medical records maintenance, billing, prepackaging unit dose drugs, inventory control, delivery, and processing returned drugs." **WAC 246-901-100(2)(a)** "A copy of the utilization plan must be maintained in the pharmacy."
Records documenting the receipt and removal of drugs from Emergency Kits in Nursing Homes you service Location:	**WAC 246-865-030(4)** "Records documenting the receipt and removal of drugs in the emergency kit shall be maintained by the nursing home and the supplying pharmacy.

Compliant			#			Rule Reference	Notes/Corrective Actions
Yes	No	N/A					
General Requirements							
			1	Does the pharmacy supply medications to nursing homes or hospice programs? ***If no, skip to question 19.***			
			2	Does the pharmacy provide pharmacy consulting services to one or more nursing homes? ***If no, skip to question 23.***			
			3	Is the staff pharmacist or consultant pharmacist coordinating the following pharmaceutical services?		**WAC 246-865-060(2) "**A staff pharmacist or consultant pharmacist shall be responsible for coordinating pharmaceutical services which include: **(a)** Provision of pharmaceutical services evaluations and recommendations to the administrative staff. **(b)** On-site reviews to ensure that drug handling and utilization procedures are carried out in conformance with recognized standards of practice. **(c)** Regularly reviewing each resident's therapy to screen for potential or existing drug therapy problems and documenting recommendations. **(d)** Provision of drug information to the nursing home staff and physicians as needed. **(e)** Planning and participating in the nursing home staff development program. **(f)** Consultation regarding resident care services with other departments."	
				a	Pharmacy services evaluations and recommendation to administrative staff;		
				b	On-site review of drug handling and utilization procedures;		
				c	Regular review of resident therapy for problems and documenting recommendations;		
				d	Providing drug information to staff and physicians;		
				e	Planning and participating in staff development programs		
				f	Consultation about resident care with other departments.		
Emergency Drug & Supplemental Drug Kits							
			4	Do you supply medications to a nursing home or hospice program to stock an emergency drug kit or supplemental dose kit?		**RCW 18.64.560(1)** "A pharmacy or pharmacist may provide a limited quantity of drugs to a nursing home or hospice program without a prescription for emergency administration by authorized personnel of the facility or program pursuant to a valid prescription. The drugs so provided must be limited to those required to meet the immediate therapeutic needs of residents or patients and may not be available from another authorized source in sufficient time to prevent risk of harm by delay resulting from obtaining drugs from another source. . . ."	

Compliant			#			Rule Reference	Notes/Corrective Actions
Yes	No	N/A					
Policies & Procedures							
			5	Does your pharmacy provide policies and procedures to the nursing homes you service?		**WAC 246-865-060(1)(c)** "There shall be a pharmaceutical services committee whose membership includes at least a staff or consultant pharmacist, a physician, the director of nursing or his/her designee, and the administrator or his/her designee. The pharmaceutical services committee develops and maintains written policies and procedures for safe and effective drug therapy, distribution, control, and use which are current and followed in practice."	
			6	Do those policies and procedures include the following?			
				a	Safe handling and administration of drugs	**WAC 246-865-060(7)(a)** "Staff shall follow written procedures which provide for the safe handling and administration of drugs to residents."	
				b	Reporting and recording of medication errors and adverse drug reactions	**WAC 246-865-060(e)** "There shall be procedures established for the reporting and recording of medication errors and adverse drug reactions."	
				c	Control and accountability of all drugs in the nursing home;	**WAC 246-865-060(5)(a)** "The nursing home shall maintain and follow written procedures which provide for the accurate control and accountability of all drugs in the nursing home."	
				d	Determination of medications to be stored in the facility's emergency drug kit or supplemental dose kit	**RCW 18.64.560(3) "**The types and quantity of drugs appropriate to serve the resident or patient population of a nursing home or hospice program and procedures for the proper storage and security of dugs must be determined by a pharmaceutical services committee…"	
				e	Proper storage, security, and accountability for supplemental dose kits.	**WAC 246-865-040(4) "**The supplying pharmacy and the facility's pharmaceutical services committee shall be responsible for proper storage, security and accountability of the kit."	

Compliant			#			Rule Reference	Notes/Corrective Actions
Yes	No	N/A					
				f	Destruction of medications	**WAC 246-865-060(5)(d)** "All of an individual resident's drugs including Schedule III, IV and V controlled substances, that are discontinued by the physician and remain unused, shall be destroyed by a licensed nurse employee of the nursing home in the presence of a witness within 90 days after having been discontinued, and accurate records of destruction maintained except from drugs which are sealed in unit dose packages." **WAC 246-865-060(5)(f)** "Except in the case of Schedule II controlled substances and drugs which are sealed in unit dose packages, drugs which remain in the nursing home after the patient has died or been discharged, and drugs in containers with illegible or missing labels, shall be immediately and irretrievably disposed of by a licensed nurse employee in the presence of a witness and proper records maintained of such disposal. Destruction of Schedule II drugs shall be handled in accordance with (6)(g). Unit dose packages may be returned to the pharmacy."	
			6	g	Unscheduled therapeutic leave	**WAC 246-865-070** "When a resident of a long term care facility has the opportunity for an unscheduled therapeutic leave that would be precluded by the lack of an available pharmacist to dispense drugs prescribed by an authorized practitioner, a registered nurse designated by the facility and its consultant or staff pharmacist and who agrees to such designation, may provide the resident or a responsible person with up to a 72-hour supply of a prescribed drug or drugs for use during that leave from the resident's previously dispensed package of such drugs. The drugs shall only be provided in accordance with protocols developed by the pharmaceutical services committee and the protocols shall be available for inspection."	
				h	Self-administration of medications	**WAC 246-865-060(7)(f)** "The self-administration of medication program shall provide evidence of: **(i)** Assessment of the resident's capabilities **(ii)** Instructions for administration; **(iii)** Monitoring of progress and compliance with orders **(iv)** Safe storage of drugs."	
				i	Drug Facility and Storage Area Standards which include storage and security conditions. ***See WAC 246-865-060(3) for security and storage requirements.***	**WAC 246-865-060(3)** "Security and storage of drugs. **(a)** The nursing home shall store drugs under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security as defined by regulation and accepted standards of practice. ..."	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			7	Does the consultant pharmacist or designee ensure staff at contracted nursing homes are following the policies and procedures provided above?	**WAC 246-865-060(7)(a)** "Staff shall follow written procedures which provide for the safe handling and administration of drugs to residents."	
Controlled Substances						
			8	Does the nursing home you service have a record book for Schedule II and III controlled substances ?	**WAC 246-865-060(6)(c)** "There shall be a record book for Schedule II and Schedule III controlled substances which shall be a bound book with consecutively numbered pages in which complete records of receipt and withdrawal of Schedule II and III controlled substances are maintained."	
			9	If not using an ADDD, are all Schedule II and III controlled substances inventoried by at least two individuals licensed to administer drugs? - Schedule II – at least every 24 hours - Schedule III – at least weekly	**WAC 246-865-060(6)(d)** "At least once each 24 hours, the amount of all Schedule II controlled substances stored in the facility shall be counted by at least two persons who are legally authorized to administer drugs. A similar count shall be made of all Schedule III controlled substances at least weekly. Records of counts shall be entered in the Schedule II and III controlled substances book(s)."	
			11	Are discontinued or remaining Schedule II controlled substances destroyed properly?	**WAC 246-865-060(5)(f)** "Except in the case of Schedule II controlled substances and drugs which are sealed in unit dose packages, drugs which remain in the nursing home after the patient has died or been discharged, and drugs in containers with illegible or missing labels, shall be immediately and irretrievably disposed of by a licensed nurse employee in the presence of a witness and proper records maintained of such disposal. Destruction of Schedule II drugs shall be handled in accordance with (6)(g). Unit dose packages may be returned to the pharmacy." **WAC 246-865-060(6)(g)** "Discontinued Schedule II controlled substances and all Schedule II controlled substances which remain after the discharge or death of residents shall: **(i)** Be destroyed at the nursing home within 30 days by two of the following individuals: A licensed pharmacist, the director of nursing or a registered nurse designee, and a registered nurse employee of the nursing home with appropriate documentation maintained, or **(ii)** Be destroyed at the nursing home by a representative of the Washington state board of pharmacy if so requested by the board or the nursing home."	

Compliant			#			Rule Reference	Notes/Corrective Actions
Yes	No	N/A					
			12	Does the nursing home you service use a different controlled substance accountability system?		**WAC 246-865-060(6)(h)** "A nursing home may establish procedures which vary from those paragraphs (6)(a)(g) if they are using a unit dose drug distribution system and if that system provides for the accurate accounting, by the nursing home and the supplying pharmacy, of the receipt and disposition of all Schedule II and III controlled substances."	
Automated Drug Dispensing Devices (ADDDs)							
			13	Do the nursing homes you service use Automated Drug Dispensing Devices for purposes other than as automated emergency kits? ***If no, please skip to Question 19.***			
			14	a	User types and privileges	**WAC 246-874-030(3) "**The policies and procedures must include, but are not limited to: **(b)** User privileges based upon user type;"	
				b	Override medication criteria	**WAC 246-874-030(3) "**The policies and procedures must include, but are not limited to: **(c)** Criteria for selection of medications subject to override and an override list approved by the pharmacy or facility's pharmacy and therapeutics committee or equivalent committee;"	
				c	Diversion prevention procedures	**WAC 246-874-030(3)** "The policies and procedures must include, but are not limited to: **(d)** Diversion prevention procedures;"	
				d	Record retention and retrieval	**WAC 246-874-030(3)** "The policies and procedures must include, but are not limited to: **(e)** Record retention and retrieval requirements that adhere to all state and federal laws and regulations. Records must be retained for a minimum of two years."	

Compliant			#			Rule Reference	Notes/Corrective Actions
Yes	No	N/A					
				e	Inventory control	**WAC 246-874-030 (3)** "The policies and procedures must include, but are not limited to: **(a)** All sections of part 1; **(5)** Inventory control. **(a)** Authorized personnel must place drugs into the ADDD in the manufacturer's original sealed unit dose or unit-of-use packaging, in repackaged unit-dose containers, or in other suitable containers to support patient care and safety, and in accordance with federal and state laws and regulations; **(b)** When applicable, patient owned medications that have been properly identified and approved for use per the facility's policies, may be stored in accordance with policies for safe and secure handling of medication practices."	
				f	Securing and accounting for wasted, discarded, expired or unused medications	**WAC 246-874-050(1)** "The facility shall have a mechanism for securing and accounting for wasted, discarded, expired, or unused medication removal from the ADDD according to policies and procedures and existing state and federal laws and regulations." **WAC 246-874-050(3)** "Wasted controlled substances. All controlled substances wasted shall have a witness, who is a Washington state credentialed health care professional, acting within their scope of practice; the record of waste shall be authenticated by both persons. A waste record must be readily retrievable in the ADDD, electronic health record, or as a hard copy report in accordance with the facility's policies and procedures. The report of waste shall include patient name, drug name, drug strength, date and time of waste, the amount wasted, and the identity of the person wasting and the witness. Waste records must be maintained for a minimum of two years."	
			14	g	Maintenance of adequate records regarding use and accountability of legend drugs including controlled substances ***See all of WAC 246-874-050(2) for policy and procedure requirments.***	**WAC 246-874-050(2)** "The responsible manager shall implement procedures and maintain adequate records regarding use and accountability of legend drugs, including controlled substances, in compliance with state and federal laws and regulations including, but not limited to: ..."	

Compliant			#			Rule Reference	Notes/Corrective Actions
Yes	No	N/A					
				h	Quality Assurance Process	**WAC 246-874-060** "Each pharmacy and facility shall establish and maintain a quality assurance and performance program that monitors performance of the ADDD, which is evidenced by written policies and procedures that are made readily available on request to the commission or its designee. Electronic documents made available on a computer at the facility or pharmacy are permissible. The responsible manager shall perform annual audits of compliance with all ADDD policies and procedures. The quality assurance program shall include, but is not limited to: **(1)** Method for ensuring accurate replenishment of the ADDD; **(2)** Procedures for conducting quality control checks of drug removal for accuracy; **(3)** Method for reviewing override data and medication error data associated with ADDD and identifying opportunities for improvement."	
			15	Do policies limit access, by secure means, to ADDD(s) to Washington State credentialed health care professionals acting within their scope of practice? **See also WAC 246-874-070 regarding nursing student access to ADDDs.**		**WAC 246-874-040 (1) "**The responsible manager shall ensure adequate security systems and procedures for the ADDD, addressing access, including: **(a)** A system by which secure access of users is obtained by such methods as biometrics or some other secure technology; " **WAC 246-874-040(2)** The responsible manager or designee shall assign, discontinue, or change user access and types of drug privileges for accessing an ADDD. Access to the ADDD must be limited to those Washington state credentialed health care professionals acting within their scope of practice. Access to the ADDD by facility information technology employees or employees of similar title must be properly restricted and addressed in policies and procedures."	
			16	Unless an exception applies, do pharmacists perform prospective review and approve each medication order?		**WAC 246-874-040(3)** "A pharmacist shall perform prospective drug utilization review and approve each medication order, except if: **(a)** The drug is a subsequent dose from a previously reviewed drug order; **(b)** The prescriber is in the immediate vicinity and controls the drug dispensing process; **(c)** The system is being used to provide access to medications on override and only a quantity sufficient to meet the immediate need of the patient is removed; or **(d)** When twenty-four hour pharmacy services are not available. **(4)** When twenty-four hour pharmacy services are not available, a pharmacist shall perform retrospective drug utilization review within six hours of the pharmacy being open, except when a dispensed override medication is a one-time dose or order for discharged patients."	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			17	When 24 hour services are not available does the pharmacist perform retrospective drug utilization review of orders within six hours of being open?	**WAC 246-874-040(4)** "When twenty-four hour pharmacy services are not available, a pharmacist shall perform retrospective drug utilization review within six hours of the pharmacy being open, except when a dispensed override medication is a one-time dose or order for discharged patients."	
			18	Does the pharmacist reconcile and review all medication orders issued outside normal pharmacy hours no later than the next business day?	**WAC 246-874-040(5)** "The pharmacist shall reconcile and review all medication orders added to a patient's profile outside of the facility's normal admission discharge transfer process and procedures, no later than the next business day."	
Prepackaged Medications						
			19	Are different lot numbers combined when prepackaging a product?	**WAC 246-869-130(2)(f)** "If the drug is prepackaged, it shall not be mixed with drugs of different lot numbers and/or expiration dates unless the specific lot numbers are retrievable and the expiration dates accompany the drug. If the drug is extemporaneously packaged, it shall not be mixed with drugs of different expiration dates unless the earliest expiration date appears on the label of the drug."	
			20	If yes to question 19, do you ensure specific lot numbers and expiration dates are retrievable?	**WAC 246-869-130(2)(f)** "If the drug is prepackaged, it shall not be mixed with drugs of different lot numbers and/or expiration dates unless the specific lot numbers are retrievable and the expiration dates accompany the drug. If the drug is extemporaneously packaged, it shall not be mixed with drugs of different expiration dates unless the earliest expiration date appears on the label of the drug."	
Return and Reuse of Medication (Repackaging)						
			21	Do you repackage drugs for a long-term care facility?	**RCW 18.64.570(4)** "A pharmacy may repackage and dispense unused drugs returned by a long-term care facility or hospice program to the pharmacy in per-use, blister packaging, whether in unit dose or modified unit dose form, except as prohibited by federal law." **WAC 246-869-130(2)** "Pharmacies serving hospitals and long-term care facilities may accept for return and reuse, unit dose packages or full or partial multiple dose medication cards…"	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			22	Are unused drugs returned to the pharmacy for reuse in unit dose packages or full or partial multiple dose medication cards?	**WAC 246-869-130(2) "**Pharmacies serving hospitals and long-term care facilities may accept for return and reuse, unit dose packages or full or partial multiple dose medication cards based on the following criteria;" **WAC 246-865-060(5)(b)** "No drugs may be returned from the nursing home to a pharmacy except as provided in paragraph (4)(d) or if the drug is returned in unopened unit dose packages."	
			23	Prior to reuse, do pharmacists determine that entry or attempt at reentry of the unit dose package or blister card has not been made?	**WAC 246-869-190(2)(a)** "The pharmacist can readily determine that entry or attempt at entry to the unit dose package or blister card has not been made;"	
			24	Does a pharmacist determine that the packaging meets the standard of USP for storage conditions, and those storage conditions prevent contamination by other means that would affect the efficacy and toxicity of that drug?	**WAC 246-869-130(2) (b)** "In the pharmacist's professional judgment, the unit dose package or full or partial multiple dose medication card meets the standards of the United States Pharmacopeia for storage conditions including temperature, light sensitivity, chemical and physical stability; **(c)** The drug has been stored in such a manner as to prevent contamination by a means that would affect the efficacy and toxicity of the drug;"	
			25	Do a pharmacist determine that the drug has not come into the physical possession of the person it was prescribed for, and that the pharmacist knows the control of the drug being returned?	**WAC 246-869-130(2)(d)** "The drug has not come into physical possession of the person for whom it was prescribed and control of the drug being returned is known to the pharmacist to have been the responsibility of a person trained and knowledgeable in the storage and administration of drugs;"	
			26	Do you ensure the drug label or packaging has not been altered or defaced and includes: - Drug name, - Manufacturer - Strength - Lot Number, and - Expiration date	**WAC 246-869-130(2)(e)** "The drug labeling or packaging has not been altered or defaced so that the identity of the drug, its potency, lot number, and expiration date is retrievable."	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
Shared Pharmacy Services						
			27	Does the pharmacy act as a supplying pharmacy for other pharmacies serving long-term care facilities or hospice programs?	**RCW 18.64.570(2)** "A pharmacy may outsource shared pharmacy services for a long-term care facility or hospice program to another pharmacy if the outsourcing pharmacy: **(a)** Obtains approval from the long-term care facility or hospice program to outsource shared pharmacy services for the facility's or program's residents or patients; and **(b)** Provides a copy of the prescription or order to the pharmacy providing the shared pharmacy services."	
			28	OUTSOURCING PHARMACY: Is a copy of the prescription or chart order provided to the supplying pharmacy?	**RCW 18.64.570(2)** "A pharmacy may outsource shared pharmacy services for a long-term care facility or hospice program to another pharmacy if the outsourcing pharmacy: **(a)** Obtains approval from the long-term care facility or hospice program to outsource shared pharmacy services for the facility's or program's residents or patients; and **(b)** Provides a copy of the prescription or order to the pharmacy providing the shared pharmacy services."	
			29	SUPPLYING PHARMACY: Is a copy of the prescription or drug order and dispensing record between the outsourcing pharmacy and the supplying pharmacy maintained?	**RCW 18.64.570(3)** "Shared pharmacy services may be used for, but are not limited to, the purpose of ensuring that drugs or devices are attainable to meet the immediate needs of residents of the long-term care facility or hospice program, or when the outsourcing pharmacy cannot provide services on an ongoing basis. Where a pharmacy uses shared pharmacy services to have a second pharmacy provide a first dose or partial fill of a prescription or drug order to meet a patient's or resident's immediate needs, the second supplying pharmacy may dispense the first dose or partially filled prescription on a satellite basis without the outsourcing pharmacy being required to fully transfer the prescription to the supplying pharmacy. The supplying pharmacy must retain a copy of the prescription or order on file, a copy of the dispensing record or fill, and must notify the outsourcing pharmacy of the service and quantity provided."	

Washington State Department of Health

WA Pharmacy Quality Assurance Commission
2019 Responsible Manager
Pharmacy Self-Inspection Worksheet

USP 795 – Nonsterile Compounding Addendum

ATTENTION: Responsible Manager

Washington law holds the responsible manager and all pharmacists on duty responsible for ensuring pharmacy compliance with all state and federal laws governing the practice of pharmacy. Failure to complete this report within the month of March or within 30 days of becoming responsible manager (as required by WAC 246-869-190) may result in disciplinary action. **The following addendum is required to be filled out and kept on file with the General Pharmacy Self-Inspection Worksheet. Do not send to the Commission office.**

The primary objective of this report, and your self-inspection, is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. This worksheet does not replace *U.S. Pharmacopeia (USP) <795> Pharmaceutical Compounding – Sterile Preparations*. (NOTE: Neither the self-inspection nor a Commission inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.)

By answering the questions and referencing the appropriate laws/rules/CFR provided, you can determine whether you are compliant with many of the rules and regulations. If you have corrected any deficiencies, please write corrected and the date of correction by the appropriate question.

For additional guidance on the self-inspection addendum, please see Guidance Document #61 – United States Pharmacopeia General Chapter <795> - Nonsterile Compounding – Information.

General Rule Reference - Applies to all questions through worksheet.
RCW 18.64.270(2) "Any medicinal products that are compounded for patient administration or distribution to a licensed practitioner for patient use or administration shall, at a minimum, meet the standards of the official United States pharmacopeia as it applies to nonsterile products and sterile administered products."

Questions highlighted in blue are questions that will be focused on during routine pharmacy inspections.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
Training & Training Procedures						
			1	Are all licensed pharmacy personnel involved in compounding properly trained for the type of compounding they perform? ***USP recommends annual evaluations of personnel training.***	**USP Chapter 795 Categories of Compounding** -"Compounders shall acquire and maintain knowledge and skills in all areas (e.g. dosage, form, patient population, and medical specialty) for which they compound. **USP Chapter 795 - Training** "All personnel involved in the compounding, evaluation, packaging, and dispensing of compounded preparations shall be properly trained for the type of compounding conducted. It is the responsibility of the compounder to ensure that a training program has been implemented and that it is ongoing.... " ***Compounder in this reference can be either a pharmacist or a pharmacy technician.***	
			2	Do training procedures require all pharmacy personnel who compound to read and be familiar with <USP 795>?	**USP Chapter 795 -** "Steps in the training procedure include the following: • All employees involved in pharmaceutical compounding shall read and become familiar with this chapter. They should also be familiar with the contents of the USP Pharmacists' Pharmacopeia and other relevant publications, including how to read and interpret MSDSs."	
			3	Do training procedures require **all pharmacy personnel who compound** to read and be familiar with your pharmacy's procedures related to compounding?	**USP Chapter 795 -** "Steps in the training procedure include the following: • All employees shall read and become familiar with each of the procedures related to compounding, including those involving the facility, equipment, personnel, actual compounding, evaluation, packaging, storage, and dispensing."	
			4	Do training procedures include hazardous drug training if hazardous drugs are handled in the pharmacy?	**USP Chapter 795 -** "Steps in the training procedure include the following: All personnel who compound hazardous drugs shall be fully trained in the storage, handling, and disposal of these drugs. This training shall occur before preparing or handling hazardous drugs."	
			5	Do training procedures require all training activities to be documented by the responsible manager?	**USP Chapter 795 -** "Steps in the training procedure include the following: • All training activities shall be documented. The compounder shall meet with employees to review their work and answer any questions the employees may have concerning compounding procedures."	
				Do training procedures include the following?	**USP Chapter 795 - Training** "Steps in the training procedure include the following:	

Compliant			#			Rule Reference	Notes/Corrective Actions
Yes	No	N/A					
			6	a	Demonstration and observation of proper procedures and knowledge of procedures.	**USP Chapter 795 - Training** "• The compounder shall demonstrate the procedures for the employee and shall observe and guide the employee throughout the training process. The employee will then repeat the procedure without any assistance from, but under the direct supervision of, the compounder. • When the employee has demonstrated to the compounder a verbal and functional knowledge of the procedure, then and only then will the employee be permitted to perform the procedure without direct supervision. However, the compounder should be physically present and shall approve all ingredients and their quantities and the final preparation." ***Compounder in this reference can be either a pharmacist or a pharmacy technician.***	
				b	Requiring signatures on training documentation	**USP Chapter 795 - Training** "• When the compounder is satisfied with the employee's knowledge and proficiency, the compounder will sign the documentation records to show that the employee was appropriately trained." ***Compounder in this reference can be either a pharmacist or a pharmacy technician.***	
				c	Pharmacist monitoring of employees work	**USP Chapter 795 - "**Steps in the training procedure include the following: • The compounder shall continually monitor the work of the employee and ensure that the employee's calculations and work are accurate and adequately performed." ***Compounder in this reference means a pharmacist.***	
				d	Pharmacist responsibility for final preparation	**USP Chapter 795 -** "Steps in the training procedure include the following: • The compounder is solely responsible for the finished preparation." ***Compounder in this reference means a pharmacist.***	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
Compounding Process						
In the Rule References for Questions 7 -18 "compounder" can be either a pharmacist or a pharmacy technician, however the final check is the responsibility of a pharmacist.						
			7	Do employees engaged in compounding check to ensure that the dose, safety, and intended use of the product or preparation has been evaluated for suitability?	**USP Chapter <795>** The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. 1. The dose, safety, and intended use of the preparation or device has been evaluated for suitability in terms of: • the chemical and physical properties of the components • dosage form • therapeutic appropriateness and route of administration, including local and systemic biological disposition • legal limitations, if any.	
			8	Do employees engaged in compounding check ingredients to be used in the preparation have their expected identity, quality, and purity?	**USP Chapter 795 - Compounding Process -** "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. **3.** Ingredients used in the formulation have their expected identity, quality, and purity. If the formulation is for humans, ingredients are not on a list of federally recognized drugs or specific drug products that have been withdrawn or removed from the market for safety or efficacy reasons (see www.FDA.gov)...."	
			9	Do employees engaged in compounding verify that formulations intended for human use or food producing animals are checked to ensure they are not on a list of prohibited items for use in these formulations?	**USP Chapter 795 - Compounding Process -** "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. **3.** ... If the formulation is for food-producing animals, ingredients are not on a list of components prohibited for use in food-producing animals. Certificates of Analysis, when applicable, and MSDSs have been consulted for all ingredients used."	
			10	Is the compounding area appropriately clean and sanitized?	**USP Chapter 795 -** "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. **4.** Compounding is done in an appropriately clean and sanitized area dedicated to this activity (see the section Compounding Facilities)."	
			11	Are compounds prepared one at a time in a specific or dedicated workspace?	**USP Chapter 795 -** "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. **5.** Only one preparation is compounded at one time in a specific workspace."	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			12	Is compounding equipment inspected for cleanliness and proper functioning?	**USP Chapter 795 -** "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. **6.** Appropriate compounding equipment has been selected and inspected for cleanliness and correct functioning and is properly used."	
			13	Are appropriate BUDs assigned to finished preparations?	**USP Chapter 795 -** "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. **7.** A reliable BUD is established to ensure that the finished preparation has its accepted potency, purity, quality, and characteristics, at least until the labeled BUD."	
			14	Do employees engaged in compounding properly wash hands and wear the proper PPE based on the type of compounding performed?	**USP Chapter 795 -** "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. **8.** Personnel engaged in compounding maintain good hand hygiene and wear clean clothing appropriate to the type of compounding performed (e.g., hair bonnets, coats, gowns, gloves, facemasks, shoes, aprons, or other items) as needed for protection of personnel from chemical exposures and for prevention of drug contamination."	
			15	Are critical processes verified by a pharmacist during compounding to ensure expected qualities of the finished preparation?	**USP Chapter 795 -** "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. **10.** Critical processes (including but not limited to weighing, measuring, and mixing) are verified by the compounder to ensure that procedures, when used, will consistently result in the expected qualities in the finished preparation."	
			16	Is the final preparation assessed by a pharmacist using factors such as weight, adequacy of mixing, clarity, odor, color, consistency, pH, and analytical testing, as appropriate?	**USP Chapter 795 -** "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. **11.** The final preparation is assessed using factors such as weight, adequacy of mixing, clarity, odor, color, consistency, pH, and analytical testing as appropriate; and this information is recorded on the Compounding Record."	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			17	Is the final preparation properly labeled?	**USP Chapter 795 -** "The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section. **13.** The preparation container is labeled according to all applicable state and federal laws. The labeling shall include the BUD and storage and handling information." ***See RCW 18.64.246***	
Compounding Facilities						
			18	Is there adequate space in the compounding facility that is also designated specifically for compounding to occur?	**USP Chapter 795 -** "Compounding facilities shall have an adequate space that is specifically designated for compounding of prescriptions."	
			19	Do compounding facilities provide for placement of equipment and materials to avoid mix-ups among ingredients, containers, labels, in-process materials, and finished preparations and cross-contamination?	**USP Chapter 795** - "This space shall provide for the orderly placement of equipment and materials to prevent mix-ups among ingredients, containers, labels, in-process materials, and finished preparations and is designed, arranged, and used to prevent adventitious cross-contamination."	
			20	Are areas for non-sterile compounding and sterile compounding separate from each other?	**USP Chapter 795** - "Areas used for sterile preparations shall be separated and distinct from the nonsterile compounding area."	
			21	Is purified water used in compounding of nonsterile preparations?	**USP Chapter 795 -** "Purified Water (see Purified Water monograph) shall be used for compounding nonsterile drug preparations when formulations indicate the inclusion of water."	
			22	Are adequate hand and equipment washing facilities easily accessible to the compounding area?	**USP Chapter 795 -** "Adequate hand and equipment washing facilities shall be easily accessible to the compounding areas. Such facilities shall include, but are not limited to, hot and cold water, soap or detergent, and an air-drier or single-use towels."	
			23	Are all your compounding areas kept clean, and in good repair?	**USP Chapter 795 -** "The areas used for compounding shall be maintained in clean, orderly, and sanitary conditions and shall be maintained in a good state of repair."	
			24	Is waste handled in accordance with local, state, and federal guidelines?	**USP Chapter 795 -** "Waste shall be held and disposed of in a sanitary and timely manner and in accordance with local, state, and federal guidelines."	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			25	Are heating, ventilation, and air conditioning systems controlled to avoid decomposition and contamination of chemicals?	**USP Chapter 795 -** "Heating, ventilation, and air conditioning systems shall be controlled to avoid decomposition and contamination of chemicals (see the General Notices and Requirements, Preservation, Packaging, Storage, and Labeling, Storage Temperature and Humidity; and the manufacturers' labeled storage conditions)."	
			26	Are all compounding components, equipment, and containers stored in accordance with the manufacturer or other specified conditions, off of the floor?	**USP Chapter 795 -** "All components, equipment, and containers shall be stored off the floor and in a manner to prevent contamination and permit inspection and cleaning of the compounding and storage area."	
			27	Are hazardous drugs stored, prepared, and handled by trained personnel under conditions that protect all personnel?	**USP Chapter 795 -** "Hazardous drugs shall be stored, prepared, and handled by appropriately trained personnel under conditions that protect the healthcare workers and other personnel."	
			28	Does disposal of hazardous drugs comply with all applicable federal and state regulations?	**USP Chapter 795 -** "Disposal of all hazardous drug wastes shall comply with all applicable federal and state regulations."	
			29	Are all personnel who perform routine custodial waste removal and cleaning in hazardous drug preparation areas trained in appropriate procedure to protect themselves and prevent contamination?	**USP Chapter 795** - "All personnel who perform routine custodial waste removal and cleaning activities in storage and preparation areas for hazardous drugs shall be trained in appropriate procedures to protect themselves and prevent contamination."	
Compounding Equipment						
			30	Is equipment appropriate for use in compounding?	**USP Chapter 795** "The equipment and utensils used for compounding of a drug preparation shall be of appropriate design and capacity….The equipment shall be of suitable composition that the surfaces that contact components are neither reactive, additive, nor sorptive and therefore will not affect or alter the purity of the compounded preparations."	
			31	Is all equipment stored to protect it from contamination and located to facilitate use, maintenance and cleaning?	**USP Chapter 795 -** "Equipment shall be stored to protect it from contamination and shall be located to facilitate its use, maintenance, and cleaning."	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			32	Are automated, mechanical, electronic, or other technology used in compounding routinely tested, inspected, and calibrate to ensure proper performance?	**USP Chapter 795 -** "Automated, mechanical, electronic, and other types of equipment used in compounding or testing of compounded preparations shall be routinely inspected, calibrated as necessary, and checked to ensure proper performance."	
			33	Is equipment checked by employees engaged in compounding to determine its suitability for use in compounding?	**USP Chapter 795 -** "Immediately before compounding operations, the equipment shall be inspected by the compounder to determine its suitability for use." ***Compounder in this reference can be either a pharmacist or a pharmacy technician.***	
			34	Is equipment used during compounding cleaned after use?	**USP Chapter 795** - "After use, the equipment shall be appropriately cleaned."	
			35	If the same equipment is being used for all drug products, are there procedures in place that allow meticulous cleaning of equipment before use with other drugs?	**USP Chapter 795 - "** … when the same equipment is being used for all drug products, appropriate procedures shall be in place to allow meticulous cleaning of equipment before use with other drugs."	
Component Selection, Handling, and Storage						
			36	Are components used in compounding manufactured by FDA-registered facilities?	**USP Chapter 795 -** "The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations. **2.** Compounders shall first attempt to use components manufactured in an FDA-registered facility." ***Compounder in this reference can be either a pharmacist or a pharmacy technician.***	
			37	If components are not available from FDA-registered facilities, is professional judgment used when selecting components and to establish purity and safety by reasonable means?	**USP Chapter 795 -** "The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations. **2.** ... When components cannot be obtained from an FDA-registered facility, compounders shall use their professional judgment in selecting an acceptable and reliable source and shall establish purity and safety by reasonable means, which should include Certificate of Analysis, manufacturer reputation, and reliability of source." ***Compounder in this reference can be either a pharmacist or a pharmacy technician.***	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			38	Do ingredients used in preparations meet the requirements of compendial monographs for those ingredients? **See point 4 in rule reference column to the right, for when compendial quality components are not obtainable.**	**USP Chapter 795 -** "The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations. **3.** Official compounded preparations are prepared from ingredients that meet requirements of the compendial monograph for those individual ingredients for which monographs are provided. These preparations may be labeled USP or NF as appropriate. **4.** When components of compendial quality are not obtainable, components of high quality such as those that are chemically pure, analytical reagent grade, or American Chemical Society–certified may be used."	
			39	When components are transferred from an original container to a different container, is that container identified with: - Component Name - Original Supplier - Lot or Control Number - Transfer Date, and - Expiration Date	**USP Chapter 795 -** "The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations. **5.** For components in containers that have an expiration date from the manufacturer or distributor, the material may be used in compounding before that expiration date **(a)** when the material is stored in its original container under conditions to avoid decom-position of the chemicals ... **(b)** when there is minimal exposure of the remaining material each time material is withdrawn from the container, and **(c)** when any withdrawals from the container are performed by those trained in the proper handling of the material. If the component has been transferred to a different container, that container shall be identified with the component name, original supplier, lot or control number, transfer date, and expiration date and shall provide integrity that is equivalent to or better than that of the original container."	
			40	When components do not have an expiration date assigned by the manufacturer/supplier, is the container labeled with date of receipt, and assigned a conservative expiration date that does not exceed 3 years from receipt?	**USP Chapter 795 - "**The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations. **6.** For components that do not have expiration dates assigned by the manufacturer or supplier, the compounder shall label the container with the date of receipt and assign a conservative expiration date, not to exceed three years after receipt, to the Component (see the General Notices and Requirements, Preservation, Packaging, Storage, and Labeling, Labeling, Expiration Date and Beyond-Use Date) based on the nature of the component and its degradation mechanism, the container in which it is packaged, and the storage conditions."	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			41	Are manufactured drug products used by your pharmacy as the source of active ingredient manufactured by FDA-registered facilities and is appropriately labeled with a batch control number and expiration date?	**USP Chapter <795>** The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations. **7.** If a manufactured drug product is used as the source of active ingredient, the drug product shall be manufactured in an FDA-registered facility, and the manufacturer's product container shall be labeled with a batch control number and expiration date.	
			42	Does the compounder consider all ingredients, including excipients, present in the drug product relative to the intended use of the compounded preparation and the effect of manipulating the drug product on the therapeutic appropriateness and stability of the components?	**USP Chapter 795 -** "The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations. **7.** ... When compounding with manufactured drug products, the compounder shall consider all ingredients, including excipients, present in the drug product relative to the intended use of the compounded preparation and the effect of manipulating the drug product on the therapeutic appropriateness and stability of the components."	
			43	Do ingredients used for dietary or nutritional supplements meet USP, FCC or NF standards?	**USP Chapter 795 -** "The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations. **8.** If the preparation is intended for use as a dietary or nutritional supplement, then the compounder must adhere to this chapter and must also comply with any federal and state requirements. Generally, dietary supplements are prepared from ingredients that meet USP, FCC, or NF standards. Where such standards do not exist, substances may be used in dietary supplements if they have been shown to have acceptable food-grade quality using other suitable procedures."	
			44	Does your pharmacy receive written assurance from suppliers that components derived from ruminant animals are in compliance with federal laws?	**USP Chapter 795 -** "The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations. **9.** When a component is derived from ruminant animals (e.g., bovine, caprine, ovine), the supplier shall provide written assurance that the component is in compliance with all federal laws governing processing, use, and importation requirements for these materials."	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			45	Are components used in compounding stored properly per manufacturer?	**USP Chapter 795 -** "All components used in the compounding of preparations must be stored as directed by the manufacturer, or according to USP, NF, or FCC monograph requirements, in a clean area, and under appropriate temperature and humidity conditions."	
			46	Are components used in compounding stored off the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first.	**USP Chapter 795 -** "All components shall be stored off the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first."	
Stability Criteria and Beyond-Use Dating						
			47	Is the BUD determined from when the preparation is compounded?	**USP Chapter 795 -** "The BUD is the date after which a compounded preparation shall not be used and is determined from the date when the preparation is compounded."	
			48	When assigning a BUD, are drug specific and general stability documents and literature consulted?	**USP Chapter 795 -** "When assigning a BUD, compounders shall consult and apply drug-specific and general stability documentation and literature when available …"	
			49	When a manufactured product is used as the source of the API for a nonsterile compounded preparation, does the compounder refer to the manufacturer, literature and stability factors to assign a beyond use date?	**USP Chapter 795 -** "When a manufactured product is used as the source of the API for a nonsterile compounded preparation, the product expiration date cannot be used solely to assign a BUD for the compounded preparation. The compounder shall refer to and consider the following: **1.** Manufacturer for stability information **2.** literature for applicable information on stability, compatibility, and degradation of ingredients **3.** stability factors in USP <1191> All stability data shall be carefully interpreted in relation to the actual compounded formulation."	
			50	Are preparations, at all steps in compounding, dispensing, and storage, observed for signs of instability and deterioration?	**USP Chapter 795 -** "At all steps in the compounding, dispensing, and storage process, the compounder shall observe the compounded drug preparation for signs of instability."	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
Packaging and Drug Preparation Containers						
			51	Do containers and closures used for packaging preparations meet USP requirements?	**USP Chapter 795 -** "The compounder shall ensure that the containers and container closures used in packaging compounded preparations meet USP requirements (see <659>; Containers—Glass <660>; Plastic Packaging Systems and their Materials of Construction <661>; Plastic Materials of Construction <661.1>; Plastic Packaging Systems for Pharmaceutical Use <661.2>; Containers—Performance Testing <671>; <1136>); and when available, compounding monographs. **...** Container suppliers shall supply, upon request, verification of USP container compliance." ***Compounder in this reference can be either a pharmacist or a pharmacy technician, however the final check is the responsibility of a pharmacist.***	
			52	Are the containers and closures used for packaging preparations made of suitable clean material?	**USP Chapter 795 -** "The containers and closures shall be made of suitable clean material in order not to alter the quality, strength, or purity of the compounded drug preparation. The container used depends on the physical and chemical properties of the compounded preparation."	
			53	Are the containers and closures used for packaging preparations stored appropriately off the floor in way to prevents contamination and rotated?	**USP Chapter 795 -** "The containers and closures shall be stored off the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first."	
			54	Are the containers and container closures stored in such a way as to permit inspection and cleaning of the storage area?	**USP Chapter 795 -** "The containers and container closures shall be stored in such a way as to permit inspection and cleaning of the storage area."	

Compliant			#			Rule Reference	Notes/Corrective Actions
Yes	No	N/A					
Compounding Documentation							
			55		Does the compounder compound preparation in any other way than the manufacture's labeling instructions?	**USP Chapter 795 "**When the compounder compounds a preparation according to the manufacturer's labeling instructions, then further documentation is not required. All other compounded preparations require further documentation as described below. This includes a master formulation and compounding record." ***Compounder in this reference can be either a pharmacist or a pharmacy technician, however the final check is the responsibility of a pharmacist.***	
			56		If yes to Question 55, does the **Master Formula** contain?	**USP Chapter <795> "**When the compounder compounds a preparation according to the manufacturer's labeling instructions, then further documentation is not required. All other compounded preparations require further documentation as described below. This includes a master formulation and compounding record." ***Compounder in this reference can be either a pharmacist or a pharmacy technician, however the final check is the responsibility of a pharmacist.***	
				a	Official or assigned name, strength, and dosage form of the preparation	**USP Chapter 795** "this record shall include: Official or assigned name, strength, and dosage form of the preparation."	
				b	Calculations needed to determine and verify quantities or components and doses of active pharmaceutical ingredients	**USP Chapter 795** "this record shall include; calculations needed to determine and verify quantities or components and doses of active pharmaceutical ingredients."	
				c	Description of all ingredients and their quantities	**USP Chapter 795** "this record shall include: description of all ingredients and their quantities."	
				d	Compatibility and stability information, including references when available	**USP Chapter <795>** "this record shall include: compatibility and stability information, including references when available."	
				e	Equipment needed to prepare the preparation, when appropriate	**USP Chapter <795>** "this record shall include: equipment needed to prepare the preparation, when appropriate."	
				f	Mixing instructions	**USP Chapter 795** "this record shall include: Mixing instructions that should include order of mixing, mixing temperatures and environmental controls, duration of mixing, other factors pertinent to the replication of the preparation as compounded.	

Compliant			#			Rule Reference	Notes/Corrective Actions
Yes	No	N/A					
				g	Container used in dispensing	**USP Chapter 795** "this record shall include: container used in dispensing."	
				h	Packaging and storage requirements	**USP Chapter 795** "this record shall include: packaging and storage requirements."	
				i	A description of the final preparation	**USP Chapter 795** "this record shall include: description of the final preparation."	
				j	Quality control procedures and expected results	**USP Chapter 795** "this record shall include: Quality control procedures and expected results."	
			57		If yes to Question 55, does the **Compounding Formula** contain?	**USP Chapter 795 "**When the compounder compounds a preparation according to the manufacturer's labeling instructions, then further documentation is not required. All other compounded preparations require further documentation as described below. This includes a master formulation and compounding record." ***Compounder in this reference can be either a pharmacist or a pharmacy technician, however the final check is the responsibility of a pharmacist.***	
				a	Official or assigned name, strength, and dosage of the preparation	**USP Chapter 795** "this record shall include: official or assigned name, strength, and dosage of the preparation."	
				b	Master formula Record reference for the preparation	**USP Chapter 795** "this record shall include: Master formula Record reference for the preparation."	
				c	Names and quantities of all components	**USP Chapter 795** "this record shall include: names and quantities of all components."	
				d	Sources, lot numbers, and expiration dates of all components	**USP Chapter 795** "this record shall include: sources, lot numbers, and expiration dates of all components."	
				e	Total quantity compounded	**USP Chapter 795** "this record shall include: total quantity compounded."	
				f	Name of the person who prepare the preparation, name of the person who performed the quality control procedures, and the name of the compounder who approved the preparation	**USP Chapter 795** "this record shall include: Name of the person who prepare the preparation, name of the person who performed the quality control procedures, and the name of the compounder who approved the preparation."	
				g	Preparation date	**USP Chapter 795** "this record shall include: date of preparation."	

Compliant			#			Rule Reference	Notes/Corrective Actions
Yes	No	N/A					
				h	Control or prescription number	**USP Chapter 795** "this record shall include: assigned control or prescription number."	
				i	Assigned BUD	**USP Chapter 795** "this record shall include: assigned BUD.	
				j	Duplicate label described in the Master Formulation Record	**USP Chapter 795** "this record shall include: duplicate label as described in the Master Formulation Record."	
				k	Description of final preparation.	**USP Chapter 795** "this record shall include: description of the final preparation."	
				l	Results of the quality control procedures	**USP Chapter 795** "this record shall include: results of the quality control procedures (e.g., weight range of filled capsules, pH of aqueous liquids)"	
				m	Documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or the caregiver	**USP Chapter 795** "this record shall include: documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or the caregiver."	
			56		Are Safety Data Sheets readily accessible to all employees working with drug substances or bulk chemicals located on the compounding facility?	**USP Chapter 795 -** "Material Safety Data Sheets (MSDSs) shall be readily accessible to all employees working with drug substances or bulk chemicals located on the compounding facility premises."	
Quality Control							
			57		Do pharmacists supervising compounding activities perform a final check that reviews each procedure used in the compounding process and observe the finished preparation to ensure it appears as expected?	**USP Chapter 795 -** "As a final check, the compounder shall review each procedure in the compounding process. To ensure accuracy and completeness, the compounder shall observe the finished preparation to ensure that it appears as expected and shall investigate any discrepancies and take appropriate corrective action before the prescription is dispensed to the patient." ***Compounder in this reference means a pharmacist.***	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			58	Are controls in place to ensure compounding accuracy?	**USP Chapter 795 - Compounding Controls** "**1.** The Master Formulation Record, the Compounding Record, and associated written procedures shall be followed in execution of the compounding process. Any deviation in procedures shall be documented. **2.** The compounder shall check and recheck each procedure at each stage of the process. If possible, a trained second person should verify each critical step in the compounding process. **3.** The compounder shall have established written procedures that describe the tests or examinations conducted on the compounded preparation (e.g., the degree of weight variation among capsules) to ensure their uniformity and integrity. **4.** Appropriate control procedures shall be established to monitor the output and to verify the performance of compounding processes and equipment that may be responsible for causing variability in the final compounded preparations." ***Compounder in this reference can be either a pharmacist or a pharmacy technician, however the final check is the responsibility of a pharmacist.***	

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
Compounding for Animal Patients						
			59	Do you compound products for animal patients? ***If no, you do not need to answer the questions below.***		
			60	Is the intended use by the animal determined prior to compounding preparation?	**USP Chapter 795 -** "Intended use of any animal patient (e.g., companion, performance, food) shall be determined before compounding for that patient."	
			61	Do employees engaged in compounding for animals have knowledge of drug regulation and disposition for animal patients?	**USP Chapter 795 -** "All compounders preparing formulations for animals shall possess a functional knowledge of drug regulation and disposition in animal patients." ***Compounder in this reference can be either a pharmacist or a pharmacy technician.***	
			62	Do labels include withdrawal time lengths for animals that are food-producing?	**USP Chapter 795 -** "Veterinarians are required by law to provide food-producing animal caregivers with an accurate length of time to withhold treated animal tissues (e.g., meat, milk, eggs) from the human food supply. This length of time is referred to as a withdrawal time (WDT) and must also, by law, be included on the dispensing label of every prescription prepared for a food-producing species."	
			63	Do your pharmacists have knowledge of individual species' limitations in physiology and metabolic capacities? What are your resources? _____	**USP Chapter 795 -** "The pharmacist shall be knowledgeable about the individual species' limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used in compounded preparations."	