# January 13, 2023 (Updated 1/11/2023)

## Washington State Pharmacy Quality Assurance Commission

# Commission Business Meeting Materials

**SAFETY. QUALITY. INNOVATION.**

Ernie Gates, CEO
Gates Healthcare Associates, Inc.
1 Central Street, Suite 201
Middleton, MA 01949
Phone: 978-646-0091
https://gateshealthcareassociates.com/

## WASHINGTON STATE BOARD OF PHARMACY

Gates Healthcare Associates (GHA) requests the opportunity to present information about our services to the Washington State Board of Pharmacy. We are requesting to be approved as a third- party entity to provide inspections, assessments, remediation, and monitoring services of licensees.

## ABOUT GATES HEALTHCARE

Gates Healthcare Associates (GHA) is a pharmaceutical and healthcare consulting firm that provides extensive clinical, programmatic, and regulatory knowledge and insight to an array of organizations nationally and abroad.

GHA is well equipped with a proven track record of providing compliance and regulatory standards guidance and monitoring services to pharmacies across the country in support of State Boards of Pharmacy.

GHA has conducted our services, compliance and regulatory inspections, auditing, remediation, and monitoring services in all 50 United States as well as Canada. GHA has worked with all State Boards of Pharmacy and in recent years has been authorized to provide state inspection services in many states including performing sterile, non-sterile, hazardous, general, 503B, nuclear and more compounding inspections for many states some of which are the State of Michigan, New Jersey, Vermont, Maine, Iowa, New Hampshire, Wisconsin and others.

## PROJECT OVERVIEW

For compliance and licensure inspections we send a fully trained, experienced licensed pharmacist to perform the inspection(s) on-site for one day. Please see the attached inspector bios.

The inspector, using detailed inspection tools (developed and maintained by Denise Frank) will perform the inspection.
Inspections include:

- General Pharmacy Operations
- Nonsterile Compounding (USP Chapter <795>)
- Sterile Compounding (USP Chapter <797>)
- Hazardous Drug Handling (USP Chapter <800>)
- Nuclear Pharmacy Compounding (USP Chapter <825>)
- Outsourcing Facility (cGMP) compliance.

Ernie Gates, CEO
Gates Healthcare Associates, Inc.
1 Central Street, Suite 201
Middleton, MA 01949
Phone: 978-646-0091
https://gateshealthcareassociates.com/

We also have an extended cGMP audit/inspection (more like FDA, narrative in style) that occurs over a few days, overseen and performed by Jeff Watson (former FDA).

After performing the inspection(s) needed, the inspector will review items of partial compliance or noncompliance with the staff at the facility and discuss a plan of correction, if applicable.

The inspector will prepare a report with findings that includes the plan of correction and submit the report to both the facility and the State Board of Pharmacy within ten business days.

The State Board of Pharmacy will then use the detailed inspection reports and any plan of correction to assess compliance for the purpose of licensure or license renewal.

GHA is also available to perform these inspections and any periodic mandated monitoring of facilities for compliance subsequent to a disciplinary action or to ensure remediation of noncompliant items for licensure or renewal.

> NOTE: I have included a partial redacted sterile compounding inspection performed for the a state of pharmacy. The sample inspection is the complete, original inspection AND results of a follow-up inspection to confirm remediation of items found to be noncompliant or partially compliant on the original inspection. See page 4 of the inspection, "Executive Summary & Plan of Correction" for the original noncompliant and partially compliant items, and, in blue, the verification and remediation upon second inspection.
>
> For monitoring, we would perform the inspection initially, including the specific items which warranted the monitoring. We will report to you in a narrative the items that were the basis of the action and if they have been remediated. We will also report to you any additional items we found to be noncompliant or partially compliant upon our inspection as well as the action plan to remediate these items. We would provide quarterly (or whatever frequency you would require, for as long as you would require) site visits to confirm progress or completion of the remediation, as well as checking that remediated items are still compliant.
>
> The other inspections we provide, as well as monitoring for these various inspections, are similar in the thoroughness and detail to this sterile compounding inspection and remediation. Below we have detailed the focus areas of each inspection/monitoring content.

Ernie Gates, CEO
Gates Healthcare Associates, Inc.
1 Central Street, Suite 201
Middleton, MA 01949
Phone: 978-646-0091
https://gateshealthcareassociates.com/

## GENERAL PHARMACY INSPECTION

Sections:

- General Operations and Licensure including record retention and financial management
- Crisis Plans
- Personnel including training
- Compliance Plan
- Facility and Security
- Product Ordering, Receipt, and Inventory (including controlled substances)
- Prescription Processing
- Billing Practices
- Privacy and Confidentiality including Nondiscrimination
- Dispensing, Mail and Delivery
- Off-Site Processes
- Off-Site Inventory
- Patient Counseling and Communication
- Patient Care Programs
- Quality Program

## USP CHAPTER <795> NONSTERILE COMPOUNDING INSPECTION

Sections:

- General Compounding Operations
- Component Selection and Use
- Animal Compounding
- Beyond-Use Dating (BUD)
- Environment
- Training
- Compounding Equipment
- Documentation
- Compounding Procedures
- Finished Preparation Release Checks and Tests
- Quality Assurance/Quality Improvement
- Patient Consultation

Ernie Gates, CEO
Gates Healthcare Associates, Inc.
1 Central Street, Suite 201
Middleton, MA 01949
Phone: 978-646-0091
https://gateshealthcareassociates.com/

## USP CHAPTER <797> STERILE COMPOUNDING INSPECTION

Sections:

- General Compounding Operations
- Component Selection and Use
- Animal Compounding
- Environment
- Cleaning
- Training
- Garbing
- Environmental Monitoring and Certification
- Compounding Equipment
- Compounding Procedures and Documentation, BUD
- Sterilization and Depyrogenation
- Finished Preparation Release Checks and Tests
- Patient Counseling and Communication
- Quality Assurance/Quality Improvement

## USP CHAPTER <800> HAZARDOUS DRUG HANDLING INSPECTION

Sections:

- General Operations for Handling HDs
- General Pharmacy Activities in Handling HDs including environment and garbing
- Nonsterile Compounding HDs including environment and garbing
- Sterile Compounding HDs including environment and garbing
- Environmental Sampling
- Training
- Medical Surveillance

Ernie Gates, CEO
Gates Healthcare Associates, Inc.
1 Central Street, Suite 201
Middleton, MA 01949
Phone: 978-646-0091
https://gateshealthcareassociates.com/

## USP CHAPTER <825> RADIOPHARMACEUTICALS PREPARATION AND COMPOUNDING

Sections:

- Personnel Qualifications, Training and Hygiene
- Facilities and Engineering Controls
- Microbiological Air and Surface Monitoring
- Cleaning and Disinfection
- Documentation including BUD
- Preparation
- Compounding Nonsterile and Sterile
- Dispensing
- Repackaging
- Quality Assurance

## OUTSOURCING FACILITY cGMP COMPLIANCE

Sections:

- Quality Systems
- Facilities and Equipment Systems – General
- Facilities and Equipment Systems – Sterile
- Environmental Monitoring – Sterile
- Personnel Monitoring – Sterile
- Materials System
- Equipment, Containers and Closures – Sterile
- Components – Sterile
- Production System – General, Nonsterile and Sterile
- Additional Production and Process Controls – Sterile
- Stability and Expiration Dating
- Release Testing – Sterile
- Packaging and Labeling System
- Laboratory Control System

Ernie Gates, CEO
Gates Healthcare Associates, Inc.
1 Central Street, Suite 201
Middleton, MA 01949
Phone: 978-646-0091
https://gateshealthcareassociates.com/

## Inspector Bios (full resumes/CVs upon request)

**Denise M. Frank, RPh, BPharm, FACA – Senior Associate and Project Lead**

Denise M. Frank, a Senior Associate with Gates Healthcare Associates, is the project lead for inspections and gap analyses including the development and maintenance of inspection tools and checklists. Ms. Frank is a longtime pharmacist, consultant, and training specialist in the areas of pharmacy practice, sterile and nonsterile compounding, hazardous drug handling, community pharmacy accreditation, and operational and regulatory compliance in pharmacies and drug supply chain; and has a certificate in cGMP. Ms. Frank, a licensed pharmacist in Minnesota, previously served as the accreditation and inspection services manager for the National Association of Boards of Pharmacy. During her decade-long tenure with the NABP as a surveyor and later as a manager, her responsibilities included supervising a nationwide group of inspectors and surveyors performing inspections and surveys of hundreds of independent and corporate chain pharmacies, wholesalers, sterile and nonsterile compounding pharmacies including nuclear pharmacies. Many of the inspections included state compliance officers observing or training in the performance of sterile compounding pharmacy inspections. She was responsible for the training and quality assurance of the NABP inspector/surveyors, and in developing and maintaining inspection and survey tools. Prior to joining NABP, Ms. Frank worked for many years as a staff pharmacist, pharmacy manager and district manager for retail pharmacy networks in Minnesota. She is also an active member in many state and national organizations including APhA, ASHP, ACA, APC, ASPL, MPhA, MSHP, NASP, CETA and ASTM.

**Ken Speidel - Vice President, Compounding Compliance RPh, BS Pharm, PharmD, FACA, FIACP**

Dr. Ken Speidel, Vice President of Compounding Compliance at Gates Healthcare Associates, has more than 25 years of experience across all facets of pharmacy practice. Dr. Speidel brings to Gates Healthcare a long track record of professional leadership and success. He has received numerous industry awards and recognition. Dr. Speidel is known throughout the pharmaceutical sector in North America and is distinguished as a consultant in the development of national standards for pharmacy compounding practices. He provides consulting services for companies and provider organizations in the U.S. and abroad. A frequent presenter and speaker at clinical and industry educational programs from coast to coast, Dr. Speidel is a prolific author of articles and papers for leading pharmaceutical industry publications. He assisted in developing, writing, and researching several nationally recognized continuing educational programs for the University of Florida. Dr. Speidel served two terms as president of a large hospice program and guided and advised the organization through a period of growth and organizational restructuring. Dr. Speidel is a former multi-term president of the National Home Infusion Association. Dr. Speidel received his Bachelor of Science and Doctor of Pharmacy degrees from Ohio Northern University.

Ernie Gates, CEO
Gates Healthcare Associates, Inc.
1 Central Street, Suite 201
Middleton, MA 01949
Phone: 978-646-0091
https://gateshealthcareassociates.com/

**William A. Mixon - Senior Associate RPh, MS, FIACP, D.Ph.**

William ("Bill") Mixon is a Senior Associate for Gates Healthcare Associates. He is the former owner-manager of The Compounding Pharmacy in Hickory, NC, and his notably broad practice experience and numerous academic accreditations and publications give him insight into many issues currently facing pharmacists. Mr. Mixon has 35 years of experience in hospital and community pharmacy, long-term care, and hospice care. He is a fellow of the International Academy of Compounding Pharmacists (IACP) and the American College of Apothecaries, Professional memberships include: American Society for Pharmacy Law; National Association of Boards of Pharmacy; the North Carolina Association of Pharmacists (NCAP), and the American Pharmacists Association (APhA). Mr. Mixon has won numerous awards and honors, including an election to the U.S. Pharmacopeia Council of Experts for compounding. He has been a Certified Geriatric Pharmacist and a Certified Diabetes Educator.

**Gary McCrory – Associate RPh, FACA**

Gary McCrory, an Associate with Gates Healthcare Associates. Graduate of Northeast Louisiana University, in 1977 with a bachelor's degree in pharmacy, received CCN (Certified Clinical Nutritionist) 2010. Operated a pharmacy in El Paso, Texas for 38 years, extensive knowledge in the field of compounding and third-party prescription billing. Experienced in sterile preparations and genetic testing. Frequent presenter to pharmacies on improving their patient experience. Most recently was Director of Pharmacy Compliance/Network Management for PCCA, working with many PBM's. This involved credentialing, accreditation and audit protection. Served as the Chairperson of the Compounding Pharmacy section of the Texas Pharmacy Association (1998.) Served three terms on the Texas Pharmacy Association insurance board. Served as an Advisory Board Member for AmerisourceBergen and Western States Pharmacy Board Member. Active member of APC (Alliance of Pharmacy Compounding.) Served 12 years on their Board of Directors and was President, Chairman and Executive Director of ACP. Member of ACA and became a full fellow (2020.) USP Delegate Recognized by the El Paso Veterinarian Association for developing compound solutions for animals. PCCA awarded Pharmacist of the Month in May 1997, and PCCA US Compounding Pharmacist of the Year 2012.

**Dawn Kimmence – Associate., RPh, FACA, MBA**

Dawn Kimmence, has over eighteen years of pharmacy industry experience. She has experience across many sectors of the pharmaceutical industry, inclusive of retail, compounding, fertility, home infusion, specialty, long term care, and mail order pharmacy, pharmaceutical distribution, medical supply manufacturing, sample distribution and distribution and manufacturing compliance. Ms. Kimmence has extensive experience as a pharmacy operation executive and has had leadership roles that span the industry from Fortune 500 companies to startups. Ms. Kimmence's areas of expertise include executive operations leadership, compliance, quality, and accreditations inclusive of URAC, ACHC, VIPPS and PCAB. She has written numerous policy and procedure manuals for Home Infusion pharmacy, Compounding Pharmacy and Specialty Pharmacy. Ms. Kimmence received her bachelor's degree from Massachusetts College of Pharmacy and Health Sciences and her master's in business administration from Southern New Hampshire University.

Ernie Gates, CEO
Gates Healthcare Associates, Inc.
1 Central Street, Suite 201
Middleton, MA 01949
Phone: 978-646-0091
https://gateshealthcareassociates.com/

**Jeffrey M. Watson – Associate, FDA/cGMP**

Jeffrey Watson is an Associate with Gates Healthcare Associates, has more than a quarter-century of experience with the U.S. Food and Drug Administration (FDA) and advanced training and expertise in sterile and non-sterile pharmaceutical manufacturing as well as current Good Manufacturing Practices (cGMP). Mr. Watson previously served as Vice President of Quality Assurance at Leiter's Compounding, a full-service compounding pharmacy and FDA-registered 503B Outsourcing Facility in San Jose, Calif. He oversaw all sterile and non-sterile operations and led a team of 14 quality assurance employees. Prior to Leiter's, Mr. Watson was the Consumer Safety Officer in the FDA's San Francisco District Office, overseeing sterile and non-sterile dosage forms of therapeutic biologics and pharmaceutical drugs, and completing more than 200 inspections for cGMPs, recalls, seizures, new drug applications, pre-approval inspections, adverse drug events, and other issues. He began his 23-year tenure with the FDA as a microbiologist specializing in sterility and endotoxin analyses of drugs and devices, facilities and equipment, and procedures and documentation. He has been recognized for his leadership and communications skills. He authored the FDA District Office microbiology laboratory's Cleanroom SOP and co-authored an FDA sterility analytical manual for the Department of Health and Human Services' Public Health Service. Mr. Watson earned a bachelor's degree in biology, with an emphasis in microbiology, from the University of San Francisco. He completed graduate courses for regulatory affairs in the biotechnology, pharmaceutical and medical device industries through San Diego State University, as well as graduate courses in biomanufacturing principles through North Carolina State University.

# 503A Sterile Compounding Facility Inspection

Conducted for

# [Pharmacy Name]

**Conducted on**
July X, XXX
**Revisited**
February XX, XXXX

**Prepared by**
Denise Frank

**Location**
[Street Address]
[City, State ZIP]

# Sterile Compounding Assessment

## [Pharmacy Name] / [original inspection date]

| | |
|---|---|
| Client / Site | [Pharmacy Name] |
| Conducted on | [Date] |
| Prepared by | GHA Consultant Denise Frank, RPh |
| Location | [Street Address] |

## Information

Additional Personnel Present During Site Visit:

[pharmacist name], RPh, Pharmacist-in-Charge, staff pharmacist, 3 technicians

Facility and Equipment Description:

Sterile compounding suite with an ISO 7 ante room leading into both an ISO 7 buffer room and a negative pressure ISO 7 hazardous room. In the positive pressure buffer room, one ISO 5 CAI, and in the hazardous room, one ISO 5 BSC.

Sterile Compounding Performed:

The pharmacy compounds the following types of preparations:

Injectables (SQ, MDV), eye drops

Compounding Risk Categories:

The pharmacy compounds in the following risk categories:

Low, medium and high risk.

## Executive Summary & Plan of Correction

Overall a busy, well-run facility, willing to improve, with policies and procedures in place.
Note: Performed an on-site inspection on 2/XX/XXXX to verify remediation of the items below.

1. Sprinkler heads in anteroom and clean rooms are not flush. Was not an issue with the state board of pharmacy. Will explore removing the sprinklers (if allowed) or changing to flush-mounted heads. Exposed sprinkler heads in the compounding suite have been replaced with sprinkler units that are flush with the ceiling. Compliant.

2. The sink is on the dirty side of the line of demarcation, which will be allowed in the new USP 797 chapter that is currently under review. It is not compliant with the current (old) USP 797. Garbing procedures are adapted to this configuration. The line of demarcation has been moved in the anteroom, so the sink is on the clean side of the line of demarcation. Garbing procedures including sequence has been revised for this new configuration. Compliant.

3. Current humidity is 52-55%. Is in the process of installing new HVAC system to bring humidity down to 40% or less. Will be completed and operational by the end of July. HVAC system did not fully take care of humidity during the summer months. New policy and procedure implemented to store opened packages of prescription products and APIs whose labeling indicates store in a “dry place” in closed containers along with desiccants to ensure humidity remains below 40% during months where the humidity in the compounding and storage areas is above 40%. Compliant.

4. Personnel testing, observed competencies, media fill testing and gloved fingertip testing performed by outside vendors: Aseptic Testing Solutions and LabMetrics. Viewed report indicating the tests were performed and "passed". No detail. All tests performed annually and should be every 6 months for high-risk compounding. Unknown if any CFUs were found and identified – only that the tests did not exceed action limits. PIC Sharron Seymour will review the detail of the competencies and testing performed, ensure it does include the most complicated compounding manipulations performed at this pharmacy. She will also immediately schedule testing to occur every 6 months, at a minimum. Using Aseptic Testing Solutions to perform testing every 6 months. Compliant. Observational competencies content compliant. Gloved fingertip testing compliant. Media fill testing partially compliant, unknown if testing included the use of the pump.

5. Certification testing of the PECs and SECs.

a. Certification was not performed dynamically. PIC Sharron Seymour will utilize a certification day checklist to ensure all tests are performed correctly including all tests to be performed dynamically and document the number of persons and activities performed during certification. Using certification day checklist that includes documenting tests are performed correctly and dynamically. Compliant.

b. Unknown if appropriate media was used to perform surface sampling. Also, no information or documentation indicating the lot numbers of the media used were subject to growth promotion testing and sterility quality control testing. Will obtain from the certification vendor. Certification vendor is providing additional information in the reports and the correct media is being used and documented. Compliant.

6. Dry heat sterilization. Not using a biological indicator each time but does send every batch for sterility testing. Will obtain and use biological indicators in addition to sterility testing. Biological indicators have been obtained and are being used to confirm sterilization cycles. Compliant.

## Inspection Detail

## General Operations

| | |
|---|---|
| 1. The pharmacy has a designated person in charge of sterile compounding operations, responsible for ensuring training and compliance of compounding personnel.<br><br>PIC [pharmacist name] | Compliant |
| 2. The pharmacy makes copies of approved commercial products ONLY when the products have been verified as unavailable or in short supply. *Products are verified as appearing on the FDA Drug Shortage List (see FDA Drug Shortages app) at the time of compounding, distribution, and dispensing and this is documented. The Drug Shortage List is monitored and when a drug product is no longer on the list, any remaining stock is quarantined and not available for distribution or dispensing. | Not Applicable |
| 3. The pharmacy compounds medications that are essential copies of commercially available products NOT on the Drug Shortage List ONLY if the compounded preparation produces a significant clinical difference from a commercially available drug that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner. | Compliant |
| 4. The pharmacy appropriately dispenses compounded preparations pursuant to a legitimate prescription. There is a valid patient-prescriber relationship. | Compliant |
| 5. Patient profiles are complete including demographics, disease states or conditions, allergies and sensitivities, and DUR information including other prescription and OTC medications the patient is taking. If the pharmacy uses more than one prescription processing system (such as a billing system and a separate clinical management system), appropriate data is entered into each for performing DUR. | Compliant |
| 6. The pharmacy does not distribute compounded preparations to health care providers or other pharmacies for office use or stock. *There are no compounded preparations that leave the pharmacy that are not dispensed pursuant to a prescription and labeled for a specific patient. | Compliant |
| 7. Compounded preparations for immediate use that are prepared outside of ISO Class 5 environment are appropriately handled and administration begins within one hour of the start of the compounding process. | Not Applicable |

| | |
|---|---|
| 8. Compounded preparations are appropriately defined as “low-risk”.<br>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.<br>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.<br>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 of other sterile products, and containers for storage and dispensing. | Compliant |
| 9. Compounded preparations appropriately defined as “medium-risk”,<br>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.<br>2. The compounding process includes complex aseptic manipulations other than the single-volume transfer.<br>3. The compounding process requires unusually long duration, such as that required to complete dissolution or homogeneous mixing. | Compliant |
| 10. Compounded preparations defined as “high-risk”.<br>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.<br>2. Any of the following are exposed to air quality worse than ISO Class 5 for more than 1 hour (see Immediate-Use CSPs):<br>• sterile contents of commercially manufactured products,<br>• CSPs that lack effective antimicrobial preservatives, and<br>• sterile surfaces of devices and containers for the preparation, transfer, sterilization, and packaging of CSPs.<br>3. Compounding personnel are improperly garbed and gloved (see Personnel Cleansing and Use of Barrier Protective Equipment).<br>4. Nonsterile water-containing preparations are stored for more than 6 hours before being sterilized. NOTE: For sterile compounded preparations to be administered via an implantable infusion pump, are BUDs assigned to include the full length of time during which the CSP will be administered or present in the reservoir of the pump? If not, indicate the maximum length of time of administration that may be beyond the BUD assigned | Compliant |
| 11. The pharmacy has appropriate current references for compounding, either hard copy or accessed electronically. USP Compounding Compendium, state regulations, compatibility references, formula and stability references, references for specific types of compounding and clinical dosage/ toxicology for the patient base (general, veterinary, geriatric, pediatric, etc.). | Compliant |

| | |
|---|---|
| Has USP Compounding Compendium, Online access to BOP regulations, Plumb's Veterinary Compendium, Facts and Comparisons. | |
| 12. The pharmacy staff has access to Safety Data Sheets (SDS), formerly known as Material Safety Data Sheets (MSDS) for those chemicals used for compounding and cleaning. | Compliant |
| 13. The pharmacy has appropriate policies and procedures/standard operating procedures for compounding that includes but is not limited to the recommended SOPs in USP <797>. | Compliant |
| 14. The compounding facility shall have written, properly approved SOPs designed to ensure the quality of the environment in which a CSP is prepared. | Compliant |
| 15. There is a process to communicate and provide training for any new SOPs or revisions of the SOPs and it is documented. | Compliant |

## Component Selection and Use for High-Risk Compounding

| | |
|---|---|
| 1. The pharmacy obtains bulk powder APIs used in compounding from verified sources. *Purchase APIs directly from the manufacturer or wholesaler that purchases from manufacturer, verify that the source of the API is an FDA-registered facility, if not FDA facility, how verified? | Compliant |
| Purchases APIs from Letco only. | |
| 2. Active Pharmaceutical Ingredients (APIs), bulk drug substances used are: 1) Compliant with the standards of an applicable USP or NF monograph, if one exists; or 2) A component of an FDA-approved human drug product; or 3) On the list of bulk drug substances for use in compounding developed by the FDA and issued through regulation (note: must comply with (1) or (2) above until the FDA list is issued)" | Compliant |
| 3. Certificates of analysis (COAs) obtained for all bulk APIs used for compounding. *NOTE: The COA for an API should be reviewed upon receipt of the API to verify the quality of the API before being used for compounding. | Compliant |
| Are scanned in and attached to the drug product file. | |
| 4. USP- or NF-grade substances used, if available. *If compendial quality components are not available, chemically pure, analytical reagent grade or American Chemical Society-certified components are used and are determined to be free from impurities. | Compliant |
| 5. APIs or other components have labeling indicating use for pharmaceutical compounding or manufacturing. *Labels do not indicate "for research purposes only", "not for drug use", or are handwritten labels from other pharmacies. | Compliant |

| | |
|---|---|
| 6. All substances and components have a complete label including a batch control or lot number, and an expiration date. *For APIs without an expiration date assigned by the manufacturer or supplier, the pharmacy assigns a conservative expiration date. The expiration date assigned is not greater than one (1) year, is supported with data and/or testing. Note: purity and quality testing may be performed to extend. All APIs are labeled with the date they were received. | Compliant |
| 7. If the pharmacy repackages APIs into smaller containers for ease of use, the expiration date assigned is conservative. *(typically, the lesser of one year or the actual expiration from the original container). Product may be tested to extend the expiration date but may not exceed the original package expiration date. | Compliant |
| 8. Components obtained from foreign sources that are derived from ruminant animals (cow, sheep, goat) have documentation that the component is in compliance with federal laws governing processing, use, and importation. Animals from which the component is derived were free from disease, and they were born, raised, and slaughtered in locations where bovine spongiform encephalopathy and scrapie are not known to exist. Applies if facility purchases APIs directly from foreign manufacturers. N/A if purchasing only from US manufacturers or distributors that are FDA approved | Not Applicable |
| No direct purchases from other countries. Only sourced from Letco. | |
| 9. There are no preparations made or ingredients used that appear on the FDA list of drug products withdrawn or removed from the market for safety reasons (facility has a copy of the list or other way to determine). | Compliant |
| 10. There are no preparations compounded that present demonstrable difficulties for compounding as identified by the FDA. | Compliant |
| 11. When manufactured products are used for high-risk compounding, all the other excipients (in addition to the active ingredient) in the manufactured product are considered relative to the use, effectiveness, and stability of the compounded preparation to be made. | Compliant |

## Animal Compounding

| | |
|---|---|
| 1. For animal compounding, the compounding meets the same standards as compounding for human patients. | Compliant |
| 2. The pharmacist is knowledgeable by specialized training and/or has veterinary references regarding the individual species' limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used. | Compliant |
| Plumb's Compendium. | |

| | |
|---|---|
| 3. The pharmacist is familiar with all state and federal regulations regarding drug use in animals, including but not limited to the Food, Drug, and Cosmetic Act; the Animal Drug Amendment; the Animal Medicinal Drug Use Clarification Act; and any FDA guidance documents regarding compounding of drugs for use in animal patients. | Compliant |
| 4. It is determined and documented if the animal is used for food (meat, milk, eggs, etc.) or that the animal is a pet.<br>Dogs and cats and some zoo animals. Will ask if rabbit or guinea pig. | Compliant |
| 5. The pharmacist familiar with or has a reference regarding drug residues in the food chain and withdrawal times if compounding for food-producing animals. The facility has a list of drugs and components not allowed when compounding for food-producing animals.<br>Plumb's | Compliant |
| 6. The pharmacist is familiar with, or has a reference regarding regulations for drug use in performance animals (e.g., race or show horses, racing dogs)<br>Has reference, no performance animal patients at this time. | Compliant |
| 7. If compounding for both humans and animals, APIs or other components that are labeled for veterinary use only are segregated or marked in such a way to prevent them from being used for human compounding | Compliant |

## Environment

| | |
|---|---|
| 1. If the facility performs both sterile and non-sterile compounding, the areas are separated and distinct. | Compliant |
| 2. If the facility performs compounding using blood products (or other biological materials), this compounding area is separate and distinct from the general compounding areas. Components used in compounding with blood products are restricted to the blood compounding area (not used in other compounding areas). | Not Applicable |
| 3. Entry into the sterile compounding areas is limited to task critical employees (limited to only the pharmacist(s) and other trained and authorized pharmacy personnel). At a minimum, signage indicating authorized personnel only. | Compliant |
| 4. The ante-room has a line of demarcation or other separation of the dirty to the clean side. Note: the line of demarcation may NOT be the doorway between the ante room and the clean/buffer room. | Compliant |
| 5. Carts used to bring supplies from the storeroom are kept on the outside of the line of demarcation. | Compliant |

| | |
|---|---|
| 6. Carts used in the clean room/buffer room are kept on the clean side of the line of demarcation. | Compliant |
| 7. All surfaces of the sterile product compounding area carts, shelves, stools, chairs, and other items are resistant to disinfectants, non-permeable, non-carpeted or upholstered, and low particulate generating. | Compliant |
| 8. Equipment, carts, tables, PECs are free from any rust or corrosion. | Compliant |
| 9. Walls painted with epoxy-based paint or comprised of an impermeable surface and are seamless or have sealed seams where panels meet and in corners. There are no unsealed holes or cracks in the walls. Unused outlets have plugs or covers. | Compliant |
| 10. The ceiling tiles are composed of a vinyl surface or other impermeable material, with the tiles caulked and sealed (re-sealed if cut at certification to access HEPA filter) and the seams where the walls meet the ceiling are caulked and sealed. | Compliant |
| 11. The clean room and ante-room are free from dust collecting overhangs, such as ceiling utility pipes, or ledges; and the sprinkler heads are flush with the ceiling. | Non-Compliant |
| Sprinkler heads are not flush. | |
| 12. The exposed surfaces of the light fixtures are smooth, mounted flush, and sealed. | Compliant |
| 13. A sink with hot and cold running water is located on the clean side of the line of demarcation in the ante room that enables pharmacy personnel to wash hands and enter the sterile compounding area without contaminating his/her hands, and an eyewash station. RECOMMENDED: The sink and the soap dispenser(s) are hands-free. | Unknown |
| The sink is on the dirty side of the line of demarcation, which will be allowed in the new USP 797 chapter that is currently under review. It is not compliant with the current (old) USP 797. Garbing procedures are adapted to this configuration. | |
| 14. Hand drying is with non-linting paper towels. | Compliant |
| 15. Hand drying is with an electronic or HEPA filtered hand dryer. (Hand dryers not allowed by some states) If using a hand dryer, particle count and smoke testing validation is performed while dryer is in use (while someone is actively using the dryer) at certification, and the immediate area around the dryer is part of the viable air and surface testing program performed. | Not Applicable |
| 16. There is NO sink or drain in the clean room/buffer room. | Compliant |
| 17. All air ducts controlling air flow into the sterile compounding clean/buffer room and ante room are equipped with HEPA filtered air that maintains the cleanroom with an ISO Class 7 environment or better. | Compliant |

| | |
|---|---|
| 18. There are no other sources of air coming into the anteroom or clean room such as blowers, fans, air conditioning units, etc. | Compliant |
| 19. Incoming air ducts through HEPA filters are on or near the ceiling and air return ducts are low on the walls in the ante-room and clean room. | Compliant |
| 20. If there is particle generating equipment in the clean room or ante-room (such as computers and printers), the equipment is located by an air return so air flows over and out of the room taking particles with it, and this air flow has been confirmed by smoke testing while the equipment was in use. | Not Applicable |
| 21. If there are particle generating appliances in the clean room or ante-room (such as refrigerators, dishwashers, etc.), the equipment located by an air return so air flows over and out of the room taking particles with it, and this air flow has been confirmed by smoke testing while the equipment was in use and appliances are also part of the viable surface sampling program. | Not Applicable |
| 22. If compounding occurs using nonsterile ingredients, products, components, or devices (for example compounding with non-sterile APIs or using nonsterile vials and closures), the pharmacy has appropriate equipment to sterilize the finished product.<br>Dry heat sterilization oven. | Compliant |
| 23. RECOMMENDED: Pre-sterilization procedures for high risk level CSPs (such as weighing and mixing) are performed in no worse than an ISO Class 8 environment | Compliant |
| 24. Completely enclosed ante room and clean room (with a door) are equipped with monitors or gauges to measure differential pressure. | Compliant |
| 25. The ante room is at least 0.02" w.c. positive pressure to general pharmacy areas. Note that some states have a maximum pressure limit.<br>0.079 | Compliant |
| 26. The clean room/buffer room is at least 0.02" w.c. positive pressure to the ante room. Note that some states have a maximum pressure limit.<br>0.033 | Compliant |
| 27. Pressures are read and recorded each shift (minimum of once daily) or are continuously recorded. There is a plan in place to detect and react to pressure differentials outside of limits. | Compliant |

| | |
|---|---|
| 28. If the clean room and/or anteroom are not fully enclosed (open or with plastic strips - no door that closes), the air flow is measured across the openings and is at least 40 feet per minute across the entire opening. Airflow is read and recorded each shift (minimum of once daily) or continuously recorded. There is a plan in place to detect and react to air flow measurements outside of limits. This area is used only for low- and medium-risk compounding. (High-risk not allowed) | Not Applicable |
| 29. Temperature: The temperature of the compounding area is controlled by a thermostat and an air conditioning system is in place. | Compliant |
| 30. Temperature in the compounding area is maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements. | Compliant |
| 31. The temperature range for performing sterile compounding while garbed is between 64-72°F (18-22°C). Note that some states have a specific temperature maximum in sterile compounding areas. | Compliant |
| 68.5 | |
| 32. Temperature monitoring in the compounding area is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained. | Compliant |
| 33. Temperature monitoring is also performed in drug storage areas (if separate from the compounding areas). | Compliant |
| 34. Temperature in the refrigerator or cooler is maintained to provide controlled cold temperature of 2° to 8°C (36° to 46°F). | Compliant |
| 35. Temperature monitoring in the refrigerator, or cooler is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained. | Compliant |
| 36. Temperature in the freezer is maintained to provide controlled frozen temperature of -10° to -25°C (-13° to 14°F). | Not Applicable |
| 37. Temperature monitoring in the freezer is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained. | Not Applicable |
| 38. There is an action plan for any temperature excursions is in place for temperature excursions including evaluating excursion effects on drug product integrity and documentation. | Compliant |
| 39. Humidity: Humidity in the compounding area is maintained to provide humidity in the ranges warranted by specific drug product storage requirements. If drug products require storage in a “dry place”, humidity is not to exceed 40%. Generally recommended range is 35-60% for performing sterile compounding. | Unknown |

| | |
|---|---|
| Current humidity is 52-55%. Is in the process of installing new HVAC system to bring humidity down to 40% or less. Will be completed and operational by the end of July. | |
| 40. Humidity monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Humidity records are maintained. | Compliant |
| 41. There is an action plan in place for humidity excursions including evaluating excursion effects on drug product integrity and documentation. | Compliant |
| 42. Humidity monitoring is also performed in drug storage areas (if separate from the compounding areas). | Compliant |
| 43. Blowers on ISO 5 PECs are operated continuously during compounding activity, including during interruptions of less than eight hours. | Compliant |
| 44. When the ISO 5 LAFW blower is turned off, and before other personnel enter to perform compounding activities, only one garbed person is allowed to enter the buffer area for the purposes of turning on the blower (for at least 30 minutes) and of sanitizing the work surfaces | Compliant |
| 45. The doors into the ante-room from the general pharmacy area and from the anteroom into the clean room are prevented from both being open at the same time. By interlocking, training of personnel, or signage. | Compliant |
| Signage and training. Doors are clear, easy to see if other doors are open. | |
| 46. The inside and outside doors of a pass-through are prevented from both being open at the same time. By interlocking, training of personnel, or signage. | Not Applicable |
| 47. Pass-throughs are located between outside areas and the anteroom, or between the anteroom and the buffer room. The pass-through is NOT between the buffer room directly to unclassified general pharmacy space (some states do not allow). | Not Applicable |
| 48. RECOMMENDED: The immediate area around the doorway or pass-through into the ante room from the general areas is free of particle generating materials (such as corrugated cardboard, etc.) and is located in an area that limits particles (not next to an outside door or window, bathroom door, food preparation areas, etc.) to limit potential contamination from being brought in through the entry. Suggested minimum distance is 10 feet from entrance to ante room. | Compliant |
| 49. If the pharmacy has a lyophilizer (freeze dryer), it is located in an ISO Class 5 SEC, is part of the viable air and surface sampling, media fill testing procedures, and cleaning schedules and procedures. | Not Applicable |

## LAFW or BSC that is NOT located in an ISO Class 7 buffer room

| | |
|---|---|
| 1. BSC or LAFW has been certified to maintain ISO Class 5 during compounding activities. | Not Applicable |
| 2. Used only for low-risk compounded preparations and assigned a BUD of 12-hours or less. | Not Applicable |
| 3. All sterile compounding garbing requirements are adhered to. | Not Applicable |
| 4. Located in an area that is maintained under sanitary conditions only be traveled by persons engaging in the compounding of sterile preparations | Not Applicable |
| 5. Location does not contain any unsealed windows or doors that connect to the outdoors or areas of high traffic flow, and is not adjacent to construction sites, warehouses, or food preparation area | Not Applicable |
| 6. Has the sink separated from the immediate area of the ISO Class 5 workbench (not adjacent) and an eyewash station | Not Applicable |

## CAI or CACI that is NOT located in an ISO Class 7 buffer room

| | |
|---|---|
| 1. CAI/CACI has been certified to maintain ISO Class 5 under dynamic conditions including transferring of ingredients, components and devices, and during preparation of CSP. | Not Applicable |
| 2. The pharmacy has documentation from the manufacturer that the CAI or CACI will meet this standard when located in worse than ISO Class 7 environments. | Not Applicable |
| 3. The CAI or CACI is located in an area that is maintained under sanitary conditions and only traveled by persons engaging in the compounding of sterile preparations. | Not Applicable |
| 4. There is a sink in the compounding area, not directly adjacent to the CAI or CACI, that enables pharmacy personnel to wash hands and an eyewash station | Not Applicable |

## Cleaning

| | |
|---|---|
| 1. All personnel performing cleaning are appropriately garbed. | Compliant |
| 2. Appropriate non-shedding cleaning equipment dedicated to the buffer or ante room, and supplies are available. *All cleaning tools, such as wipers, sponges, and mops, must be non-shedding, dedicated to and labeled for use in either the buffer or clean area (no wooden handles are allowed). | Compliant |

| | |
|---|---|
| 3. Cleaning tools that are reused are rinsed and sanitized and kept in an appropriate clean storage area, with buckets inverted to prevent moisture accumulation. *Are reusable tools appropriately labeled to prevent them from being used inappropriately? For example, a mop used for the floors cannot also be used for the ceilings and walls. | Compliant |
| 4. If cleaning and sanitizing agents are not premixed, there are formulas and instructions for mixing or diluting the agents prior to use, and for documentation. | Not Applicable |
| 5. Cleaning and sanitizing agents are appropriately labeled including expiration dates. | Compliant |
| 6. Appropriate cleaning and sanitizing agents are used that are effective for bacteria, viruses, fungi, and spores. Sporicidal typically used weekly. | Compliant |
| 7. ISO 5 PECs are cleaned at the beginning of each shift, between compounding activities, at least every 30 minutes while compounding and after spills or suspected surface contamination. | Compliant |
| 8. Cleaning of the ISO 5 PEC includes cleaning with sterile water and sanitizing with sterile 70% IPA using a non-linting wipe. | Compliant |
| 9. Daily cleaning and sanitizing includes counters and easily cleanable work surfaces. | Compliant |
| 10. Daily cleaning includes the floors starting from the clean room and working outwards. *Floor cleaning does not occur during compounding. | Compliant |
| 11. If fatigue mats are used, they are cleaned daily and let dry on both sides and the area underneath is cleaned. | Not Applicable |
| 12. The tacky mat is located outside of the ISO spaces (anteroom and clean room). There is a procedure for placement of a tacky mat, and frequency of replacement. *If there is a tacky mat in the anteroom, it must on the dirty side of the LOD, and be removed prior to cleaning the floor each day and not replaced with a new mat until the floor has completely dried. | Compliant |
| 13. Monthly cleaning includes the ceilings, walls, all shelving, bins, carts, chairs, and the tops and sides of the primary engineering controls (PECs). *This includes removing everything from shelves and bins before cleaning, cleaning the undersides of cart surfaces and stools, wheels, etc. | Compliant |
| 14. Sufficient time is allocated and scheduled for cleaning activities. | Compliant |
| 15. There is a waste disposal system in place. | Compliant |

## Training

| | |
|---|---|
| 1. There is documentation that compounding personnel are appropriately trained including policies and procedures, documentation, and aseptic technique. *Note that "compounding personnel" includes personnel performing compounding, supervising compounding, and performing verification of compounding. | Compliant |
| 2. Personnel performing compounding are not allowed to compound until all training and initial testing is successfully completed. | Compliant |
| 3. Personnel that SUPERVISE compounding and/or perform verifications of other's compounding are not allowed to supervise or verify compounding until training and initial testing is successfully completed. | Compliant |
| 4. There is documentation that all personnel (including housekeeping or other outside personnel) that perform cleaning activities in the compounding areas are appropriately trained in garbing, cleaning and disinfection. | Compliant |
| Contracted cleaning service, training is required by the service. Training records are available for the service personnel. | |
| 5. There is documentation of training on the operation of any equipment that may be used when preparing compounded sterile products. Documentation needs to include training on operation, and troubleshooting | Compliant |
| 6. If the pharmacy uses relief personnel from outside agencies to perform sterile compounding, training and certifications are verified. View documentation. | Not Applicable |
| 7. There is documentation that all compounding personnel (including those supervising or performing verifications) have passed an initial written exam, and subsequent annual written exams for the appropriate risk levels of compounding performed in the pharmacy. | Compliant |
| 8. There is documentation that all compounding personnel have passed an initial and subsequent annual competency assessments of aseptic compounding skills for the types of compounds prepared by the pharmacy using observational audit tools. Compounding skills evaluation includes the use of equipment. | Compliant |
| 9. There is documentation that new compounding personnel have passed an initial observed gowning procedure and three gloved fingertip sampling tests. *Personnel must pass the tests upon initial validation before being allowed to compound. Action required if the tests yield any garbing deficiencies, or if the sampling results are >0 colony-forming units (CFU)/plate on the three initial validations. | Unknown |
| Uses outside vendors to perform: Aseptic Testing Solutions and LabMetrics. Viewed report indicating the tests were performed and "passed". | |

| | |
|---|---|
| 10. There is documentation that compounding personnel preparing low or medium risk-level products have passed an annual observed gowning procedure and gloved fingertip sampling test. *Action required if the tests yield any garbing deficiencies, or if the fingertip sampling results are >3 CFU (total both hands, all 10 fingers). | Unknown |

Uses outside vendors to perform: Aseptic Testing Solutions and LabMetrics. Viewed report indicating the tests were performed and "passed".

| | |
|---|---|
| 11. There is documentation that a media fill test procedure is performed for each compounding employee at least annually for individuals that prepare low or medium risk-level products. *The test conditions must closely simulate the most challenging or stressful conditions encountered during compounding of the highest risk level product and include any automation used in compounding. Media-filled vials are incubated, and failure is indicated by visible turbidity in the medium on or before 14 days. | Unknown |

Uses outside vendors to perform: Aseptic Testing Solutions and LabMetrics. Viewed report indicating the tests were performed and "passed".

| | |
|---|---|
| 12. The media-fill testing procedures includes:<br>• Media selection (including positive and negative controls documentation)<br>• Fill volume<br>• Incubation time and temperature (30-35°C for a minimum of 7 days then 20-25°C for 7 days)<br>• Inspection of filled units<br>• Documentation<br>• Interpretation of results<br>• Action levels set with the corrective actions required | Unknown |

No detail provided.

| | |
|---|---|
| 13. High-Risk Sterile Compounding: There is documentation that compounding personnel have passed an observed gowning procedure and gloved fingertip sampling test every six (6) months. *Action required if the tests yield any garbing deficiencies, or if the sampling results are >3 CFU/plate upon revalidation. | Non-Compliant |

Uses outside vendors to perform: Aseptic Testing Solutions and LabMetrics. Viewed report indicating the tests were performed and "passed". Performed annually.

| | |
|---|---|
| 14. High-Risk Sterile Compounding: There is documentation that a media fill test procedure is performed for each compounding employee at least every six (6) months for individuals that prepare high risk-level products. *The test conditions must closely simulate the most challenging or stressful conditions encountered during compounding of the highest risk level product and include any automation used in compounding. Media-filled vials are incubated and failure is indicated by visible turbidity in the medium on or before 14 days. | Non-Compliant |

Uses outside vendors to perform: Aseptic Testing Solutions and LabMetrics. Viewed report indicating the tests were performed and "passed". Performed annually.

| | |
|---|---|
| 15. Failed testing: Employees who have failed any testing are prohibited from compounding until training is performed/reviewed and subsequent testing is performed successfully. | Compliant |
| 16. Gloved fingertip tests performed periodically (not the initial three tests) where CFUs are detected have the organisms identified down to the genus to determine the most likely source of the contamination. *This data is used to develop plans to prevent contamination. | Unknown |
| Uses outside vendors to perform: Aseptic Testing Solutions and LabMetrics. Viewed report indicating the tests were performed and "passed". No indication if there was any growth, only that the testing did not exceed action limits. | |
| 17. There is a plan to evaluate the sterile compounds prepared by an employee with failed gloved fingertip tests performed just after compounding (not the initial tests) to detect potential contamination of the sterile preparations compounded by the employee the day the tests were performed. | Compliant |

## Garbing

| | |
|---|---|
| 1. Personnel are prohibited from compounding or entering the clean/buffer room or ante room if they have a rash, sunburn, weeping sores, conjunctivitis, or an active respiratory infection. | Compliant |
| 2. Personnel have removed all personal outer garments such as hats, scarves, sweaters, vests, coats, or jackets and any makeup or cosmetics (including mascara and eyeliner) before entering compounding areas. | Compliant |
| 3. Personnel have removed all hand and wrist jewelry, and all visible jewelry or piercings such as earrings, lip or eyebrow piercings, etc. when entering clean/buffer room. This also includes tongue and nose piercings. Rings must be removed. If a ring cannot be removed, the person may not perform sterile compounding. Eyeglasses and hearing aids are to be wiped down with sterile IPA. | Compliant |
| 4. Personnel are not wearing artificial nails or extenders, and natural nails neat and trimmed. No fingernail polish (including clear polish). | Compliant |
| 5. Dedicated shoes or shoe covers are donned as the line of demarcation is crossed. *Observed: The dedicated or covered shoe never touching the same side of the line of demarcation as the dirty shoe. | Compliant |
| 6. Head covers, facial hair covers, and masks are donned appropriately and there is a mirror to check that all hair is contained. *Note that facial hair requires both a facial hair cover AND a mask. Eye shields are optional unless using cleaning agents. | Compliant |

| | |
|---|---|
| 7. Hand cleaning is performed in the ante-room and includes removing debris from under the nails with a nail cleaner followed by a vigorous washing of the hands and forearms with soap for at least 30 seconds with hands and arms then dried. Hands are kept higher than elbows to ensure water running off does not contaminate hands. There is a clock that indicates seconds (second hand or digitally counts off seconds) to time handwashing. *Drying is with a non-linting disposable towel or a hand dryer. Hand dryers not recommended and not allowed by some states. Hand dryers must be part of certification of the anteroom room with certification measurements made while the dryer is running. Scrub brushes are NOT recommended as they cause skin irritation and damage.<br>Observed. | Compliant |
| 8. The gown is non-shedding with sleeves that fit snugly around the wrists and enclosed at the neck. | Compliant |
| 9. All bare skin is covered on the arms and the legs. *Must be wearing socks, no bare ankles, wrists, etc. | Compliant |
| 10. Prior to donning sterile gloves, a waterless alcohol based surgical hand scrub with persistent activity is used and hands allowed to dry. *Note: regular Purell Hand Sanitizer is NOT appropriate. Purell, Avagard or other brand surgical hand scrub is appropriate - must have residual activity. Typically, will contain alcohol and chlorhexidine. *Note: This can be just inside the cleanroom or the last thing done before entering the cleanroom as long as the door is hands-free.<br>Observed. | Compliant |
| 11. Sterile gloves are appropriately donned in the clean room. *Gloves are donned without skin touching sterile surfaces thereby contaminating them as demonstrated by staff at survey. | Compliant |
| 12. When leaving the sterile product compounding buffer room and anteroom to enter general pharmacy areas, gowns are taken off and disposed of, or, to be reused, they are left in the anteroom and not reused for longer than one shift. | Compliant |
| 13. Pharmacists or other personnel do NOT enter the ante-room and cross the line of demarcation without donning shoe covers or dedicated shoes. *Watch for personnel traversing back and forth across the line of demarcation without doffing and donning new shoe covers or dedicated shoes. | Compliant |
| 14. Pharmacists or other personnel do NOT enter the clean room without fully washing and garbing (wearing just a mask to check technician's work, for example) | Compliant |

## Environmental Monitoring

| | |
|---|---|
| 1. The most recent PEC and room certification report is available. | Compliant |

| May XX, XXXX reports | |
|---|---|
| 2. All ISO Class 7 and 8 SECs (cleanrooms and ante rooms) have been certified within the last 6 months. | Compliant |
| 3. All ISO Class 5 PECs have been certified within the last 6 months. *note if laminar airflow workbenches or areas, BSCs, CAIs, CACIs, and barrier isolators) | Compliant |
| 4. Certification is performed at least every six months (view date of previous certification) and whenever a device or room is moved, or major work is done to the space. | Compliant |
| 5. The PIC is familiar with what testing is required and interpretation of results, ensures all testing is performed appropriately (under dynamic conditions where appropriate), has action levels identified, evaluates results to detect issues or trends, and action levels are further customized based on trended data of performance. | Compliant |
| 6. Certification of the rooms is performed to the Controlled Environment Testing Association (CETA) standard (USP: CETA CAG-003-2006-11 Certification Guide for Sterile Compounding Facilities) and is noted on the report. | Compliant |
| 7. If the certification standard used and noted on the report is NOT CETA CAG-003-2006, the facility has performed a comparison and determined the standard used is the same or better than the CETA CAG-003-2006 standard. | Not Applicable |
| 8. The certification technician appropriately garbed and washed when entering clean rooms and appropriately cleaned and sanitized equipment, transferring to a clean cart on the clean side of the line of demarcation. | Compliant |
| 9. RECOMMENDED: Certification technician performs viable testing first, to reduce contamination introduced by certification process. | Compliant |
| 10. The certification report includes information about the equipment used for performing calibration test including: identification of the equipment used by model, serial number, last calibration date (or date when next calibration is due) | Compliant |
| 11. The equipment used had not exceeded its calibration date at the time of certification | Compliant |
| 12. The HEPA filtered air changes per hour (ACPH) were measured for the compounding rooms | Compliant |
| 13. ISO Class 7 sterile compounding room is certified as having a minimum of 30 ACPH with at least 15 ACPH from outside air sources. Recirculated air from the PECs may account for up to 15 ACPH. | Compliant |
| 14. ISO class 7 ante-room is certified as having a minimum of 30 ACPH. | Compliant |

| | |
|---|---|
| 15. ISO class 8 ante-room is certified as having the recommended minimum of 20 ACPH. | Not Applicable |
| 16. If a CACI is used in a non-HEPA filtered room, the room is certified to maintain a minimum of 12 ACPH. | Not Applicable |
| 17. Air pattern analysis using smoke testing was performed under dynamic conditions (people working in the hoods and rooms). *The smoke flow is described in the report for the various tests such as turbulent, sluggish, smooth, etc. or a video recording was made (required by some states), documentation of which personnel were present and what activities they were performing. | Unknown |
| Not performed under dynamic conditions. Will make sure is dynamic on next certification. | |
| 18. Air pattern analysis was conducted at the critical area (direct compounding area inside the ISO Class 5 PEC) to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions (personnel compounding or simulating compounding in PEC), documentation of which personnel were present and what activities they were performing. | Unknown |
| Report just indicates "pass", not descriptive. No video recording. | |
| 19. Air pattern analysis was conducted to confirm positive pressure at all points around all openings, doorways, and pass-throughs | Compliant |
| 20. Air pattern analysis conducted around particle generating equipment while the equipment was in operation to confirm air flow. | Unknown |
| Not performed. | |
| 21. Differential air pressure between rooms was measured to be at least 0.02" water column positive from the cleanroom to the ante-room and between the ante-room and all adjacent spaces with the doors closed. | Compliant |
| 22. If the compounding area is not an enclosed room, displacement airflow between rooms or areas was measured at a minimum of 40 feet per minute. Note: This is for a clean room without a door that closes to the ante room - may be an open space or may have plastic strips in doorways. Displacement airflow (for low and medium-risk non-hazardous rooms only) was measured at a minimum differential velocity of 40 feet per minute from the clean room to the ante-room. Note that it is very important to maintain this velocity across the entire opening and the report should indicate multiple points of measure across all openings. | Not Applicable |
| 23. Particle counts of particles 0.5um and larger were measured under dynamic conditions in all ISO Class 5 compounding areas and hoods and are certified as having less than 3,520 particles per cubic meter of air. | Unknown |
| Particle levels are compliant. Test not performed dynamically. | |

| | |
|---|---|
| 24. Particle counts of particles 0.5um and larger were measured under dynamic conditions in all ISO Class 7 compounding areas and are certified as having less than 352,000 particles per cubic meter of air. | Unknown |
| Particle levels are compliant. No map to indicate where samples were taken, and test not performed dynamically. | |
| 25. Particle counts of particles 0.5um and larger were measured under dynamic conditions in all ISO Class 8 compounding areas and are certified as having less than 3,520,000 particles per cubic meter of air. | Not Applicable |
| Clean rooms and anteroom are all ISO Class 7. | |
| 26. HEPA filter tests were performed and all SEC (room) HEPA filters were leak tested and if leaks found, they were fixed | Compliant |
| 27. HEPA filter tests were performed and all PEC (hood) HEPA filters were leak tested and if leaks found, they were fixed | Compliant |
| 28. Rooms or hoods with failed tests are not used for compounding until the conditions are corrected and verified by subsequent testing. | Compliant |
| 29. All testing that is required to be performed under dynamic conditions is documented by the certifier or the facility staff. Documentation to include who was present and what they were doing. The maximum number of people allowed to be in the rooms working does not exceed the maximum number of personnel present during testing (not counting the certifier). This "occupancy" maximum is posted for each ante and clean room. | Non-Compliant |
| No testing was performed dynamically. | |
| 30. Viable air and surface sampling tests have been conducted at least every 6 months. | Compliant |
| 31. Appropriate growth media used (containing tryptic soy agar medium with polysorbate and lecithin (TSApl) added to neutralize cleaning agents for surface sampling) with appropriate corresponding incubation time and temperature used. *Required to use media that supports both bacterial and fungal growth for high risk compounding. | Unknown |
| Media appropriate for viable air sampling. Not enough information about media used for surface sampling and whether the media was appropriate for both bacterial AND fungal growth and if it had polysorbate and lecithin to neutralize cleaning product residue. | |
| 32. Viable air sampling by active impaction using a volumetric air sampling device. *NOTE: Passive air sampling or settling plates are not compliant with USP Chapter <797>. | Compliant |
| 33. Air samples were taken in each ISO Class 5 PEC with a sample size of at least 400 liters in volume. *Recommendation in ISO 5 PEC is 1000 liters. | Compliant |
| 34. Air samples were taken in each ISO Class 7 or 8 SEC with a sample size of at least 400 liters in volume. | Compliant |

| | |
|---|---|
| 35. Viable air samples did not exceed USP action levels (or internal action levels if more restrictive). ISO Class 5: >1 CFU/m3, ISO Class 7: >10 CFU/m3, ISO Class 8: >100 CFU/m3. CFUs are TOTAL of bacterial plus fungal/mold plates. If air sampling volume is less than 1000 liters (one cubic meter), the number of CFUs found must be multiplied by the appropriate factor | Compliant |
| 36. Surface sampling performed on all direct compounding areas inside of each ISO 5 PEC | Compliant |
| 37. Surface sampling performed in each SEC, inside any pass-throughs, and on surfaces likely to be contaminated due to position relative to doorways, etc.<br>Unknown if media supports fungal growth. | Compliant |
| 38. Viable surface samples did not exceed USP action levels (or internal action levels if more restrictive). ISO Class 5: >3 CFU/plate, ISO Class 7: >5 CFU/plate, ISO Class 8: >100 CFU/plate, | Compliant |
| 39. CFUs are TOTAL of bacterial plus fungal/mold plates from each sampling location. | Compliant |
| 40. CFUs detected by any means are analyzed to determine the organism down to the genus. All CFUs detected must be identified even if the number of CFUs does not exceed an action level. Microbiological methods must be employed to determine if any recovered Staphylococcus colonies are coagulase positive.<br>No CFUs detected. | Not Applicable |
| 41. If the number of CFUs detected exceeds action levels, compounding ceases until evaluated, immediate remediation and investigation into the cause conducted, and compounding not resumed until subsequent tests are performed successfully. | Compliant |
| 42. Recovery of any mold, yeast, coagulase positive staphylococcus or gram-negative rods in any area is considered not to be in compliance with USP <797> Pharmaceutical Compounding—Sterile Preparations standards and immediate remediation and investigation into the cause is conducted. | Compliant |
| 43. The testing report indicates growth promotion testing or documentation and sterility quality control testing of the media plates was performed. *Positive and negative control tests important to validate results of viable testing.<br>No information in the report about positive and negative control testing on each lot of media used. | Unknown |
| 44. The testing results report includes media lot numbers and expiration dates, and the name or signature of the laboratory analyst and/or reviewer. | Compliant |

| | |
|---|---|
| 45. Facilities performing routine air or surface sampling with internal qualified personnel routinely validate sampling procedures. | Not Applicable |

## Compounding Equipment

| | |
|---|---|
| 1. Appropriate equipment and utensils are available, clean, and in good working order. *Automated, mechanical, or electronic equipment (autoclaves, ovens, etc.) are periodically inspected, and calibrated yearly or in accordance with the equipment manufacturer guidelines.<br>New equipment. | Compliant |
| 2. All environmental monitoring equipment and gauges (differential pressure gauges or probes, air flow and velocity measuring equipment for rooms not fully enclosed, etc.) are periodically inspected, and calibrated yearly or in accordance with the equipment manufacturer guidelines. Calibration is documented.<br>New equipment. | Compliant |
| 3. All temperature and humidity monitoring devices (thermometers, hygrometers, probes, etc.) are periodically inspected, and calibrated yearly or in accordance with the equipment manufacturer guidelines. Calibration is documented<br>New equipment. | Compliant |
| 4. Scales, balances, or other equipment used for measurement are regularly calibrated, and validated at least annually. *If scales are NOT validated and sealed by a state or local weights and measures agency, describe procedure used<br>Sent for validation and calibration yearly in August. | Compliant |
| 5. PEC (hood) pre-filters are checked and replaced regularly and documented. *View replacement log or documentation of filter check and replacement by certification company. | Compliant |
| 6. Automated Compounding Devices (ACDs) are used for sterile compounding (such as repeater pumps) and there is a P&P for the use and calibration, documentation of the ACD tubing being changed or discarded every 24 hours and the ACD is used when performing media fill testing. | Not Applicable |

## Compounding Procedures and Documentation

| | |
|---|---|
| 1. Gloves and critical sites are sanitized with adequate frequency and with an approved disinfectant, such as sterile 70% isopropyl alcohol (IPA) spray and a non-linting wipe | Compliant |
| 2. There are no objects that shed particles in the buffer or clean area, including pencils, cardboard cartons, paper towels, reading material, and cotton items (e.g., gauze pads) | Compliant |

| | |
|---|---|
| 3. Essential paper related products (syringe overwraps, work records contained in a protective plastic sleeve) are wiped down with sterile 70% IPA before being brought into the buffer or clean area. | Compliant |
| 4. Supplies required for the scheduled operations of the shift are prepared and decontaminated by wiping or spraying the outer surface with sterile 70% IPA (or removing the outer wrap as the item is introduced into the aseptic work area) and brought into the buffer or clean area in a bin or on a movable cart. | Compliant |
| 5. Compounding employees are using appropriate aseptic technique. *Pay attention to first air, entry and exit of materials in ISO Class 5 PEC, appropriate frequent sanitizing of gloves, appropriate cleaning and cleanliness of the direct compounding area (DCA).<br>Verbalized. Not observed (not compounding at the time of inspection). | Compliant |
| 6. Compounding personnel ascertain that the ingredients for CSPs are of the correct identity and appropriate quality by reading vendors' labels, and a unit-by-unit physical inspection of the product before use.<br>Unit by unit check of NDCs. | Compliant |
| 7. All rubber stoppers of vials and bottles and the neck of ampules are sanitized every time with sterile 70% IPA (and a wait of at least 10 seconds to dry) prior to the introduction of a needle or spike for the removal of product. | Compliant |
| 8. Single-dose vials exposed to ISO Class 5 or cleaner air are used within six (6) hours of the initial puncture and any remaining contents discarded. If exposed to less than ISO Class 5 air, used within 1 hour and discarded. | Compliant |
| 9. The remaining contents of opened single-dose ampules are discarded immediately. May not be stored for any time period. | Compliant |
| 10. Multiple-dose vials formulated for removal of portions on multiple occasions are used within 28 days (or the manufacturer's specific BUD if less) after the initial entry or puncture and any remaining contents discarded.<br>Does write date first punctured. Does not use beyond 28 days (or less if indicated on the packaging from the manufacturer). | Compliant |

| | |
|---|---|
| 11. The compounding record is complete.<br>1. Official or assigned name, strength, and dosage of the preparation<br>2. Names, lot numbers and expiration dates of all components<br>3. Total quantity or number of units compounded<br>4. Person compounding the preparation<br>5. Person performing the quality control procedures<br>6. Person who approved the preparation<br>7. Date of compounding<br>8. Assigned internal identification number or prescription number<br>9. Assigned BUD and reference if extended beyond USP guidelines<br>10. Duplicate label<br>11. Sterilization method (if applicable)<br>12. Indication of the quality control procedures to perform (testing, filter integrity, etc.) and results of the testing, quality control issues, and investigation/recall if applicable | Compliant |
| 12. Procedure for in-process checks is followed. These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists and visual inspection of product. | Compliant |
| 13. Documentation of the compounding accuracy is recommended to be performed by someone other than the compounder to ensure proper measurement, reconstitution, and component usage. | Compliant |
| 14. Labels on BATCH preparations include the name and quantity of all contents, date, and time of preparation (or internal code indicating this information), preparer and verification pharmacist identifiers, stability (BUD), and any auxiliary labels indicated. *RECOMMENDED: Labels on batch single-use containers are clearly marked as "Single Use Only" | Compliant |
| 15. Labels on PATIENT-SPECIFIC containers, in addition to standard label requirements, also include identifiers for the persons preparing and performing the final verification, stability or BUD, and flow rate (if applicable). *RECOMMENDED: Labels on patient-specific single-use containers are clearly marked as "Single Use Only" | Compliant |
| 16. Preparations without additional stability testing or supported by data are assigned BUDs within USP<797> guidelines.<br>Low Risk: 48 hours room temp, 14 days refrigerated, 45 days frozen<br>Medium Risk: 30 hours room temp, 9 days refrigerated, 45 days frozen<br>High Risk: 24 hours room temp, 3 days refrigerated, 45 days frozen | Compliant |
| 17. Extended BUDs are assigned and are supported with stability documentation. View records, preparation must exactly match the preparation cited in the documentation including concentration of all active ingredients, excipients, etc. | Compliant |

| | |
|---|---|
| 18. Extended BUDs are assigned, and the facility has performed its own stability testing. View records, preparation must exactly match the preparation tested by the facility including concentration of all active ingredients, excipients, etc. | Compliant |
| 19. Compounded multiple-dose vials with extended BUDs assigned have additional instruction provided that indicates remainder must be discarded 28 days after first puncture or use. | Compliant |
| 20. Stock solutions: If the pharmacy compounds stock solutions or components (that are then used to compound a finished product) using APIs, these stock solutions are categorized as high-risk compounding, are tested and are used within appropriate time frames. *The stock solutions are assigned BUD based on the USP<797> high-risk compound BUD, OR there is documentation of stability or testing to support an extended BUD. Sterility testing is performed on stock solutions. Endotoxin testing is performed after sterilization on stock solutions to be used for parenteral preparations. Once punctured, the stock solution is discarded after 6 hours if kept in ISO Class 5 (or 1 hour if in less than ISO Class 5). | Not Applicable |
| 21. Compounded preparations using the stock solution are classified as high-risk compounds with appropriate handling with regard to BUD and testing requirements. | Not Applicable |

## Sterilization and Depyrogenation

| | |
|---|---|
| 1. Filter sterilization in an ISO 5 environment and documentation includes:<br>1. The 0.2 micron sterile microporous membrane filter used to sterilize CSP solutions is chemically and physically compatible with the CSP; and the filter is intended for human-use applications for sterilizing CSPs (labeling does not indicate ""research only"", for example).<br>. That filtering is completed rapidly without filter replacement<br>3. Confirmation of filter integrity (bubble testing) is performed for each filter used with each batch sterilized by filtration. View documentation on compounding records of items sterilized by filtration to confirm. | Not Applicable |
| 2. Steam sterilization documentation includes:<br>1. The autoclave has been validated for the exposure time and mass of the items to be sterilized<br>2. Ensures live steam contacts all ingredients and surfaces to be sterilized, effectiveness verified with biological indicators and temperature sensing devices<br>3. Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization<br>4. Heated filtered air is evenly distributed throughout the chamber with a blower<br>5. That the CSP will not be adversely affected by the steam and heat<br>6. The description of steam sterilization includes conditions and duration for specific CSPs | Not Applicable |

| | |
|---|---|
| 3. Dry heat sterilization documentation includes:<br>1. Dry heat is only used for those items that cannot be sterilized by steam or would be damaged by moisture<br>2. Sufficient space is left between materials to allow for air circulation<br>3. The description of dry heat sterilization includes conditions and duration for specific CSPs<br>4. That the effectiveness of dry heat sterilization is verified each time using appropriate biological indicators<br>5. The oven is equipped with a system for controlling and recording temperature and exposure period | Unknown |
| Not using biological indicators -- does send out each batch for testing. Will obtain and use indicators each batch that is sterilized. | |
| 4. Depyrogenation by dry heat documentation includes:<br>1. Dry heat depyrogenation is used to render glassware and containers (such as vials) free from pyrogens as well as viable microbes<br>2. The description of the cycle and duration for specific load items<br>3. The effectiveness of the cycle is verified annually using endotoxin challenge vials (ECVs)<br>4. Bacterial endotoxin testing is performed on the ECVs toverify the cycle is capable of achieving a three-log reduction in endotoxins | Compliant |
| New equipment, has not reached annual date to perform ECV testing. | |
| 5. Other methods of sterilization are used with documented procedures and validation performed. | Not Applicable |

## Finished Preparation Release Checks and Tests

| | |
|---|---|
| 1. Products checked for particulates or other foreign matter against both a light and a dark colored background. | Compliant |
| 2. Container and closure integrity are checked. | Compliant |
| 3. Compounding accuracy is documented by verification of steps and documented. | Compliant |
| 4. Verification of ingredient identity and quantity is verified and there is a reconciliation of components. | Compliant |
| 5. Labels are verified as being correct and a copy of the label is included in the record. *Complies to regulation, contains the correct names and amounts or concentrations of ingredients, total volumes, BUD, storage conditions, and route of administration. | Compliant |

| | |
|---|---|
| 6. Sterility testing is performed to USP <71>.<br>Sterility testing includes both bacterial and fungal testing.<br>Sterility testing is performed for all CSPs that have extended BUDS.<br>Sterility testing is performed for CSPs prepared in batches of more than 25 identical containers<br>Sterility testing is performed for CSPs exposed longer than 12 hours at 2°C-8°C or longer than six hours at warmer than 8°C before being sterilized | Compliant |
| 7. The appropriate quantities of units are sterility tested. Parenterals, number of units in the batch is:<br>1. Less than 100, test 10% or four units, whichever is greater<br>2. 100 up to 500, test 10 units<br>3. More than 500, test 2% or 20 units, whichever is less For large volume parenterals: 2% or 10 containers, whichever is less.<br>For non-parenterals (eye drops, inhalation, etc.):<br>1. Less than 200 containers, test 5% or 2 containers, whichever is greater<br>2. 200 or more containers, test 10 containers<br>3. If the product is packaged in unit doses, use the parenteral testing above. | Compliant |
| 8. For products failing testing, the product is quarantined, an investigation is performed including microbial identification and action taken. | Compliant |
| 9. If items are dispensed or distributed prior to sterility testing completion, there is a written procedure requiring daily observation of the incubated media. *If there is any evidence of microbial growth, there is an immediate recall and both the patient and the physician/prescriber of the patient to whom a potentially contaminated CSP was administered are notified of the potential risk.<br>Does not send out until after sterility testing is completed. | Not Applicable |
| 10. Endotoxin testing is performed to USP <85>:<br>Endotoxin testing is performed for all high-risk level CSPs for administration by injection prepared in groups of more than 25 single-dose packages (such as ampules, bags, syringes, vials)<br>Endotoxin testing is performed for high-risk CSPs prepared in multiple dose vials for administration to multiple patients,<br>Endotoxin testing is performed for high-risk CSPs exposed longer than 12 hours at 2°C-8°C (25°F-46°F) or longer than six (6) hours at warmer than 8°C (46°F) before they are sterilized | Compliant |
| 11. For products failing endotoxin testing, the product is quarantined, an investigation is performed, and action taken. | Compliant |
| 12. RECOMMENDED: Potency testing is performed. | Compliant |

| | |
|---|---|
| 13. Testing records: Products that have failed sterility, endotoxin, purity or potency testing have been quarantined and destroyed, or recalled if dispensed or distributed, appropriately investigated to determine cause, and a corrective action or training requirement is performed to prevent future occurrence. | Not Applicable |
| Has not had any products that have failed testing to date. Will investigate and keep all documentation if that happens. | |
| 14. Testing that is performed in-house is periodically validated by an outside lab. | Not Applicable |

## Patient Counseling and Communication

| | |
|---|---|
| 1. Required printed drug information materials (drug information, Patient Package Inserts (PPIs), MedGuides, etc.) are provided for the compounded products. Drug information sheet provided on initial fill, PPIs and MedGuides are provided for each fill and refill. | Compliant |
| 2. Patients are instructed on the signs of product instability or contamination (as appropriate) and instructed to report any changes in the physical characteristics of the product to the pharmacy. | Compliant |
| 3. There is a product recall system in place for products failing testing, or when any ingredient or component used in the preparation has been recalled for those compounded preparations that have been dispensed or distributed. System includes contacting both the patient and prescriber regarding the potentially contaminated CSP that was dispensed and/or administered to the patient and the potential risks. | Compliant |

## Quality Assurance/Quality Improvement:

| | |
|---|---|
| 1. The pharmacy continuous quality improvement program includes sterile compounding measures.<br>• Quality Related Events (QREs) related to the preparation of compounded products<br>• Nonviable environmental monitoring and testing<br>• Viable environmental testing<br>• Personnel testing and validation<br>• Equipment calibration, testing and validation<br>• Sterilization method testing and validation<br>• End product testing (such as: potency, particulates, sterility, endotoxin, etc.)<br>• Patient or prescriber reports or complaints regarding CSPs | Compliant |
| 2. The QA program identifies action limits or thresholds and the appropriate follow-up mechanisms when action limits or thresholds are exceeded. Includes a recall system for products dispensed or distributed. | Compliant |

| | |
|---|---|
| 3. All incidents are appropriately investigated, cause determined, remediated and processes implemented to prevent future incidents. *CFUs detected by personnel, environmental, or product testing; or any other checks or tests including endotoxin, purity, potency, etc. | Compliant |
| 4. The QREs involving CSPs that may have been contaminated or are recalled are reported to the Board of Pharmacy (where required).<br>Not required by [state in which pharmacy is located]. | Not Applicable |

## Link to Washington State Legislature Bill Information 2023

January 9, 2023 – First day of session.
February 13, 2023 – Policy Committee Cutoff. **Next cutoff**
February 20, 2023 – Fiscal Committee Cutoff.
March 7, 2023 – House of Origin Cutoff.
March 24, 2023 – Policy Committee Cutoff – Opposite House.
March 31, 2023 – Fiscal Committee Cutoff – Opposite House.
April 9, 2023 – Opposite House Cutoff.
April 23, 2023 – Sine die. Last day allowed for regular session under state constitution.

TVW - http://www.tvw.org/

| **Bills Requiring Active Involvement/Input** | | | |
|---|---|---|---|
| **Bill # /Companion** | **Short Title** | **Brief Description** | **Committee Action (subject to change)** |
| HB 1041 | Prescriptive authority of psychologists. | Due to an identified "lack of prescribers comfortable with prescribing psychiatric medications to support the behavioral health needs of the state," this bill authorizes successfully credentialed psychologists to prescribe psychotropic medications.<br><br>Section 2 of the bill revises and adds numerous definitions to the RCW 18.83.010 to accommodate the proposed action while Sections 3 and 4 create and grant prescriptive authority to credentialed psychologists in statute.<br><br>Of note to the commission is Section 6(6) which requires the examining board of psychology to transmit a list of prescribing psychologists and update or modify the list as necessary going forward. | **HB 1041**<br>*Sponsors*: Representatives Bateman, Macri, Ryu, and Simmons<br>*Pre-file (House)*: 12/15/2022.<br>*Introduced (House)*: 1/9/2023, referred to the House Health Care & Wellness Committee.<br>*Public hearing (House)*: 1/13/2023 |
| SB 5120 | 23-hour crisis receiving centers | This bill would establish 23-hour crisis receiving centers (CRCs) in Washington State. The purpose of CRCs is to address the mental and physical health needs of people in crisis.<br><br>CRC is defined in RCW 71.24.025 per Section 1, and Section 2 describes the various roles that a CRC would fulfill, including but not limited to: Offering walk-in options and drop-off options for first responders, provide services to address mental health and substance use crisis issues, screen all individuals for suicide risk and violence risk, etc.<br><br>Of interest to the commission is that CRCs are eligible to obtain an HCE license, which would have some effect on licensure management and inspection practices. | **SB 5120**<br>*Sponsors*: Senators Dhingra and Wagoner<br>*Pre-file (Senate)*: 12/30/2022.<br>*Introduced (Senate)*: 1/9/2023, referred to the Senate Health & Long Term Care Committee.<br>*Public hearing (Senate)*: 1/13/2023 |
| HB 1009 | Military spouse employment | The Military Spouse Employment Act creates occupational flexibility for military spouses, 34 to 50 percent of whom work in fields requiring a professional license. RCW 180.340.020 is amended to streamline the process by which licensing | **HB 1009**<br>*Sponsors*: Representatives Leavitt, Barkis, Ryu, Paul, |

| Bills Requiring Active Involvement/Input | | | |
|---|---|---|---|
| **Bill # /Companion** | **Short Title** | **Brief Description** | **Committee Action (subject to change)** |
| | | authorities may expedite the issuance of a license to a qualified applicant who is also a military spouse.<br><br>Section 5 of the bill also mandates training for each board or commission member on "the culture of military spouses, the military spouse experience, and issues related to military spouse career paths." Boards and commissions are encouraged to appoint a military spouse to serve on its licensing board or commission.<br><br>The bill would also create a military spouse assistance web page (Section 6), require the department to develop a campaign with local business associations and chambers of commerce to increase military spouse employment (Section 8), and allow military spouses to terminate their own employment more easily in cases of a permanent change of station for their spouse (Section 9). | Donaghy, Slatter, Simmons, Low, Volz, Schmidt, Christian, Lekanoff, Griffey, Doglio, Robertson, Orwall, Caldier, Reeves, Bronoske, Bergquist, Shavers, Riccelli, and Ormsby<br>*Pre-file (House)*: 12/6/2022.<br>*Introduced (House)*: 1/9/2023, referred to the House Innovation, Community & Economic Development, & Veterans Committee.<br>*Public hearing (House)*: 1/11/2023<br>*Executive session (House)*: 1/13/2023 |

| Additional Bills to Watch (Not in PQAC Jurisdiction) | | |
|---|---|---|
| **Bill # /Companion** | **Short Title** | **Committee Action (subject to change)** |
| HB 1006 | Expanding access to drug testing equipment. | **HB 1006**<br>*Sponsors*: Representatives Orwall, Mosbrucker, Goodman, Davis, Hackney, Simmons, Griffey, Peterson, Leavitt, Ryu, Bateman, Reed, Graham, Ramel, Pollet, Doglio, Rude, Macri, Caldier, Reeves, Wylie, Gregerson, Kloba, Riccelli, Farivar, Fosse<br>*Pre-file (House)*: 12/5/2022.<br>*Introduced (House)*: 01/09/2023, referred to House Community Safety, Justice, & Reentry Committee<br>*Public Hearing (House)*: 1/9/2023 |
| SB 5022 | Exempting fentanyl testing equipment from the definition of drug paraphernalia. | **SB 5022**<br>*Sponsors*: Senators Muzzall and Cleveland<br>*Pre-file (Senate)*: 12/6/2022.<br>*Introduced*: 1/9/2023, referred to Senate Law & Justice Committee |

| Additional Bills to Watch (Not in PQAC Jurisdiction) | | |
|---|---|---|
| **Bill # /Companion** | **Short Title** | **Committee Action (subject to change)** |
| | | |
| SB 5035 | Amending drug possession classifications. | **SB 5035**<br>*Sponsors*: Senators Padden, Fortunato, Short, J. Wilson, Schoesler, Warnick, Dozier, and Wagoner<br>*Pre-file (Senate)*: 12/8/2022.<br>*Introduced (Senate)*: 1/9/2023, referred to Senate Law & Justice Committee |

| Dead/dormant Bills (relevant if needed to implement the budget) | | |
|---|---|---|
| **Bill # /Companion** | **Short Title** | **Bill Summary** |
| HB XXXX<br><br>SB XXXX | Concise name of proposed bill. | Bill analysis info and other context relevant to the commission. |

# PQAC Rules Tracker

| Title | Status | Short Description | Most Recent WSR # |
|---|---|---|---|
| **COVID - CII Prescribing (emergency)** | Needs refile approval | Emergency rules for prescribing Schedule II drugs during COVID-19 pandemic | WSR 22-22-006 (Filed October 20, 2022) |
| **Medication assistance (emergency - filed jointly with DOH)** | Needs refile approval | Medication assistance emergency rules in accordance with chapter 69.41 RCW | WSR 22-23-073 (Filed November 10, 2022) |
| **Retired pharmacist (emergency)** | Under review (should be filed January 20) | Emergency rules for retired active pharmacist license status | WSR 22-20-023 (Filed September 23, 2022) |
| **Accessible labeling (visual/print access and translated labels)** | Drafted outline presented for public feedback; to be discussed at January 2023 business meeting | Standard/significant rules for setting/improving standards for prescription drug information access/comprehension | WSR 22-09-065 (Filed April 19, 2022) |
| **Retired pharmacist (standard)** | CR-103p submitted for division review | Permanent rules for retired active pharmacist license status | WSR 22-20-101 (Filed October 4, 2022) |
| **Medication assistance (standard - will file jointly with DOH)** | Rule language under review | Medication assistance rules in accordance with chapter 69.41 RCW | WSR 22-02-015 (Filed December 27, 2021) |
| **Remote dispensing OUD medications - SSB 6086 (standard)** | SBEIS draft being finalized | SSB 6086 - Implementing remote dispensing of OUD medications | WSR 20-17-123 (Filed August 18, 2020) |
| **Donation of unexpired drugs - SSB 6526 (supplemental CR-102)** | Supplemental CR-102 under review | SSB 6526 - Implementing the donation and reuse of unexpired drugs | WSR 22-20-100 (Filed October 4, 2022) |

# PQAC Rules Tracker (cont.)

| Title | Status | Short Description | Most Recent WSR # |
|---|---|---|---|
| **Health Equity Training – ESSB 5229 (standard)** | CR-101 filed | Amend sections in Chapter 246-945 WAC pertaining to continuing education standards and establishing health equity CE requirements per ESSB 5229. | WSR 23-01-113 (Filed December 19, 2022) |
| **Uniform Controlled Substances Act – Title 21 CFR (expedited)** | CR-105 drafted; updated proposal before committee (11/17) | Amend language in WAC 246-945-040 to incorporate by reference any changes in Title 21 CFR made after the rule's effective date | Not yet filed |
| **Dialysate and dialysis device manufacturer licensing** | CR-101 draft pending | Determine sections in chapter 246-945 WAC (subsection -090 through -093 at least) to amend to comply with SSB 1675 | Not yet filed |
| **Access to drugs stored outside pharmacy (standard)** | CR-101 submitted for division review in RMS | Allowing access to drugs stored outside the pharmacy by unlicensed employees of a health care facility | WSR 23-01-111 (Filed December 19, 2022) |
| **Mobile OTP unit licensing** | CR-101 draft pending | Amend WAC 246-945-060 to clarify licensing standards for mobile OTP units | Not yet filed |
| **Zero Order Reports and Suspicious Orders (standard)** | CR-101 draft pending; proposal before committee | Amending WAC 246-945-001 and WAC 246-945-585 to adjust suspicious order and zero reporting requirement | Not yet filed |
| **Technical edits to chapter 246-945 WAC (expedited)** | Additional edits to be presented at the January 2023 business meeting | Typos and small edits to multiple sections in chapter 246-945 WAC | Not yet filed |
| **AIDS education repeal - ESHB 1551 (expedited)** | CR-105 filed; public comment period concluded January 3 | ESHB 1551 - Repealing AIDS education and training requirements | WSR 22-22-092 (Filed November 1, 2022) |

# Accessible Labeling Rule Concepts Draft

***PLEASE NOTE:*** This is a preliminary outline intended to guide a draft for the rule language. This is not draft rule language. There will be further opportunities to provide comment once the draft rule language is complete.

Compliance with the proposed sections does not eliminate the need for patient counseling or any other requirement in any applicable law or rule.

**WAC 246-945-(AAA) Visual Accessibility Requirements for Prescription Information and Prescription Labeling.**

**Subsection 1: Definitions**

(1) Proposed terms for definition in this section:

(a) "Visually impaired"

(b) "Print impaired"

(c) "Prescription reader"

(d) *Other definitions deemed relevant to visually accessible labeling and information standards…*

**Subsection 2: Accessible Info Requirements**

(2) Prescription drug containers dispensed to outpatients under this section shall contain all of the required information in WAC 246-945-016, RCW 18.64.246, and RCW 69.41.050. The following options must be provided in a timely manner upon request by a prescribing practitioner, a patient, or an authorized representative of a patient.

(a) *Accessible print/audio methods on patient request provided in a timely manner to be printed on the prescription container label:*

(i) Larger type font (can specify size requirement); and,

(ii) *Braille; or,*

(iii) *Prescription reader provided through a technological device.*

(a) If a prescription reader is provided, it must be provided for at least the duration of the drug therapy. The device must be capable of conveying all required information listed in WAC 246-945-016;

(b) The pharmacy must also provide directions or advice to the person on obtaining a prescription reader appropriate to his or her visual or print impairment.

(b) *An element to consider:* Should it not be reasonably possible to put the required information on the container label, can it be printed on a separate information sheet?

**Subsection 3: Patient notification requirements**

(3) A pharmacy shall notify each person to whom a drug is dispensed that prescription readers, larger print labels, and braille labels are available.

**Subsection 4: Implementation Timeframe**

(4) Implementation timeframe

[]

**WAC 246-945-(BBB) Translation and interpretation requirements for prescription drug information and standardized medication labeling.**

**Subsection 1: Definitions**

(1) For the purposes of this section:

(a) "Limited English proficient individual" or "LEP individual"

(b) "Translation"

(c) "Interpretation"

(d) *Other definitions may be considered specific to this section…*

**Subsection 2: Translation Service Directive**

(2) Each pharmacy that dispenses to outpatients shall, upon the request of a prescribing practitioner, a patient, or an authorized representative of a patient, provide free, competent translations services and interpretation services to each LEP individual of the information required by WAC 246-945-016 in English and any language in which the information is required to be provided pursuant to subsection 4. If a label on a prescription container is provided in a language other than English, the same information must also be included on the prescription container in English.

(a) *Other elements to consider here:* Can these services be provided by a staff member of the pharmacy or a third-party contractor. If provided by a staff member, is it written, verbal, or both?

**Subsection 3: Translated Info Requirements**

(3) Labels on prescription drug containers dispensed to patients and separate sheets packaged with prescription drug containers dispensed under this section shall include all required elements in WAC 246-945-016, RCW 18.64.246, and RCW 69.41.050.

(a) Information described in subsection 3(a) and printed on a prescription container label or separate sheet packaged with the prescription container must comply with the visual accessibility requirements described in WAC 246-945-(AAA).

**Subsection 4: Language Selection**

(4) Pharmacies must make available a minimum of [*placeholder number*] languages other than English in the provision of translation services and interpretation services.

(a) The number of languages made available for translation services and interpretation services are based on:

(i) *Factors needed to determine a list of languages…*

**Subsection 5: Notification Requirement**

(5) Each pharmacy shall provide conspicuously posted notices and oral notifications to inform LEP individuals of their rights to free, competent oral interpretation services and translation services.

(a) The printed notice shall:

(i) Be posted in a conspicuous location to which both pharmacy staff and patients may reference; and

(ii) include the following statement in English and in each language provided by the pharmacy: "Point to your language. Language assistance will be provided at no cost to you."

(b) Pharmacy staff must also provide an oral notification to LEP individuals either by reference to the posted notice or a direct explanation of the translation services and interpretation services offered for prescription information.

**Subsection 6: Third-party Vendor Usage**

(6) If a pharmacy enters into a contract with a third party for the translation of the information that the pharmacy is required to provide pursuant to this section, the pharmacy and any employee of

the pharmacy are not liable in any civil action for any injury resulting from the translation by the third party which is not the result of negligence, recklessness or deliberate misconduct of the pharmacy or employee.

**Subsection 7: Implementation Timeframe**

(7) Implementation Timeframe

[]

| Commenter | Title/Organization | Comments |
|---|---|---|
| Cheryl Cumings | None Given | I am totally blind and it will make a significant difference in my life if I can get my medication with accessible labels. At present I have to ask the pharmacist to tell me the information and then try to remember what was shared.<br><br>It is important that when I pick up medication, I can get the accessible label at the time I pick up the medication. If this isn't the case then I will have to delay the use of medication until an accessible label is available. I think this option is life threatening.<br><br>Just as important is that there should be clarity on the implementation of accessible labels. The technology already exists and it is time that it is available to people living in Washington state.<br><br>This rule making on accessible labels should be done within 90 days after and the implementation should take no more than 365 days later. In this way, there will be compliance and implementation which is consistent across the state and not dependent on individual pharmacies to decide when they will make accessible labels available.<br><br>Thank you for your time and attention. |
| Shay Tigner | None Given | I am completely blind in one eye and have just a little bit of foggy blur in the other eye. I am a cancer survivor and I take a ton of medication daily to combat treatment side effects.<br><br>Please please help with making prescription labels more accessible, my life depends on medication to keep me alive. I often have to delay taking medication until someone cited [sic] is near me to read the bottles. I am so frightened that my recovery from cancer will be derailed because I can't take medication on a regular basis or might accidentally take too much of one thing. |
| Joleen Ferguson | None Given | Thank you for allowing comments on the need to have accessible prescription labeling for those of us who are blind or visually impaired or otherwise print disabled. In short, they need to be as timely for us as for any other customer. Now that there is technology available, it is important that we can have the same information as readers of standard print. It can be a life-or-death issue for us. Increasing our independence with accessible prescription labeling could be less expensive as it could avoid unnecessary medical costs and negate the need for care-giver management of medications in many instances. |

| | | |
|---|---|---|
| | | My choice a few years ago was to use our local [pharmacy name and location] because of the structured negotiation they had with the law office of Lainey Feingold to provide accessible prescription labeling. To my dismay, they knew nothing about it. The next step was to go to the [pharmacy] website where there was no information. A call to the national office yielded no help. After a few additional calls, someone suggested that my regional [pharmacy] representative would have some information. Her response was that they do provide accessible labels, but hardly anyone asks for them. How can people ask if information is not available.<br><br>Eventually, [pharmacy] did provide audible labels. The next problem was that they would notify me that my prescription was ready. Upon arriving at the store there was frequently no accessible label, and it was necessary to wait for them to have time to record it. They wanted no help or suggestions from me concerning the order the information was given on the recordings. English was not the first language for some of their pharmacists, and the recording quality was very poor and difficult to hear and understand.<br><br>Their method was to use digital recorders that were affixed to the bottle caps—the same as for sale—possibly 3 for 10 dollars. There was no extra charge for me, but there was a paper to sign each time; perhaps to testify of my continuing need and possibly a way for them to be reimbursed. Each time, they used a new digital recorder. They seemed unwilling to discuss options other than using new devices for every refill. These were rather heavy for the double edge tape to hold in place. They worked well if the bottles were not jostled much, but if they were put into a bag for traveling, the recorders would fall off the bottles. It became difficult to stay with that pharmacy.<br><br>Currently, we use [pharmacy]. They are an independent pharmacy offering delivery service for prescription medications.<br><br>Honestly, the accessible labels were mostly for the medications of my husband who is sighted. He is unable to manage his own meds, making it necessary for me to fill his pill box weekly. The home health nurse identified his problem managing his medications 12 years ago. Any such rule must also include the need to administer medications to others such as children or family members.<br><br>The shape of the medications is an identifying factor and a huge help, but when they change manufacturers , it can be confusing without accessible prescription labels. Thankfully, my current, |

| | | |
|---|---|---|
| | | personal need is small because there are only two medications, but my husband takes 6 prescriptions and other OTC pills.<br><br>Yesterday, my sister who is 88 years old and experiencing macular degeneration told me of a potentially dangerous situation. She recently had a hospital stay where her medications were changed. She told me that she has been taking a double dose of one of her medications because she unknowingly had two bottles of the same pills. She realized her error when she noticed that two of the pills were the same shape and asked for help. This gave an opportunity to tell her of the work that is being done to have accessible prescription label information for those of us who cannot read standard print. She was excited to think that it might be possible for her to have increased assurance that she is taking her medications correctly.<br><br>Thank you again for reading and considering this important matter. |
| Lynne Koral | None Given | I am a totally blind person who needs access to medication. I am writing to you because they cannot be any delay in getting prescription medications as this causes a safety risk. According to Title II of the Americans with Disabilities Act no delay in providing medication for my health and well-being should be given in either audio or Braille formats for labels so that there are no overdose problems. We should be getting medication at the same time any other patient gets their medication with labeling provided in Braille or audio format.<br><br>This compliance must be done now and no more delays should ensue. Real lives are being affected. I have my medications mail-ordered and mine are pretty straight-forward, but if I need some liquid that would be more problematic and the dosage should I need a medication not given to me in a way I can read privately and accurately. The Pharmacy Board should not delay in their rule-making as this affects many blind and visually impaired people. Another problem is also that other languages must be accommodated. Comprehension and analyzing the prescription is important in the language of the person who is requesting the medication. |
| John Miller | None Given | And I am writing to support the pharmacy bill<br>For making it easy to read and to order my meds<br>Thank you very much |

| | | |
|---|---|---|
| Don Downing | Clinical Professor, University of Washington School of Pharmacy | 1. The language in subsection 2 refers to **prescription drug containers** that shall contain required information, etc. I believe that by limiting solutions to **prescription drug containers** that we might be eliminating potential solutions for patients. One might argue that using this language might preclude the use of cloud-based solutions that could conceivably provide visual and audible prescription information and that might also, when needed, be translated to innumerable languages.<br>2. Using innovative cloud-based systems might unburden individual pharmacies from purchasing their own solutions, often a substantial cost…thus potentially slowing down pharmacy adoption of accessible prescription labeling. Cloud based solutions that allow consumers direct access to accessible prescription information may not be universally available to all patients, but, I would argue, that no other suggestions provide universal accessibility either.<br>While basing solutions to accessibility on prescription drug containers themselves offers, perhaps, the most obvious immediate answers, I hope that possible non-drug container solutions might not be summarily eliminated by drafted language. |
| Jennifer Nguyen | Pharmacist, Seattle Children's Hospital | I am a pediatric inpatient pharmacist at Seattle Children's Hospital and in my work, I often help the medical team by reviewing prescriptions to make sure they are correct in order to ensure all families are set up to be successful in the outpatient setting. I have seen that there are many opportunities for improvement in health equity. Patients who use a language other than English do not have as much opportunity or access to communication as patients who use English.<br><br>A 2010 national survey of pediatricians found that 44% of pediatricians reported no professional interpreter use, and 57% relied in family members to communicate with patients who use a language other than English. In this way, family members are utilized as ad hoc interpreters which is defined as an untrained person called upon to interpret. (https://pediatrics.aappublications.org/content/132/2/e396)<br><br>Other disparate health outcomes for families who use a language other than English include: they are less likely to have a primary care provider (https://pubmed-ncbi-nlm-nih-gov.offcampus.lib.washington.edu/22424655/), more likely to have adherence-related problems (https://pubmed.ncbi.nlm.nih.gov/15730117/), 3 times more likely to have a second ED visit within 72 hours (https://pubmed.ncbi.nlm.nih.gov/26569079/), and are twice as likely to have a serious adverse event while hospitalized (https://doi- |

| | | |
|---|---|---|
| | | org.offcampus.lib.washington.edu/10.1542/peds.2005-0521 76% of studies found that language-concordant care led to improved outcomes including better patient experience, better glycemic and blood pressure control, higher adherence to medications, patient understanding of diagnosis, and fewer ED visits after discharge (http://www-ncbi-nlm-nih-gov.offcampus.lib.washington.edu/pmc/articles/pmc6667611/). Being a child with parents who use a language other than English was the single greatest risk factor for adverse events during a hospitalization (https://jamanetwork.com/journals/jamapediatrics/fullarticle/2771980?utm_campaign=articlePDF&utm_medium=articlePDFlink&utm_source=articlePDF&utm_content=jamapediatrics.2020.3215). What does that mean for the outpatient setting? Imagine that you are not able to understand the prescription labels on your child's medications. Consider how this demonstrates dominant language, power and structural inequity. We have the power to make a difference, and it would be all the difference if it was your child or loved one.<br><br>I have taken care of a Spanish-speaking Rheumatology patient who misunderstood how to properly take their steroid taper and was subsequently readmitted after decreasing their prednisone dose too fast. I am strongly in favor of advocating for prescription language access as the PQAC reviews what should be put on the prescription label. We must remember that patients rely on prescription bottles with clear and understandable messages in order to safely take their medications. We as pharmacists want to empower our patients to be able to take their medications accurately and appropriately, and thus avoid harm while optimizing treatment benefits. Language is essential to understanding. Access to interpreter usage in the community pharmacy is also important in order to facilitate medication access. To share another example that comes to mind, I have been helping an Afghan refugee family who speaks Pashto. The children speak some English but parents do not. I helped them pick up their medications by speaking with the pharmacist/pharmacy technician to explain why they were there in the pharmacy and verified their name and date of birth (note: DOB given to them on arrival as refugees so it is "made up"), and then confirmed with the family afterward to have them "teach back" to me what they understood after they received counseling from the pharmacist. The pharmacist did not use teach back during counseling.<br><br>We all want our patients to have optimal health and successfully take their own medications. Clear, concise prescription labels would help with that, along with patient's language of care on the label in addition to English. |

| | | |
|---|---|---|
| Richard Molitor, R.Ph. | Individual Pharmacist | I would like to share my concern that it appears that no mention is being made of preparing a Small Business Economic Impact Statement (SBEIS) before moving forward with the regulatory process. In the legislation's language it mentions that pharmacies are required to provide this service to customers for FREE without any opportunity to recoup the potentially significant (>$1000) costs of equipment, software, third-party services, and even staffing. A small, independent pharmacy is at a significant disadvantage with regards to available capital and resources to bring about this service.<br><br>To my best recollection these issues would certainly trigger an accurate SBEIS being performed. |
| Lisa M. Cahoon | Retail Pharmacist | If the patient is visually impaired, it would be very useful to be able to put on the label the sig as well as "refer to included instructions" or something of the sort, and then we provide a full size paper that is basically the label blown up to be 8.5 x 11", with the instructions nice and clear.<br><br>Braille / I<br><br>I've always known that we have interpretation services available to use, but have never witnessed them being used. Logistically, it's also been a problem of "ok, do we use the phone that is 10 feet away, call in, and 3 way call the patient's cell phone?" Or can there be a requirement to, at the counseling window OR register OR a common spot in between to have a phone or 2 that is easily accessible to be used for both the patient and the staff? From asking other staff in many places / chains / pharmacies, it's always been those logistics stopping these services from being used. It's basically just been a sign on the wall next to pharmacy drop off and pharmacy pick up.<br><br>Side note, but also something to consider- these places are never very private and don't convey well to ensuring HIPAA. I feel like most corporations bank on the "well, someone that happens to be passing by and hears something isn't a violation" clause. I would love to see pharmacies more enclosed so that people outside the pharmacy can't hear conversations between staff and offices, and to somehow make the register and counseling area more protected while still being ADA compliant *AND* functional for pharmacy workflow / pharmacist's time.<br>It's a lot to ask, I know. But I feel that these are all great steps towards offering a better future of health, safety, and privacy to all involved. |
| Sharla Glass | Public Policy and Community | **WAC 246-945-(AAA)**<br>2(a)I: probably want to replace “and” with “or” |

| | | |
|---|---|---|
| | Outreach Liaison, En-Vision America | 2(b): I suggest establishing a standard for "reasonably possible" and maybe even replacing it with something like "necessary basic information" otherwise this becomes a loophole and undermines the whole rule. The result is some pharmacies will say it is not reasonably possible for them to put anything extra on the container at all. It must be clear, at least "necessary basic information" must be provided in an accessible format on the container, even if you are providing the rest of the required information in an additional accessible format.<br><br>2(c)?: If Braille or large print are requested, after providing the "necessary basic information" on the container, the remainder of information can be provided in an electronic format for access through text-to-Braille or enlarged print output devices; or with printed sheets in large print or Braille.<br><br>**WAC 246-945-(BBB)**<br>2(a) If oral counseling at the counter is required by law in Oregon, then the same interpreted service must be available. Providing only written translations does not provide opportunities for patients to ask questions.<br><br>3 As above, you may need to clarify, because pharmacists will want to know what to do if the instructions are very long. Whatever information can fit on a prescription label in English, needs to be on the container in the 2nd language as well. If in English, the instructions do not fit on the container and require another sheet of paper, then the same can happen in the 2nd language. The way it is currently written, it makes it seem like you could provide the 2nd language info on a separate sheet of paper which is counterproductive to the intent of the rule.<br><br>Thank you for the opportunity to provide comments. Please feel free to reach out to me if you have any questions about how ScriptAbility can help pharmacies meet these requirements. |
| Rob Geddes, PharmD | Director, Pharmacy Legislative and Regulatory Affairs, Albertsons | Albertsons Companies Inc. ("ACI") operates 188 community pharmacies in the state of Washington under the banners Albertsons, Safeway, and Haggen. In total we operate 1726 pharmacies in 34 states and the District of Columbia. We pride ourselves in being accessible to the patients that we serve.<br><br>ACI would like to take this opportunity to comment on Washington's intent to draft regulations regarding accessible prescription labels. We are aware of similar enacted requirements in Oregon, |

| | | |
|---|---|---|
| | | Nevada, New York, and California. Currently, our pharmacies offer a solution for visually impaired patients by making a prescription reader device available upon request by a patient, patient's agent, or patient's prescriber. These devices use radio frequency identification (RFID) technology to read out the contents of the prescription label and are made available at no cost to the patient. For patients with limited English proficiency (LEP) we translate the instructions into the language of choice for the patient on their prescription label. Additionally, we offer language interpretation services for any patient with LEP. These services assist with identifying the language spoken by the patient, interpreting the counseling and advice of the pharmacist to the patient, and facilitating the communication of any questions or needs the patient has with our pharmacy staff through real-time interpretation. Given ACI's experience with ensuring patients have adequate access to their prescription information, we provide our comments for your state to consider when drafting the regulations below.<br><br>**WAC 246-945-(AAA) Visual Accessibility Requirements for Prescription Information and Prescription Labeling.**<br><br>First, as currently outlined, we believe the regulations are unclear about what options pharmacies must offer to patients with visual accessibility needs. Therefore, we have suggestions to provide clarity to the offered language and question the PQAC members may need to consider as they discuss this language in a future board meeting. The language in Subsection 2, "Accessible Info Requirements," that states "the following options *must* be provided" (emphasis added) implies a pharmacy must offer *all* of the options outlined in (i)-(iii) of Subpart (a). However the use of "and" between Subparts (i) and (ii), combined with the use of "or" between Subparts (ii) and (iii) support a contradictory interpretation wherein a pharmacy could elect to offer *EITHER* (i) and (ii) *OR* (iii). We ask that the language be revised to ensure it is clear which accessibility options a pharmacy must offer to a patient. Furthermore, we suggest retaining the current use of the word "or" to allow pharmacies the leeway to determine which accessibility option(s) best fits what they are able to provide. For example, a pharmacy may have the ability to provide large print font and a prescription reader device but lacks the ability to provide braille labels. Ultimately, the patient's needs will be met by providing a solution that works for them, but the pharmacy will not have to incur the cost of providing all three solutions.<br><br>Second, we would like to respond to the question posed in the draft outline in Subsection 2: "*Should it not be reasonably possible to put the required information on the container label, can it* |

| | | |
|---|---|---|
| | | *be printed on a separate information sheet?"* We posit that the use of a separate information sheet should be allowed, as the larger sized font required for most visually impaired patients will generally not fit on the area of a label designated for the instructions to the patient. Therefore, the use of large font size is generally going to require printing on a separate sheet of paper for the patient to use with their prescription vial.<br><br>Third, regarding the timeframe for implementation contemplated by Subsection 4, we respectfully ask the Commission to consider a 1 year implementation effective date for this Section to ensure all pharmacies have adequate time to update their dispensing systems or execute contracts with third parties, where necessary, to aid in developing a compliant solution.<br><br>**WAC 246-945-(BBB) Translation and interpretation requirements for prescription drug information and standardized medication labeling.**<br><br>First, as referenced above, ACI has recent experience with expanding the accessibility of our labels to the LEP population in other states, including Oregon and Nevada. Oregon was the first state in which we operate that passed a law requiring pharmacies to offer label translation services similar to those that Washington is now considering. The process for developing a solution to translate just the instructions on the label took almost two years. This process was also very expensive for ACI and other pharmacies, so we ask first and foremost that the Commission consider aligning its requirements with Oregon and Nevada as much as possible to prevent starting from scratch on a new solution.<br><br>Second, Subsection 2: Translation Service Directive requires that pharmacies provide both translation and interpretation services of information required by WAC 246-945-016 (i.e., label information). We note first that this Subsection is duplicative of Subsection 3, as both subsections require translation of label information. We propose that the Commission consolidate these expectations into a single section for sake of clarity. Additionally, to align with technology already developed and implemented by pharmacies in Oregon and Nevada, we request that the Commission only require that the instructions be translated to the language of the patient. Requiring all information provided to the patient to be translated will increase cost for the pharmacy and further delay these solutions from being deployed in Washington. The draft outline also poses a question in Subpart (a) as to whether translation and interpretation services can be provided by a staff member or a third-party contractor – we suggest that both solutions should be |

| | | |
|---|---|---|
| | | allowed. We encourage the Commission to not dictate specifically how translation and interpretation services are offered to allow for innovation in the future and to allow pharmacies to exercise their reasonable discretion to meet the needs of the pharmacy and the patients they serve.<br><br>Third, Subsection 3: Translated Info Requirements is confusing and, as discussed above, duplicative of Subsection 2. Subpart (a) cites to itself stating "information described in subsection 3(a)" -- yet there is no information specifically described therein. We presume the reference was intended to read, "information described in subsection 3", but additional clarity is needed.<br><br>Fourth, we understand that Subsection 4: Language Selection is still a work in progress, with the intent that this Subsection will establish those languages in which a pharmacy must provide translation and interpretation services. However, we suggest the Commission mimic what Oregon and Nevada did to determine the appropriate number of languages required to be offered to the public. They reviewed the needs of their state and the number of people who speak a given language. They also reviewed the likelihood of an individual speaking a language and being proficient in English. For example, it is common for European country populations to be proficient in English and therefore the likelihood those language speakers would need translation are relatively low. Requiring too many languages will increase the cost for development and may result in a pharmacy undertaking the cost and never using the service for a patient speaking an obscure language. If there is an area of Washington where there is a significant population of speakers that is unique to that area, a pharmacy can choose to differentiate themselves from others by going above and beyond these requirements to offer label translations services in that language. This would prevent other pharmacies outside of that location of need from having to incur the cost of offering a language that is not needed in their patient population.<br><br>Fifth, in Subsection 6: Third-party Vendor Usage, the limitation of liability as currently drafted is limited to translation services provided by a third-party. Because the proposed regulation contemplates requiring interpretation services in addition to translation services, and because third-parties are likely to perform both services on behalf of a pharmacy, we recommend that the limitation of liability extend to both interpretation and translation services by a third party.<br><br>Finally, regarding the implementation timeline in Subsection 7, from our experience it takes time to either develop a solution or execute a contract with a third-party company to provide label translation services. The work only begins with the contract being executed because that third party |

| | | |
|---|---|---|
| | | will have to integrate their software with the dispensing system the pharmacy uses to translate the labels being used for the prescription vial. If Washington aligns its regulations with Oregon and Nevada regulations, any pharmacy who operates in those states will have a head start on compliance. There are many regional chains and independent pharmacies that won't have that advantage and will have to start from scratch. Additionally, if Washington chooses to require translation of more than the instructions on the label, we will all be starting over from scratch to build a compliant solution that will require extensive user acceptance testing to ensure the solution is not only compliant but yields a high-quality translation for the patient. Regardless of that decision, for the sake of all interested parties a minimum of two years for implementation after the regulation passes, should be considered. |
| Deeb Eid, PharmD | Senior Advisor, Pharmacy Regulatory Affairs, CVS Health | **WAC 246-945-(BBB)**<br>**Subsection 2**<br>Suggestion to allow for translation information to be accessible via a separate sheet/handout. Placing too much information on labels can be hazardous/cause confusion for patients. Allowance for pharmacies would ensure patients can receive materials in a easy to read format.<br><br>**Subsection 3**<br>What is the intention here for the term "separate sheets"? Does this mean an allowance for separate printed sheets/handouts, or would this include other sheets such as required REMS, manufacturer drug monographs, etc.?<br><br>**Subsection 5**<br>Notifications delivered orally/verbally to LEP who need translation by pharmacy staff who likely do not speak various languages will be unsuccessful. Other states such as NV and OR do not require verbal/oral notifications. Remove Subsection 5(b) for this reason. |
| Lorri Walmsley, RPh, FAzPA | Director, Pharmacy Affairs, [pharmacy] Co. | Regarding visually impaired labeling, we would respectfully request that a pharmacy may have multiple ways in which they comply. As proposed in the draft, it would appear that a pharmacy would need to provide both large font and braille or a prescription reader. Additionally, the requirement to include all elements in WAC 246-945-016 is not a current standard of practice for these devices. Current practice is to include the following most critical label elements; drug name, dosage, instructions, warnings, contraindications, pharmacy information, doctor name, prescription number, and date. Specifically WAC 246-945-016(1)(c),(d),(e) and 246-945(2),(3) would be difficult |

| | | |
|---|---|---|
| | | for any pharmacy to comply with. We would suggest that larger font be allowed to be provided on a separate sheet; this allows for a larger font than what could appear on a label due to space constraints.<br><br>Regarding translated labeling requirements, we respectfully request that only the directions for use be considered in this requirement. Of the four states that have any translation mandate (CA, NV, NY, OR), none of these states require that all label elements be translated. Anything further than directions would need significant IT updates for all organizations to comply. Regarding the notification requirement, we request that the Commission keep the requirement simple: a notice must be posted so that organizations can determine how best they can comply to keep signage uniform from state to state. Alternatively, the Commission should provide standard signage that a pharmacy may use to comply. |
| Beth Greenberg | 2nd Vice President, Clark County Council for the Blind | My name is Beth Greenberg and I live in Vancouver Washington. I go to a [pharmacy] at 25th and Main in Vancouver, it is the closest pharmacy to my house at a 3/4 mile walk away.<br><br>I have been going to this [pharmacy] for 4 yrs now. I have created a profile with [pharmacy] and use their app to fill my scripts. On this profile I have requested my scripts be in large print but I have not seen a large print label on the script bottles. I am legally blind and since they are not labeled in large print I have to use the magnifier on my phone to read the labels. Which can be cumbersome when you are trying to fill a pill case for the week. Sometimes instead just go by the color of the pill to know what script it is and to fill it with how many I need. This has caused me some problems lately. Both my Tacrolimus (an immunosuppressant) and my Gabapentin (to help me with my migraines and hot flashes) are both yellow and white capsules. I did not know of taking more Gabapentin has not hurt me, but not taking enough tacrolimus has hurt my stem cell graph in my left eye and I have had some pain and eye strain headaches and had to get a steroid shot in my eye yesterday to help with the inflammation. I have learned no by feel that the Gabapentin is a bigger capsule than the Tacrolimus. But the damage has been done. Only if I had known that I had taken more Gabapentin and not Tacrolimus and was taking 3 extra pills of Gabapetin (suppose to take 2 10mg a day) than was prescribed and NO tacrolimus (which I am suppose to take 5 1mg pills a day).<br>As I have mentioned, the Tacrolimus is one of the immune suppressants that I take (I take 2). It is really important that I don't miss a dose of either one and getting a label on the script when it is needed in a timely manner like that day I order it or the next day NOT in 3 days. “Per Title II of the |

| | | |
|---|---|---|
| | | ADA, no delay of care; no unequal treatment: Labeling options shall be offered to the patient in the same dispensing timeframe as offered on medications using traditional labeling. “<br><br>I am not the only blind/visually impaired person that needs this legislation to go through NOW.<br><br>There are so many more senior citizens that are having a hard time seeing or hearing that don't need to have extra medical bills because they took too much or too little of a medication that they are supposed to take. I don't want to see anymore people get hurt because they can not read the labels or God forbid die.<br><br>Thank you for your time. |
| Zandra Brown | Past President, Capital City Council of the Blind | It has been brought to my attention that the Pharmacy Commission will be working on Accessible Prescription Label Rulemaking at the January meeting, and have asked for comments on this issue by January 5, 2023. As a visually impaired prescription consumer at [pharmacy name and location], I am concerned that I am unable to receive equal access to my prescriptions compared to the general public.<br><br>When I request a large print label and talking label, I am required to wait three business days, and sometimes more, for my prescription with an accessible label. I get a text frequently from the [pharmacy name and location] that my prescription is ready, typically within a couple hours of ordering a refill, or having a new prescription FAXed to them from my health care provider. However I am then required to wait for at least three business days for the accessible labels. Since my insurance provider only allows a short period of time for me to request refills before the previous date the medication has completed and is ready for renewal, the requirement to wait three business days for accessible labels means I often have to go without my medication for a few days, or pick it up without accessible labels. Either way this is a major safety issue, and is not equal access. This is especially a problem when three day weekends are figured in to that “three business day” formula.<br><br>For instance, let’s say the earliest my insurance provider will allow me to request a refill of a needed medication is on a Thursday. I call it in that Thursday, then Friday being the first full day, we have a three day weekend for a holiday, the earliest I could pick up my prescription with an accessible label would be the following Wednesday, and that is if they’ve received the accessible labels from their |

| | | |
|---|---|---|
| | | source, which is often delayed by the holiday weekend. So, the three business day requirement becomes more like a week. This even though the prescription itself had been filled and was ready the same day I called it in. The only delay was for the accessible labels.<br><br>I feel that there should be equal access at the pharmacy for those of us needing accessible labels as compared to those receiving standard labels. Certainly the technology is there for each pharmacy to have accessible label making equipment in all local pharmacies. And indeed some pharmacies do just that. I assert that they all should be required to. It is not a cost prohibitive request, and to not allow equal access to accessible labels for the visually impaired, as compared to traditional labels, feels discriminatory, and an unnecessary burden, in my opinion. It also appears to be against the intent of the Americans With Disabilities Act, (ADA).<br><br>As the recent past president of Capital City Council of the Blind I have heard a similar story form one of my members using the [pharmacy name and location], that she has been required to wait for a week or more for accessible labels for her prescriptions. I have also heard that some [pharmacy] locations do not offer accessible labels at all.<br><br>On another note, since Washington Council of the Blind, and other WA community members have requested rulemaking over a year ago, I would request tighter timelines on completion of this issue at this point. I would request rulemaking be completed within 90 days, and that WA Pharmacies be given a deadline of no more than 365 days once rulemaking is established to implement the criteria.<br><br>In conclusion I request that language be tightened up to avoid more "wiggle room" around the issues of equal access to prescription labels. Instead of vague wording in the draft like "in a timely manner" I stress the importance of equal access for accessible labels. I also stress the need for concrete timelines for implementation of this rulemaking as outlined above.<br><br>Thank you in advance for hearing and considering my concerns. Please feel free to contact me if you have any questions or comments. |
| Alison Poulsen | Executive Director, Better Health Together | On behalf of the Board and staff of Better Health Together, thank you for the opportunity to provide feedback on the outline draft for the Accessible Labeling rulemaking process. Better Health Together works with a diverse and growing set of partners from throughout a six-county region and three tribal reservations in Eastern Washington to create accessible access to whole-person care. |

| | | |
|---|---|---|
| | | Better Health Together strongly supports efforts to ensure prescription drug labeling is accessible to members of our community with limited English proficiency or visual impairment. This is not only an issue of patient safety but also an issue of equity.<br><br>As you prepare to engage in the rulemaking process, we would like to encourage you to consider lessons learned from states such as Oregon and Nevada that have already adopted similar rules. In particular, we encourage our state's rules:<br><br>1. **Ensure the number of languages available for translation matches our state's population.** We recommend that the Commission leverage available technology to ensure the maximum number of languages are available for translation. Specifically, we recommend that translation be available for languages spoken by 5% of the state's population or 1,000, whichever is fewer. We also recommend inclusion of large-print Braille and talking audio labels be available by request.<br>2. **Prescription instructions in English as well as the patient's preferred language.** This is important if a patient brings their prescription to an emergency room or another medical setting. In these instances, it would be necessary for medical professionals to have quick access to the prescription instructions in English.<br>3. **Timing.** We all share the goal of patient safety and minimizing adverse patient outcomes. As such, we recommend an implementation timeline that balances the need for pharmacies to make practice changes with the shared priority of patient safety. This is another opportunity to look to other states for lessons learned to expedite implementation. |
| Judy Brown | Advocacy Committee Co-Chair, Washington Council for the Blind | Some of you may recognize my name as the person who asked for rulemaking regarding accessible medication labels in November of 2020. I have been part of many discussions on this issue since that initial request. I am now writing to tell a personal story and how, as a legally blind, full-time working nurse, I gave myself the wrong medication because I could not read the label.<br><br>I lost most of my vision March 18, 2017 due to a genetic defect in my optic nerves. The vision loss started three months earlier in my right eye. I was experiencing fuzzy vision and altered color perception. The condition had no diagnosis. I was still able to see from my left eye and with glasses my right eye still had some usable vision. I was still able to safely work and drive. Then, on 3/18/17 I woke up and my vision was worse than 20/400 in BOTH eyes. I could no longer work. I could no |

| | | |
|---|---|---|
| | | longer drive. I could not read. I could not recognize my daughter by sight. My color-vision was basically gone except for some blue colors and yellow. Red looked like a muddy brown. Brown looked black. Green looked yellow. I could not recognize even the most familiar things to me – the trees outside my window.<br><br>I have a seizure disorder. Since the age of 12, my seizures and the cause have been misdiagnosed. They have been treated with various medications, but I always had occasional focal seizures that caused brief left leg weakness. These seizures were undertreated for years until I finally found the right specialist here in Washington state. I was placed on a medication that eliminated the focal seizures without over sedating me.<br><br>My dosage was changed again after I lost my vision. I got the new medication prescription filled at Rite Aid. I asked for a large print label so I could read the med name and dosage instructions. I was told that large print was impossible. I asked about a talking label. I was told there was no such device. I was told to find someone sighted to administer my medication to me. My independence, self-worth and privacy were all taken away from me by that one statement in 2017.<br><br>I tried to memorize the instructions because I had not yet figured out an alternate method of knowing what my medication label said. I had lost my vision only a few weeks prior and still was undiagnosed and had not yet had any support services from the Department of the Services for the Blind. At that point, I did not know that agency existed. I had no options except to try to rely on my memory during one of the most stressful times in my life.<br><br>I overdosed myself.<br><br>Luckily, I figured out what the issue was when I developed a pronounced ataxic gait, so I was not hospitalized. But the fact remained, that a former critical care trauma and recovery room nurse with decades of experience had overdosed herself because she could not read the label on her medications.<br><br>I later found out that talking labels have been available since the early 2000's. Also, in December of 2016, Rite Aid had agreed to a structured settlement with the American Council of the Blind to offer accessible medication labels nationwide. Since there was no built-in enforcement in this structured settlement, Rite Aid did not comply with the terms of the settlement. So when I tried to have |

| | | |
|---|---|---|
| | | accessible medication labels in April 2017, the local Rite Aid was not aware of the terms of the settlement and offered nothing.<br><br>Recently, I had a surgical procedure and was prescribed post-op medications. I made my own large print type of labeling since nothing was available to me from the dispensing pharmacy.<br><br>Patients should not be forced to make their own accessible medication labels. This is dangerous. This is poor patient care. Misreading or not understanding your medication labels is a major cause of emergency room and, at times, hospital, admissions. Millions of healthcare dollars are spent annually treating patients who make medication errors. Some patients die due to these errors.<br><br>The technology for audio/talking labels has been available for over 20 years. Making a label in a large font size is technology that could have been available for years. Braille was created in 1824. All of the pieces of accessible medication labels have been around for decades, yet nothing has been done in this state to accommodate persons with a visual impairment.<br><br>The Commission needs to act swiftly and definitively to correct this long-standing issue.<br><br>Patients in Washington state deserve no less. |
| Marci Carpenter | President, National Federation of the Blind of Washington | The following represents the feedback from the hundreds of members of the National Federation of the Blind of Washington on this subject. This position was reached after multiple conversations within our community and with blind people who are not members of any organization. We strongly support the promulgation of rule making on accessible prescription labels and labels in languages other than English.<br><br>First, a note about definitions:<br><br>“blind” - those persons who identify as blind. Most of the people classified under the legal definition of blindness do, in fact, have some residual eyesight. A definition which is confined to the legal definition of blindness does not include all who identify as blind. Many people have eye conditions which, while they do not qualify under the legal definition of blindness, nonetheless require that the person utilize alternative, non-visual techniques and are functionally blind. |

| | | |
|---|---|---|
| | | "low vision" - those who identify as low vision.<br><br>"print disabled" - those who do not have a physical eye condition which prohibits them from comfortably using standard print but who may have a learning disability or other condition which results in a major difficulty in reading standard print.<br><br>"large print" - 18 point font size (18 point) is a generally accepted standard for large print. Some people are more comfortable with different font sizes and you will never find one size which every person says they need but this is the standard.<br><br>Our feedback:<br>1. Accessible labels must be provided in the reading media used by the patient and must include the following options: Large print, braille and audio formats. It is vital that a pharmacy not limit provision of labels in just one or two formats. This may necessitate some state assistance for small pharmacies, especially in rural areas. a person requiring accessible labels may move into a rural community at any time and must have the option to obtain accessible labels in their preferred reading media<br><br>2. Accessible labels must be provided at the same time as the prescription is dispensed. Delays cause a danger to patient safety. Again, we recognize that this may necessitate some kind of state assistance.<br><br>3. Rules must take effect no more than one year after they are issued. Delays in implementation will cause health risks for patients.<br><br>4. When stand-alone readers are provided to assist patients in reading talking prescription labels, these readers must be provided at no additional cost to patients.<br><br>5. We fully support the provision of prescription labels in languages other than English. There are many people in Washington who may not speak English and who are also blind, low vision or print disabled.<br><br>A note about PQAC meeting platforms: |

| | | |
|---|---|---|
| | | Zoom is the most accessible meeting platform and is the one utilized by blindness consumer organizations, the Washington State School for the Blind, the Washington Talking Book and Braille Library and the Washington State Department of Services for the Blind when hosting public meetings. It is the easiest platform to use for those who need screen reader technology to access online meetings. It is also extremely difficult for us to access chat and Q&A features when using this technology because it requires trying to listen to the ongoing conversation at the same time as we are attempting to listen to chat or Q&A features. I would be happy to discuss this further should you have any questions.<br><br>We are eager to work with PQAC on the further development of proposed rules. We would ask that you provide multiple ways of giving feedback by our community, including evening or weekend listening sessions to gain input for those who work full time and also assessable online feedback methods. |
| Dorene Cornwell | Advocacy Committee, Washington Council for the Blind | I am writing to strongly support moving forward on rulemaking to ensure patient access to prescription label information both in the language of their choice and in formats that are accessible to people who are blind, low vision, and print impaired.<br><br>These two dimensions of access to information have been addressed differently in different states. WA is the only state I know of where advocates for language access and nonvisual access are collaborating.<br>Technologies exist to go a long way toward improving access in terms of both dimensions.<br><br>What is needed is both political will and targeted implementation timelines to support testing, outreach, education of both pharmacy<br>providers and the public. Rulemaking also needs to recognize that<br>one size does not fit all in terms of pharmacy size, population, familiarity with technology. Rulemaking also needs to provide standards to ensure the quality of the language services provided. Finally, rulemaking should suggest some ways to document that community needs are identified and documented and to measure how well community needs are being met.<br><br>Many of you are probably familiar with my voice in legislative work last year and over the past year with the Pharmacy Quality Assurance Commission, the WA Pharmacy Association , the health Equity Circle Language Access Team, representatives from WCB and NFB of WA and various other |

| | | |
|---|---|---|
| | | stakeholders about collaborative efforts to ensure that patients have meaningful access to prescription label information in the language of their choice and in formats accessible to patients who are blind low-vision and print impaired.<br><br>I speak wearing several hats.<br><br>I am legally blind and cannot easily read my own prescription labels.<br><br>I informally collect lots of accounts of people aging into blindness who do not identify as blind, are not connected with blind consumer groups, and struggle in many parts of life<br><br>I have worked enough in translating and interpretation to recognize the difficulties of words that, for example, look the same in English and Spanish but mean completely different things. Likewise prescription drug names can sound very similar except that one or two syllables different indicate drugs with completely different functions.<br><br>I live in a multilingual low-income community and observe that work as a caregiver is a fairly low barrier job entry point for many immigrant women, women who may understand spoken English better than written English. I am also for family reasons aware that in multigenerational households, different family members frequently have different levels of fluency and comprehension in English or in another language.<br><br>I have worked enough in healthcare report writing both to understand many IT issues and to be aware of cost and quality of care consequences of prescription mistakes<br><br>While I myself love technology, I also recognize that many people either don't love it, find it hard to learn, or don't have access at all.<br><br>I personally hope the Commission sees its role as setting standards and then letting organizations providing pharmacy services in WA figure out how to meet them. While i understand that change takes time, I also support rulemaking that encourages people providing services in WA take steps as soon as possible to plan and implement efforts to improve access to prescription label information that is both linguistically appropriate and usable for people who are blind, low-vision, and print-impaired. |

| | | |
|---|---|---|
| | | Thank you very much for noting these comments. I look forward to hearing specific plans from the Commission for next steps forward more stakeholder engagement, and continual evolution of accessible and inclusive work processes. |
| Delphine Zhu<br>Domeg Moore | Health Equity Circle Language Access Team | We are writing this letter to advocate for greater language access services across Washington State Pharmacies.<br><br>We write to you as members of the Health Equity Circle Language Access Team, an interdisciplinary group of future healthcare providers, and allies. This issue is important to us because of our personal experiences with language access. Barriers to language access are unfortunately a common issue in healthcare that adds fear, confusion, and potentially grave consequences to the already complex task of navigating healthcare. One of our members shared her experience while helping her father with limited English skills navigate his spine injury as a child:<br><br>"I think it is one thing to see your family member in pain while suffering an illness, but seeing my parents' confusion and inability to advocate for themselves created an entirely new element of devastation and worry for their health. As we navigated one appointment and treatment plan to another without available language services to aid continuity of care, my father's loss in his quality of life and decreased presence in my childhood extended for years instead of months. It felt unfair to bear the burden of advocacy and pain as a child but the lack of accessible language translation services left our family with limited options to take my father's disease into his own hands."<br><br>We heard similar stories through conversations with numerous community members across the state; one of the foremost threads we heard was a need for translated prescription labels. Providing accessible communication in the form of translated prescription labels allows people to have a greater ability to care for themselves. We believe prescription label accessibility must extend to members of our community with limited English proficiency and who are blind, low-vision, and/or are print-disabled.<br><br>We are grateful for our numerous conversations with pharmacy groups, including the Washington (WA) State Pharmacy Association, Walgreens, Northwest Grocery Association, and the WA State Hospital Association. Our shared interest in patient safety has allowed for informative discussions that shape our priorities for the languages and visual accessibility accommodations offered, what |

| | | |
|---|---|---|
| | | we can learn from other states, and technological capabilities in translation. We ask you to consider each of the below points as unique and core to our team's efforts in order to improve continuity of care, provider-patient communication, caregiver and patient burden, and patient independence and safety.<br><br>**Language translations and accommodations for visual access offered at pharmacies:**<br><br>On the behalf of our communities and all of those impacted by language access barriers, we would like to advocate for the use of existing federal Civil Rights Title VI requirements as a guide for regulations to meet standards as soon as possible.[1] The WA DOH COVID-19 Language Access Emergency Plan has already identified 37 languages within the state that are spoken by at least 5% or 1,000 people in Washington.[2] The Title VI requirements establish an equitable and effective standard to address the known needs of our communities. As the number of people who are bilingual, low-vision, blind, or print-disabled continue to increase within our state, it is imperative that we prepare to the best of our abilities to serve them. This is an opportunity for WA state to be a national leader in accessibility on prescription labels and pave the way for future states to follow.<br><br>In the effort to comply with existing civil rights laws as soon as possible, we recommend rules that will improve the standard for patient-pharmacy experiences across WA pharmacies. This includes:<br><br>• Prescription labels printed in English and the requested language on the bottle<br>• Common Sig codes translated on labels for languages spoken by 5% of the state's population or 1,000 people, whichever is fewer<br>• Large-print, Braille, and "talking" audio labels offered in all pharmacies<br><br>**Timeline for implementation:**<br><br>Additionally, Oregon's precedent in adopting improved language services highlighted the ability to comply and urgency of prioritizing patient safety and reducing adverse patient outcomes when considering a timeline. As such, we recommend:<br><br>• 90 days for completion of the PQAC rule-making process<br>• Maximum of 365 days for compliance following the adoption of new rules |

| | | |
|---|---|---|
| | | **Current technological capabilities and potential:**<br><br>We acknowledge that previously there have been technological barriers that have made prescription drug label translations challenging. However, new technology and precedents from other states (including New York, California, and most recently Oregon and Nevada) have shown that we are ready to take the next steps towards overcoming language barriers in fulfilling the civil rights goal of Title VI. Our team has identified several software options that offer translated SIG codes in 31 languages with more to be added within the next year. We have worked meticulously to address some of the challenges and concerns expressed by pharmacists by confirming companies prioritize quality translations, flexibility with integration and interoperability, and alternative label printing that allow for dual-language printing. Our explorations of software capabilities and from experiences from other states supports that implementation can happen now and be successful at meeting Title VI requirements.<br><br>The Health Equity Circle supports the WA Council of the Blind and National Federation of the Blind - WA Chapter groups in their efforts to have labels offered in Braille, large-print, and audio format. We urge the Commission to review and adopt the suggestions for labeling as outlined in the WA Council of the Blind and National Federation of the Blind - WA Chapter's letters.<br><br>We ask that you review the points highlighted in this letter as you move forward with drafting rules language and extend our deepest appreciation of your time. |
| Michael MacKillop | Executive Director, Department of Services for the Blind | As the Pharmacy Quality Assurance Commission considers solutions for the accessibility of prescription labeling for Washington State residents, I wanted to offer my gratitude to you for seeking solutions for individuals who are blind, low vision, deaf blind, or have print-access disabilities. Safe and accurate access to required medications is a key to maintaining one's health and independence.<br><br>Visual disabilities often occur with more frequency as we age. The American Community Survey conducted annually by the US Census Bureau shows that 2.2% of Washington State's population, 6% of Washingtonians aged 65 and over, and almost 10% of those aged 75 and over experience a visual disability. There are over 160,000 individuals who are blind, low vision or deaf blind in this state. |

| | | |
|---|---|---|
| | | The steep increase in incidence of vision loss as we age indicates that the access solutions need to be simple and easy to learn. Complex technical solutions could be a challenge for many individuals new to blindness, especially if that occurs later in the life cycle.<br><br>There is a need to consider multiple access solutions.<br><br>Braille is the best access solution for many, but it is not a universal solution – many individuals who lose vision in their 70's aren't fluent in reading Braille.<br><br>Audio access is a great solution for many, but does not work for those who experience both a visual and hearing disability.<br><br>Technology, such as use of a smart phone app or QR code can provide an excellent solution for savvy tech users, but many people don't have the means to acquire technology, and there can be steep learning curves for those new users who do.<br><br>Also, access solutions for those with a visual disability need to align with language and literacy access – visual disabilities cross all cultural backgrounds. It is not unusual for a blind individual in Washington State to only be able to access their medical information in a language other than English.<br><br>It is critical that you arrive at a solution that works for all and that is implemented as soon as possible. People with visual disabilities risk their lives, health and independence when they don't have real-time access to their medication information. This lack of access to prescription and medical information can be a primary deciding factor for people in determining whether they can stay at home and live independently after experiencing a vision loss, or determine that they will need to rely on care.<br><br>The solutions you create now will have major quality of life impact of Washingtonians with visual disabilities. Again, I am grateful that you are working towards a solution.<br><br>If you have questions or hope to be connected with other community voices on the subject, please let me know. |