



WASHINGTON STATE PHARMACY QUALITY ASSURANCE COMMISSION

newsletter to promote pharmacy and drug law compliance

No. 1368 Retired Active Pharmacist License Status Rulemaking Update

The CR-101 was filed on April 19, 2021, under Washington State Register 21-09-063, initiating permanent rulemaking to allow retired pharmacists to apply for a retired active pharmacist license status and practice pharmacy under certain conditions, such as in a state of emergency. For more information on the permanent rulemaking, please visit this [link](#). For more information on the current emergency rules for the retired active pharmacist license status, please visit this [link](#).

No. 1369 Inspection Required for Remodels and Modifications

At the March 5, 2021 business meeting, the Washington State Pharmacy Quality Assurance Commission provided clarification on Washington Administrative Code (WAC) 246-945-230(3) (a) and the inspection requirement for modifications or remodels for facilities licensed by the Commission. This guidance on inspection requirements for remodels or modifications is now available [here](#).

No. 1370 SHB 1445 (Definition of Compounding) – Signed!

Substitute House Bill (SHB) 1445 amends the definition of compounding for the practice of pharmacy in Revised Code of Washington (RCW) 18.64.011(6) to:

(6) 'Compounding' means the act of combining two or more ingredients in the preparation of a prescription. **Reconstitution and mixing of (a) sterile products according to federal food and drug administration-approved labeling does not constitute compounding if prepared pursuant to a prescription and administered immediately or in accordance with package labeling, and (b) nonsterile products according to federal food and drug administration-approved labeling does not constitute compounding if prepared pursuant to a prescription.**

This change will align Washington State's definition of compounding with that of Food and Drug Administration (FDA) and United States Pharmacopeial Convention (USP) in their forthcoming revised USP chapters and lower administrative burdens for pharmacists across the state.

Governor Jay Inslee signed SHB 1445 on April 16. The law will go into effect 90 days after the last day of the session, or **July 25, 2021**.

No. 1371 Commission Approves New Third-Party Program for Out-of-State Wholesalers

At the April 23, 2021 business meeting, the Commission voted to recognize the National Coalition for Drug Quality & Security (NCDQS) as a third-party inspection program for out-of-state wholesaler applicants. Please see the Commission's updated FAQ below.

Q. Are there any Commission-recognized third-party inspection programs for out-of-state wholesalers?

A. Yes, the Commission recognizes **NCDQS** as well as the **National Association of Boards of Pharmacy® Drug Distributor Accreditation** (formerly known as Verified-Accredited Wholesale Distributors®) as third-party inspection programs for wholesaler applicants located outside of Washington State. The Commission added approval for NCDQS at the April 23 business meeting.

As stated in **WAC 246-945-246(3)(a)**, wholesaler applicants located outside of Washington State need to include a site inspection report conducted by the regulatory authority in the resident US jurisdiction or a third-party inspection report from a program recognized by the Commission with their application.

No. 1372 Specialized Function FAQ Update

Q. Do tech-check-tech training programs or other specialized functions performed by technicians require Commission approval under the new rules?

A. No, there are no specific training requirements for pharmacy technician specialized functions under the new rules. However, **WAC 246-945-315(2)(a)** states that when delegating a pharmacy function to a pharmacy technician, "A pharmacist shall consider the pharmacy technician's scope of practice, education, skill, and experience and take them into account . . ." **Lastly, the additional function (formerly the specialized function) must be included in the ancillary utilization plan (AUP), which still requires Commission approval.**

Note, the Commission may adopt guidance documents to define the scope of training for specialized functions as deemed necessary (eg, **pharmacy technician administration**).

Follow this [link](#) for all FAQs on Chapter 246-945 WAC.

No. 1373 Controlled Substances WA DOH E-Prescribing Waiver

In June 2020, in response to the coronavirus disease 2019 (COVID-19) crisis, former Secretary John Wiesman waived the authority contained in Senate Bill 5380. This waiver was set to expire on September 30, 2021. Umair Shah, MD, MPH, the secretary of health for Washington State, has extended the waiver to be in compliance with the electronic prescribing requirement in

RCW 69.50.312(1) **until January 1, 2022**. All health care providers subject to the e-prescribing requirement must either be in compliance with RCW 69.50.312(1) or meet at least one of the exemption criteria in RCW 69.50.312(2) on that date. The exemption criteria include the possibility of health care providers receiving another waiver issued by the Washington State Department of Health (DOH). View Dr Shah's letter [here](#).

For more information or questions on the e-prescribing requirement and the secretary's waiver, please contact PharmacyRules@doh.wa.gov.

No. 1374 Updated: Statewide Standing Order for Administering COVID-19 Vaccines

Centers for Disease Control and Prevention and FDA have recommended that use of Johnson & Johnson's Janssen COVID-19 vaccine resume in the US, [effective April 23, 2021](#). The updated Janssen (Johnson & Johnson) COVID-19 Vaccine Standing Order is now available. The updated standing order removes some of the inactive ingredients noted in Table 1 of the document. For further review, please see [Janssen COVID-19 Vaccine](#) (Johnson & Johnson) Standing Orders for Administering Vaccine to Persons 18 Years of Age and Older.

As a reminder, these standing orders enable health care professionals authorized by law to administer COVID-19 vaccines in the state of Washington to assess and vaccinate persons who meet the criteria in the "Procedure" section of the standing order without the need for clinician examination or direct order from the attending provider at the time of the interaction.

For example, under state law, nurses may administer vaccines only under the prescription of certain kinds of prescribers, which do not include pharmacists. These standing orders provide nurses the legal authority they need to assist pharmacies with their vaccination efforts. Providers need to abide by their normal standards of practice and governing laws in operating under these standing orders.

The links below will take you to the other standing orders for the administration of the Moderna and Pfizer vaccines.

- [Moderna COVID-19 Vaccine](#) Statewide Standing Order for Administering Vaccine to Persons 18 Years of Age and Older
- [Pfizer-BioNTech COVID-19 Vaccine](#) Statewide Standing Order for Administering Vaccine to Persons 16 Years of Age and Older

No. 1375 What Are 'Drugs of Concern' in Washington State?

Drugs of concern are defined in [WAC 246-945-001\(23\)](#) as those drugs identified by the Commission as demonstrating a potential for abuse by all professionals licensed to prescribe or dispense such substances in the state. Currently, there are no drugs of concern listed in Washington State.

If the Commission identifies a drug of concern at a future date, it will collaborate with the prescription monitoring program on implementation in accordance with [RCW 70.225.020](#). Any decision regarding listing a substance as a drug of concern would be done at an open public meeting.

No. 1376 AUP Technical Assistance

For pharmacies submitting an AUP, please follow the process of submitting the pharmacy AUP along with the completed pharmacy license application (eg, new, change of ownership, or change of location) to the credentialing department at the address provided on the application. Once all the information is received by the credentialing department, it is reviewed for any deficiencies. If the application meets all the requirements, it is then forwarded to the Commission program staff for review and preparation for an upcoming Commission meeting. There is a 60-day minimum requirement before the Commission meeting for submitting any materials to the Commission for review. If the applications do not fall within that window, they are moved to the next Commission meeting consent agenda. To avoid longer wait times and discrepancies, the materials must be submitted to the credentialing department directly. The Commission thanks licensees in advance for their patience as the Commission knows there have been unforeseen delays due to the pandemic. The applications can be found at <https://www.doh.wa.gov/LicensesPermitsandCertificates/FacilitiesNewReneworUpdate/Pharmacy/PharmacyLicensing>.

No. 1377 Technician Training Program FAQ

Q. Do I need to include a separate AUP with my pharmacy technician training program application?

A. Yes. Both the technician training program's AUP and the general AUP mentioned above require two separate approvals by the Commission as these are two independent processes with the department. These AUPs may be identical or different depending on the duties/responsibilities specified in the technician training program.

New pharmacy technician training program and renewals should be submitted directly to the credentialing department for Commission review and approval. Materials outlined in the [Guidelines for the Implementation of a Washington Pharmacy Technician Training Program](#) should be submitted to the credentialing department at the address provided on the application. In some cases, your AUP may be identical to the one for active pharmacy technicians or slightly different depending on the responsibilities permitted for those technicians in training. Once materials are received by the credentialing department, they are reviewed for any deficiencies. If there are no deficiencies, they are forwarded to the program staff for review and preparation at a minimum of 60 days before a Commission meeting. Pharmacy technician training program approvals are part of the consent agenda and once they are approved, Commission staff moves them back to the credentialing department for final processing (eg, approval letter). The application for the pharmacy technician training program can be accessed by using the Pharmacy Technician Education and Training Program [Approval Form](#).

No. 1378 Important Update for Wholesalers – Suspicious Orders and Due Diligence – Zero Reports

Updated Guidance From the Commission

At the June 3, 2021 business meeting, the Commission provided additional guidance on [WAC 246-945-585\(1\)\(b\)](#) (Wholesaler – Suspicious Orders and Due Diligence – Zero Reports).

Zero Reports: The Commission voted to authorize rulemaking to amend WAC 246-945-585(1)(b) in order to modify the zero report submission requirement. In this rulemaking, the Commission will consider alternatives to the zero report requirement, such as storing reports on site in lieu of submitting them to the Commission. This approach varies from the current submission to the Commission option for zero reports.

The Commission voted to extend enforcement discretion of the submission of zero reports for 12 months (until June 1, 2022) or until the rulemaking is complete, whichever comes first.

Suspicious Order Reports: As of June 1, 2021, suspicious order reports **must be submitted** to HSQAComplaintintake@doh.wa.gov. Reports may be submitted in any readable electronic format (eg, email, Excel attachment), but must include **all** information required in [WAC 246-945-585\(1\)\(a\)\(i\)-\(ix\)](#).

Exemption From Reporting: Wholesalers may apply to the Commission for an exemption from the reporting requirements if they do not distribute controlled substances or drugs of concern using this [form](#).

Please contact the Commission with any questions at PharmacyRules@doh.wa.gov.

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Lauren Lyles-Stolz, PharmD - State News Editor

Lemrey "Al" Carter, PharmD, MS, RPh - National News Editor & Executive Editor

Amy Sanchez - Publications and Editorial Manager

Department of Health | PO Box 47852 | Olympia, WA 98504-7852 | www.doh.wa.gov/licensespermitsandcertificates/professionsnewrenewupdate/pharmacycommission