**WSR 24-01-102**
**PERMANENT RULES**
**DEPARTMENT OF HEALTH**
(Pharmacy Quality Assurance Commission)
[Filed December 18, 2023, 12:59 p.m., effective January 18, 2024]

Effective Date of Rule: Thirty-one days after filing.

Purpose: Incorporation by reference for sections of Title 21 C.F.R. In 2020, the pharmacy quality assurance commission (commission) consolidated multiple chapters of rules into chapter 246-945 WAC that covers the practice of pharmacy. This adopted rule amends WAC 246-945-040(1) to incorporate Title 21 C.F.R. by reference for the purpose of capturing any changes made to Title 21 after WAC 246-945-040 went into effect on July 1, 2020. A new subsection, WAC 246-945-040(2), was also adopted for the purpose of providing individuals directions for acquiring copies of the reference material listed in subsection (1) for public inspection.

Citation of Rules Affected by this Order: Amending WAC 246-945-040.

Statutory Authority for Adoption: RCW 18.64.005, 34.05.353 (1)(b), (c), 69.50.201.

Adopted under notice filed as WSR 23-15-015 on July 7, 2023.

Number of Sections Adopted in Order to Comply with Federal Statute: New 0, Amended 0, Repealed 0; Federal Rules or Standards: New 0, Amended 1, Repealed 0; or Recently Enacted State Statutes: New 0, Amended 0, Repealed 0.

Number of Sections Adopted at the Request of a Nongovernmental Entity: New 0, Amended 0, Repealed 0.

Number of Sections Adopted on the Agency's own Initiative: New 0, Amended 1, Repealed 0.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, Amended 1, Repealed 0.

Number of Sections Adopted using Negotiated Rule Making: New 0, Amended 0, Repealed 0; Pilot Rule Making: New 0, Amended 0, Repealed 0; or Other Alternative Rule Making: New 0, Amended 1, Repealed 0.

Date Adopted: December 18, 2023.

Kenneth Kenyon, PharmD, BCPS, Chair
Pharmacy Quality Assurance Commission

**OTS-4277.3**

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

**WAC 246-945-040 Uniform Controlled Substance Act.** (1) The commission adopts ((~~21 C.F.R. as its own~~)) and incorporates Title 21 of the Code of Federal Regulations in effect as of March 2, 2023, by reference. The following sections of 21 C.F.R. do not apply: ((~~Sec. 1301.13, Sec. 1301.33, Sec. 1301.35-.46, Sec. 1303, Sec. 1308.41-.45, and Sec. 1316.31-.67~~)) Sec. 6.1 - 6.5, Sec. 58.1 - 58.15, Sec. 83 - 98, Sec. 100 - 199, Sec. 225 - 226, Sec. 291, Sec. 370 - 499, Sec. 501.1 - 501.110, Sec. 502.5 - 502.19, Sec. 505, Sec. 507.1 - 507.215, Sec. 508, Sec. 509.3 - 509.30, Sec. 536, 539, 540, 544, 546, 548, 555,

and 564, Sec. 556.1 - 556.770, Sec. 558.3 - 558.665, Sec. 570, 571, and 573, Sec. 579.12 - 579.40, Sec. 584, Sec. 589, Sec. 590 - 599, Sec. 601 - 607, Sec. 620, Sec. 630.1 - 630.40, Sec. 640.1 - 640.130, Sec. 650, Sec. 700 - 799, Sec. 804 - 805, Sec. 813, Sec. 897, Sec. 900, Sec. 1000 - 1050, Sec. 1100 - 1150, Sec. 1210.1 - 1210.31, Sec. 1220, Sec. 1240.3 - 1240.95, Sec. 1250.3 - 1250.96, Sec. 1251 - 1269, Sec. 1270.1 - 1270.43, Sec. 1271.1 - 1271.440, Sec. 1272 - 1299, Sec. 1301.13, Sec. 1301.28, Sec. 1301.33, Sec. 1301.35 - 1301.46, Sec. 1308.41 - 1308.45, Sec. 1316.31 - 1316.67, and Sec. 1400 through 1499. Any inconsistencies between ((~~21 C.F.R. Sec. 1300 through 1321~~)) the material incorporated by reference in this subsection and the remainder of this chapter should be resolved in favor of this chapter. Nothing in this chapter applies to the production, processing, distribution, or possession of marijuana as authorized and regulated by the Washington state liquor and cannabis board.

(2) Copies of the reference material listed in subsection (1) of this section are available for public inspection at the commission's office at Department of Health, Town Center 2, 111 Israel Road S.E., Tumwater, WA 98501. Requestors may also access copies at https://www.ecfr.gov/current/title-21.

(3) Registration. A separate registration is required for each place of business, as defined in 21 C.F.R. Sec. 1301.12, where controlled substances are manufactured, distributed, or dispensed. Application for registration must be made on forms supplied by the commission, and all requested information must be supplied unless the information is not applicable, which must be indicated by the applicant. An applicant for registration must hold the appropriate license provided for in chapter 18.64 RCW.

((~~(3)~~)) (4) Recordkeeping and inventory. Every registrant shall keep and maintain inventory records required by 21 C.F.R. Sec. 1304.04. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include:

(a) Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug;

(b) Distribution records, including invoices, or any other document regardless of how titled from wholesalers, manufacturers, or any other entity to which the substances were distributed and prescriptions records for dispensers;

(c) In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission;

(d) For transfers of controlled substances from one dispenser to another, a record of the transfer must be made at the time of transfer indicating the drug, quantity, date of transfer, who it was transferred to, and from whom. Records must be retained by both the transferee and the transferor. These transfers can only be made in emergencies pursuant to 21 C.F.R. Sec. 1307.11.

((~~(4)~~)) (5) Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records.

((~~(5)~~)) (6) Credential holders and pharmaceutical firms may maintain records for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the business records of the registrant.

((~~(6)~~)) (7) A federal order form is required for each distribution of a Schedule I or II controlled substance. Credential holders and pharmaceutical firms must keep and make readily available these forms and other records to the commission or its designee.