EXPEDITED RULE MAKING

CR-105 (December 2017)
(Implements RCW 34.05.353)

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STATE OF WASHINGTON
FILED

DATE: July 07, 2023
TIME: 8:14 AM

WSR 23-15-015

Agency: Department of Health - Pharmacy Quality Assurance Commission

Title of rule and other identifying information: (describe subject) Incorporation by reference for sections of Title 21 of the Code of Federal Regulations (CFR). The Pharmacy Quality Assurance Commission (commission) is proposing a revision to WAC 246-945-040, the Uniform Controlled Substance Act, to incorporate sections of Title 21 CFR by reference and provide information for acquiring copies of reference material.

Purpose of the proposal and its anticipated effects, including any changes in existing rules: In 2020, the commission consolidated multiple chapters of rules into chapter 246-945 WAC that covers the practice of pharmacy. This proposed rulemaking amends WAC 246-945-040(1) to incorporate Title 21 of the CFR 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), is also proposed for the purpose of providing individuals directions for acquiring copies of the reference material listed in subsection (1) for public inspection.

Reasons supporting proposal: As currently written, WAC 246-945-040 does not account for changes made to Title 21 CFR after the effective date of July 1, 2020. The proposed rule language qualifies for expedited rulemaking under RCW 34.05.353(1)(b) as the language would incorporate by reference without material change the federal regulations. The proposed subsection WAC 246-945-040(2) also qualifies for expedited rulemaking under RCW 34.05.353(1)(c) as the section adds addresses to clarify the locations by which individuals may acquire copies of the reference material.

Statutory authority for adoption: RCW 18.64.005, RCW 34.05.353(1)(b), RCW 34.05.353(1)(c), RCW 69.50.201

Statute being implemented: RCW 18.64.005

Is rule necessary because of a:

Federal Law?	☒ Yes	☐ No
Federal Court Decision?	☐ Yes	☒ No
State Court Decision?	☐ Yes	☒ No

If yes, CITATION:
U.S. Food & Drug Administration (March 28, 2023). *CFR - Code of Federal Regulations Title 21*. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm

Name of proponent: (person or organization) Washington State Pharmacy Quality Assurance Commission

☐ Private
☐ Public
☒ Governmental

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting:	Joshua Munroe	111 Israel Rd SE, Tumwater, WA 98501	360-502-5058
Implementation:	Joshua Munroe	111 Israel Rd SE, Tumwater, WA 98501	360-502-5058
Enforcement:	Marlee O'Neill	111 Israel Rd SE, Tumwater, WA 98501	360-480-9108

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: None

Expedited Adoption - Which of the following criteria was used by the agency to file this notice:

☐ Relates only to internal governmental operations that are not subject to violation by a person;

☒ Adopts or incorporates by reference without material change federal statutes or regulations, Washington state statutes, rules of other Washington state agencies, shoreline master programs other than those programs governing shorelines of statewide significance, or, as referenced by Washington state law, national consensus codes that generally establish industry standards, if the material adopted or incorporated regulates the same subject matter and conduct as the adopting or incorporating rule;

☒ Corrects typographical errors, make address or name changes, or clarify language of a rule without changing its effect;

☐ Content is explicitly and specifically dictated by statute;

☐ Have been the subject of negotiated rule making, pilot rule making, or some other process that involved substantial participation by interested parties before the development of the proposed rule; or

☐ Is being amended after a review under RCW 34.05.328.

Expedited Repeal - Which of the following criteria was used by the agency to file notice:

☐ The statute on which the rule is based has been repealed and has not been replaced by another statute providing statutory authority for the rule;

☐ The statute on which the rule is based has been declared unconstitutional by a court with jurisdiction, there is a final judgment, and no statute has been enacted to replace the unconstitutional statute;

☐ The rule is no longer necessary because of changed circumstances; or

☐ Other rules of the agency or of another agency govern the same activity as the rule, making the rule redundant.

Explanation of the reason the agency believes the expedited rule-making process is appropriate pursuant to RCW 34.05.353(4): The proposed amending language states that WAC 246-945-040 incorporates Title 21 CFR by reference except in those sections as identified in rule. This clarifies the chapter to acknowledge changes to Title 21 CFR made after the effective date of WAC 246-945-040.

NOTICE

THIS RULE IS BEING PROPOSED UNDER AN EXPEDITED RULE-MAKING PROCESS THAT WILL ELIMINATE THE NEED FOR THE AGENCY TO HOLD PUBLIC HEARINGS, PREPARE A SMALL BUSINESS ECONOMIC IMPACT STATEMENT, OR PROVIDE RESPONSES TO THE CRITERIA FOR A SIGNIFICANT LEGISLATIVE RULE. IF YOU OBJECT TO THIS USE OF THE EXPEDITED RULE-MAKING PROCESS, YOU MUST EXPRESS YOUR OBJECTIONS IN WRITING AND THEY MUST BE SENT TO

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Agency: Pharmacy Quality Assurance Commission

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AND RECEIVED BY (date) 9/18/2023

Date: 7/6/2023

Name: Kenneth Kenyon, PharmD, MBA

Title: Pharmacy Quality Assurance Chair

Signature:

Kenneth Kenyon

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.