Significant Legislative Rule Analysis

Chapter 246-945 WAC
A Rule Concerning Pharmacy Quality Assurance Commission

[10/3/2019]
SECTION 1:

Describe the proposed rule, including a brief history of the issue, and explain why the proposed rule is needed.

Beginning in September 2017 the Pharmacy Quality Assurance Commission (commission) was able to dedicate the time and resources necessary to update its rules. Current pharmacy rules regulating the practice of pharmacy, facilities, production, distribution and drugs are spread over 34 chapters. Many of these chapters are outdated and overly prescriptive, limiting the ability for licensees to adapt to changes in practice and technological advances.

By creating this new chapter, the commission is repealing all currently existing WAC chapters under the commission’s jurisdiction. The standards set forth in this new chapter were discussed over the course of two years with conversations between the Commission members, commission staff and the public to provide feedback.

The proposed new rules incorporate current WACs, amended WACs, and newly created WACs. The proposed rules will also include the Hospital Pharmacy Associated Clinics emergency rules, and make those rules permanent. The proposed new rules incorporate current practice, including some current policy and interpretative statements, while allowing for flexibility as practice evolves. New rules are needed in order to update outdated practices, eliminate redundancies, and allow for professional judgment while still ensuring patient safety and access to quality care.

The commission is proposing a new chapter of administrative rules that covers the practice of pharmacy including: (1) General Provisions, (2) General Licensing, (3) Professional Standards, and (4) Operational Standards. Each of these four topics are covered in separate parts of the new chapter with additional subparts grouping like topics together for ease of access.

The first part of the new chapter is general provisions that apply to the practice of pharmacy as well as all drugs under the commission’s authority. This will include operations for the commission including inspection requirements, prescriptions and refill requirements, labeling requirements, record retention, advertising, legend drugs, controlled substances, precursors and home dialysis. In addition, definitions that apply throughout the pharmacy WAC chapter.

Part two of the new chapter is general licensing for all personnel, facilities and production or distribution under the commission’s authority. This will include licensing and registration requirements, continuing education, qualifications, renewals and associated fees.

Part three of the new chapter is professional standards for all pharmacy personnel under the commission’s jurisdiction. This will include professional responsibilities, unauthorized conduct, delegation and non-delegable tasks, counseling, refills and continuity of care, prescription modification, substitution and transfers, as well as Collaborative Drug Therapy Agreements, monitoring of drug therapy and patients’ rights.

Part four of the new chapter is operational standards for all facilities under the commission’s jurisdiction. This chapter will include building standards, dispensing and reporting requirements,
technology implementation, and the management of drugs. Proposed rules for this chapter also include requirements for animal control agencies, wholesalers, and distributors.

Much of this new chapter is taking current WAC’s and updating them to meet current practice, but there are a few sections of significant change, this includes mandating electronic recordkeeping for all facilities, refilling and adapting of prescriptions by pharmacist, and requiring that all prescriptions be electronically transferred.

---

### SECTION 2:

**Is a Significant Analysis required for this rule?**

The proposed rules require significant analysis as described in RCW 34.05.328(5)(c)(iii)(C) because they adopt new, or make significant amendments to, policies or regulatory programs. However, the commission has determined that no significant analysis is required for the following portions of the proposed rules:

<table>
<thead>
<tr>
<th>Definitions 246-945-001</th>
<th>This section does not establish enforceable standards, and in many cases the definitions are taken from existing rule or law and simply moved to a single definitions section. This section does not meet the definition of a significant legislative rule under RCW 34.05.328(5)(c)(iii).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administrative Proceedings and Appeals 246-945-002</td>
<td>New WAC 246-945-002 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-856-020 without material change.</td>
</tr>
<tr>
<td>Labeling: Prepackaged Product. 246-945-018</td>
<td>New WAC 246-945-018 is not significant under RCW 34.05.328(5)(b)(iii) and is exempted from analysis. The new section adopts existing requirements currently cited in WAC 246-873-060 without making material change.</td>
</tr>
<tr>
<td>Prescription Drug Price Advertising 246-945-025</td>
<td>New WAC 246-945-025 is not significant under RCW 34.05.328(5)(b)(iii) and is exempted from analysis. The new section adopts existing requirements currently cited in WAC 246-881-020 and WAC 246-881-030 without making material change.</td>
</tr>
<tr>
<td>Ephedrine prescription restrictions. 246-945-031</td>
<td>New WAC 246-945-031 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-883-030 without material change.</td>
</tr>
<tr>
<td>Section Description</td>
<td>Description</td>
</tr>
<tr>
<td>---------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Over the Counter Drugs 246-945-033</td>
<td>New WAC 246-945-033 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-885-030(4) without material change.</td>
</tr>
<tr>
<td>Drug sample prohibitions. 246-945-035</td>
<td>New WAC 246-945-035 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-877-020 without material change.</td>
</tr>
<tr>
<td>Regulated steroids. 246-945-037</td>
<td>New WAC 246-945-037 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-877-020 without material change.</td>
</tr>
<tr>
<td>Availability and Identity of Amygdalin. 246-945-038</td>
<td>New WAC 246-945-038 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-897-020 and WAC 246-897-060 without material change.</td>
</tr>
<tr>
<td>Uniform Controlled Substances Act. 246-945-040</td>
<td>New WAC 246-945-040 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-887-020 without making material change.</td>
</tr>
<tr>
<td>Designation of nonnarcotic stimulant drugs for the purpose of RCW 69.50.402(1)(c) 246-945-043</td>
<td>New WAC 246-945-043 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-887-040 without making material change.</td>
</tr>
<tr>
<td>Prescribing, dispensing, or administering of Schedule II nonnarcotic stimulants 246-945-045</td>
<td>New WAC 246-945-045 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-887-045 without making material change.</td>
</tr>
<tr>
<td>Sodium pentobarbital registration disciplinary action. 246-945-047</td>
<td>New WAC 246-945-047 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-887-080 without making material change.</td>
</tr>
<tr>
<td>Authority to control. 246-945-050</td>
<td>New WAC 246-945-050 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-887-090 without making material change.</td>
</tr>
<tr>
<td>Schedule I. 246-945-051</td>
<td>New WAC 246-945-051 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-887-100 without making material change.</td>
</tr>
<tr>
<td>Schedule II. 246-945-052</td>
<td>New WAC 246-945-052 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-887-140 without making material change.</td>
</tr>
<tr>
<td>Schedule II immediate precursors. 246-945-053</td>
<td>New WAC 246-945-053 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-887-150 without making material change.</td>
</tr>
<tr>
<td>Schedule III. 246-945-054</td>
<td>New WAC 246-945-054 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-887-160 without making material change.</td>
</tr>
<tr>
<td>Schedule IV. 246-945-055</td>
<td>New WAC 246-945-055 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-887-170 without making material change.</td>
</tr>
<tr>
<td>Schedule V. 246-945-056</td>
<td>New WAC 246-945-056 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-887-180 without making material change.</td>
</tr>
<tr>
<td>Other controlled substance registrants—Requirements. 246-945-060</td>
<td>New WAC 246-945-060 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-887-200 without making material change.</td>
</tr>
<tr>
<td>Precursor Substance Control 246-945-065</td>
<td>New WAC 246-945-065 was amended to remove redundancies that are already identified in RCW 69.43. This does not meet the requirement of a significant legislative rule under RCW 34.05.328(5)(c)(iii).</td>
</tr>
<tr>
<td>Reports of precursor receipt. 246-945-070</td>
<td>New WAC 246-945-070 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-889-030 without making material change.</td>
</tr>
<tr>
<td>Precursor Substance Monthly Reporting 246-945-072</td>
<td>New WAC 246-945-072 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-889-040 without making material change.</td>
</tr>
<tr>
<td>Section Description</td>
<td>Description</td>
</tr>
<tr>
<td>------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Suspicious transactions and reporting requirements. 246-945-075</td>
<td>New WAC 246-945-075 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-889-050 without making material change.</td>
</tr>
<tr>
<td>Precursor Substance Requirements for the sale of restricted product. 246-945-077</td>
<td>New WAC 246-945-077 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-889-085 without making material change.</td>
</tr>
<tr>
<td>Record of sales—Electronic methamphetamine precursor tracking. 246-945-078</td>
<td>New WAC 246-945-078 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-889-095 without making material change.</td>
</tr>
<tr>
<td>Acceptable forms of photo identification. 246-945-080</td>
<td>New WAC 246-945-080 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-889-090 without making material change.</td>
</tr>
<tr>
<td>Maintenance of and access to retail sales records of restricted products. 246-945-085</td>
<td>New WAC 246-945-085 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-889-110 without making material change.</td>
</tr>
<tr>
<td>Exemptions from electronic reporting 246-945-087</td>
<td>New WAC 246-945-087 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-889-115 without making material change.</td>
</tr>
<tr>
<td>Denial of a Sale 246-945-088</td>
<td>New WAC 246-945-088 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-889-120 without making material change.</td>
</tr>
<tr>
<td>Home dialysis program—Legend drugs. 246-945-090</td>
<td>New WAC 246-945-090 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-905-020 without making material change.</td>
</tr>
<tr>
<td>Topic</td>
<td>Description</td>
</tr>
<tr>
<td>------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Home dialysis – Pharmacist consultant.</strong> 246-945-091</td>
<td>New WAC 246-945-091 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-905-030 without making material change.</td>
</tr>
<tr>
<td><strong>Home dialysis – Records. 246-945-092</strong></td>
<td>New WAC 246-945-092 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-905-040 without making material change.</td>
</tr>
<tr>
<td><strong>Home dialysis – Quality assurance. 246-945-093</strong></td>
<td>New WAC 246-945-093 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-905-050 without making material change.</td>
</tr>
<tr>
<td><strong>Applicable Forms 246-945-150</strong></td>
<td>New WAC 246-945-150 is not significant under RCW 34.05.328(5)(c)(i) as it falls under the definition of a ”procedural rule” not a “significant legislative rule.”</td>
</tr>
<tr>
<td><strong>Pharmacy Interns – Registration Requirements 246-945-155</strong></td>
<td>New WAC 246-945-155 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-858-020 (1), WAC 246-858-030, and WAC 246-858-040 without making material change.</td>
</tr>
<tr>
<td><strong>Pharmacist Inactive Credential 246-945-175</strong></td>
<td>New WAC 246-945-175 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-863-070 without making material change.</td>
</tr>
<tr>
<td><strong>Pharmacy Assistant 246-945-200</strong></td>
<td>New WAC 246-945-200 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-901-080 and WAC 246-901-120 (referring only to assistants) without making material change.</td>
</tr>
<tr>
<td><strong>Pharmacy Technician – Temporary Practice Permit – Military Spouse Eligibility and Issuance 246-945-210</strong></td>
<td>New WAC 246-945-210 is not significant and exempt from analysis because: 1. the commission is incorporating by reference WAC 246-12-051 without material change and, exempt under RCW 34.05.328 (5)(b)(iii) and 2. The rules fall under the definition of “procedural rule” and are exempt. RCW 34.05.328(5)(c)(i)</td>
</tr>
<tr>
<td>Category</td>
<td>Description</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Technician expired status 246-945-217</td>
<td>New WAC 246-945-217 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-901-065 without making material change.</td>
</tr>
<tr>
<td>Pharmacy Licensing 246-945-232</td>
<td>New WAC 246-945-232 is exempt because there are no new requirements and exempt under RCW 34.05.328(5)(c)(i) as it falls under the definition of a &quot;procedural rule&quot; not a &quot;significant legislative rule.&quot;</td>
</tr>
<tr>
<td>Pharmaceutical Manufacturer License 246-945-247</td>
<td>New WAC 246-945-247 is exempt under RCW 34.05.328(5)(c)(i) as it falls under the definition of a &quot;procedural rule&quot; not a &quot;significant legislative rule.&quot;</td>
</tr>
<tr>
<td>Shopkeeper Registration 246-945-253</td>
<td>New WAC 246-945-253 is exempt under RCW 34.05.328(5)(c)(i) as it falls under the definition of a &quot;procedural rule&quot; not a &quot;significant legislative rule.&quot;</td>
</tr>
<tr>
<td>Animal Control and Humane Society Registration 246-945-253</td>
<td>New WAC 246-945-253 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing minimal registration requirements under WAC 246-886-020 without making material change.</td>
</tr>
<tr>
<td>Tech Check Tech 246-945-317</td>
<td>New WAC 246-945-317 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-901-035(1) without making material change, and includes the definition from WAC 246-901-010(10).</td>
</tr>
<tr>
<td>Collaborative Drug Therapy Agreements, 246-945-350</td>
<td>New WAC 246-945-350 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-863-100 without making material change.</td>
</tr>
<tr>
<td>Patient Rights 246-945-360</td>
<td>New WAC 246-945-360 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-863-095(4) without making material change.</td>
</tr>
<tr>
<td>Sexual Misconduct 246-945-370</td>
<td>New WAC 246-945-370 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-860-100 without making material change.</td>
</tr>
<tr>
<td>Applicability</td>
<td>New WAC 246-945-405 is not significant under RCW 34.05.328(5)(c)(i) as it falls under the definition of a &quot;procedural rule&quot; not a “significant legislative rule.”</td>
</tr>
<tr>
<td>-----------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Provision of emergency department discharge medications when pharmacy services are unavailable. 246-945-435</td>
<td>New WAC 246-945-435 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-873-060 without material change.</td>
</tr>
<tr>
<td>Investigational drugs. 246-945-445</td>
<td>New WAC 246-945-445 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-873-100 without material change.</td>
</tr>
<tr>
<td>Staffing and Supervision of Pharmacy Staff 246-945-460</td>
<td>New WAC 246-945-460 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-901-130 without material change.</td>
</tr>
<tr>
<td>Nuclear Pharmacies 246-945-490</td>
<td>New WAC 246-945-490 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-903-020 without material change.</td>
</tr>
<tr>
<td>Nuclear Pharmacies: Minimum equipment requirements 246-945-492</td>
<td>New WAC 246-945-492 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-903-040 without material change.</td>
</tr>
<tr>
<td>Teat Dip Containers 246-945-553</td>
<td>New WAC 246-945-553 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-895-090 without material change.</td>
</tr>
<tr>
<td>Wholesaler – Minimum Standards – Scope 246-945-555</td>
<td>New WAC 246-945-555 is not significant under RCW 34.05.328(5)(c)(i) as it falls under the definition of a &quot;procedural rule&quot; not a “significant legislative rule.”</td>
</tr>
<tr>
<td>Wholesaler – Recordkeeping 246-945-575</td>
<td>New WAC 246-945-575 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-879-040 without material change.</td>
</tr>
</tbody>
</table>
Salvaging and Reprocessing 246-945-600
New WAC 246-945-600 is not significant under RCW 34.05.328(5)(b)(iii) and is exempt from analysis. The new section adopts existing requirements currently cited in WAC 246-879-100 without material change.

Many of these new WAC’s are taking current WAC and making minor modifications, changes or clarifications which are not significant and exempt from significant analysis under RCW 34.05.328(5)(b)(iv) but worth separating out from the above table for additional explanation.

1. **WAC 246-945-012 Prescription Refills**

   This proposed rules establishes the guidelines under which prescriptions can be refilled. Schedule II prescriptions cannot be refilled. Schedule III, IV or V prescriptions can be refilled a maximum of five times and will expire after 6 months regardless of if there are refills remaining. Non controlled legend drugs can be refilled as indicated by the prescriber and there is not limit on the number of refills but the prescription will expire after twelve months.

   While this is a new section it consolidates current requirements with no change. Current WAC 246-887-020(7)\(^1\) states that a Schedule II substance cannot be refilled, and WAC 246-887-020(9) states that Schedule III, IV, and V substances cannot be refilled more than 5 times.

2. **WAC 246-945-015 Minimum Requirements for Dispensing Practitioners**

   This proposed rule establishes that a practitioner who is authorized to prescribe or administer legend drugs, including controlled substances, can dispense directly to the ultimate user without a prescription and that any drugs dispensed must bear a label that meets the requirements of RCW 69.41.050.

   While this is a new rule it incorporates what is already in current rule. WAC 246-887-020(9) and makes clear that the same labeling requirements apply.

3. **WAC 246-945-017 Prescriptions – Hospital Inpatient Labels – Minimum Requirements**

   This proposed rule establishes the minimum requirements for inpatient labels of medications. The label must show the drugs name, and strength (when applicable.) Accessory or cautionary statements and expiration date shall be applied when appropriate. In addition to those requirements, compounded products must be labeled in compliance with USP <795>, <797>, <800> and <825>.

   While this is a new rule it incorporates current WAC 246-873-080(5)(a) and compliance with USP is also already established in RCW 18.64.270.

---

4. **WAC 246-945-020 Records Retention Period and Commission Access to Records**

**Description of the proposed rule:** This proposed rule establishes the length of time records must be stored and requires that the commission, or its designee, be allowed access to the records for the purpose of monitoring compliance. Specifically, the proposed rule states that, unless otherwise specified, records required as evidence of compliance with statutes and rules enforced by the commission must be maintained and readily retrievable for at least two years from the date the records were created or received, whichever is the most recent.

While this is a new proposed rule, it incorporates aspects of various existing rules. Current WACs 246-870-030² and 246-874-050³ both use the term “readily retrievable” with regards to various records that must be kept and accessed in order to monitor compliance. Current WACs 246-869-100⁴, 246-869-190⁵, 246-871-050⁶, 246-873-080⁷, 246-874-050⁸ and 246-875-070⁹ all state that records must be kept for a period of two years. The proposed change from current rule would apply this to all facilities covered under this chapter (pharmacies, healthcare entities, and hospital pharmacy associated clinics), rather than having the individual requirements for each specific license type.

Proposed new WAC 246-945-020(2) requires that the facility allow the commission, or its designee, to access the records to monitor compliance. Current WAC 246-869-100¹⁰ applies specifically to prescription records for pharmacies and states that those records shall be available for inspection to representatives of the commission. Current WAC 246-869-110¹¹ states that refusal to permit an inspection, including inventory and/or records, constitutes grounds for a suspension or revocation. Current WAC 246-869-190¹² covers all inspections and states that a pharmacy is subject to periodic inspections to determine compliance with the laws regulating the practice of pharmacy; this would include the review of all records. Proposed new WAC 246-945-005 also covers commission inspections and explicitly states that records are subject to commission inspections.

5. **WAC 246-945-100 Minimum Standards – Compounding**

This proposed rule establishes that all licensees of the Commission must, at minimum, comply with the following chapter of the United States Pharmacopoeia (USP) when engaged in compounding. USP <795> for nonsterile preparations, USP <797> for sterile preparations, USP <800> for handling of hazardous drugs, and USP <825> for

radiopharmaceuticals. Copies of these chapters are available for public inspection at the Commission’s office.

6. **WAC 246-945-163 Certification of Internship Hours**

   The proposed rule language establishes that internship hours reported to the commission under WAC 246-945-162, WAC 246-945-173 and WAC 246-945-175 shall occur. The hours must be completed within 18 months of graduation. The hours reported can come from a commission accredited school or college of pharmacy, other US jurisdiction board or commission, or the supervising pharmacist at the internship site. The hours must be reported 30 days after the completion of the hours. Documentation must include a supervising pharmacist evaluation and certification of hours and a site evaluation. The proposed rule would allow the commission to reject the hours if the intern has not adequately performed the practice of pharmacy.

   While this is a new rule it incorporates current WAC 246-858-050 which requires interns to file with the commission an internship evaluation, they must be reported within 30 days of completion, and that the commission may reject hours if the intern has not performed the practice of pharmacy adequately.

7. **WAC 246-945-180 Nuclear Pharmacist Endorsement**

   This proposed rule establishes the process a pharmacist must go through to receive a nuclear endorsement. The applicant must be licensed as a pharmacist in Washington state, meet the minimum standards of training and experience established in WAC 246-240-075 Training for an authorized nuclear pharmacist, and submit proof of compliance to the commission. They will then receive a letter of recognition from the commission.

   While this is a new rule it incorporates what is already established in current WAC 246-903-030 however instead of just referencing the requirements of the state radiation control agency it makes a cross reference to those standards.

8. **WAC 246-945-230 General Information, Change of Location, Ownership, or New Construction**

   This proposed rules establishes a process for pharmaceutical firms to follow for initial licensure, remodeling, change of ownership, or change of location. The proposed rule clarifies what is meant by both license and facility. The proposed rule states that a facility must submit an application, pay the appropriate fees, undergo an inspection and obtain a controlled substance registration, if they plan on possessing and distributing controlled substances. Once an initial license is issued a facility must notify the Commission and pay an inspection fee for any modifications or remodels. A new application must be

---

submitted if the facility changes or any change in ownership. A facility that is undergoing a change in ownership can begin operations if they provide the commission with a power of attorney. The proposed rule establishes that all changes in information must be provided to the commission within 30 days of the change. Notification of a change in the responsible pharmacy manager must be reported in accordance with WAC 246-945-005. Licenses must be renewed in accordance with the fees set by the Secretary.

While this is a new rule it incorporates aspects of current rules for licensure. This rule eliminates the need to repeat the same requirements for each individual license and rather includes the requirements that apply to all licensed facilities.

Current WAC 246-907 requires payment of all applicable fees for licensure, and the Department’s website provides the form necessary to apply for pharmacy and pharmaceutical firm licensure, this includes a requirement of a DEA registration for the possession of controlled substances, which is also required under current WAC 246-879-080. This proposed rule also identifies initial inspections as a requirement for licensure and cross references proposed new WAC 246-945-005, and as identified earlier in this analysis incorporates current inspection requirements. The requirement of remodel notification takes what is currently established on the pharmacy application for remodel and puts it into rule. The requirement for a new application for a change in location form puts into rule what is currently already established in the Pharmacy Application for Change of Location and Ancillary Utilization Plan Approvals Policy/Procedure. The requirement for notification of change of ownership is currently in WAC 246-869-030, WAC 246-879-070 (3) (which also includes change of location) and WAC 246-873A-020. This proposed rule language would implement the current process identified on the Department’s website for licensure as well as what is already established in current rule.

9. **WAC 246-945-305 Pharmacist Professional Responsibilities**

This proposed rule establishes that the pharmacist’s primary professional responsibilities. A pharmacist must know and comply with all applicable rules and laws, and provide safe

17 [https://www.doh.wa.gov/LicensesPermitsandCertificates/FacilitiesNewReneworUpdate/Pharmacy/ApplicationsandForms](https://www.doh.wa.gov/LicensesPermitsandCertificates/FacilitiesNewReneworUpdate/Pharmacy/ApplicationsandForms)
18 [https://www.doh.wa.gov/LicensesPermitsandCertificates/FacilitiesNewReneworUpdate/PharmaceuticalFirms](https://www.doh.wa.gov/LicensesPermitsandCertificates/FacilitiesNewReneworUpdate/PharmaceuticalFirms)
20 [https://www.doh.wa.gov/Portals/1/Documents/690323.pdf](https://www.doh.wa.gov/Portals/1/Documents/690323.pdf)
and appropriate medication therapy. It makes clear that the pharmacist is responsible for any delegated acts and that these shall be done under their supervision. Finally, it establishes that any delegated pharmacy functions comply with WAC 246-945-315.

While this is a new rule it incorporates aspects of current rule. This proposed rule takes current WAC 246-863-095(1)\(^{25}\) and WAC 246-863-095(3)(a) and incorporates the language into the new proposed section. This rule takes language from current rule and incorporates it. It also clarifies that the pharmacist is responsible for knowing all applicable rules and laws, and covers that all delegated pharmacy functions comply with WAC 246-945-315, which also incorporates portions of current WAC 246-863-095 and will be addressed further in this analysis.

10. WAC 246-945-310 Responsible Pharmacy Manager

The proposed rule establishes that a responsible pharmacy manager must be licensed to practice pharmacy in Washington state, is designated as required by WAC 246-945-410, and has the responsibility to assure that the areas within the facility where drugs are stored, compounded, delivered, or dispensed are operated in compliance with all applicable state and federal rules and laws.

While this is a new rule it incorporates aspects of current rule. Current WAC 246-869-070\(^{26}\) requires the responsible pharmacy manager to ensure the pharmacy complies with all rules and laws. Current WAC 246-904-030\(^{27}\) requires Health Care Entities to employ a pharmacist in charge, this is the same role as the responsible pharmacy manager, and the term has been changed to ensure consistency throughout the new chapter. Current WAC 246-873-040 requires the director of pharmacy at a hospital pharmacy to be responsible for compliance with all rules and laws, and the term has been changed to ensure consistency throughout the new chapter. Finally, current proposed WAC 246-873A-030\(^{28}\) requires a responsible pharmacy managers in compliance with current WAC 246-873-080\(^{29}\). The role of the responsible pharmacy manager is already established in current rule and required in all pharmacy settings, including HCE’s and HPAC’s. This is not a new requirement but makes the term applicable and consistent throughout.

11. WAC 246-945-410 – Minimum Facility Standards for Dispensing of Prescription Drugs

This proposed rule establishes the minimum standards that facilities which dispense drugs must meet. The rule covers security requirements, sanitation and storage as well as staffing levels. The proposed rule requires pharmacies to be adequately stocked to meet the needs of their patients. Requires the designation of a responsible pharmacy manager by the date of opening and within 30 days of a vacancy. The facility must also create and implement policies and procedures related to; the purchasing, ordering, storing, compounding, delivering, dispensing, and administering of drugs, accuracy of inventory

\(^{27}\) https://apps.leg.wa.gov/wac/default.aspx?cite=246-904-030
records, patient records, and any other records required by federal law, adequate security of drugs, and controlling access to drugs. The proposed rule also requires that prescriptions may only be dispensed pursuant to a valid prescription. A drug utilization review of each prescription before dispensing and delivery must occur except in emergency situations or if the drug is a subsequent dose, the prescriber is in the immediate facility, medication override is being used and meets the immediate patient needs, or if 24 hour services are not available and a pharmacist reviews all prescriptions added to the patient profile within 6 hours. Each drug dispensed must bear a complete and accurate label in accordance with WAC 246-945-015 through WAC 246-945-018, and the information must be supplemented by oral or written communication. The proposed rule requires access to the drug storage area be limited to the pharmacist unless ancillary personnel are under the supervision of the pharmacist, the pharmacist authorizes temporary access to an individual performing a legitimate non pharmacy function under the immediate supervision of the pharmacist or the facility has a policy and procedure restricting access to professionals licensed un RCW 18.130.040 and the actions are within their scope of practice. The facility must submit an ancillary utilization plan prior to using ancillary personnel. Finally, a facility that has paper prescriptions must be maintained in accordance with WAC 246-945-020 and schedule II prescription must be in a separate file, and schedule III-V must be maintained as a separate file or in a file with prescriptions for non-controlled drugs as allowed under federal law.

While this is a new rule it incorporates many aspects of current rule.

Proposed WAC 246-945-410(1) states that a facility must be constructed and equipped with adequate security to prevent unauthorized access. There are several places in current rule that cover this requirement. Current WAC 246-869-020(1)\(^\text{30}\) applies to pharmacies and states that a “pharmacy must provide adequate security for its drug supplies and records.” WAC 246-869-160(7)\(^\text{31}\) also applies to pharmacies and states that the “prescription department shall be situated so that the public shall not have free access to the area where … items are stored, compounded or dispensed.” WAC 246-873-070(3)\(^\text{32}\) applies to hospital pharmacies and states that “all areas occupied by the hospital pharmacy shall be locked by key or combination in order to prevent access by unauthorized personnel.” WAC 246-904-020\(^\text{33}\) applies to health care entities and states that “Physical requirements for the areas of a health care entity where drugs are stored, compounded, delivered or dispensed shall comply with WAC 246-873-070.” WAC 246-873A-040\(^\text{34}\) applies to hospital associated clinics and states that “Physical requirements must be consistent with the applicable subsections of WAC 246-873-070 according to the HPAC category type.”

Proposed WAC 246-945-410(2) states that the facility must be properly equipped to ensure the safe, clean and sanitary conditions, necessary and appropriate for proper


operation, preparation and product integrity. Current WAC 246-869-150(3)\textsuperscript{35} applies to pharmacies and hospital associated clinics as referenced in WAC 246-873A-050(3)\textsuperscript{36} and states that all stock and materials on shelves or display for sale must be free from contamination, deterioration and adulteration.” WAC 246-869-170\textsuperscript{37} covers pharmacies’ sanitary conditions. WAC 246-873-070(4)\textsuperscript{38} applies to hospitals, as well as health care entities and hospital associated clinics as referenced above; it states that “drugs shall be stored under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation and security.” WAC 246-878-040\textsuperscript{39} covers facilities that compound drugs, and set standards for adequate lighting and ventilation, as well as adequate washing facilities including water, soap, and detergent. It also states that the areas for compounding shall be maintained in clean and sanitary condition. The requirements for safe compounding are also covered separately in RCW 18.64.270\textsuperscript{40} requires all compounding be done in compliance with USP.

Proposed WAC 246-945-410(3) states that a facility must be staffed sufficiently to allow appropriate supervision and remain open during posted hours of operation. Current WAC 246-869-020(5) applies to pharmacies and states that “no drugs … restricted to sale either by or under the personal supervision of a pharmacist can be sold or delivered without a pharmacist being present in the pharmacy.” WAC 246-873-040(2)\textsuperscript{41} applies to hospitals and states that “the director of pharmacy shall be assisted by sufficient numbers of additional pharmacist and/or pharmacy assistance and clerical personnel required to operate safely and efficiently to meet the need of the patients.” WAC 246-901-130(2)\textsuperscript{42} applies to all pharmacy ancillary personnel, and it states that “The responsible pharmacy manager will ensure that the number of pharmacy technicians on duty can be satisfactorily supervised by the pharmacist(s) on duty.”

Proposed WAC 246-945-410(4) states that a facility must be adequately stocked to meet the needs of its patients, this is current language from WAC 246-869-150(1)\textsuperscript{43}.

Proposed WAC 246-945-410(5) requires the designation of a responsible pharmacy manager. This is a current requirement in WAC 246-869-070\textsuperscript{44} requires the responsible pharmacy manager to ensure the pharmacy complies with all rules and laws. Current WAC 246-904-030\textsuperscript{45} requires Health Care Entities to employ a pharmacist in charge, this is the same role as the responsible pharmacy manager, and the term has been changed to ensure consistency throughout the new chapter. Current WAC 246-873-040 requires the director of pharmacy at a hospital pharmacy to be responsible for compliance with all rules and laws, and the term has been changed to ensure consistency throughout the new

\textsuperscript{35} https://app.leg.wa.gov/wac/default.aspx?cite=246-869-150
\textsuperscript{36} https://www.doh.wa.gov/Portals/1/Documents/2300/2016/OTS-8053.pdf
\textsuperscript{37} https://app.leg.wa.gov/wac/default.aspx?cite=246-869-170
\textsuperscript{38} https://app.leg.wa.gov/wac/default.aspx?cite=246-873-070
\textsuperscript{39} https://app.leg.wa.gov/wac/default.aspx?cite=246-878-040
\textsuperscript{40} https://app.leg.wa.gov/RCW/default.aspx?cite=18.64.270
\textsuperscript{41} https://app.leg.wa.gov/wac/default.aspx?cite=246-873-040
\textsuperscript{42} https://app.leg.wa.gov/wac/default.aspx?cite=246-901-130
\textsuperscript{43} https://apps.leg.wa.gov/wac/default.aspx?cite=246-869-150
\textsuperscript{44} https://apps.leg.wa.gov/wac/default.aspx?cite=246-869-070
\textsuperscript{45} https://apps.leg.wa.gov/wac/default.aspx?cite=246-904-030
chapter. Finally, current proposed WAC 246-873A-030\(^{46}\) requires a responsible pharmacy managers in compliance with current WAC 246-873-080\(^{47}\).

Proposed WAC 246-945-410(6) requires the creation and implementation of policies and procedures. Current WAC 246-863-110(3)\(^{48}\) which applies to pharmacies, 246-865-060\(^{49}\) which applies to long term care pharmacies, 246-870-070\(^{50}\) which applies to pharmacies using electronic transmission, 246-871-020\(^{51}\) which applies to pharmacies providing parenteral products, 246-873-040\(^{52}\) which applies to hospital pharmacies, 246-874-030\(^{53}\) which applies to pharmacies and facilities using an ADDD, 246-904-030\(^{54}\) which applies to Health Care Entities, and 246-873A-030\(^{55}\) which applies to Hospital Associated Clinics, all require policies and procedures. This proposed new rule makes that same requirement but eliminates the need to have it mentioned for each specific license type.

Proposed WAC 246-945-410(7) states that prescriptions must only be dispensed pursuant to a valid prescription. Current WAC 246-869-010\(^{56}\) states that a pharmacies have a duty to deliver lawfully prescribed drugs. WAC 246-871-050\(^{57}\) states that a prescription must be from an authorized prescriber before dispensed. WAC 246-873A-030\(^{58}\) (current emergency HPAC rules) states that a dispensing of appropriately labeled drugs may be done only pursuant to a valid patient order or prescription. This new rule identifies valid prescriptions as opposed to lawfully prescribed in current WAC. Valid prescriptions are also defined in the proposed WAC 246-945-011.

Proposed WAC 246-945-410(8) states that a drug utilization review must be done of each prescription drug order, except in emergency situations. Current WAC 246-875-040\(^{59}\) states that upon receipt of a prescription the dispenser must examine the patients’ medical records and determine drug interaction, duplication and improper utilization. Current WAC 246-874-040(3)\(^{60}\) requires prospective drug utilization reviews and mirrors the exemptions stated in the proposed new rule. This is also covered under the pharmacist professional responsibility rules, current WAC 246-863-095\(^{61}\) and new WAC 246-945-305 of ensuring patients receive safe and appropriate medication therapy. Drug utilization review is also defined in the proposed new rule WAC 246-945-001.

Proposed WAC 246-945-410(9) states that a prescription must bear a complete and accurate label. This is covered in current WAC 246-869-210. The requirements of what must be on a label are outlined in new WAC 246-945-015 through 246-945-018. It also states that information on the label will be supplemented through oral or written information as required by proposed new WAC 246-945-325, which is covered in current WAC 246-869-220.

Proposed WAC 246-945-410(10) establishes that access to the drug storage area is limited to a pharmacist. Current WAC 246-869-020(1), which applies to pharmacies, states that a pharmacy must provide adequate security for its drug supplies and in the absence of a pharmacist the pharmacy must be closed and access limited to persons authorized by the pharmacist. Current WAC 246-873-070(3), which applies to hospital pharmacies states that all areas occupied by the hospital pharmacy shall be locked by key or combination in order to prevent access by unauthorized personnel. The director of pharmacy shall designate in writing, by title and/or position, those individuals who shall be authorized access to particular areas within the pharmacy, including authorization of access to keys and/or combinations. This proposed new WAC does not change the current standard that drug storage areas should have limited access, it makes the language explicit and provides for exemptions.

Those exemptions are covered in proposed WAC 246-945-410(10)(a)-(c).

Proposed WAC 246-945-410(10)(a) establishes that access for interns, technicians and assistants should be done under the direct supervision of the pharmacist. Current WAC 246-860-020(7) applies to all pharmacy ancillary personnel and defines "Pharmacy ancillary personnel" as persons certified as a pharmacy technicians or registered as a pharmacy assistant under chapter 18.64A RCW to engage in the practice of pharmacy under the direct supervision of a licensed pharmacist and to the extent permitted by the board in accordance with chapter 18.64A RCW. The allowance of pharmacy ancillary personnel to access the drug storage area is not a change in practice, but the proposed new rule makes clear that, as part of their role, pharmacy ancillary personnel can only access the drug storage area under the immediate supervision of a pharmacist.

Proposed WAC 246-945-410(10)(b) establishes that an individual may have temporary access to the drug storage area for legitimate non-pharmacy functions. Current WAC 246-869-020, as mentioned above, establishes that a pharmacy must provide “access limited to persons authorized by the pharmacist; for example, janitorial services, inventory services, etc.” The allowance of access for authorized temporary access for legitimate non-pharmacy functions is not a new standard, but the proposed new rule eliminates the use of “for example” in rule and maintains that this access must be done under the supervision of the pharmacist.

---

Proposed WAC 246-945-410(10)(c) allows for licensed health care professionals to access the drug storage area provided that the facility has a policy and procedure in place to address this. Current WAC 246-873-050(a)\textsuperscript{68}, which applies to hospital pharmacies, states, “the director of pharmacy shall establish written policy and recording procedures to assist the registered nurse who may be designated to remove drugs from the pharmacy, when a pharmacist is not present, in accordance with Washington State Pharmacy Practice Act, RCW \textbf{18.64.255}(2), which states that the director of pharmacy and the hospital be involved in designating the nurse.” Current WAC 246-874-040 refers to access to ADDDs and states, “access to the ADDD by facility information technology employees or employees of similar title must be properly restricted and addressed in policies and procedures.” Both of these current WACs require the development of policies and procedures to access the drug storage area, unique to their individual setting. The proposed new rules allow for this policy and procedure requirement to apply to all facilities under this chapter, keeping in line with the goal of the rules rewrite to have less prescriptive regulations.

Proposed WAC 246-945-410(11) states that a facility must submit and have an approved ancillary utilization plan prior to using ancillary personnel. This is a current requirement in WAC 246-901-100\textsuperscript{69}.

Proposed WAC 246-945-410(12) identifies how paper prescriptions or chart orders must be maintained. Current WAC 246-887-020(4)\textsuperscript{70} hold these same requirements, this proposed new WAC just separates out the sentence based on Schedule II and Schedule III-V.

This rule takes current requirements and applies them to all facilities rather than having individual chapters per facility. This is a change from current practice; instead of having specific requirements from each different entity, the proposed rule would now apply to all facilities as defined in WAC 246-945-405. This is not a change in standard, but rather move from facility specific standards to standards that apply to all licenses facilities.

12. WAC 246-945-418 Paper Recordkeeping Procedure

This proposed new rule establishes the requirements for HCE’s and HPAC’s that do not maintain an electronic recordkeeping system. The proposed rule states that their paper records must contain the same information required in WAC 246-945-417, and consist of the hard copy of a prescription and refill information. The data must be organized to ensure all information relating to a patient will be reviewed each time a prescription is filled.

While this is a new rule it incorporates current WAC 246-875-030\textsuperscript{71} without the specific requirements listed as those are addressed in the cross referenced WAC.

13. WAC 246-945-440 Administration of Patient Owned Medications

\textsuperscript{68} https://app.leg.wa.gov/wac/default.aspx?cite=246-873-050
\textsuperscript{69} https://apps.leg.wa.gov/wac/default.aspx?cite=246-901-100
\textsuperscript{70} https://apps.leg.wa.gov/wac/default.aspx?cite=246-887-020
\textsuperscript{71} https://apps.leg.wa.gov/wac/default.aspx?cite=246-875-030
This new proposed rule states that facilities must have policies and procedures for the administration of patient owned medication.

While this is a new rule it incorporates what is already a requirement in WAC 246-873-090(3).72

14. WAC 246-945-450 Accessing Technology Use to Dispense – Nursing Students

This proposed new rule establishes the circumstances under which a nursing student may access technology used to dispense. The proposed rule requires that a nursing student must be enrolled in an approved nursing program by the Washington State Nursing Care Quality Assurance Commission. A facility that provides the opportunity for nursing students to be granted access to technology used to dispense must meet certain criteria. The facility, in collaboration with the nursing program, must provide orientation and practice experiences that demonstrate competency prior to using the dispensing technology, must provide adequate training, must have policies and procedures to provide safe administration of medications and the must have a way of reporting and resolving any medication errors, adverse events and alleged diversion.

This is not new rule language; the current WAC 246-874-070 establishes the same requirements. However, as the commission moves away from prescriptive rules with the goal of allowing new technologies to come into the practice of pharmacy, the proposed new rule removes the reference to ADDD and instead replaces it with dispensing technologies.

15. WAC 246-945-500 Humane Societies, Animal Control Agencies, and Department of Fish and Wildlife Chemical Capture Programs – Designated Person

This proposed new rule establishes that each registered humane society, animal control agency and Department of Fish and Wildlife (DFW) chemical capture programs must have a designated person. The designated person is responsible for the ordering, possession, safe storage, and use of all approved drugs, maintaining all records and ensuring those records are available for inspection. The commission must be notified in 10 calendar days of a change in the designated person.

While this is a new rule this rule incorporates what is already required in current WAC 246-886-060 which applies to animal control and humane societies and 246-886-160 which applies to DFW. This new rule combines the requirements for these agencies into a single chapter.

16. WAC 246-945-503 Humane Societies, Animal Control Agencies and Department of Fish and Wildlife Chemical Capture Programs – Authorized Personnel

The proposed rule establishes that Humane Societies, Animal Control Agencies and Department of Fish and Wildlife (DFW) must ensure only authorized trained personnel...

administer approved drugs and approved controlled substances. For humane societies and animal control agencies authorized personnel are those individuals who have completed a commission approved training program or a training that is substantially equivalent and been approved by the designated person. For DFW authorized personnel are those individuals who have completed a commission approved training program or a training that is substantially equivalent, been approved by DFW and are a DFW officer, biologist or veterinarian. A commission approved training program must include didactic and practical training under the direction of a licensed veterinarian, and must ensure that the authorized personnel are able to demonstrate adequate knowledge of the potential hazards and the proper techniques for administration.

While this is a new rule it incorporates current rules. Current WAC 246-886-040 covers training of personnel for humane societies and animal control. WAC 246-886-040(3)(c) requires it be taught by a licensed veterinarian or a person who has completed a commission approved training program. WAC 246-886-040(3)(d) requires both didactic and practical training, and (3)(f) requires knowledge of routes or drug administration and human hazards. Current WAC 246-886-190 covers training for DFW.

17. WAC 246-945-505 Humane Societies and Animal Control Agencies – Approved Legend Drugs and Approved Controlled Substances

This proposed rule identifies the legend drugs and controlled substances that may be used by animal control agencies within their scope. Animal control agencies registered with the commission may use Acetylpromazine, Dexmedetomidine, Medetomidine, and Xylazine for pre-euthanasia sedation. Animal control agencies and humane societies can only use sodium pentobarbital to euthanize injured, sick, homeless or unwanted domestic pets and domestic or wild animals. Any approved drugs must be marked “for veterinary use only.” Staff may administer legend drugs and controlled substances prescribed by a licensed veterinarian for a specific animal which have been dispensed by a pharmacy or veterinarian and are properly labeled.

While this is a new rule, it incorporates current WACs and combines them into a single section. Proposed new WAC 246-945-505(1) lists the approved drugs for animal control agencies; current WAC 246-886-030 has the same list.

Proposed new WAC 246-945-505(2) and (3) states that animal control agencies and humane societies may only use sodium pentobarbital for euthanasia and requires that all approved drugs be labeled for veterinarian use only; this is covered in current WAC 246-886-035.

Proposed new WAC 246-945-505(4) states that humane societies and animal control may only administered drugs prescribed by a veterinarian and dispense by a pharmacy or veterinarian and are problem labeled. This is covered in current WAC 246-886-050.

77 https://apps.leg.wa.gov/wac/default.aspx?cite=246-886-190
18. WAC 246-945-507 Department of Fish and Wildlife Chemical Capture Programs – Approved Legend Drugs and Controlled Substances

The proposed new rule establishes the drugs that may be used by DFW. DWF’s chemical capture programs officer and biologist are authorized to use legend drugs Atipamezole, Azaperone, Detomidine, Isoflurane, Naltrexone, Tolazoline, and Yohimbine. DFW’s officers and biologists authorized for chemical capture programs are only allowed to use controlled substances Butorphanol, Diazepam, Diprenorphine, Carfentanil, Fentanyl, Ketamine, Midazolam, Tiletamine, and Zolazepam. Staff of registered DFW programs may administers legend drugs and controlled substances which have been prescribed by a veterinarian and dispense by a pharmacy or veterinarian and that are properly labeled in accordance with RCW 18.64.246 or 69.41.050 and WAC 246-945-015 through WAC 246-945-017 or WAC 246-933-340(5)(a) and (b).

While this is a new rule it incorporates current rules. Proposed new WAC 246-945-507(1) lists the approved legend drugs for DFW; current WAC 246-886-18081 has the same list.

Proposed new WAC 246-945-507(2) lists the approved controlled substances for DFW; current WAC 246-886-22082 has the same list.

This rule incorporates current WAC chapters. It adds the additional clarification that a veterinarian must prescribe the drugs and they must be dispensed by a pharmacy or veterinarian and contain proper labels. This is not a new requirement but states the current requirements in order for DFW to possess drugs.

17. WAC 246-945-510 Humane Societies, Animal Control Agencies and Department of Fish and Wildlife Chemical Capture Programs – Recordkeeping and Reports

This proposed new rule establishes the recordkeeping requirements for humane societies, animal control agencies and DFW. Each agency must record the receipt, use and disposition in a log book or electronic record. The record must have sufficient detail to allow for an audit trail of drug usage; date and time of administration, route of administration, identification number or other identifier assigned to the animal, estimated weight, estimated age/breed or species, name of drug, dose of drug, amount of drug wasted, and initials of the primary person who administered. The authorized person must document any errors or discrepancies in the drug inventory and report to the registered entity for investigation. Any unresolved discrepancies must be reported to the commission within 7 days, and loss of controlled substance reported to the DEA. The designated person must perform a physical inventory of the approved drugs every twelve months. The designated person or designee shall destroy or waste non controlled drugs that are unfit for administration, a second member of staff must witness the destruction. All unwanted or unused controlled substances must be returned to the manufacturer or destroy them in accordance with the rules and requirements of the commission, DEA and department of ecology. This must be documented in the log book. The registered entity must have a list of all authorized persons. All records must be available for inspection by the commission and maintained for 2 years.

While this is a new rule it incorporates current rules. Current WAC 246-886-080\(^83\) has the same requirements but it only applies to humane societies and animal control. The change in this rule is the allowance for an electronic record and the application to DFW as well. Recordkeeping is not a new requirement for DFW this is covered in current WAC 246-886-210\(^84\).

\textbf{20. WAC 246-945-550 Manufacturers – Minimum Standards}

This proposed rule establishes the standards for manufacturers. The proposed new rule requires compliance with the “Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs”\(^85\); and "Current Good Manufacturing Practice for Finished Pharmaceuticals; General”\(^86\)(CGMP). It requires those manufactures registered with the FDA as an outsourcing facility must also comply with the FDA guidance document\(^87\). Virtual manufacturers must ensure its own drugs are manufactured in compliance with this section.

While this is a new rule it incorporates what is already established in current rule. Current chapter 246-895 WAC\(^88\) covers all rules relating to manufacturing, in comparison with the above referenced requirements in the CGMP there were only a few differences: WAC 246-895-010 (Definitions), WAC 246-895-090 (Reuse of teat dip containers and closures), WAC 246-895-040(5) (Providing suitable housing and space for the care of all laboratory animals), WAC 246-895-060(12) (Appropriate procedures to destroy beyond recognition and retrievability any and all components), WAC 246-895-080(3) (drug product containers and closures shall not be reused – unable to confirm if this is prohibited by CGMP), WAC 246-895-160 (Complaint Files), and WAC 246-895-170 (Variance and procedure). The Commission reviewed these differences and determined that the reference to the CGMP was sufficient to ensure proper manufacturing.

This rule eliminates the various chapters related to manufacturing and cites the federal requirements without making anything more stringent.

\textbf{21. WAC 246-945-560 Wholesaler Facility Standards.}

This proposed rule establishes the minimum standards that a wholesaler facility must meet. Facilities must be of suitable size, construction, and location to accommodate cleaning maintenance and proper operation. They must also have adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment and security. There must be a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated or that are in immediate or sealed secondary containers that

\(^83\) https://apps.leg.wa.gov/wac/default.aspx?cite=246-886-080  
\(^84\) https://apps.leg.wa.gov/wac/default.aspx?cite=246-886-210  
\(^85\) https://www.law.cornell.edu/cfr/text/21/part-210  
\(^86\) https://www.law.cornell.edu/cfr/text/21/part-211  
\(^88\) https://apps.leg.wa.gov/wac/default.aspx?cite=246-895
have been opened. They must be maintained in a clean and orderly condition and be free
from infestation by insects, rodents, birds, or vermin of any kind. They cannot be a part
of a home or residential dwelling. They must provide for the secure and confidential
storage of information with restricted access and policies and procedures. They must
provide and maintain appropriate inventory controls in order to detect and documents any
theft, counterfeiting or diversion.

Wholesale distribution facilities must also be secure from unauthorized entry; this
requires that access from the outside the premise must be kept to a minimum, the
perimeter must be well lit, entry to areas where drugs are held must be limited to
authorized personnel, the facility must be equipped with an alarm system and security
system sufficient to protect against theft, diversion, or record tampering.

While this is a new rule it incorporates current WACs. Proposed new WAC 246-945-
560(1) which covers the facility standards is taken directly from current WAC 246-879-
020(1)\(^9\), although it adds proposed new WAC 246-945-560(1)(f) stating that it cannot be
part of a home or residential dwelling.

Proposed new WAC 246-945-560(2) covers facility security requirements and is taken
directly from current WAC 246-879-050\(^9\).

22. WAC 246-945-565 Wholesaler – Drug Storage

**Description of the proposed rule:** Drugs at a wholesale distribution facility must be
stored at temperatures and under conditions required by the labeling or by current
requirements of USP-NF, to preserve product identity, strength, quality, and purity. If no
storage requirements are established for a drug it may be held at a controlled room
temperature. Temperature and humidity recording equipment or logs must document
proper storage. Controlled substances should be isolated from non-controlled and stored
in a secured area.

Drugs that are outdated, damaged, deteriorated, misbranded or adulterated must be
physically separated from other drugs in a designated quarantine area until destroyed or
retuned to the original manufacturer or third party returns processor. This includes drugs
who’s immediate, sealed outer, or sealed secondary containers have been opened. Any
conditions that cause doubt to a drug’s safety, identity, strength, quality, or purity must be
quarantined unless under examination, testing, or other investigation the drug is proven to
meet required standards.

While this is a new rule it incorporates current rules. Proposed new WAC 246-945-
565(1)-(3) covers drugs storage conditions and is taken from current WAC 246-879-
020(2)\(^8\).

WAC 246-945-565(4) states that storage of controlled substances must be in a secure
area separate from non-controlled substances this is also a federal requirement\(^9\).

Proposed new WAC 246-945-565(5)-(6) covers when drugs must be quarantined and is
taken directly from WAC 246-879-020(4).\(^8\)

---

23. WAC 246-945-570 Wholesaler – Drug Shipment Inspection Requirements

This proposed rule establishes the inspection requirements for drug shipments. Each shipping container must be visually examined upon receipt for identity and to avoid accepting any drugs that are contaminated or otherwise unfit for distribution. Outgoing shipments must be inspected to verify accuracy and product integrity.

While this is a new rule, it incorporates portions of current statute. Current WAC 246-879-020(3)\(^{92}\) requires the examination of materials upon receipt and outgoing using substantially similar language to this new rule.

24. WAC 246-945-575 Wholesaler – Recordkeeping Requirements

This proposed rule establishes the recordkeeping requirements for wholesalers and other entities engaged in wholesale drug distribution. They must maintain inventories and records of transactions related to the receipt and distribution or other disposition of drugs. Those records must include the source of the drugs, including the name and address of the seller or transferor. The records must also include the identity and quantity of the drugs received and distributed, or otherwise disposed of, and the dates of such actions. Those records must be maintained in a readily retrievable manner in accordance with WAC 246-945-020.

While this is a new rule, it incorporates existing rules. Proposed new WAC 246-945-575(1) requires the establishment and maintenance of inventories and records and it establishes what those records must include. Current WAC 246-879-040(1)(a)-(c)\(^{93}\) has the same requirements. Proposed new WAC 246-945-575(2) requires that records be maintained in an immediately retrievable manner; current WAC 246-879-040(3) requires that records that can be immediately retrieved whether onsite or through electronic means must be readily available. If records are not kept onsite and not available by electronic means they must be made available for inspection within two working days.

25. WAC 246-945-580 Wholesaler – Personnel

**Description of the proposed rule:** This proposed rule establishes the requirements for personnel employed by a wholesaler. The wholesaler must establish and maintain a list of officers, directors, managers, a designated individual, and other persons responsible for wholesale drug distribution, storage, and handling. This list must also include a description of each individual’s duties and a summary of their qualifications. A wholesaler must employ personnel in sufficient numbers and with adequate education, training, and experience to safely and lawfully engage in wholesale drug distribution activities.

While this is a new rule, it incorporates portions of existing rules. Proposed new WAC 246-945-580(1) requires a list of all personnel that will be responsible for any aspect of the wholesale distribution, storage, and handling, including their duties and qualifications. This language is taken directly from current WAC 246-879-020(6)\(^{94}\). Proposed new WAC 246-945-580(2) requires that the wholesaler employ sufficient

personnel with adequate experience to safely and lawfully engage in wholesale drug distribution. Current WAC 246-879-070(d)\(^{95}\) states that each person employed have the education, training and experience or any combination thereof, sufficient to perform functions to provide assurance that the drug product quality, safety, and security will be maintained as required by law. While not identical, the intent is substantially equivalent, with the addition of requiring sufficient personnel.

---

SECTION 3:

Clearly state in detail the general goals and specific objectives of the statute that the rule implements.

The general goals of RCW 18.64.005(7) include establishing standards for the practice of pharmacy and protecting patient safety. The specific objectives of the statute include adopting rules for the dispensing, distribution, wholesaling, and manufacturing of drugs, devices, and the practice of pharmacy for the protection and promotion of the public health, safety, and welfare. The proposed new rules in Part 1 of the new chapter implement these general goals and specific objectives by creating clarity for licensees when performing these activities.

The proposed new rules in Part 2 General Licensing implements the general goals that are under the commission’s authority delegated in RCW 18.64.005. Specifically, RCW 18.64.005(3) and RCW 18.64.080 direct the commission to establish licensure qualifications for pharmacist and interns, and RCW 18.64.005(8) directs the commission to identify continuing education standards for all pharmacy personnel. RCW 18.130.075 allows the commission the authority to create the temporary practice permits. This proposed rule also implements RCW 18.64.043 Pharmacy License, including separate license standards for Hospital Associated Clinics, RCW 18.64.044 Shopkeeper’s Registration, RCW 18.64.045 Manufacturer’s License, RCW 18.64.046 Wholesaler's License, RCW 18.64.370 Nonresident Pharmacies License, and RCW 18.64.460 Health Care Entity License. Also, covered by this proposed chapter is the registration of humane societies and animal control agencies pursuant to RCW 69.50.310. All of the goals of these statutes are implemented in this proposed new chapter of rule by consolidating the regulations in one section. The specific objectives of the statutes are achieved through rulemaking placed in one specific new chapter of rules.

RCW 18.64.005(1) requires the commission to regulate the practice of pharmacy and enforce all laws placed under its jurisdiction. The practice of pharmacy is defined in RCW 18.64.011 as “the practice of and responsibility for: Interpreting prescription orders; the compounding, dispensing, labeling, administering, and distributing of drugs and devices; the monitoring of drug therapy and use; the initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs; the participating in drug utilization reviews and drug product selection; the proper and safe storing and distributing of drugs and devices and maintenance of proper records

thereof; the providing of information on legend drugs which may include, but is not limited to, the advising of therapeutic values, hazards, and the uses of drugs and devices.”

In addition, RCW 18.64.005(7) requires the commission to adopt rules for the dispensing, distribution, wholesaling, and manufacturing of drugs, devices, and the practice of pharmacy for the protection and promotion of the public health, safety, and welfare.

The proposed new rules in Part 3 Professional Standards identify requirements for all pharmacy personnel in order to achieve the requirements stated above.

The proposed new rules in Part 4 Operational Standards implements the general goals of multiple statutes. These goals include:

- Regulating the dispensing, distribution, wholesaling, and manufacturing of drugs and devices (RCW 18.64.005). Additionally, this RCW’s goals include protecting and promoting public health, safety, and welfare within the practice of pharmacy;

- Licensing hospitals, health care entities, and hospital associated clinics in the practice of pharmacy (RCW 18.64.043);

- Regulating record keeping for all prescriptions (RCW 18.64.245);

- Regulating record keeping requirements for health care entities (RCW 18.64.470); and

- Establishing requirements for healthcare entities to comply with all rules relating to dispensing drugs, including facility standards and allowances in the absence of a pharmacists to access drugs (RCW 18.34.255).

Specifically, these goals aim to establish locations in which drugs will be housed, dispensed, and administered to ensure that facilities and other covered entities are operating to adequately ensure patient safety and drug quality. Additionally, they aim to provide access to drugs in pharmacies while preventing misuse or diversion of drugs through record keeping and facility requirements.

SECTION 4:

Explain how the department determined that the rule is needed to achieve these general goals and specific objectives. Analyze alternatives to rulemaking and the consequences of not adopting the rule.

The commission did a full review of all pharmacy rules. They determined these rules were out of date and too prescriptive to allow for pharmacists to use their professional judgement. There are no alternatives to rulemaking, because the subject matter of this proposed rule is necessary to be enforceable. Initially, it was discussed to merely amend the current WACs, but upon further review, it was determined a significant overhaul of all the chapters under the commission’s jurisdiction was needed.
If the proposed rule is not adopted, the commission will remain with outdated rules and licensees will continue to be burdened with prescriptive rules that prevent them from adapting and utilizing their professional judgement as the practice of pharmacy evolves.

SECTION 5:

Explain how the department determined that the probable benefits of the rule are greater than the probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

1. WAC 246-945-005 Commission Inspections and Investigations

**Description of the proposed rule:** This proposed rule establishes the inspection and investigations process under the commission’s jurisdiction. While this is not a new rule it expands on what is current WAC 246-869-190\(^96\). This proposed rule establishes that all pharmaceutical firms (defined in WAC 246-945-001) are subject to inspections by the commission. This includes ensuring the commissions or its designee has the ability to access all records and conduct initial and periodic inspections. It also establishes the process for a statement of deficiency as well as the plan of correction after the inspections are conducted. This proposed rule also designates the responsible pharmacy manager, or equivalent manager for other pharmaceutical firms, as responsible for completing the self-inspection worksheet. It also establishes the informal dispute process for the inspections which includes allowing for a one time extension. Finally, it establishes the requirement for cooperation with investigations.

Current WAC 246-869-190 refers to pharmacy inspections and is similar to the language in the new rule without establishing new requirements. Current WAC 246-879-030\(^97\) refers to Wholesaler inspections. Wholesalers are currently required to be inspected by the Commission but this new rule includes them in the self-inspection worksheet requirement as well. Current WAC 246-904-020\(^98\) requires inspections of Health Care Entity’s upon initial licensure, this new rule includes them in the self-inspection worksheet requirement and aligns them with periodic inspection requirements. Current WAC 246-869-110\(^99\) establishes that all licensed wholesalers, manufacturers, pharmacies and shopkeepers cannot refuse to permit an inspection. This aligns with this proposed rule, that all pharmaceutical firms licensed by the commission can be inspected.

**Cost/Benefit Analysis:** There are costs associated with this rule. While the inspection requirement is not a new requirement the requirement to complete a self-inspection form is new for some licensees. This will cost the pharmaceutical firm the time of the


responsible pharmacy manager, or equivalent manager, approximately 4 hours, to complete this form once per year. This is equal to approximately $18/hour costing a total of $72/year. These costs are outweighed by the benefit of ensuring continued oversight of licensees as well as allowing them to ensure their business is operating within the law. The cost of time spent performing the self-inspection would also be outweighed by the potential cost of action if a pharmaceutical firm is out of compliance when inspected by a Commission designee, the self-inspection form helps to maintain continual compliance.

2. **WAC 246-945-010 Prescription and Chart Order: Minimum Requirements**

**Description of the proposed rule:** This rule establishes the minimum requirements that must be on either a prescription or chart order. This rule differentiates between prescriptions and chart orders to make clear that the requirements for a prescription do not supersede the requirements for a chart order under RCW 18.64.550. This proposed rule establishes that a prescription for a non-controlled legend drug must include the prescribers name, the patient name, authorized entity or animal name/species, the date of issuance, drug name, strength and quantity, directions for use, number of refills, instructions on drug substitution, the prescriber’s signature and the prescription, if written, must be on tamper resistant paper.

For controlled substances this proposed rule establishes that all the previous requirements apply as well as the patient’s address, the dosage form, the prescriber’s address, the prescriber’s DEA registration number and any other requirements listed in 21 CFR Chapter II.

A Schedule II substance can only be dispensed pursuant to a valid prescription expect in an emergency. An emergency exists when the immediate administration of the drug is necessary for proper treatment and no alternative treatment is available, and it is not possible for the practitioner to provide a written or electronic prescription at the time. If a Schedule II drug is dispensed in an emergency the practitioner must deliver a signed prescription to the dispenser within seven days after authorizing an emergency oral prescription or if delivered by mail it must be postmarked within the seven day period. The pharmacist must note on the prescription that it was filled on an emergency basis. A Schedule III-V drug can only be dispensed pursuant to a valid prescription or an oral prescription. However, an oral prescription must be promptly reduced to a written or electronic prescription. A non-controlled legend drug can only be dispensed pursuant to a valid prescription or an oral prescription. However, an oral prescription must be promptly reduced to a written or electronic prescription.

While this is a new rule, this rule incorporates aspects of several current rules. This rule eliminates the variance between prescriptions in different settings and makes the minimum requirements across the board. Current WAC 246-869-090 applies to

---

100 [https://app.leg.wa.gov/RCW/default.aspx?cite=18.64.550](https://app.leg.wa.gov/RCW/default.aspx?cite=18.64.550)

prescription transfers and requires prescriptions to have the patient's name and address, the date of issuance, number of refills, date of the last refill and the original prescription number. Current WAC 246-870-030\(^{102}\) covers prescription requirements for electronic transmission of a prescription and requires that the prescription must include: the prescribers' names and physical address, DEA registration number, date of issuance, patient's name and address, drug name, dose, route, form, directions for use and quantity, signature of the prescriber, refills, place to note allergies, generic equivalent substitution, and any other requirements under 21 CFR. Current WAC 246-871-050, which applies to parenteral prescriptions must have: patient name and address, drug name, strength and quantity, directions for use, date written, prescriber's name and a provision for generic substitution. Finally, this is a new rule it incorporates what is in WAC 246-887-020(6) and (9)\(^{103}\) for the dispensing of schedule II drugs in an emergency and dispensing of Schedule III-V drugs with an oral prescription.

**Cost/Benefit Analysis:** There are no costs associated with this rule. While this is a new rule it incorporates requirements that are already required in a variety of settings. This new rule will not change what is current practice but instead creates minimum requirements that will apply to all prescriptions, thus adding to the benefit of ensuring that there is a baseline that all valid prescription shall meet.

3. **WAC 246-945-011 Prescriptions: Validity**

**Description of the proposed rule:** This proposed rule requires a pharmacist to verify that a prescription is valid prior to dispensing. This rule language identifies what would make a prescription invalid which includes; if it appears altered, erased or added to, does not contain the minimum requirements of WAC 246-945-010, is expired, or does not contain the standards in RCW 69.50.308\(^{104}\). The proposed rules also establish time references for pharmacists to use when determining if a prescription is valid. Controlled substance prescriptions expire after six months, and non-controlled after twelve.

**Cost/Benefit Analysis:** There are no costs associated with this proposed new rule. In both chapter 18.64 RCW and current WACs, pharmacist are required to dispense to a valid prescription. This new section simply outlines and clarifies what would constitute an invalid prescription.

4. **WAC 246-945-013 Partial Filling of Prescriptions**

**Description of the proposed rule:** This proposed rule establishes that a pharmacist may partially fill a non-controlled legend drug and controlled substances III-V, provided the partial fill is required by the patient or prescriber, it is recorded in the same manner as a refill, and the total quantity dispensed and delivered does not exceed the total quantity prescribed. Partial fills of Schedule III-V must be done in compliance with 21 CFR

---


1306.23. It also states that Schedule II substances may be partially filled within the limits of RCW 18.64.265, 21 U.S.C. § 829, and 21 C.F.R. § 1306.13.

**Cost/Benefit Analysis:** There are no costs associated with this rule. This rule establishes the guidelines within which medications can be partially filled and makes clear that these will be noted as refills to align with processes the pharmacist already does.

5. **WAC 246-945-016 Prescriptions – Outpatient Labels – Minimum Requirements**

**Description of the proposed rule:** This proposed rule creates requirements for labeling of outpatient prescriptions. RCW 18.64.246 lists the minimum requirements that must be on a label for a prescription. This proposed rule requires compliance with RCW 18.64.246 and RCW 69.41.050, but adds additional requirements. It requires the prescription label to list the quantity dispensed, number of refills remaining, a warning that prohibits the transfer of the drug to any person or “for veterinary use only” when dispensed for an animal, the name and species of the patient if a veterinary prescription, and the name of the facility or entity authorized to possess a legend drug if the patient is the facility or entity. This proposed rule also establishes that any compounded product must meet the labeling requirements of USP <795>, <797>, <800> and <825>. This also includes requirement that it have a Beyond Use Date that shall be equivalent to the expiration date required by RCW 18.64.246. The proposed rule establishes that in determining the expiration date the dispenser shall take into account the nature of the drug, the container it was packaged in and that expiration date, the characteristics of the patients container, the expected conditions to which the drug may be exposed, the expected length of time of the course of therapy and any other relevant factors.

While this is a new rule it incorporates current rules. Current WAC 246-869-210 requires a label to contain the quantity dispensed, a warning statement, and the expiration date. Compliance with USP is also already established in RCW 18.64.270. The rule also establishes the factors that the dispenser must take into account when determining the expiration date which are the same as required in the new rule.

**Cost/Benefit Analysis:** There are no costs associated with this proposed rule. Labeling requirements are already established in RCW 18.64.246 and the current WAC 246-869-210; this rule adds the additional requirement that the number of refills must be noted on the label. Which is already collected information and will not require additional staff time to include on the label.

6. **WAC 246-945-030 Identification of Legend Drugs for Purposes of Chapter 69.41 RCW**

**Description of the proposed rule:** This proposed rule establishes what drugs meet the definition of legend drugs. Drugs determined by the FDA to require a prescription under federal law should be classified as legend drugs under state law. The proposed rule further finds that legend drugs are those drugs designated as legend drugs under federal law.

106 [https://app.leg.wa.gov/RCW/default.aspx?cite=18.64.270](https://app.leg.wa.gov/RCW/default.aspx?cite=18.64.270)
107 [https://app.leg.wa.gov/RCW/default.aspx?cite=18.64.246](https://app.leg.wa.gov/RCW/default.aspx?cite=18.64.246)
law and listed in either the Orange Book, Green Book or Purple Book. The proposed rule establishes that copies of these referenced book are available for public inspection at the Commissions office. The proposed rule further identifies ephedrine products in WAC 246-945-031 as legend drugs. Finally, the rule establishes the marketing status of the drugs identified in this section may change. If that happens the Commission may grant authority for the over the counter distribution of those drugs, the determination will be made after a public hearing and published as an amendment to this chapter.

**Cost/Benefit Analysis:** There are no costs associated with this rule, this rule establishes reference materials for the identification of legend drugs and makes clear the process by which legend drugs can be reclassified to be sold as over the counter medication.

7. **WAC 246-945-032 Child Resistant Containers**

**Description of the proposed rule:** This proposed rule establishes the requirement that all legend drugs be dispensed in a child-resistant container as required by federal law unless authorization is received. The proposed rule establishes that authorization can be from the prescriber or from the patient or representative of the patient. A pharmacist nor pharmacy employee may designate themselves as the patient’s agent.

While this is a new rule it incorporates current WAC 246-869-230 but it eliminates the specific ways in which authorization can be given.

**Cost/Benefit Analysis:** There are no costs associated with this rule, it incorporates current rule with more flexibility in how that authorization may be received.

8. **WAC 246-945-145 License Required**

**Description of the proposed rule:** This proposed rule establishes that any individual who provides pharmacy services to Washington residents must be credentialed by the commission, but exempts those who are in the employ or affiliation of a licensed nonresident pharmacy.

**Cost/Benefit Analysis:** There are no costs associated with this rule, this rule incorporates what is already established in RCW 18.64.020 while making clear that those who are in the employ of a nonresident pharmacy do not need to be credentialed by the commission, thus preventing them from having to incur any of the licensure costs required by the state.

9. **WAC 246-945-156 Pharmacy Intern – Temporary Practice Permit**

**Description of the proposed rule:** This proposed rule establishes the temporary practice permit that allows for a pharmacy intern credentialed in another state, which holds

---

substantially similar standards to those of Washington state, to practice as a pharmacy intern. The proposed rule language creates limitations under which the permit would be issued, identifies when the permit would expire, and identifies what one would have to do in order to receive a temporary permit. This is not creating a new license type because the temporary practice permit was already established in current WAC 246-836-035\textsuperscript{110} but clarifies that an out of state intern can get a temporary practice permit.

**Cost/Benefit Analysis:** The cost associated with this are identical to those for any other pharmacy intern and are as follows:

<table>
<thead>
<tr>
<th>Type of cost</th>
<th>Cost to pharmacy intern</th>
</tr>
</thead>
<tbody>
<tr>
<td>Original credential</td>
<td>$45</td>
</tr>
<tr>
<td>Credential renewal</td>
<td>$45</td>
</tr>
<tr>
<td>Late renewal penalty</td>
<td>$45</td>
</tr>
<tr>
<td>Verification of internship hours</td>
<td>$25</td>
</tr>
<tr>
<td>Expired credential reissuance</td>
<td>$45</td>
</tr>
</tbody>
</table>

These costs are outweighed by the benefit of allowing individuals who may be credentialed in another state to practice in Washington, increasing the state’s potential pool of qualified individuals in the field and increasing patient access to pharmacy care.

10. **WAC 246-945-162 Pharmacist License Qualifications**

**Description of the proposed rule:** This proposed rule requires an applicant to hold a baccalaureate degree in pharmacy or a doctor of pharmacy degree from an accredited school or college. Applicants must provide documentation of their education and practice experience. Evidence of practice experience for an applicant who graduated before July 1, 2020 shall provide certification of fifteen hundred hours. An applicant who graduated after July 1, 2020 and whose official transcript confer or award a doctorate of pharmacy is deemed to have satisfied the pharmacy practice experience and education requirement without documentation of internship hours.

The proposed rule also establishes documentation required for licensure for any foreign trained applicants; this includes certification by the Foreign Pharmacy Graduate Examination Committee which includes passing the Foreign Pharmacy Graduate Equivalency Examination and, official transcripts or diploma, certification of 1500 internship hours, and passage of approved licensure examinations.

This proposed rule establishes that all applicants must complete seven hours of AIDS education, with an exemption if the applicant is a graduate of a school or college accredited by the Accreditation Council for Pharmacy Education because the curriculum satisfies this requirement.

\textsuperscript{110} https://apps.leg.wa.gov/WAC/default.aspx?cite=246-863-035
While this is a new rule it incorporates aspects of current rules. Current WAC 246-858-020(3)\textsuperscript{111} states that “no pharmacist license will be issued to the applicant until the fifteen hundred internship hours have been completed.” This rule continues to apply that fifteen hundred hours to graduates prior to the effective date of this rule. However, they are removing the specific requirement of graduates from a commission accredited school or college of pharmacy after the effective date of these rules to provide documentation of the fifteen hundred internship hours because this is now covered in their graduation requirements.

The requirements for a foreign trained pharmacist are currently in WAC 246-863-040\textsuperscript{112} which include passing the FPGEE, receiving educational equivalency certificate by the commission, pass the licensure exams and perform fifteen hundred internship hours.

The AIDS education requirement is already established in current WAC 246-863-120\textsuperscript{113}; however, the exemption is taken from current commission policy document\textsuperscript{114} and put into rule.

**Cost/Benefit Analysis:** There are no costs associated with this rule, the requirements for this rule mirror what is already established in several chapters throughout current WAC, this rule simply takes those requirements and puts them into a single section so any pharmacist licensee can know where to look for their specific requirements. A change from current WAC requirements is that a licensee is no longer be required to track their hours and submit to the commission, which could be a potential cost saving to them.

11. WAC 246-945-165 Pharmacist Licensure and Jurisprudence Examinations

**Description of the proposed rule:** This proposed rule establishes the requirements for examinations in order to apply for a pharmacist license. An individual is authorized by the commission applying for a pharmacist license shall take and pass the pharmacy licensure and jurisprudence exam approved by the commission. A score of 75 is required on each exam. An individual who fails either the licensure or jurisprudence exams three times shall not be authorized to take further exams until they have completed a study or tutorial program approved by the commission. An applicant who has passed a licensure exam in another state may transfer their score to meet the commission’s licensure requirement provided the applicant meets the requirements of WAC 246-945-162 and the applicant completed the score transfer prior to it expiring one year from the date the Department receives the application.

\textsuperscript{111} https://apps.leg.wa.gov/wac/default.aspx?cite=246-858-020
\textsuperscript{112} https://apps.leg.wa.gov/wac/default.aspx?cite=246-863-040
\textsuperscript{113} https://apps.leg.wa.gov/WAC/default.aspx?cite=246-863-120
While this is a new rule it incorporates current WAC 246-863-020\textsuperscript{115}. This rule holds the same requirements as described above. The only change is the licensure exam is added to the limit of three attempts of passage before a study or tutorial program is required.

**Cost/Benefit Analysis:** There are no costs associated with this rule. This rule incorporates what is already established in current WAC while adding the additional limitation of failing the licensure exam three times requires completion of an approved study or tutorial program before the commission will authorize the individual to retake the exam. This additional requirement is necessary to ensure patient safety.

12. **WAC 246-945-170 Pharmacist Licensure by License Transfer – Temporary Practice Permits**

**Description of the proposed rule:** This proposed rule establishes the way in which an individual may transfer a license to practice in Washington state and how to obtain a temporary practice permit. The proposed rule establishes that an individual who holds an active pharmacist license and is in good standing in another state may apply for a pharmacist license in Washington through license transfer. The individual must complete the commission’s application, file for a license transfer through NABP eLTP (NABP’s Electronic Licensure Transfer Program) process and take and pass the approved jurisprudence exam.

The proposed rule also establishes the process by which an applicant for a pharmacist license by transfer may obtain a temporary practice permit. In order to receive a temporary practice permit the applicant must comply with the requirements in (1) and meet the following criteria. The applicant cannot be subject to denial of a credential or issuance of a conditional or restricted credential in any US Jurisdiction, cannot have a criminal record in Washington state and the applicants fingerprint-based national background check results are pending. The applicant must submit a written request for a temporary practice permit and pay the applicable fees.

A temporary practice permit expires when a pharmacist license is issued, when a notice of decision is mailed or one hundred and eighty days after the temporary practice permit is issued. The applicant may apply for a one time extension.

A temporary practice holder cannot qualify as a responsible pharmacy manager.

While this is a new rule it incorporates many aspects of current rules. Current WAC 246-863-030\textsuperscript{116} covers reciprocity applicants, the new rule covers license transfer from another US jurisdiction, this current rule requires the passing of the jurisprudence exam. The new rule requires the applicant to apply for the license transfer through NABP eLTP. Current WAC 246-945-035\textsuperscript{117} covers temporary practice permits, the requirements are

\begin{itemize}
  \item \textsuperscript{115} https://apps.leg.wa.gov/wac/default.aspx?cite=246-863-020
  \item \textsuperscript{116} https://apps.leg.wa.gov/wac/default.aspx?cite=246-863-030
  \item \textsuperscript{117} https://apps.leg.wa.gov/wac/default.aspx?cite=246-863-035
\end{itemize}
the same except this new rule allows for a one time extension to the temporary practice permit.

**Cost/Benefit Analysis:** There are no costs associated with this rule, this rule is different from current WAC in that it requires an applicant to apply for a license transfer through NABP eLTP, this is a cost of $375. While this is not explicitly stated in current rule, this is a current requirement. The benefit of updating this WAC is that it allows for rule to more completely reflect current practice. The other change in rule is the one time extension, and there are no costs associated with this.

13. **WAC 246-945-173 Expired Pharmacist License**

**Description of the proposed rule:** This proposed new rule establishes the process by which a pharmacist can return to active status after their license has expired. If a license is expired for less than three years the pharmacist shall meet the requirements of chapter 246-12 WAC, Part 2\(^\text{118}\) and complete 15 Continuing Pharmacy Education (CPE) hours per year the license was expired.

If the license has been expired for three or more years and the pharmacist holds an active credential in another US jurisdiction and is in good standing then they shall meet the requirements of chapter 246-12 WAC, Part 2. They shall also provide certification of active pharmacist license which includes name and license number, issue and expiration dates, and verification that the license is not subject of final or pending disciplinary action. They shall submit verification of current active pharmacy practice\(^\text{119}\) and take and pass the approved jurisprudence exam.

If a license has been expired for three years or more and the pharmacist has not been in active practice then the pharmacist shall meet the requirements of chapter 246-12 WAC, Part 2, serve 300 internship hours in compliance with WAC 246-945-163, and take and pass the approved jurisprudence and licensure exams.

While this is a new rule it incorporates sections of current rule. WAC 246-863-090\(^\text{120}\) currently covers what an individual must do in order to return to active status after having an expired license. This new rule differs from current WAC in 3 ways. First, it removes the option for an expired license for 3-5 years and instead makes it so that any license expired for 3 years or more, who has not been in active practice elsewhere, must take the full commission exam, meaning both the jurisprudence and licensure exam, rather than just the jurisprudence exam. This rule also adds additional information required to confirm an active pharmacist license and specially states how the individual will submit verification of active practice by referencing the current reporting form.

---

\(^{118}\) [https://apps.leg.wa.gov/WAC/default.aspx?cite=246-12-040](https://apps.leg.wa.gov/WAC/default.aspx?cite=246-12-040)

\(^{119}\) [https://www.doh.wa.gov/Portals/1/Documents/Pubs/690104.pdf](https://www.doh.wa.gov/Portals/1/Documents/Pubs/690104.pdf)

**Cost/Benefit Analysis:** As noted above this rule makes some changes to the current WAC by removing the difference between an individual whose license has been expired from 3-5 years and 5 years or more, and instead creates requirements for an individual whose license has been expired for 3 years or more. The new requirement from this change is that a person whose license has been expired between 3-5 years must take both the licensure and jurisprudence exam as opposed to just the jurisprudence exam. While there is a cost of taking the licensure exam that cost is outweighed by ensuring that an individual who is wishing to return to active practice in Washington state has an adequate knowledge of current Washington pharmacy laws. The cost of this examination is $100 application and $475 exam.

**14. WAC 246-945-178 Pharmacist Continuing Education**

**Description of the proposed rule:** This proposed rule establishes that each pharmacist shall complete 3.0 continuing pharmacy education (CPE) units administered by the Accreditation Council for Pharmacy Education (ACPE) accredited provider. The proposed rule language requires the pharmacist to register with a program designated for tracking completed hours. A one-time suicide screening and referral training is required, and shall be at least 3 hours long and chosen from the department’s model list of approved programs. The suicide training can count towards the overall CPE hour requirements. Finally, the proposed rule clarifies that CPE hours cannot be carried over from one renewal cycle to another.

**Cost/Benefit Analysis:** There are no costs associated with this rule. The current rule, WAC 246-861-090(1), requires 1.5 CPEs each year; however, included in this new chapter is a change in the pharmacist renewal cycle from one to two years. There is not an overall increase in the number of hours required; instead, the proposed rule allows the pharmacist the ability to obtain these CPE hours over the course of the two year renewal period. The one-time suicide prevention training is also established in both current rule, WAC 246-861-105, and in law, RCW 43.70.442.

**15. WAC 246-945-103 Pharmacy Technician-in-Training Authority for Experiential Training**

**Description of the proposed rule:** This proposed rule requires an individual who is enrolled in a pharmacy technician in training program to obtain a technician in training endorsement. This will allow them to get initial certification or to completed additional practical experience before receiving a technician certification. The technician in training endorsement is limited to those locations identified on the application. Finally, the proposed rule also requires the applicant to file an application to become a pharmacy assistant, including information highlighting enrollment in an approved training program.

123 [https://app.leg.wa.gov/RCW/default.aspx?cite=43.70.442](https://app.leg.wa.gov/RCW/default.aspx?cite=43.70.442)
the proposed rule establishes the circumstances when the in-training authority becomes inoperable or suspended.

**Cost/Benefit Analysis:** There are no additional costs associated with this proposed rule. The individual would be required to pay the established $35 credentialing fee for a pharmacy assistant license, but would not be required to pay to receive the in-training authority.

16. **WAC 246-945-205 Pharmacy Technician Certification**

**Description of the proposed rule:** This proposed rule states requirements to be certified as a pharmacy technician to ensure licensee applications align with the qualifications set out in RCW 18.64A.020. This proposed rule requires 8 hours of guided study on state and federal pharmacy law, and 4 clock hours of AIDS education with an exemption if the applicant takes a commission approved program and has materials on file with the commission. The proposed rule language also requires proof of successful completion of a technician training program (including the requirements from WAC 246-945-215), and passage of a national certification exam. The proposed rule also establishes requirements for individuals who are graduates of a foreign school, including taking and passing the TOEFL iBT (if English is not their primary language), completing 520 hours of supervised experience and pass the national certification exam. Finally, the proposed rule establishes that out of state applicants must meet the same requirements as pharmacy technicians trained in Washington state.

**Cost/Benefit Analysis:** There are no costs associated with this proposed rule, as it incorporates much of what is already established in statute, WAC 246-901-030, and WAC 246-901-060. The proposed rule also incorporates WAC 246-901-120, although it separates out technicians from assistants and provides an exemption for a commission approved program. This language is taken from a current commission policy statement and puts that statement into rule. While not currently stated in WAC the requirement that a commission approved training program include eight hours of pharmacy law is stated on the commissions website for education requirements, this is simply putting that established criteria into rule.

17. **WAC 246-945-215 Pharmacy Technician Education and Training Programs**

---

129 [https://www.doh.wa.gov/LicensesPermitsandCertificates/ProfessionsNewReneworUpdate/PharmacyTechnician/LicenseRequirements](https://www.doh.wa.gov/LicensesPermitsandCertificates/ProfessionsNewReneworUpdate/PharmacyTechnician/LicenseRequirements)
Description of the proposed rule: This proposed rule establishes a list of approved pharmacy technician training programs; American Society of Health-Systems Pharmacist, Accreditation Council for Pharmacy Education, Pharmacy Technician Certification Board, and the United States Armed Services. It also establishes the minimum requirements for approved training programs. The proposed rule language requires the program director of these training program to be a pharmacist and meet minimum requirements, which include preparing students for entry-level practice in a variety of settings, multicultural health curriculum, and a minimum of 15 weeks but less than 24 months that covers three different options for trainings, including vocation or technical, formal or academic, or on-the-job. The proposed rule also establishes a process for programs that would like official recognition from the commission, which includes submitting an application, designating a licensed pharmacist, providing copies of training manuals, content of instruction, methods for evaluation, and verification of 8 hours of pharmacy law. Finally, the proposed rule requires the programs to be approved every 5 years, and establishes that any substantive changes to the program needs to be reported to the commission.

Cost/Benefit Analysis: There are no additional costs associated with this rule. This proposed rule is simply codifying the Commission’s current approval practice and minimum criteria for technician training programs through the department’s “Guidelines for the Implementation of a Washington Pharmacy Technician Training Program,” which has been used as a standard for the Commission to approve all technician training programs, required by RCW 18.64A and WAC 246-901-050 which states that the board (now commission) will establish standards for approval of technician training programs.

18. WAC 246-945-242 Pharmacy Technician – Continuing Education Requirements

Description of the proposed rule: The proposed rule requires a pharmacy technician to complete 20 hours of CPEs administered by an ACPE accredited program in order to renew their license. The proposed rule language state that the pharmacy technician shall register with a program designated by the commission to track completed CPE hours. Finally, the proposed rule establishes that completed CPE hours may not be carried over into the next renewal period.

Cost/Benefit Analysis: There are no costs associated with this proposed rule. This proposed rule language takes what is in current WAC 246-901-061 but increases the number of required hours from 10 to 20; however, at the same time, this chapter increases the renewal cycle to two years rather than one, so there is not an increase in the overall number of hours. This proposed rules also eliminates all the specific requirements of what must be covered in CE and instead makes reference to ACPE accredited programs.

130 https://www.doh.wa.gov/Portals/1/Documents/Pubs/690001.pdf
19. WAC 246-945-233 Hospital Pharmacy Associated Clinics (HPACs)

**Description of the proposed rule:** This proposed rule establishes the process for Hospital Pharmacy Associated Clinics (HPACs) to receive licensure. This proposed rule identifies that a parent hospital pharmacy may add or remove HPACs listed on their license at any time in compliance with WAC 246-945-230(a), (b), and (d). The proposed rule requires a designation of a responsible pharmacy manager and creates categories of HPACs. The first category of HPAC receives drugs transferred from the parent hospital pharmacy but does not perform compounding. The second category of HPACs receives drugs and performs sterile and non-sterile compounding services. Finally, the proposed rule makes clear that if the HPAC possesses controlled substances, they must register with the DEA.

**Cost/Benefit Analysis:** The standards established in this proposed rule have been in place by emergency rule since July 22, 2016, after the passage of ESSB 5460. The costs associated with this proposed rule are the registration fees associated with the license, currently established in WAC 246-907-0302. This proposed rule would permanently codify the HPAC emergency rules.

<table>
<thead>
<tr>
<th>Category 1 HPAC tier</th>
<th>Number of Category 1 HPACs under parent hospital pharmacy license</th>
<th>Total annual fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>1-10</td>
<td>$895.00</td>
</tr>
<tr>
<td>B</td>
<td>11-50</td>
<td>$2,240.00</td>
</tr>
<tr>
<td>C</td>
<td>51-100</td>
<td>$3,125.00</td>
</tr>
<tr>
<td>D</td>
<td>Over 100</td>
<td>$4,025.00</td>
</tr>
</tbody>
</table>

**Category 2**

| Category 2 | $755.00 |

This proposed rule would also require a DEA registration, which would be subject to any associated costs (currently $731 for a registration of 3 years). It is already established on the department’s HPAC FAQ webpage that each clinic will get a DEA registration.

Additional costs for HPACs would be determined based on their new category. Category 2 facilities would be subject to all USP standards as established in RCW 18.64.270 for any compounding of drugs that takes place within the facility. Depending on the type of compounding practices taking place at the HPAC, there could be more stringent requirements requiring additional infrastructure. While there is a potential additional cost for ensuring compliance with USP, this has been established in RCW since 2013, so

---


135 [https://www.doh.wa.gov/LicensesPermitsandCertificates/ProfessionsNewReneworUpdate/PharmacyCommission/HPACFAQs](https://www.doh.wa.gov/LicensesPermitsandCertificates/ProfessionsNewReneworUpdate/PharmacyCommission/HPACFAQs)

136 [https://app.leg.wa.gov/RCW/default.aspx?cite=18.64.270](https://app.leg.wa.gov/RCW/default.aspx?cite=18.64.270)

these costs should already be assumed by the licensee. By ensuring that best practices are taking place when performing compounding, which has the potential for negative consequences to patient safety if not done correctly, the costs are justified and outweighed by the benefits.

20. WAC 246-945-235 Non-Resident Pharmacy License

Description of the proposed rule: This proposed rule establishes the process a non-resident pharmacy will follow in order to be licensed. The proposed rule language states that in order to receive a license, the non-resident pharmacy must provide all requirements from RCW 18.64.360\(^{138}\) and that it is in good standing in their resident state. A responsible pharmacy manager must be identified upon application, and the commission must be notified of changes.

Cost/Benefit Analysis: There are no costs associated with this rule. While current WAC 246-869-030, 246-869-040 and 246-869-070 establish rules for all pharmacies, this new rule differentiates requirements for non-resident pharmacies, and puts into rule requirements the current application procedure that is outlined on the department’s licensing website for non-resident pharmacies and what is used to determine licensure eligibility.

21. WAC 246-945-245 Health Care Entity Licensure

Description of the proposed rule: The proposed rules establishes compliance with WAC 246-945-230, designation of a responsible pharmacy manager and states that the license is location specific and non-transferable; it also states that each clinic must obtain a separate license for each location.

Cost/Benefit Analysis: There are no costs associated with this proposed rule. This proposed rule is putting into rule what has already been established in current WAC 246-904-020\(^{139}\) and WAC 246-904-030\(^{140}\), but changes “pharmacist in charge” to “responsible pharmacy manager” to remain consistent throughout the rules. This proposed rule also puts into rule what has been established procedure and requirements for licensure under the department’s HPAC FAQ\(^{141}\) page, which compares requirements between HPACs and HCEs, and is utilized to determine licensure.

22. WAC 246-945-246 Wholesaler

Description of the proposed rule: The proposed rule establishes who qualifies as a wholesaler and is eligible to be licensed, and requires compliance with WAC 246-945-230. The proposed rule creates additional requirements for wholesalers located outside of Washington state must submit a copy of an inspection, copy of their state license and a

\(^{138}\) [https://app.leg.wa.gov/RCW/default.aspx?cite=18.64.360](https://app.leg.wa.gov/RCW/default.aspx?cite=18.64.360)  
\(^{141}\) [https://www.doh.wa.gov/LicensesPermitsandCertificates/ProfessionsNewReneworUpdate/PharmacyCommission/HPACFAQs](https://www.doh.wa.gov/LicensesPermitsandCertificates/ProfessionsNewReneworUpdate/PharmacyCommission/HPACFAQs)
list of licenses held in other states. The proposed rule also creates additional requirements for the export of non-controlled drugs to foreign jurisdictions, requiring letters from the consulate of the country of which the drugs are being exported, and makes clear that an export license does not authorize delivery within the US. The proposed rule establishes the minimum qualifications that the Commission will consider when reviewing the qualification for individuals who are engaged in wholesale distribution. The items considered will be any convictions relating to drug samples, wholesale or distribution, any felony convictions, the applicants past experience in the manufacture and distribution of drugs, any false or fraudulent information on the application, a suspension or revocation of any license previously or currently held, compliance with licensing requirements under any previously granted licenses, compliance with record requirements, and any other factors that the commission considers relevant and consistent with public health and safety. Finally, the proposed rule makes clear that if operations are conducted at more than one location, each location must be licensed.

Cost/Benefit Analysis: There are no costs associated with this rule. The new rule lists the wholesaler entities that would require a license, this aligns with the current list of wholesaler entities listed on the department’s website. This proposed rule is incorporating WAC 246-879-070 (6)(b)\(^\text{142}\). The proposed rule also creates a list of required information in order for an out of state wholesaler to be licensed; this is a minor change from current rule which asks for information compiled by NABP (WAC 246-879-120)\(^\text{143}\); instead this rule requires a copy of a site inspection, resident license and a list of licenses, registrations and permits in other states which is currently listed on the departments licensing page\(^\text{144}\). This is not a new requirement for licenses or rather codifies the requirement in rule. This rule incorporates WAC 246-879-090\(^\text{145}\) for export wholesalers. Finally, it incorporates current WAC 246-945-070(6)(a)(vi) requiring each location activities occur to be licensed.

23. WAC 246-945-250 Researcher, and Other Controlled Substance Registration

Description of the proposed rule: This proposed rule establishes a researcher registration for non-controlled legend drugs and a separate authority to be added to the license for controlled substances. Those who register for a controlled substance research registration must apply through the commission, as well as register with the DEA. The proposed rule also establishes other controlled substance registrations for opioid treatment programs, analytical laboratories, dog handlers, and other agencies who have demonstrated a legitimate need to use precursor chemicals. The proposed rule requires all applicants to list all legend drugs and controlled substances to be used and their purpose, the name of the primary registrant, and the names of all persons authorized to

\(^\text{142}\) https://apps.leg.wa.gov/wac/default.aspx?cite=246-879-070
\(^\text{143}\) https://apps.leg.wa.gov/wac/default.aspx?cite=246-879-120
\(^\text{144}\) https://www.doh.wa.gov/LicensesPermitsandCertificates/FacilitiesNewReneworUpdate/PharmaceuticalFirms-LicenseRequirements
access the controlled substance. Finally, the applicants must undergo an initial and periodic inspections as deemed appropriate by the commission.

**Cost/Benefit Analysis:** There are no costs associated with this rule; this rule may save some researchers costs. Current WAC only has a researcher registration that covers all drugs, both non-controlled and controlled; this proposed new rule allows for a researcher who does not use controlled substances to get a different license that then has a lower fee associated with it.

**24. WAC 246-945-255 Chemical Capture – Department of Fish and Wildlife**

**Description of the proposed rule:** The proposed rule establishes the registration requirements for the department of fish and wildlife to apply to the commission in order to purchase, possess and administers controlled substances and legend drugs for use in the chemical capture program. The proposed rule requires that each field office which stores controlled substances or legend drugs must register with the commission, including the names of individuals who are authorized. Finally, the proposed rule requires the department of fish and wildlife to designate an individual who is responsible for the ordering, possessing, storage and utilization of the controlled substances and legend drugs.

While this is a new rule it incorporates current WAC 246-886-160\(^{146}\) which has these same requirements, however, this new rule adds legend drugs to the registration.

**Cost/Benefit Analysis:** There are no costs associated with this rule. This rule just adds an allowance for legend drugs to also be used by the Department of Fish and Wildlife.

**25. WAC 246-945-315 Delegation of Pharmacy Functions to Pharmacy Ancillary Personnel**

**Description of the proposed rule:** This proposed rule establishes the functions that may be delegated under the immediate supervision of the pharmacist. The proposed rule further establishes that immediate supervision can be done through the use of technology, taking what is also established in the definitions. It requires that the use of technology must comply with all applicable rules and laws ensuring confidentiality. The proposed rule further clarifies that the use of technology must be sufficient to provide the personal assistance, direction and approval required to meet the standard of practice for the delegated tasks. The proposed rule makes clear that limited functions may be delegated to a pharmacy assistant. The proposed rule states that a pharmacist may delegate tasks to a pharmacy technician provided those tasks are within the scope of practice, education, skill, and experience of the technician and that none of the delegated functions are in WAC 246-945-320. Finally, he proposed rule makes clear that limited functions may be delegated to a pharmacy assistant in accordance with RCW 18.64A.030 as well as the ability to prepackage and label drugs for subsequent use and count, pour and label for individual prescriptions.

While this is a new rule it incorporates aspects of current rules. Current WAC 246-901-020\(^{147}\) states that technicians can perform nondiscretionary tasks consistent with their training under the immediate supervision of a pharmacist. This rule references the non-delegable tasks and maintains that this must be done under the supervision of the pharmacist and within their education, skill and experience. Current WAC 246-901-070\(^{148}\) is the same language used in the proposed (3).

**Cost/Benefit Analysis:** There are no costs associated with this proposed rule. This proposed rule incorporates current WAC but adds an additional allowances for supervision via technology with the requirements for that supervision defined. The potential benefit of this is to allow a pharmacist to utilize their time in a more efficient manner when they can properly delegate certain tasks to an appropriately trained technician or assistant.

26. WAC 246-945-320 Non Delegable Tasks

**Description of the proposed rule:** This proposed rule establishes what tasks are not allowed to be delegated by the pharmacist to a technician. These tasks include: receipt of a verbal prescription, consultation with a patient, consultation with a prescriber, interpretation of data in a medical record, ultimate responsibility for all aspects of the completed prescription, patient counseling, substitution, the decision not to dispense a lawful prescription and prescription adaptation. The proposed rule also clarifies that a pharmacy intern can perform any pharmacy function based on their education, skill, and experience, except supervising other pharmacy personnel.

While this is a new rule it incorporates aspects of current WAC 246-863-095(2)\(^{149}\) with the addition of patient counseling which is currently not allowed to be delegated and prescription adaptation which is a new allowance under these rules.

**Cost/Benefit Analysis:** There are no costs associated with this rule. This rule takes much of what is already established in current WAC and adds two other actions that cannot be delegated, the addition of these two actions does not create a cost.

27. WAC 246-945-325 Patient Counseling

**Description of the proposed rule:** This proposed rule requires that the pharmacist offer to counsel on the initial fill of a prescription for a new or change of drug therapy, or when the pharmacist using their professional judgement determines counseling is necessary. The proposed rule makes clear that counseling is not required for medications administered by health professionals acting within their scope of practice.

While this is a new rule patient counseling is currently a requirement under WAC 246-869-220\(^{150}\), this proposed rule makes clear that the offer to counsel is required on the initial fill of a prescription rather than the current requirement on every prescription which stakeholders mentioned is a frustration they often encounter from patients. The exemption for administered medications is also in current WAC 246-869-220(4).

\(^{147}\) https://apps.leg.wa.gov/wac/default.aspx?cite=246-901-020
Cost/Benefit Analysis: There are no costs associated with this rule. This rule incorporates current rules but allows for some professional discretion when making the decision to counsel.

28. WAC 246-945-330 Refilling Prescriptions

Description of the proposed rule: This proposed rule establishes that a prescription drug order may be refilled when permitted by state and federal law and authorized by a prescriber. This also allows a pharmacist to renew a prescription for a non-controlled drug one time in a six month period when the prescriber is not available for authorization. The refill is limited to the most recent quantity filled or a thirty day supply, whichever is less, it must be requested by the patient or patient’s agent, the patient has a chronic medical condition, no changes have been made to the prescription and the renewal is communicated to the prescriber within one business day.

While this is a new rule it expands on what is already established in current WAC 246-869-100(1) which allows for an emergency refill of up to 72 hours. This current rule has been an area of concern has some medication is not available in a 72 hours supply.

Cost/Benefit Analysis: There are no costs associated with this rule. This rule expands on what is already established in current rule and allows pharmacist to utilize their professional judgement and ensure that patients are not denied care due to an inability to reach their prescriber.

29. WAC 246-945-332 Continuity of Care

Description of the proposed rule: This proposed rule establishes that when the Governor issues an emergency proclamation pharmacists and pharmacies may provide emergency prescription supplies. An initial supply of up to thirty days for legend drugs or seven day supply for controlled substances may be filled under specified conditions: presentation of a valid prescription container with a legible label indicating the number of refills available, if the prescription is expired or has no refills and a prescriber is unable to be reached they may dispense a one-time refill, or if the patient is unable to provide a valid prescription or contain a pharmacist may use their professional judgement when accepting a provider reconciled medication list. For any medication dispensed the pharmacist shall document it as a prescription and note which condition it was filled under, inform the patients provider and the pharmacy, and mark the face of the prescription as an emergency. Finally, the proposed rule clarifies that nothing in this rule modifies insurer’s requirements for coverage and payment.

While this is a new rule it incorporates current WAC 246-869-105 with the addition allowance for a the use of a provider reconciled medication list.

Cost/Benefit Analysis: There are no costs associated with this rule. This rule incorporates what is already established in current rule with the addition allowance for a the use of a provider reconciled medication list. The addition of the provider reconciled medication list would eliminate barriers for patients during an emergency, but would have no effect on a pharmacy or pharmacist.

30. **WAC 246-945-335 Prescription Adaptation**

**Description of the proposed rule:** This proposed rule allows for a pharmacist, upon the consent of the patient, to adapt drugs provided the prescriber has not indicated that adaptation is not permitted. The pharmacist may change the quantity if the quantity or package size is not commercially available, the change in quantity is related to a change in dosage form, the change is intended to dispense up to the total amount authorized by the prescriber including refills in accordance with RCW 18.64.520 or the change extends a maintenance drug for the limited quantity necessary to coordinate refills in a medication synchronization program. The pharmacist may change the dosage form if it is in the best interests of patient care as long as the prescriber’s direction are also modified to match. The pharmacist may complete missing information provided there is evidence to support the change. Finally, the proposed rule establishes that a pharmacist who adapts a prescription must document it in the patients’ medical records.

**Cost/Benefit Analysis:** There are no costs associated with this proposed rule. This proposed rule aligns with RCW 18.64.011 “Practice of Pharmacy” by allowing the pharmacist to utilize their professional judgment in order to meet the patient’s needs. This rule ensures that there is not a gap in care for patients.

31. **WAC 246-945-340 Prescriptions; Drug Product Substitutions**

**Description of the proposed rule:** This proposed rule establishes that a pharmacist may substitute a drug or biologic product pursuant to a prescription if in compliance with applicable rules and laws. A pharmacist may substitute under the following conditions; the substitution is permitted under RCW 69.41.120, the substitution is permitted by a formulary or the substitution is otherwise permitted by law. In addition to any other requirements a pharmacist can only substitute a drug or biologic if an employee or contractor of the institutional facility prescriber the drug or biologic to be substituted, the interdisciplinary team was composed of a non-pharmacist prescriber and a pharmacist, and the formulary is readily retrievable by the pharmacist.

**Cost/Benefit Analysis:** There are no costs associated with this rule. This rule does not impose any new requirements but rather states the circumstances under which a drug or biologic may be substituted.

32. **WAC 246-945-345 Prescription Transfers**

**Description of the proposed rule:** This proposed rule establishes the requirements in order for a prescription to be transferred and makes clear that this rule applies to the transfer of noncontrolled drugs, controlled substances need to be transferred in accordance with 21 CFR 1306.25. Upon a patient’s request, a prescription can be transferred in accordance with state and federal law. Sufficient information needs to be exchanged to maintain an auditable trail and all elements of a valid prescription. An exemption is made for pharmacies electronically sharing a real-time database; in that case, a prescription can be dispensed without a transfer. It requires that prescriptions be transferred electronically or by fax, except in emergent situations.
**Cost/Benefit Analysis:** There are costs associated with this proposed rule. The transfer of prescriptions is already permissible in current rule (WAC 246-869-090\(^{153}\)). However, this proposed new rule eliminates the specific requirements and instead states that “sufficient information” needs to be maintained. This proposed rule also requires the prescriptions to be transferred electronically or by fax; this would require pharmacies to have one of those technologies in place in order to participate in the transfer. The cost of a fax machine is approximately $500. However, recent numbers from SureScripts show that 99% are set up to send and receive electronic prescriptions, so most pharmacies should already be equipped to handle this, thus minimizing the potential costs. The benefits of strengthening the auditable trail for pharmacies and limiting the potential for errors is outweighed by any cost to implementing these proposed requirements.

33. WAC 246-945-355 Monitoring of Drug Therapy by Pharmacist

**Description of the proposed rule:** This proposed rule establishes what is meant by the term “monitoring drug therapy” as used in RCW 18.64.011(28)\(^{154}\) in the absence of a Collaborative Drug Therapy Agreement (CDTA.) The proposed rule language determines that monitoring drug therapy shall mean the review of the drug therapy regimen of patients for the purpose of evaluating and rendering advice to the prescriber regarding adjustment of the regimen. This shall include, but is not limited to, evaluation of patient history, physical examination, ordering, administering or reviewing lab test, imaging, and social evaluation. This should be done in relation to an existing diagnosis and drug therapies for the optimization of that drug therapy.

**Cost/Benefit Analysis:** There are no costs associated with this proposed rule. Monitoring drug therapy is already established in law, RCW 18.64.011(28)\(^{10}\) and rule WAC 246-863-110\(^{155}\). This new rule takes what is current practice and puts it into rule.

34. WAC 246-945-365 Approval of Impaired Practitioner Substance Abuse Monitoring Program

**Description of the proposed rule:** The proposed new rule establishes the commission’s rules regarding impaired practitioners substance abuse monitoring program. The commission will approve recovery, assistance and monitoring programs. The commissioner will consider a licensee to have not completed the program if they are discharged for a failure to comply with the programs terms or conditions. A licensee referred or required to participate in the program will be subject to disciplinary action if they fail to sign or revoke a waiver allowing the program to release information to the commission. An approved program will report a licensee who fails to comply within seven days. Finally, a licensee must report themselves to the commission if they fail to comply with RCW 18.130.175, terms and conditions, or any part of this section within 7 days, regardless of if the program has reported as well.

**Cost/Benefit Analysis:** There is no cost associated with this proposed rule. Current WAC 246-867-040\(^{156}\) established a process for approved programs; however, the


\(^{154}\) https://app.leg.wa.gov/RCW/default.aspx?cite=18.64.011


\(^{156}\) https://apps.leg.wa.gov/WAC/default.aspx?cite=246-867&full=true
proposed new rule eliminates these specific standards and allows for the commission to approve programs. This will allow for more flexibility in approving programs specific to the needs of those this is meant to assist. The proposed rule also references RCW 18.130-175\textsuperscript{157}, which established the law around voluntary substance abuse monitoring programs.

35. WAC 246-945-415 Dispensing and Delivery of Prescription Drugs

**Description of the proposed rule:** The proposed new rule establishes the requirements for the dispensing and delivering of prescription drugs. A pharmacy may deliver filled prescriptions as long as appropriate measures are taken to ensure product integrity and receipt by the appropriate person.

Pharmacies has a duty to deliver lawfully prescribed drugs and devices in a timely matter consistent with reasonable expectations except for under certain circumstances. Those circumstances are when; a prescription has an obvious or known error, inadequacies, contradictions, or incompatible prescriptions, a national or state emergency or guideline affecting availability, usage or supply of drugs, lack of specialized equipment or expertise necessary to safely produce, store or dispense the drug or device, potentially fraudulent prescriptions, or unavailability of a drug despite a good faith effort to have an adequate supply in stock. Nothing in this proposed rule requires a pharmacy to deliver without payment. If despite good faith compliance with having an adequate stock a prescription cannot be filled the pharmacy must provide the patient a timely alternative, which may include; contact the prescriber to address concerns, if requested by the patient return the unfilled prescription or transfer the prescription to a pharmacy of the patient’s choice. If a pharmacy destroys unfilled lawful prescriptions, refuses to return unfilled prescriptions, violates the patient’s privacy, discriminates against the patients or intimidates or harasses a patient it shall constitute grounds for discipline or other enforcement actions.

The proposed rule also allows for prescriptions to be picked up or returned for delivery by authorized personnel when the pharmacy is closed, if the prescriptions are placed in a secured area outside of the restricted drug area. The area must be a part of the licensed pharmacy and adequately equipped for security.

A health care entity must dispense in accordance with RCW 18.64.450. Hospital associated clinics may dispense patient specific drugs only pursuant to a valid prescription and the prescription is authenticated in the medical record according to the policies and procedures of the parent hospital pharmacy.

While this is a new rule it incorporates aspects of several current rules.

Proposed WAC 246-945-415(1) states that filled prescriptions may be delivered as long as appropriate measures are taken to ensure product integrity and receipt by the patient or a patient’s agent. The allowance for delivery and requirement of measures to ensure product integrity are currently in WAC 246-871-050 (5)\textsuperscript{158}; this section applies to parenteral products for nonhospitalized patients. The new language applies to all prescriptions.

\textsuperscript{157} https://app.leg.wa.gov/RCW/default.aspx?cite=18.130.175

\textsuperscript{158} https://apps.leg.wa.gov/wac/default.aspx?cite=246-871-050
Proposed WAC 246-945-415(2)-(5) is taken directly from current WAC 246-869-010159. Proposed WAC 246-945-415(6) is not in the current WACs; it creates an allowance for deliveries to be picked up and returned outside of the regular business hours. This will allow for continued patient care and expanded access as the ability for patients to have their drugs delivered to them continues to increase. In order to achieve this, appropriate measures need to be taken to ensure the security of the drugs.

Proposed WAC 246-945-415(7) simply specifies that the HCE’s must dispense according to the RCW.

Proposed WAC 246-945-415(8) takes current language from current emergency rule WAC 246-873A-050(2)160.

**Cost/Benefit Analysis:** There are no costs associated with this rule. This rule incorporates language from several current rules. The only new language is creating an allowance for filled prescriptions to be picked up and delivered when the pharmacy is closed for business. This is not a requirement but an option for pharmacies that wish to utilize this kind of service, there would be requirements to ensure safety and security of the drugs but that is not a new requirement.

### 36. WAC 246-945-417 Electronic Systems for Patients Medication Records, Prescriptions, Chart Orders, and Controlled Substance Records

**Description of the proposed rule:** This proposed new rule establishes the requirements for the electronic systems for patient medical records, prescriptions, chart orders, and controlled substance records. All pharmacies are required to use an electronic record keeping system to store patient medication records, prescription orders, including refill and transfer information, and other information necessary to provide safe and appropriate patient care. The system must prevent auto-population of user identification information. Pharmacies that provide offsite pharmacy services without a pharmacist for product fulfillment or prescription processing must track the identity of each individual involved in each step of the process.

The electronic recordkeeping system must be capable of real time retrieval of the information of the ordering, verification, and processing where possible.

The electronic recordkeeping system must include security features to protect the confidentiality and integrity, including safeguards to prevent and detect unauthorized access and functionality that documents any alteration of the prescription drug order information after it is dispensed. This includes identification of the individual responsible for the alteration.

The pharmacy must have policy and procedures in place for downtime, including once the system is operational all data is entered into the patients record within two business days.

---

All records must be maintained in accordance with WAC 246-945-020. Electronic prescriptions for controlled substances must be maintained in accordance with 21 C.F.R. § 1311.

Finally, HCEs and HPACs that maintain an electronic record must do so in accordance with these rules.

This proposed new rule incorporates many aspects of existing statute. The key difference between this proposed rule and previous rules is the requirement for all pharmacies to maintain an electronic recordkeeping system. Current statutes relating to recordkeeping allow for the option for electronic recordkeeping, but it is not a mandate.

Proposed new WAC 246-945-417 requires that all pharmacies must use electronic recordkeeping for patient medication records. Substitute Senate Bill 5380 was passed in 2019 mandating the use of electronic prescribing for all controlled substances, as well as integration of the prescription monitoring program with electronic health records. This proposed new rule aligns with both state and federal efforts to create a better system of electronic records and ease of access. Current WAC 246-875-001 establishes the purpose for the PHARMACY—PATIENT MEDICATION RECORD SYSTEMS chapter. This section states, “a patient medical record system is maintained by all pharmacies and other sites where the dispensing of drugs takes place, in order to insure the health and welfare of the patients served. This system will consist of certain patient and prescription information, and shall provide the pharmacist within the pharmacy means to retrieve all new prescription and refill prescription information relevant to patients of the pharmacy.”

Proposed new WAC 246-945-417(1)(b) states that the recordkeeping system for pharmacies providing offsite pharmacy services must track the identity of each individual involved in the process. Current WAC 246-875-001 states that the patient medical record system “shall be designed … to provide an audit trail.” Audit trail is then defined in WAC 246-875-010 as meaning “all materials and documents required for the entire process of filling a prescription, which shall be sufficient to document or reconstruct the origin of the prescription order, and authorization of subsequent modifications of that order.”

Proposed new WAC 246-945-417(2) states that the recordkeeping system must be capable of real-time retrieval of information where possible. Current WAC 246-875-060 requires that information be retrievable within 72 hours. This section of rule has not been updated since 2003; while it is a change requiring the information be immediately retrievable, advances in technology may allow for easier compliance.

Current WAC 246-875-001 states that the patient medical record system “shall provide the pharmacist within the pharmacy means to retrieve all new prescription and refill prescription information relevant to patients of the pharmacy.”

163 https://app.leg.wa.gov/wac/default.aspx?cite=246-875-010
165 https://app.leg.wa.gov/wac/default.aspx?cite=246-875-001
Proposed new WAC 246-945-417(3) states that the recordkeeping system must include security features to protect the confidentiality of the patient records, including safeguards to prevent and detect unauthorized access, modification or manipulation of prescription drug order information, as well as a functionality that documents any alterations and includes the identity of the individual responsible. Current WAC 246-875-070(3)\textsuperscript{166} states that security codes or systems must be established to prevent unauthorized modification of data. While there are current rules in place on minimum security requirements of data, this proposed new rule ensures that patient records are secure.

Proposed new WAC 246-945-417(4) states that a pharmacy must have policies and procedures in place for system downtime. Current WAC 246-875-050\textsuperscript{167} says that a procedure must be available for use when the automated data system is temporarily inoperative and once the system is functional the information shall be put into the patients’ medical record within two business days.

Proposed new WAC 246-945-417(5) states that a facility shall maintain records in accordance with WAC 246-945-020, this is not a new requirement as addressed in that section.

Proposed new WAC 246-945-417(6) requires controlled substance records compliance with the federal regulations, and proposed (7) requires that if an HCE or HPAC choose to use electronic recordkeeping then this section applies.

**Cost/Benefit Analysis:** There are costs associated with this rule. The costs associated would include purchasing an electronic recordkeeping system that meets the requirements. However, due to the fact that many of the requirements are already established in current statutes for patient medication record systems, it is likely that these systems already exist and would not need to be modified to adjust to the new rules. It is also likely that with the emphasis of moving towards increased electronic records systems on both a state and federal level that many facilities may already have these systems in place or may be moving towards them outside of the rules required here. The most recent data states that approximately 99% of pharmacies in Washington State are already equipped to handle electronic recordkeeping. There would also be cost savings in this as current rules require maintenance of records for 2 years, if a pharmacy is using paper recordkeeping those documents need to be stored. The cost of a pharmacy management system that meets these minimum requirements can range but an average minimum cost is approximately $3,317. The costs of this new rule are outweighed by the benefits of an electronic system for recordkeeping which could increase patient access and safety by allowing for quick and easy access to medical information so a pharmacist can make an informed decision about a patients medication therapy. It may also help protect against diversion or theft as the records would be safeguarded against manipulation or unauthorized access.

37. WAC 246-945-420 Facility Inventory Requirements

**Description of the proposed rule:** This new rule establishes the facility inventory requirements. A facility shall conduct a separate inventory of all prescription drugs when

\textsuperscript{166} https://app.leg.wa.gov/wac/default.aspx?cite=246-875-070

\textsuperscript{167} https://app.leg.wa.gov/wac/default.aspx?cite=246-875-050
it closes. A controlled substance inventory must be done every two years, or within 30 days of the designation of a new responsible pharmacy manager or when a new substance is scheduled as a controlled substance. A pharmacy that exclusively stores, dispense or delivers drugs without a pharmacist onsite must maintain a perpetual inventory. A pharmacy that exclusively stores, dispense or delivers drugs without a pharmacy staff onsite must maintain a perpetual inventory.

While this is a new rule, it incorporates many aspects of current rules.

Proposed new WAC 246-945-420(1) requires that when a pharmacy closes, a closing inventory of the prescription drugs must be performed and maintained. This is covered in current WAC 246-869-250 which requires confirmation that all legend and controlled substances have been transferred or destroyed. This is also addressed in further detail in proposed new WAC 246-945-480.

Proposed new WAC 246-945-420(2) requires an inventory of controlled substances every two years, which is a federal requirement.

Proposed new WAC 246-945-420(3)(a) requires an incoming responsible manager, or designee, to conduct a controlled substance inventory within 30 days of starting work. While there are no current statutes that explicitly states this, it is addressed in several current WACs. Current WAC 246-869-190(b) states that when a change in the responsible manager occurs, the new responsible pharmacy manager must complete a self-inspection worksheet within 30 days of becoming the responsible pharmacy manager. The self-inspection worksheet includes identifying the location of the controlled substances inventory. As defined in WAC 246-904-030, the pharmacist in charge is responsible for the accuracy of inventory records, patient medical records as related to the administration of controlled substances and legend drugs, and any other records required by state and federal regulations. As defined in WAC 246-869-070, the "responsible manager" ensures that the pharmacy complies with all the laws, rules, and regulations pertaining to the practice of pharmacy. Finally, WAC 246-887-020(3) states, "every registrant shall be required to keep inventory records required by section 1304.04 of the federal rules which have been adopted by reference by Rule 1) and must maintain said inventory records for a period of two years from the date of inventory. Such registrants are further required to keep a record of receipt and distribution of controlled substances. Such record shall include: (a) Invoices, orders, receipts, etc. showing the date, supplier and quantity of drug received, and the name of the drug.” These current WACs place the requirement of maintaining and ensuring the accuracy of the controlled substance inventory under the jurisdiction of the responsible pharmacy manager. The proposed new rule requires that any new responsible pharmacy manager complies with these laws within 30 days of taking on that role.

170 https://app.leg.wa.gov/wac/default.aspx?cite=246-869-190
Proposed new WAC 246-945-420(3)(b) is a new requirement; however, it aligns with other statutes requiring and inventory of controlled substances be maintained.

Proposed new WAC 246-945-420(4) and (5) are both new requirements requiring perpetual inventory for pharmacies that operate without either a pharmacist or pharmacy staff on site.

Cost/Benefit Analysis: There are minimal costs associated with this rule. The requirements in (1)-(3) are already current rules aside from (3)(b). Section 3(b) of this rule is not currently established in rule, however, it aligns with current requirements that inventory records of controlled substances must be maintained. This rule makes clear that when new substances are added they must be inventoried and included thereafter; this ensure that the pharmacy is complying with state and federal laws with regards to controlled substances. This requirement will cost the responsible pharmacy managers time, at a rate of approximately $260/hour\(^{175}\), but these costs are outweighed by the benefit of ensuring that all controlled substances, including newly added ones, are accurately inventoried to prevent theft or diversion. The costs for this cannot be estimated as the time it would take would vary depending on the inventory sizes, and other pharmacy specific factors.

The requirements for a perpetual inventory only apply when a pharmacy operates without a pharmacist or pharmacy staff on site. This is necessary to protect against diversion and ensure proper oversight.

38. WAC 246-945-425 Shared Pharmacy Services

Description of the proposed rule: This proposed rule establishes the requirements that will allow for a pharmacy to provide shared pharmacy services. The rule allows for a pharmacy or pharmacist to perform prescription fulfillment or processing provided they comply with the rules. Long term care pharmacy rules must comply with RCW 18.64.570\(^{176}\). Central fill shared pharmacy services must comply with 3 conditions.

The originating pharmacy must have written a policy and procedure outlining the offsite services provided and the responsibilities of each party. The parties must share a secure real-time database or utilize other secure technology that allow access by the central pharmacy or offsite pharmacist or technician to the information necessary to perform offsite pharmacy services. A single prescription may be shared by the originating pharmacy and a central fill pharmacy or offsite pharmacist or technician. The fulfillment, processing, and delivery of the prescription by one pharmacy for another pursuant to this section will not be construed as a fulfillment of a transferred prescription or wholesale distribution.

Cost/Benefit Analysis: There no costs associated with this rule. This rule is codifying what is currently required in order to provide shared pharmacy services under the commissions “Technology and Services Guidelines\(^ {177}\)” While this is a new rule, this is not creating new standards. The benefit of this rule is it codifies a policy that is currently

---

\(^{175}\) [https://www.indeed.com/salaries/Pharmacy-Manager-Salaries,-Washington-State](https://www.indeed.com/salaries/Pharmacy-Manager-Salaries,-Washington-State)

\(^{176}\) [https://app.leg.wa.gov/RCW/default.aspx?cite=18.64.570](https://app.leg.wa.gov/RCW/default.aspx?cite=18.64.570)

in place and can increase patient access to in areas where there may not be pharmacy services available.

39. WAC 246-945-430 Pharmacies Storing, Dispensing and Delivery Drugs to Patients without a Pharmacist On-Site

Description of the proposed rule: This proposed rule establishes the requirements that a pharmacy must follow in order to store, dispense and deliver drugs without a pharmacist onsite. The rule establishes that, in order to dispense drugs to patients without a pharmacist onsite, the pharmacy must maintain adequate visual surveillance of the full pharmacy and retain high quality recording for a minimum of 30 days. Access to the restricted drug storage area must be limited, authorized, and regularly monitored. The visual and audio communication system used to counsel and interact with each patient or patient caregiver must be clear, secure, and HIPPA compliant. A pharmacist must complete and retain a monthly in-person inspection and they must be capable of being onsite within 3 hours if an emergency arises. Finally, the pharmacy must be closed to the public if any component of the surveillance or video and audio communication system is malfunctioning and remain closed until system corrections or repairs are completed or a pharmacist is onsite to oversee the pharmacy operations.

While this is a proposed new rule it incorporates aspects of current statutes. Proposed new WAC 246-945-430(4) requires that access to the restricted drug storage area must be limited, authorized and regularly monitored. Current WAC 246-869-020 (1) states, “in the absence of a pharmacist such pharmacies must be locked and secured so that only persons authorized by the pharmacist can gain access.” This proposed new rule creates more stringent requirements regarding the specific security requirements, as the rule would allow for the dispensing of drugs without a pharmacist onsite, something that is not allowed in current rules.

Cost/Benefit Analysis: There are no costs associated with this rule. This proposed rule would allow dispensing of drugs without a pharmacist on site however those locations would have to be licensed as a pharmacy and the requirements of this section would need to be met in order to be licensed. This includes meeting the minimum security requirements for any pharmacy to ensure the safety and security of the medication as well as patient care. As well as a video surveillance system that covers the full pharmacy and can maintain those recordings for 30 days, at least. Restricted identification controls are already required in the minimum facility standards. The requirement to have video and audio communication aligns with the requirement that a pharmacist must provide counseling, so while this is not necessarily creating a new requirement, it will be something that a pharmacy must ensure is still provided without a pharmacist onsite. The monthly inspection worksheet is not a new requirement and will not be an additional cost other, than what was covered in the analysis of proposed new WAC 246-945-005. There are no costs associated with the requirement that a pharmacist be onsite within 3 hours of an emergency.

40. WAC 246-945-455 Drugs Stored Outside of the Pharmacy

**Description of the proposed rule:** This proposed new rule establishes circumstances in which drugs may be stored outside of the facility. The proposed rule language states that drugs may be stored in a designated area outside of the pharmacy including, but not limited to, floor stock, emergency cabinet, emergency kits, or as an emergency outpatient drug delivery from an emergency department at an institutional facility as long as certain conditions are met. Drugs stored outside of the facility must remain under the control of, and be routinely monitored by, the supplying pharmacy. The supplying pharmacy must develop and implement policies and procedures to prevent and detect unauthorized access, document drugs used, returned and wasted, and establish regular inventory procedures. Access should be limited to health care professionals acting within their scope of practice, except nursing students provided in proposed new WAC 246-945-450. The area must be properly equipped to ensure security and protection from diversion and tampering. The facility must be able to possess and store drugs. For nursing homes and hospice programs an emergency or supplemental dose kit must comply with RCW 18.64.560.179

**Cost/Benefit Analysis:** There are costs associated with this rule, however this proposed rule language is not a mandate. These costs would only apply if a facility chooses to store drugs outside of the pharmacy. The costs associated with this proposed rule would include the creation of policies and procedures to detect and prevent unauthorized access and documentation of drugs used, returned, and wasted, for a total of 3 new policies and procedures. This task would likely be performed by pharmacists, with an average annual salary of $123,670 per year. We anticipate developing these 3 new policies and procedures would take approximately 1 hour each, for a total three hours at $60 per hour. This is a one-time cost of approximately $180. However, the creation of policies and procedure is a requirement for all licensed facilities so if they choose to store drugs outside of the pharmacy this would be an absorbable cost as it’s a standard part of their practice. These costs are outweighed by the public safety benefit of preventing theft and diversion. There is also a cost associated with ensuring that the area in which the drugs are stored is appropriately equipped to ensure security and protection from diversion or tampering but this would be based upon the policies and procedures and would be determined based on the setting and cannot be accurately determined. This cost is outweighed by the public safety benefit of preventing theft and diversion.

41. WAC 246-945-480 Facility Reporting Requirements

**Description of the proposed rule:** This proposed rule establishes the reporting requirements for all facilities covered under this chapter. The outgoing and incoming responsible pharmacy manager must report to the commission a change in the responsible manager designation within 10 business days.

When a facility is permanently closing they must report, no later than 30 days prior to closing:

- The date they are closing;

[179] https://app.leg.wa.gov/RCW/default.aspx?cite=18.64.560
• The name and address of the persons who will have custody of the prescription files, compounding records, repackaging records, invoices and controlled substance inventory records;

• The name and address of any person who will acquire any legend drugs (if known at the time of notification); and

• Customer notification which should include distribution by direct mail, or public notice in a newspaper and posting a closing notice sign in the public area of the pharmacy.

No later than 15 days after closing, the facility must return the facility license, confirm all legend drugs were transferred or destroyed (name and address of person(s) if they were transferred, confirm if controlled substances were transferred (date of transfer, name, address and detailed inventory), confirm return of DEA registration and all unused DEA222 forms, confirm all pharmacy labels and blanks prescriptions were destroyed, confirm all signs and symbols indicating the presence of a pharmacy have been removed, and the commission may conduct an inspection to verify.

The commission may conduct an inspection to verify compliance.

Disasters, accidents and emergencies which may affect the strength, purity, or labeling of drugs, medications, devices or other materials used in the diagnosis or treatment of injury, illness and disease must be reported immediately to the commission.

Any facility credentialed by the commission must report any disciplinary action including denial, revocation, suspension, or restriction to practice by another state, federal or foreign authority.

While this is a new rule, it incorporates aspects of current statutes and policy statements. Proposed new WAC 246-945-480(1) requires reporting a change in the responsible pharmacy manager within 10 days; current WAC 246-863-060\(^\text{180}\) states that pharmacist employed as the responsible manager for the pharmacy must notify the board at once, and also notify the board of termination of that role. The change in rule here is the change from at once to within 10 days.

Proposed new WAC 246-945-480(2) lists the reporting requirements when a pharmacy closes; this is taken directly from current WAC 246-869-250\(^\text{181}\) with an additional requirement for public notice. The public notice requirements are taken from a current policy/procedure statement, “Closing a Pharmacy – Patient Notification\(^\text{182}\).”

**Cost/Benefit Analysis:** There are costs associated with this rule. The requirements outlined in proposed new WACs 246-945-480(1) and 246-945-480(2) are not new requirements, and would not lead to an increase in cost from current practice. Proposed new WAC 246-945-480(3) requires immediate reporting of any event that may affect the quality of a drug or device; this would require the facility to take the time to make the


report, costing time. This is not an annual cost that can be calculated but rather an administrative cost that would apply only in emergent situations. However, that cost is outweighed by to ensure patient safety. Proposed new WAC 246-945-480(4) requires reporting and disciplinary action by another authority. This would also cost time, but is outweighed by ensuring patient safety. The commission may have to take additional action depending on the disciplinary action of another authority again to ensure patient safety.

42. WAC 246-945-485 Destruction or Return of Drugs or Devices – Restrictions

**Description of the proposed rule:** The proposed new rule establishes the process by which drug or devices may be returned or destroyed. A dispensed drug or device may only be accepted for return and reuse if they are non-controlled legend drugs that have been maintained in the custody and control of the institutional facility, dispensing pharmacy, or their related facility if product integrity can be assured or if the drug or devices qualifies under RCW 69.70.

A dispensed drug or device may be accepted for return and destruction if it was dispensed in a manner inconsistent with the prescriber’s instructions, the return is in compliance with the safe medication return program, or the return and destruction is in compliance with a facility’s policies and procedures.

Proposed new WAC 246-945-485(2) states that non-controlled drugs that have been maintained in the custody and control of the institutional facility may be returned if the product integrity can be assured. Current WAC 246-869-130 allows pharmacies serving hospitals and long-term care facilities to accept for return drugs if the pharmacist can determine that entry to unit dose packages have not been made, storage conditions of the drugs meet USP, contamination has been prevented, and the labeling and packaging has not be altered or defaced. This proposed new rule covers these same requirements by stating that product integrity can be assured, allowing for professional judgment rather than prescriptive requirements.

**Cost/Benefit Analysis:** There are no cost associated with this rule. This rule outlines the options available for the return and reuse of drugs or the return and destruction of drugs.

43. WAC 246-945-515 Humane Societies, Animal Control Agencies, and Department of Fish and Wildlife Chemical Capture Programs – Drug Storage and Field Use

**Description of the proposed rule:** This proposed rule establishes the requirements for storing and using approved drugs by humane societies, animal control and DFW. All approved drugs must be stored in a substantially constructed securely locked cabinet or drawer, and only authorized personnel will have access to the drug storage.

Humane societies and animal control may allow possession of approved drugs for field use under the following circumstances; the individual is an authorized person, the individual is either a humane officer, animal control enforcement officer, animal control authority or peace officer, the approved drugs are stored in a locked metal box securely attached to a vehicle, a drug inventory is done and the beginning and end of the shift and documented, and all receipts and use of drugs are properly recorded.

DFW may allow possession of approved drugs for field use under the following circumstances; the individual is an authorized person, the approved drugs are stored in a locked metal box securely attached to a vehicle, a drug inventory is done and the beginning and end of the shift and documented, and all receipts and use of drugs are properly recorded.

While this is a new rule this rule incorporates requirements from current rules. WAC 246-886-090\textsuperscript{184} applies to humane societies and animal control and holds the same requirements. Current WAC 246-886-200\textsuperscript{185} applies to DFW and holds the same requirements but made more specific. The current rule requires that all controlled substances are accounted for at all times, this new rule requires an inventory on a monthly basis.

Cost/Benefit Analysis: 4829-6344. This rule incorporates what is already established in current rule. The only change is a more specific requirement on how to ensure accountability. This will be included in existing monthly reports already conducted by these officers. We anticipate this taking less than an hour of 1 DFW officer per month, for a total of less than $321 per year.

44. WAC 246-945-585 Wholesaler – Suspicious Orders and Due Diligence

Description of the proposed rule: This proposed new rule establishes the requirements that a wholesaler design and operate a system to identify and report suspicious orders. Suspicious orders must be submitted electronically to the commission within 5 business days of the order being identified. The information must include; customer name, address, DEA registration, state license number, transaction date, drug name, NDC number, quantity ordered, and indication of whether the drug was shipped and if not the basis for the refusal to supply. Zero reports must be submitted if no suspicious orders are identified, and wholesalers may apply to the commission for an exemption if they do not distribute controlled substances.

A wholesaler shall exercise due diligence to identify customers ordering or seeking to order controlled substances or drugs of concern, establish the normal and expected transactions, and identify and prevent the sale of controlled substances that are likely to be diverted. Due diligence measures must include, but not be limited to; questionnaires and affirmative steps by the wholesaler to confirm accuracy and validity of information provided, for a customer who is a provider confirmation of prescriber type, specialty area, and if the prescribers personally furnishes controlled substances or drugs of concern, review of drug utilization reports, and obtaining and conducting review of methods of payments, ratio of controlled vs non controlled prescriptions and sales, orders for controlled substances and drugs of concern using ARCOS, ratio of out of state patients served compared to in-state.

A wholesaler receiving a request from an existing customer of a size/quantity that exceeds the established algorithm may sell the drug of concern or controlled substance provided the customer submits documentation explaining the request.

\textsuperscript{184} https://apps.leg.wa.gov/wac/default.aspx?cite=246-886-090
\textsuperscript{185} https://apps.leg.wa.gov/wac/default.aspx?cite=246-886-200
Any customer that is believed to be engaged in potential diversion activity must be reported to the commission. Those reports must include; customer name, customer address, DEA number, state license number, detailed explanation of why they’ve identified the customer as a possible diversion risk. Such reports must be submitted within 30 days.

All licensed wholesalers must submit all reports to the commission in a DEA ARCOS format where applicable.

This is a new rule but it creates criteria that follows a federal requirement for the reporting of suspicious orders\(^\text{186}\). It also mirrors language from the NABP task force on suspicious orders that has been worked on in collaboration with wholesalers\(^\text{187}\). Finally, it allows for submission of suspicious orders through an approved system, this is something that is a part of the settlement agreement between several wholesalers which requires them to create an independent clearinghouse to aggregate data for better information on suspicious orders\(^\text{188}\).

**Cost/Benefit Analysis:** There are no costs associated with this rule. While this is a new rule it creates standards used to comply with a federal requirement for the reporting of suspicious orders.

45. WAC 246-945-590 Wholesaler – Policies and Procedures

**Description of the proposed rule:** This proposed rule requires that wholesalers adopt policies and procedures for the receipt, security, storage, inventory, and distribution of drugs. This include policies and procedures for identifying, recording, and reporting losses or thefts. It also requires policies and procedures for correcting errors and inaccuracies in inventories.

Included in the policies and procedure must be the following:

- A procedure for handling recalls and withdrawals of drugs
- A procedure to ensure that wholesalers prepare for, protect against, and handle any crisis that affects the security or operations of the facility
- A procedure to ensure that outdated drugs are segregated from other drugs, and either returned to the manufacturer or destroyed, including appropriate witnessing and written documentation
- A procedure for the destruction of outdated drugs
- A procedure for disposing and destroying containers, labels, and packaging to ensure they cannot be used in counterfeiting, including appropriate witnessing
- A procedure for identifying, investigating and reporting significant drug inventory discrepancies and reporting of such discrepancies

\(^{186}\) [https://www.deadiversion.usdoj.gov/21cfr/21usc/832.htm](https://www.deadiversion.usdoj.gov/21cfr/21usc/832.htm)


• A procedure for reporting criminal or suspected criminal activities involved in the inventory of drugs

• Procedure addressing the design and operation of the suspicious order monitoring and reporting, and mandatory training for all staff.

• A procedure for timely responding to customers who submit orders for patients emergent needs

While this is a new rule it incorporates current rule which requires policies and procedures. Current WAC 246-879-020(5) establishes the policies and procedure required, this language is included in new proposed WAC 246-945-590(1), (2), and (3).

**Cost/Benefit Analysis:** There are costs associated with this rule. This rule establishes the requirements for what must be included in the policies and procedures. This new rule expands upon the current requirements by adding 3 additional mandatory topics and will require the cost of time to develop new policies and procedures that meet these requirements. This task would likely be performed by a facility manager with an average salary of $63,000 per year. The standards required in the policies and procedures are not new so this should already be current practice it will just be documenting them. We estimate 1 hour of staff time per new topic, which would equal approximately $90. This would be a one-time cost for facilities.

46. WAC 246-945-595 Wholesaler and Manufacturer – Prohibited Acts

**Description of the proposed rule:** The proposed new rule establishes that it is unlawful for a wholesaler or manufacturer to perform or aid and abet any of the following acts:

• The manufacture, repackaging, sale, delivery, or holding or offering for sale any drug that is adulterated, misbranded, counterfeit or suspected of being counterfeit or other unfit for distribution

• The adulteration, misbranding or counterfeiting of any drug

• Any act of misbranding through changing of the label

• The false representing of any drug without the authority of the manufacture

• Purchase or receipt of drug from anyone not authorized to distribute drugs

• The sale or transfer of a drug to a person not authorized to receive it

• The sale or transfer of a drug from a pharmacy to distributors for resale

• The failure to maintain records required by law

• Providing the commission or its representatives or any state/federal official with false or fraudulent records or making false or fraudulent statements

• Obtaining or attempting to obtain any drug by fraud, deceit, misrepresentation, or fraud

• The distribution of a drug to a patient without a valid prescription

• The distribution or wholesale of a drug that was previously dispensed by a pharmacy or distributed by a practitioner
Cost/Benefit Analysis: There are no costs associated with this rule. This rule establishes prohibited acts that a wholesaler or manufacturer cannot engage in but does not create any requirements for compliance nor prohibit any acts that are currently allowable.

SECTION 6:
Identify alternative versions of the rule that were considered, and explain how the department determined that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives state previously.

There were four options considered when examining the 34 commission chapters to determine how to approach rewriting the rules. The first option would be to do nothing and leave the rules as they currently stand. The second option was to review each chapter and amend them to update them in line with current best practices. The third option was to create four new chapters and start the rules from scratch. The fourth option was to combine the four newly created chapters into a single chapter divided into parts.

The first option of not rewriting the rules was not viable, as many of those chapters had not been updated in a number of years and contained outdated information, untenable and conflicting requirements, and prescriptive rules that had not evolved with the advancement of the practice of pharmacy.

The second option of going through each chapter and amending them individually was not chosen by the commission. While this option would have addressed the concerns outlined in the first option, there was also the issue of having 34 chapters that licensees and the public would have to read to find answers to their questions. Most other regulated health professions in Washington have their rules in a single chapter, allowing for ease of access. Keeping the rules in 34 chapters also would have required staff to review each chapter independently every five years for updates, which would require separate rulemaking processes for each change.

The third option was to do an entire rule rewrite, and this is the option that the Commission chose to pursue. While this process has been long and involved the end product will allow for licensees and the public to have better ease of access to the rules that govern the practice of pharmacy. Updating the practice with less prescriptive rules will allow for pharmacist to utilize their professional judgement and give the profession the opportunity to evolve as technology changes. The Commission would be able to more easily review the four new chapters for regular updates that would prevent the Commission from running into the problem of having outdated rules in the future.

The fourth option was a single chapter and that is the direction the commission decided to take. The suggestion was to take the four chapters as identified above and combine them into a single chapter with the sections divided into parts. The single chapter will consist of four parts: (1) General Provisions, (2) General Licensing, (3) Professional Standards, and (4) Operational Standards. Within those part will be additional subparts breaking up the parts into easily discernable sections so licensees and the public will know where to look. This will also align the
pharmacy chapter with other profession chapters by having a single chapter to look under for all rules relating to the practice of pharmacy. These part and subpart titles can be easily changed so this will allow for additional flexibility in adding or making changes to the rules in the future.

SECTION 7:
Determine that the rule does not require those to whom it applies to take an action that violates requirements of another federal or state law.

The rule does not require those to whom it applies to take an action that violates requirements of federal or state law. The rules require pharmacies and facilities to follow applicable state and federal laws and rules.

SECTION 8:
Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.

The rule does not impose more stringent performance requirements on private entities than on public entities. All facilities, all pharmacy personnel, drug wholesalers, distributors and manufacturers, both private and public, are required to abide by the same requirements established in this chapter.

SECTION 9:
Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary.

The proposed rules do not differ from any federal regulation or statute applicable to the same activity or subject matter.
SECTION 10:

Demonstrate that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.

The proposed rules require pharmacies and facilities to comply with all applicable state and federal laws and rules, including the Controlled Substances and Legend Drug Act, including requiring registration with the DEA anytime controlled substances are involved. The rules cite the specific state and federal laws that must be followed along with rules covered in this chapter.