

WAC Section and Topic	Text of applicable rule / law	What should be included in the P&P?  Most important aspects of the P&P is that they match what actually happens in the pharmacy and follow all laws/rules for practice.
246-945-410 (6) - Purchasing	(6) The facility shall create and implement policies and procedures related to: (a) Purchasing, ordering, storing, compounding, delivering, dispensing, and administering legend drugs, including controlled substances. (b) Accuracy of inventory records, patient medical records as related to the administration of controlled substances and legend drugs, and any other records required to be kept by state and federal laws. (c) Adequate security of legend drugs, including controlled substances. (d) Controlling access to legend drugs, including controlled substances.	<ul style="list-style-type: none"> <li>• How will drugs be purchased?</li> <li>• What primary and secondary or other contracts will be in place?</li> <li>• Who is responsible to maintaining contracts?</li> <li>• Will the responsible party ensure that contracted wholesalers are licensed in Washington State?</li> <li>• Will there be special policies that apply to controlled substances?</li> </ul>
246-945-410 (6) - Ordering		<ul style="list-style-type: none"> <li>• How will drugs be ordered? (What is the process of drug ordering for each contracted vendor?)</li> <li>• How often are drug orders placed?</li> <li>• Who will be responsible for reviewing and placing orders?</li> <li>• Under what circumstances will drugs be taken out of inventory or sent back to the wholesaler?</li> <li>• Will there be minimum inventory levels?</li> <li>• How will orders be checked in? Will there be variation in checking-in legend drugs vs controlled substances?</li> <li>• Will controlled substances orders be processed differently?</li> <li>• How are 2D barcodes ensured on all products coming into the pharmacy as part of the DEA Track and Trace requirements?</li> <li>• Is there a wholesaler agreement in place to ensure the wholesaler is responsible to provide products with 2D barcodes? (must be in P&amp;P to meet DEA requirements).</li> </ul>

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<p>246-945-410 (6) - Storing</p>		<ul style="list-style-type: none"> <li>• How will drugs be stored in the pharmacy?</li> <li>• How and when will expiring drugs be handled?</li>   <li>• Will legend drugs and CIII-V controlled substances may be stored in the pharmacy on stock shelves in alphabetical order by generic name?</li> <li>• How will CII controlled substances will be stored?</li> <li>• Who will have access?</li> </ul>
<p>246-945-410 (6) - Compounding</p>	<p>USP &lt;795&gt;, &lt;797&gt;, &lt;800&gt;, and &lt;825&gt; must be followed, use this as a guide if compounding takes place</p>	<ul style="list-style-type: none"> <li>• Will drugs be compounded?</li> <li>• Are there only specific drugs that will be compounded? What are they?</li> <li>• Where in the pharmacy will compounding take place?</li> <li>• Draw a diagram.</li> <li>• What documentation will take place and where will it be kept?</li> </ul>
<p>246-945-410 (6) - Delivering</p>	<p>From RCW 18.64.011: "Deliver" or "delivery" means the actual, constructive, or attempted transfer from one person to another of a drug or device, whether or not there is an agency relationship.</p>	<ul style="list-style-type: none"> <li>• What is the process for delivering orders to patients or their agents?</li> <li>• Who will take the lead on this, who will have ultimate responsibility?</li> <li>• How will counseling be offered?</li> <li>• How will identity be verified and HIPPA maintained?</li> </ul>
<p>246-945-410 (6) - Dispensing</p>	<p>From RCW 18.64.011: "Dispense" means the interpretation of a prescription or order for a drug, biological, or device and, pursuant to that prescription or order, the proper selection, measuring, compounding, labeling, or packaging necessary to prepare that prescription or order for delivery.</p>	<ul style="list-style-type: none"> <li>• Who will be involved in each step of dispensing?</li> <li>• What processes will take place to ensure proper dispensing?</li> <li>• Draw a diagram.</li> <li>• Will there be special dispensing functions or activities for controlled substances?</li> </ul>
<p>246-945-410 (6) - Administering</p>		<ul style="list-style-type: none"> <li>• What types of drugs will be administered? (i.e. vaccines, long-acting injectables, others?)</li> <li>• Who will be responsible for administering?</li> <li>• Will the pharmacist delegate to a trained technician?</li> <li>• What records will be maintained?</li> <li>• Will there be special considerations for controlled substances?</li> </ul>

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<p>246-945-415 (6) – Access to Secured Delivery Area</p>	<p>(6) Filled prescriptions may be picked up or returned for delivery by authorized personnel when the pharmacy is closed for business if the prescriptions are placed in a secured delivery area outside of the drug storage area. The secured delivery area must be a part of a licensed pharmacy, and equipped with adequate security, including an alarm or comparable monitoring system, to prevent unauthorized entry, theft, or diversion. Access to the secured delivery area must be addressed by the policies and procedures developed by the responsible pharmacy manager.</p>	<ul style="list-style-type: none"> <li>• Will you have a secured delivery area? If not, you may say this does not apply.</li> <li>• Where will the secure delivery area be located? Draw a diagram.</li> <li>• How will the area be secured?</li> <li>• Who will have access?</li> <li>• How will the access the area?</li> <li>• How will you ensure unauthorized persons do not gain access?</li> <li>• How will the patient or their agent be identified upon pickup from a secured delivery area?</li> <li>• How will delivery to the correct patient or agent be verified?</li> </ul>
<p>246-945-417 (4) – System Downtime</p>	<p>(4) The pharmacy shall have policies and procedures in place for system downtime.</p>	<ul style="list-style-type: none"> <li>• What course of action will be taken if the computer system is down?</li> <li>• Will prescriptions be filled?</li> <li>• How will DUR occur?</li> <li>• How will records be maintained and managed?</li> </ul>
<p>246-945-425 (2)(a) – Shared Pharmacy Services</p>	<p>WAC 246-945-425 Shared Pharmacy Services.</p> <p>Pharmacy services may be provided off-site at one or more locations. When the services being performed are related to prescription fulfillment or processing, the pharmacy or pharmacist must comply with the following:</p> <p>(1) Long term care shared pharmacy services in accordance with <a href="#">RCW 18.64.570</a>.</p> <p>(2) Central fill shared pharmacy services in accordance with the following conditions:</p> <p>(a) The originating pharmacy shall have written policies and procedures outlining the off-site pharmacy services to be provided by the central fill pharmacy, or the off-site pharmacist or pharmacy technician, and the responsibilities of each party;</p> <p>(b) The parties shall share a secure real-time database or utilize other secure technology, including a private, encrypted connection that allows access by the central pharmacy or off-site pharmacist or pharmacy technician to the information necessary to perform offsite pharmacy services; and</p> <p>(c) A single prescription may be shared by an originating pharmacy and a central fill pharmacy or off-site pharmacist or pharmacy technician. The fulfillment, processing and delivery of a prescription by one pharmacy for another pursuant to this section will not</p>	<ul style="list-style-type: none"> <li>• Will the pharmacy participate in shared pharmacy services for long term care patients or with a central/originating pharmacy relationship?</li> <li>• What pharmacy services will be provided?</li> <li>• What are the responsibilities of each party involved in the shared services?</li> </ul>

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	be construed as the fulfillment of a transferred prescription or as a wholesale distribution.	
246-945-440 - Patient Owned Medication Administration	Facilities shall develop written policies and procedures for the administration of patient owned medications.	<ul style="list-style-type: none"> <li>• Will the pharmacy administer patient owned medications? If not, may say this does not apply.</li> <li>• What are the criteria to be met in order for pharmacy to administer?</li> <li>• Who will be responsible for proper storage and handling of patient owned medications?</li> <li>• How will this activity be documented?</li> <li>• How will records be maintained?</li> </ul>
246-945-455 - Drugs Stored Outside of the Pharmacy	WAC 246-945-455 Drugs stored outside of the pharmacy. (1) In order for drugs to be stored in a designated area outside the pharmacy including, but not limited to, floor stock, in an emergency cabinet, in an emergency kit, or as emergency outpatient drug delivery from an emergency department at a registered institutional facility, the following conditions must be met: (a) Drugs stored in such a manner shall remain under the control of, and be routinely monitored by, the supplying pharmacy; The supplying pharmacy shall develop and implement policies and procedures to prevent and detect unauthorized access, document drugs used, returned and wasted, and regular inventory procedures; (c) Access must be limited to health care professionals licensed under the chapters specified in RCW 18.130.040 acting within their scope, and nursing students as provided in WAC 246-945-450; (d) The area is appropriately equipped to ensure security and protection from diversion or tampering; and (e) The facility is able to possess and store drugs. (2) For nursing homes and hospice programs an emergency kit or supplemental dose kit must comply with RCW 18.64.560.	<ul style="list-style-type: none"> <li>• Under what circumstances would drugs be stored outside the pharmacy?</li> <li>• How would they be maintained?</li> <li>• Who could access them?</li> <li>• How will unauthorized access be detected?</li> <li>• How will use drugs used from kits stored outside the pharmacy be documented?</li> <li>• How will drugs be returned, or wastage documented?</li> <li>• How will inventory be tracked and maintained?</li> <li>• Who will be the person in charge of overall oversight?</li> </ul>
246-945-485 - Destruction or Return of Drugs or Devices	WAC 246-945-485 Destruction or return of drugs or devices—Restrictions. (1) A dispensed drug or prescription device must only be accepted for return and reuse as follows: (a) Noncontrolled legend drugs that have been maintained in the custody and control of the institutional facility, dispensing pharmacy, or their related facilities under common control may be returned and reused if product integrity can be assured. (b) Those that qualify for return under the provisions of chapter 69.70 RCW.	<ul style="list-style-type: none"> <li>• Under what circumstances would drugs or devices be allowed to be returned to the pharmacy?</li> <li>• How would this be handled?</li> <li>• Who is responsible?</li> </ul>

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	<p>(2) A dispensed drug or prescription device may be accepted for return and destruction if:</p> <ul style="list-style-type: none"><li>(a) The dispensed drug or prescription device was dispensed in a manner inconsistent with the prescriber's instructions;</li><li>(b) The return is in compliance with the Washington state safe medication return program laws and rules, chapters 69.48 RCW and 246-480 WAC; or</li><li>(c) The return and destruction is in compliance with the facility's policies and procedures.</li></ul>	
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