

## Read this page carefully

WA Pharmacy Quality Assurance Commission
Pharmacy Self-Inspection Worksheet
2024 Long-Term Care Pharmacy Addendum

## **Attention: Responsible Pharmacy Manager or Equivalent Manager**

Washington law holds the responsible manager (or equivalent manager) and all pharmacists on duty responsible for ensuring pharmacy compliance with all state and federal laws governing the practice of pharmacy. Failure to complete this self-inspection worksheet addendum within the month of March and within 30 days of becoming responsible manager (as required by WAC 246-945-005(4)) may result in disciplinary action. **The following addendum is required to be filled out and kept on file with the General Pharmacy Self-Inspection Worksheet.** Do not send to the commission office.

The primary objective of this worksheet addendum, and your self-inspection, is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. (**Note**: Neither the self-inspection nor a commission inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.) The inspection worksheet addendum also serves as a necessary document used by commission inspectors during an inspection to evaluate a pharmacy's level of compliance.

By answering the questions and referencing the appropriate laws/rules/CFR provided, you can determine whether your pharmacy is compliant with many of the rules and regulations. If any deficiencies have been corrected, please write corrected and the date of correction by the appropriate question.

Date responsible pharmacy manager self-inspection was completed:							
Signature of responsible manager:							
Responsible Pharmacy Manager E-mail:							
Questions highlighted in blue are common areas of non-compliance observed during routine pharmacy inspections.							

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email <a href="mailto:doh.information@doh.wa.gov">doh.information@doh.wa.gov</a>.

**Definitions** - Below are terms used in this document you should keep in mind as regulations around pharmaceutical services have different standards based on the type of facility your pharmacy services.

**RCW 18.64.011(4)** "'Closed door long-term care pharmacy' means a pharmacy that provides pharmaceutical care to a defined and exclusive group of patients who have access to the services of the pharmacy because they are treated by or have an affiliation with a long-term care facility or hospice program, and that is not a retailer of goods to the general public."

**RCW 18.64.011(16)** "'Hospice program' means a hospice program certified or paid by Medicare under Title XVIII of the federal social security act, or a hospice program licensed under chapter 70.127 RCW.

RCW 18.64.011(20) "'Long-term care facility' means a nursing home licensed under chapter 18.51 RCW, an assisted living facility licensed under chapter 18.20 RCW, or an adult family home licensed under chapter 70.128 RCW."

RCW 18.51.010(3) "Nursing home" means any home, place or institution which operates or maintains facilities providing convalescent or chronic care, or both, for a period in excess of twenty-four consecutive hours for three or more patients not related by blood or marriage to the operator, who by reason of illness or infirmity, are unable properly to care for themselves. Convalescent and chronic care may include but not be limited to any or all procedures commonly employed in waiting on the sick, such as administration of medicines, preparation of special diets, giving of bedside nursing care, application of dressings and bandages, and carrying out of treatment prescribed by a duly licensed practitioner of the healing arts. It may also include care of mentally incompetent persons. It may also include community-based care. Nothing in this definition shall be construed to include general hospitals or other places which provide care and treatment for the acutely ill and maintain and operate facilities for major surgery or obstetrics, or both. Nothing in this definition shall be construed to include any \*assisted living facility, guest home, hotel or related institution which is held forth to the public as providing, and which is operated to give only board, room and laundry to persons not in need of medical or nursing treatment or supervision except in the case of temporary acute illness. The mere designation by the operator of any place or institution as a hospital, sanitarium, or any other similar name, which does not provide care for the acutely ill and maintain and operate facilities for major surgery or obstetrics, or both, shall not exclude such place or institution from the provisions of this chapter: PROVIDED, That any nursing home providing psychiatric treatment shall, with respect to patients receiving such treatment, comply with the provisions of RCW 71.12.560 and 71.12.570.

RCW 18.20.020(2) "Assisted living facility" means any home or other institution, however named, which is advertised, announced, or maintained for the express or implied purpose of providing housing, basic services, and assuming general responsibility for the safety and well-being of the residents, and may also provide domiciliary care, consistent with chapter 142, Laws of 2004, to seven or more residents after July 1, 2000. However, an assisted living facility that is licensed for three to six residents prior to or on July 1, 2000, may maintain its assisted living facility license as long as it is continually licensed as an assisted living facility. "Assisted living facility" shall not include facilities certified as group training homes pursuant to RCW 71A.22.040, nor any home, institution or section thereof which is otherwise licensed and regulated under the provisions of state law providing specifically for the licensing and regulation of such home, institution or section thereof. Nor shall it include any independent senior housing, independent living units in continuing care retirement communities, or other similar living situations including those subsidized by the department of housing and urban development.

RCW 70.128.010(1) "Adult family home" means a residential home in which a person or persons provide personal care, special care, room, and board to more than one but not more than six adults who are not related by blood or marriage to the person or persons providing the services.

## 2024 Long-Term Care Pharmacy Addendum Document and Record Review

Please provide the location of these documents in the facility (be as specific as possible, there can be many filing cabinets and binders). The rule references require the documentation printed below, by listing the location of these documents you are also confirming your compliance with the referenced rule.

						Rule Reference		
Ancillary Utilization Plan						RCW 18.64A.060 "No pharmacy licensed in this state shall utilize the services of pharmacy ancillary		
c						personnel without approval of the commission. Any pharmacy licensed in this state may apply to the		
						•	ervices of pharmacy ancillary personnel."	
	-			osed door long-term care pharmacy and pha	•		h standards, a pharmacy technician licensed under chapter	
tech	nnicia	ans a	are p	performing administrative tasks, your plan sh		<u> </u>	pe practicing as a pharmacy technician while performing	
that	**						immediate dispensing of drugs that may lawfully be	
							sistant. Administrative tasks not associated with immediate	
							necessarily limited to medical records maintenance, billing,	
						prepackaging unit dose drugs, inventory	control, delivery, and processing returned drugs."	
Co	mpli	iant	<b> </b> #			Rule Reference	Notes/Corrective Actions	
Yes No N/A "						rule reference	Notes/Corrective Actions	
General Requirements								
				Do you fill medications for residents of a	RCW 18.64.5	50 "(1) A chart order must be		
			1	long-term care facility or hospice	considered a	prescription if it contains"		
				nrogram?				

	1	•	RCW 18.64.550 "(1) A chart order must be considered a prescription if it contains"	
	2	Does the pharmacy supply medications to long-term care facilities or hospice programs?		
	3	Are medications filled from:		
	3	Prescriptions? a See general inspection for prescription requirements.		
	3	Chart orders?  b See question 4 or chart order requirements.		
	4	*Quantity is not required, and authorized signature may be the practitioner's agent, if order is for a non-controlled legend drug or over-the counter medication.*	RCW 18.64.550(1) A chart order must be considered a prescription if it contains: (a) The full name of the patient; (b) The date of issuance; (c) The name, strength, and dosage form of the drug prescribed; (d) Directions for use; and (e) An authorized signature;	
	4	a The full name of the patient	(i) For written orders, the order must contain the	

Compliant						2024 Long-Term Care Filannacy Addendam	
		N/A	#	#		Rule Reference	Notes/Corrective Actions
			4	b	The date of issuance	prescribing practitioner's signature or the signature	
			4	С	The name, strength, and dosage form	of the practitioner's authorized agent, including the name of the prescribing practitioner; or (ii) For electronic or digital orders, the order must contain	
			4	d	Directions for use	the prescribing practitioner's electronic or digital signature, or the electronic or digital signature of the practitioner's authorized agent, including the name	
			4	е	An authorized signature	of the prescribing practitioner.	
En	ner	ger	ıcy	Dr	ug & Supplemental Drug I	Kits	
	Do you supply medications to a nursing home to stock an emergency drug kit and/or a supplemental dose kit?		ou supply medications to a nursing ne to stock an emergency drug kit or a supplemental dose kit?	RCW 18.64.560(1) and (2) "A pharmacy or pharmacist may provide a limited quantity of drugs to a nursing home or hospice program without a prescription for emergency administration by authorized personnel of the facility or program pursuant to a valid prescription. The drugs so provided must be limited to those required to meet the immediate therapeutic needs of residents or patients and may not be available from another authorized source in sufficient time to prevent risk of harm by delay resulting from obtaining drugs from another source. (2) In addition to or in connection with the emergency kit authorized under subsection (1) of this section, a nursing home that employs a unit dose drug distribution system may maintain a supplemental dose kit for supplemental nonemergency drug therapy. Supplemental dose kits must be secured in a locked room, container, or device to prevent unauthorized access, and to ensure the proper environment for preservation of the drugs. Administration of drugs from a supplemental dose kit must be under a valid prescription or chart order."			
					you supply medications to a hospice gram to stock an emergency drug kit?	RCW 18.64.560(1) "A pharmacy or pharmacist may provide a limited quantity of drugs to a nursing home or hospice program without a prescription for emergency administration by authorized personnel of the facility or program pursuant to a valid prescription. The drugs so provided must be limited to those required to meet the immediate therapeutic needs of residents or patients and may not be	

No	N/A	#			N . /o .: A ::		
	.,,,,,			Rule Reference	Notes/Corrective Actions		
				available from another authorized source in sufficient time to prevent risk of harm by delay resulting from obtaining drugs from another source."			
		/	resident from an emergency drug kit or supplemental dose kit originate from a				
		8	Are medications in the emergency drug kit or supplemental dose kit selected by a pharmaceutical services committee that meets minimum requirements?	appropriate to serve the resident or patient population of a nursing home or hospice program using an emergency kit or supplemental dose kit and procedures for the proper storage and security of drugs must be determined by a pharmaceutical services committee that includes a pharmacist licensed under this chapter, a physician licensed under chapter 18.71 RCW, an osteopathic physician licensed under chap 18.57 RCW, or an advanced registered nurse practitioner licensed under chapter 18.79 RCW, and appropriate clinical or administrative personnel of the nursing home or hospice program			
icie	es 8	& P	rocedures				
		9	and procedure(s) developed by the pharmacy service committee that provides for proper storage and security	appropriate to serve the resident or patient population of a nursing home or hospice program and procedures for the proper storage and security			
Prepackaged Medication Label							
		10	prepackaged medication contain the following information:	dispensed pursuant to RCW 70.41.480, medications dispensed in unit dose form, medications dispensed by a pharmacy to a long-term care facility must			
	cie	cies &	cies & P	resident from an emergency drug kit or supplemental dose kit originate from a valid prescription or chart order?  Are medications in the emergency drug kit or supplemental dose kit selected by a pharmaceutical services committee that meets minimum requirements?  Does the pharmacy have a copy of policy and procedure(s) developed by the pharmacy service committee that provides for proper storage and security of drugs provided by the pharmacy?  Dackaged Medication Label  Does the label for a unit dose prepackaged medication contain the following information:	Are medications administered to a resident from an emergency drug kit or supplemental dose kit originate from a valid prescription or chart order?    Are medications in the emergency drug kit or supplemental dose kit selected by a pharmaceutical services committee that meets minimum requirements?   RCW 18.64.560(3) The types and quantity of drugs appropriate to serve the resident or patient population of a nursing home or hospice program using an emergency kit or supplemental dose kit and procedures for the proper storage and security of drugs must be determined by a pharmaceutical services committee that meets minimum requirements?   RCW 18.64.560(3) The types and quantity of drugs appropriate to serve the resident or patient population of a nursing home or hospice program as set forth in rules adopted by the pharmacy service committee that provides for proper storage and security of drugs must be determined by a pharmaceutical services committee to serve the resident or patient population of a nursing home or hospice program and procedure(s) developed by the pharmacy service committee that provides for proper storage and security of drugs provided by the pharmacy?   RCW 18.64.560(3) "The types and quantity of drugs appropriate to serve the resident or patient population of a nursing home or hospice program and procedure(s) developed by the pharmacy for the proper storage and security of drugs provided by the pharmacy?   RCW 18.64.560(3) "The types and quantity of drugs appropriate to serve the resident or patient population of a nursing home or hospice program and procedures for the proper storage and security of drugs must be determined by a pharmaceutical services committee"   RCW 18.64.560(3) "The types and quantity of drugs appropriate to serve the resident or patient population of a nursing home or hospice program and procedures for the proper storage and security of drugs must be determined by a pharmaceutical services committee"   RCW 18.64.560(3) "The types and quantity of drugs appropriate to s		

Со	mpli	ant				2024 Long-Term Care Pharmacy Addendum	
	No		#			Rule Reference	Notes/Corrective Actions
			10	b	Drug strength	(1) Drug name; (2) Drug strength;	
			10	С	Expiration date	(3) Expiration date in accordance with WAC 246-945-016(3);	
			10	d	Manufacturer's name and lot number	(4) The manufacturer's name and lot number, if not maintained in a separate record; and	
			10	е	Pharmacist or provider identity	(5) The identity of the pharmacist or provider responsible for the prepackaging, if not maintained in a separate record.	
Re	tur	n a	nd	Re	use of Medication		
			11	drug care use, dose		RCW 18.64.570(4) "A pharmacy may repackage and dispense unused drugs returned by a long-term care facility or hospice program to the pharmacy in peruse, blister packaging, whether in unit dose or modified unit dose form, except as prohibited by federal law."	
			12	pha inte do t	rmacy for reuse can the product grity be assured by the pharmacy or the returned drugs qualify for reuse er the provisions of chapter 69.70	WAC 246-945-485(1)(a) (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; and (b) Those that qualify for return under the provisions of chapter 69.70 RCW.	
Sh	are	d P	ha	rm	acy Services		
			13	doe	narmacy services are provided off-site, s the pharmacy or pharmacist comply n RCW 18.64.570	WAC 246-945-425 Shared pharmacy services. 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:  (1) Long term care shared pharmacy services in accordance with RCW 18.64.570.	
					n care facility or hospice program?	<b>RCW 18.64.570(3)</b> "Shared pharmacy services may be used for, but are not limited to, the purpose of ensuring that drugs or devices are attainable to meet	

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	No		#		Rule Reference	Notes/Corrective Actions
				Does the pharmacy outsource to other pharmacies serving long term care or hospice programs? Answer question 15 (outsourcing pharmacy).  Does the pharmacy supply medications for other pharmacies serving long term	the immediate needs of residents of the long-term care facility or hospice program, or when the outsourcing pharmacy cannot provide services on an ongoing basis"	
				care or hospice programs? Answer question 16 (supplying pharmacy).		
			15	*Outsourcing Pharmacy*: Is a copy of the prescription or chart order provided to the supplying pharmacy?	RCW 18.64.570(2) "A pharmacy may outsource shared pharmacy services for a long-term care facility or hospice program to another pharmacy if the outsourcing pharmacy:  (a) Obtains approval from the long-term care facility or hospice program to outsource shared pharmacy services for the facility's or program's residents or patients; and (b) Provides a copy of the prescription or order to the pharmacy providing the shared pharmacy services."	
			16	*Supplying Pharmacy*: Is a copy of the prescription or drug order and dispensing record between the outsourcing pharmacy and the supplying pharmacy maintained?	RCW 18.64.570(3) "Shared pharmacy services may be used for, but are not limited to, the purpose of ensuring that drugs or devices are attainable to meet the immediate needs of residents of the long-term care facility or hospice program, or when the outsourcing pharmacy cannot provide services on an ongoing basis. Where a pharmacy uses shared pharmacy services to have a second pharmacy provide a first dose or partial fill of a prescription or drug order to meet a patient's or resident's immediate needs, the second supplying pharmacy may dispense the first dose or partially filled prescription on a satellite basis without the outsourcing pharmacy being required to fully transfer the prescription to the supplying pharmacy. The supplying pharmacy must retain a copy of the prescription or order on file, a copy of the dispensing record or fill, and must notify the outsourcing pharmacy of the service and quantity provided."	