

DEVELOPMENTAL DISABILITIES ADMINISTRATION Olympia, Washington

TITLE:	YOUTH TRANSITIONAL CARE FACILITY MEDICATION MANAGEMENT				
Authority:	21 CFR Chapter II Part 1301	Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances			
	Chapter 18.64 RCW	Pharmacists			
	Chapter 69.41 RCW Chapter 69.50 RCW	Legend Drugs—Prescription Drugs Uniform Controlled Substances Act			
	Chapter 171-303 WAC	Dangerous Waste Regulations			
	Chapter 246-337 WAC	Residential Treatment Facility			
	WAC 246-337-105	Medication Management			
	Chapter 246-341 WAC	Behavioral Health Agency Licensing and			
	WAC 246-341-1124	Certification Requirements Residential and inpatient mental health services—Rights related to antipsychotic medication			
	Chapter 246-945 WAC	Pharmacy Quality Assurance Commission			
Reference:	United States Pharmacopeia Standards DSHS Information Security Manual				
	DSHS Administrative Policy 5.04 Records Retention				
	DSHS Administrative Policy 15.10 Information Security				

PURPOSE

This policy establishes requirements for medication management at a Youth Transitional Care Facility (YTCF).

<u>SCOPE</u>

This policy applies to all DDA employees and contractors providing medication management for youth approved for admission to a YTCF.

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DEFINITIONS

Administer means the direct application of a drug or device, whether by injection, inhalation, ingestion, or any other means, to the body of a resident or research subject (RCW 18.64.011).

Adverse drug reaction or ADR means any unexpected adverse experience associated with the use of a drug in doses recognized in accepted medical practice that is life-threatening, unusual in nature, or a significant modification of expected pharmacological action.

Automated drug dispensing devices or ADDD means computerized drug storage and dispensing device used in a health care setting at the point of care (such as, in a medication room).

Clinical pharmacist means a licensed pharmacist designated by the facility who has the authority and responsibility to assure that each area within the facility where drugs are stored, compounded, delivered, or dispensed is operated in compliance with all applicable state and federal statutes and regulations as defined in <u>WAC 246-945-310</u>.

Controlled substance means a drug, substance, or immediate precursor included in Schedules I through V as set forth in federal or state laws, or federal or commission rules, but does not include industrial hemp (see RCW 69.50.101).

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 (see RCW 18.64.011).

Drug means:

- 1. A substance recognized as a drug in the official United States pharmacopeia, national formulary or the official homeopathic pharmacopeia of the United States, or any supplement to them;
- 2. Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in individuals or animals; and
- 3. Substances (other than food) intended to affect the structure or any function of the body of individuals or animals. The term does not include devices or their components, parts, or accessories. (see <u>RCW 69.41.010</u>)

Executive Officer means a person responsible for managing the day-to-day operations of a Youth Transitional Care Facility.

Legend drug means any drug that is required by state law or regulation of the pharmacy quality assurance commission to be dispensed on prescription only or are restricted to use by

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practitioners only (see RCW 69.41.010).

Medication means a legend drug prescribed for a resident by an authorized health care prescriber. Medication also means nonprescription drugs, also called "over-the-counter medications" that can be purchased by the general public without a prescription as defined in <u>WAC 246-337-005</u>.

Practitioner means a physician, physician assistant, optometrist, podiatric physician, veterinarian, registered nurse, advanced registered nurse practitioner, licensed practical nurse, naturopathic physician, or a pharmacist as defined in the Uniform Controlled Substances Act under <u>RCW 69.50.101</u>.

RxDestroyer System means a bottle system for the deactivation and disposal of hazardous waste, rendering it non-retrievable.

Youth means an individual, aged 13-17 approved for and receiving services at a YTCF.

Youth Transitional Care Facility or YTCF means a voluntary facility offering specialized treatment.

POLICY

- A. The Youth Transitional Care Facility must adhere to all applicable state and federal regulations that pertain to the management of medications.
- B. The Youth Transitional Care Facility procures medications from the following sources:
 - 1. Through a contract with Rainier School Pharmacy to dispense and provide ordered prescriptions labeled for individual youth use.
 - a. Routine medications must be procured via Rainier School Pharmacy unless they are needed sooner.
 - b. Prescriptions from a Youth Transitional Care Facility must be sent to Rainier School pharmacy by 10:00 AM to receive guaranteed next day delivery by 10:30 AM via contracted overnight shipping service.
 - c. Urgent-need medications may be provided at other times via the Nexsys automated drug dispensing device (ADDD) if stocked, or through use of a nearby outside pharmacy.
 - 2. A Youth Transitional Care Facility must maintain a Health Care Entity (HCE) license and may purchase a limited supply of backup medications which may include

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emergency medications, frequently ordered medications, floor stock, and those that pose acute safety risks to a youth if not continuously available.

- a. The Clinical Pharmacist or designee must order and maintain the backup medication supply of legend drugs in the Nexsys ADDD.
- b. Over-the-counter medications approved for floor stock must be kept in the nursing medication rooms.
- c. List of medications that may be stored in the Nexsys ADDD, and as floor stock, must be maintained jointly by responsible Clinical Pharmacist and medical director.
- d. Medications removed from the Nexsys ADDD must be youth specific and limited to the quantity needed to fulfill immediate needs. They must not be removed for dispensing or for future use.
- 3. For a new medication needed before the next business day that is not available in the Nexsys ADDD or floor stock, the prescribing practitioner must e-prescribe to an outside pharmacy the minimal quantity needed to bridge to the next date that Rainier School Pharmacy can provide medications.

Note: The prescribing practitioner must put in an additional order e-prescribed to Rainier School Pharmacy that will start on the next business day, or two business days later if order is sent on a weekend or holiday.

- 4. YTCF staff must not accept youth-owned medications or samples.
- 5. YTCF staff must not compound medication.
- 6. YTCF staff must not accept medications other than those it obtains from direct purchase, Rainier School Pharmacy, or from a designated outside backup pharmacy for an emergency fill.
- C. Storage and Security
 - 1. A YTCF must be properly equipped to ensure the safe, clean, and sanitary conditions necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity as provided by the Washington State Pharmacy Quality Assurance Commission (PQAC) rules.
 - 2. A YTCF must store all medications in locked medication rooms in accordance with United States Pharmacopoeia standards and PQAC rules.

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- a. Access to medication rooms is limited to applicable practitioners for the purpose of carrying out assigned duties.
- b. Staff must maintain the security of the medications by ensuring medication room doors are closed and locked.
- c. For the cottage medication rooms, half-doors can have the top half open when the registered nurse is in the medication room.
- d. Maintenance and Operations Division (MOD) staff who maintain facility systems such as temperature, light, ventilation, or plumbing must be escorted by designated nursing or pharmacy staff into a medication room.
- 3. Assigned pharmacy, nursing, and medical staff must have access to the cottage medication rooms, and Nexsys ADDD medication room located in the administrative building located on the campus of the facility.
 - a. Each pharmacy employee must be assigned an employee-specific door code for accessing medication storage areas. Additionally, pharmacy staff must have keys to the controlled substance cabinets inside of the pharmacy storage room.
 - b. Nursing staff must be assigned employee-specific door codes to the Nexsys ADDD medication room on Cedar and the cottage medication rooms.
 - c. Nursing staff must be assigned keys for the medication cart, controlled substance bin, and cabinets located in their assigned medication room.
 - i. Keys must be directly handed off between the previous and current shift's designated nursing staff.
 - ii. Both staff members must sign off on this key exchange in the designated logbook.
 - iii. In case of emergency, a master key copy must be available in a secured lock box in a designated location within a YTCF.
- 4. Once a day, the designated registered nurse must record both the medication room temperature on the RTF-F 14-03A PRTF Med Room Temp Log and the medication refrigerator temperature on the RTF-F 14-03B PRTF Fridge Temp Log.

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These logs must be maintained for two years. If electronic thermometers with logging capability are used, these may take the place of manual temperature logs.

- 5. Only medications may be stored in the medication fridges.
- The medication room must be free of staff personal items (coats, purses, etc.).
 Personal food and drink must not be consumed or stored in the medication room.
 Only items related to youth medical care may be stored in the medication room.
- 7. The Clinical Pharmacist or designee must inspect the medication room monthly to ensure compliance and document these results on the RTF-F 14-04A RTF Med Area Inspection. These RTF-F 14-04A PRTF Med Area Inspection forms must be maintained for two years.
- D. Receipt and Reconciliation
 - 1. When a YTCF receives a dispensed medication via overnight shipping service:
 - a. The registered nurse receiving the dispensed medication via the overnight shipping service must sign the applicable receipt.
 - i. The container holding dispensed medications may only be opened in the locked medication room.
 - The registered nurse must unpack the prescriptions and store all items in a locked medication cart in youth-specific slots. Larger items may be stored in locked cabinets as necessary.
 - iii. All medication delivery receipts detailing all products ordered must be stored in a binder for two years.
 - b. Dispensed controlled substance medications must be received, counted, and logged by two practitioners in the designated logbook, then placed into the locked controlled substance bin inside the medication cart.
 - 2. When a YTCF receives a stock item from a wholesaler shipment, the YTCF must receive and reconcile as follows.
 - a. For a controlled substance, two practitioners, one of which is a pharmacist, must receive the shipment from the contract wholesaler.

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			i.	The two practitioners must reconcile the items rec the invoice, sign the invoice, and maintain a copy c two years.	-	
			ii.	Controlled substances must be logged into the con substances inventory in the pharmacy storage roor the two practitioners.		
			iii.	The bulk medication must be stored in a locked cal pharmacy storage room.	pinet in the	
			iv.	Schedule 2 (CII) invoices must be maintained separ other invoices.	rately from all	
		b.	items	non-controlled substance, the pharmacy employee r received against the invoice, sign the invoice, and m nvoice for two years.		
			main	: Non-controlled substances invoices from the wholes tained electronically in the vendor's computer system cable.	•	
E.	Inven	tory of	Stock N	1edications		
	1.	0	0	d drugs must be maintained electronically in the Nexsys ADDD and by nacy staff for stock kept in the pharmacy storage room.		
	2. Controlled substances must be		olled su	ubstances must be maintained as follows:		
		a.		Clinical Pharmacist or designee must make initial inver- colled substances on site upon initial opening of a YTC	•	
		b.	subst	macy staff must maintain perpetual inventory of cont ances in pharmacy storage room, verifying count mo poration with another practitioner.		

- c. The Nexsys ADDD perpetual inventory of controlled substances must be audited at least monthly by a pharmacy employee in collaboration with another practitioner.
- d. For dispensed controlled substances stored in the cottage medication room two nurses must inventory all controlled substances when transfer of accountability occurs at nursing shift change, including expired or

discontinued controlled substances that are maintained separately from active prescriptions.

- e. Every March, the Clinical Pharmacist or designee must complete a full inventory of all current and expired controlled substances.
- F. Loss or Discrepancy of Controlled Substances
 - 1. Any unreconciled discrepancy must be reported verbally and in writing to the Nurse Manager, Executive Officer, and Director of Nursing before the end of the shift. A report must include:
 - a. Date and time the incident occurred or the loss was discovered;
 - b. Description of item or number of items missing;
 - c. Names of persons involved;
 - d. Circumstances surrounding the incident or loss; and
 - e. Statements from all employees with knowledge of or involvement in the incident or loss.
 - 2. Loss of controlled substances must be recorded and monitored in the appropriate controlled substance logbook.
 - 3. For any significant loss of a controlled substance:
 - a. The Clinical Pharmacist or designee must:
 - Notify the local DEA field office in writing within one business day of the discovery of theft or significant loss (21 CFR 1301.76(b));
 Within 45 days complete a DEA form 106, *Report of Theft or Loss of Controlled Substances*, and submit to the DEA using the DEA secure network application; and
 - ii. Email a copy of the printed DEA form 106 to the PQAC (WAC 246-945-040(c));
 - b. A copy of the printed form must be maintained for two years; and
 - c. The Executive Officer in consultation with the Clinical Pharmacist must determine if any investigation is required.

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G. Waste and Disposal

- 1. Practitioners will manage expired, dropped, refused, or partially unused pharmaceuticals following DEA, EPA, and Department of Ecology regulation as applicable.
- 2. All liquid, and solid medications (capsules, tablets) will be destroyed utilizing an RxDestroyer system to render them inactivated and irretrievable, logging the medications that were destroyed.
- 3. When controlled substances are placed into the RxDestroyer, a log with dual practitioner witness signatures will be utilized.
- 4. For destruction of controlled substances originating from the HCE backup stock, a DEA Form 41 will be completed by responsible Clinical Pharmacist, with another practitioner signing as witness.
- 5. DEA Form 41 must be kept on file for two years.
- 6. In general, waste records must be maintained for a minimum of 5 years.
- 7. When RxDestroyer contents reaches two inches from the top, the bottle will be sent to Rainier School Pharmacy for disposal in the pharmaceutical waste barrel, and a new bottle will be requested from Rainier School Pharmacy.
- 8. If a container of cream, ointment, or other pharmaceutical product still holds greater than 3% of the original capacity, then it must be sent to RS for disposal.
- 9. The following items may be placed in regular garbage:
 - a. Empty containers of tablets or capsules with all medication removed.
 - b. Empty containers of creams, gels, ointments or liquids with less than 3% of original capacity.
 - c. Aerosol cans that no longer are pressurized.

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- 10. The following containers, even if no longer holding medication must never be placed in a regular garbage:
 - a. Warfarin;
 - b. Arsenic trioxide;
 - c. Epinephrine (EpiPens, even if used);
 - d. Phentermine;
 - e. Nicotine and salts in liquid form (from vape pens);
 - f. Physostigmine and derivatives; or
 - g. Nitroglycerine.
- 11. Any item that cannot be placed in a regular garbage must be transferred to Rainier School Pharmacy for proper pharmaceutical waste disposal.
- 12. The Clinical Pharmacist must oversee all transfer of pharmaceutical waste to ensure appropriate disposal.
- H. Prescribing Medications
 - 1. An electronic health record must be used to ensure accuracy in receiving, transcribing, and implementing orders for medication administration that ensures youths receive the correct medication, dosage, route, time, and for the correct indication.
 - A prescribing practitioner must electronically sign orders for all medications, including legend drugs, controlled substances, and vaccines. The facility must use a single sign on, role-based system that interfaces with the electronic health record. All electronic prescribing must comply with <u>RCW 69.50.312</u>, <u>Chapter 246-945 WAC</u>, and <u>21 C.F.R. Sec. 1311(c)</u>.
 - a. An authorized paper system must be used when electronic prescribing capability is not available.
 - b. Controlled substance prescriptions must meet DEA requirements.

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- A YTCF must not allow the use of self-administered nonprescription medications. All medications must be staff-administered unless exceptions are specified in the treatment plan within facility regulation.
- 4. Any involuntary antipsychotic medication must be administered consistent with WAC 246-341-1124, <u>42 CFR 483.356</u>, and <u>42 CFR 483.358</u>.
- 5. Any psychotropic medication must be utilized consistent with <u>DDA Policy 5.16</u>, *Psychotropic Medications*.
- 6. Any medication administration error, adverse effect, or side effect must be reported and addressed.
 - a. The person discovering an adverse drug reaction (ADR) or medication administration error (initiator) must submit an incident report per DDA policy 12.01.
 - b. Minor to moderate expected side effects are not ADRs and are not reported via the ADE system. If an employee discovers a medication side effect, the employee must document it in the youth's medical record for the prescribing practitioner to review.
- 7. Any medication packaging incidents must be reported to Rainier School Pharmacy at <u>DSHSDLDDARSPharmacy@dshs.wa.gov.</u> The pharmacy must provide guidance for course of action.
- I. Youth Temporary Leave

A youth must be provided medications to cover for a temporary leave from a YTCF. For Rainier School Pharmacy to fill a quantity sufficient of medications to cover for temporary leave:

- 1. A YTCF must notify Rainier School Pharmacy at a minimum of three business days prior to the beginning of the temporary leave.
- 2. A YTCF must provide information with the date and expected time of departure and return of the youth the facility.
- 3. If the notice of temporary leave is not provided within this time frame, the YTCF prescribing practitioner must print paper scripts to be filled by an outside pharmacy for the time away from the facility.

J. Administration

- 1. All medications must be administered pursuant to a valid order and documented on the medication administration record. Each entry must include:
 - a. Name and dosage of the medication;
 - b. Parameters of use, including indication;
 - c. Date the medication order was initiated;
 - d. Date the medication order was discontinued;
 - e. Time of administration;
 - f. Route;
 - g. Staff or youth's initials indicating medication was administered, or observed being self-administered;
 - h. Notation if medication was refused, held, wasted, or not administered or observed being self-administered;
 - i. Allergies; and
 - j. Youth's response to medication when given "as needed."
- 2. The electronic medication administration record must automatically record or prompt the registered nurse to address all the parameters listed above.
- K. The Clinical Pharmacist or designee must provide staff a current established drug reference resource (WAC 246-337-105(6)).
- L. System Downtime
 - 1. Whether planned or unexpected, computer downtime is inevitable. In the case of a short-term loss of connection, staff will rely on downloaded down time reports. These downtime reports are updated onto local servers every hour. They can be found on the desktop of assigned computers in a folder called Netsmart OMTF. These reports contain current medication administration records (MARs), treatment administration records (TARs), and youth face sheets.

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- 2. Until the EMR becomes available, paper copies will be produced using the downtime reports and placed in the youth care area. These paper forms must be maintained in a temporary chart folder until scanned, or be manually entered into the EMR, by the clinical staff, or their designee. Temporary chart folders are considered chart copies and do not fall under the record retention timelines.
- 3. Once data from the paper forms are entered into the EMR, the paper forms will be shredded on site or placed in secured shred bins until the contracted shredding vendor bin pick up is completed.
- 4. For additional information regarding Information Technology (IT) Disaster Recovery and Business Resumptions Guidelines, review <u>DSHS Information Security</u> <u>Manual</u> and the appropriate YTCF Continuity of Operations Plan.

EXCEPTION

Any exception to this policy must have the prior written approval of the Deputy Assistant Secretary or designee.

SUPERSESSION

DDA Policy 18.05, Medication Management Issued July 17, 2024

Approved:

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Deputy Assistant Secretary Developmental Disabilities Administration Date: June 1, 2025