

Intro to VDH Pharmacy Services & Treatment of Tuberculosis

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Division of Pharmacy Services
Virginia Department of Health
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Objectives

- Describe the role of Pharmacy Services and how the goods and services provided by a centralized pharmacy model support local health departments.
- Understand and describe the various treatments of tuberculosis.
- Describe best practices for ensuring patient safety and compliance with regulations when handling medications.
- Provide examples of strategies that could be implemented to reduce medication waste.

VDH Division of Pharmacy Services

Mission:

The Division of Pharmacy Services (DPS) supports the Department of Health in its public health mission by providing vaccines, pharmaceuticals, pharmaceutical services, and biologicals to other divisions within the Department of Health and to local health departments.

Funding:

Some DPS programs like Naloxone Distribution and 340B Compliance receive funding via state General Funds and federal grants. The rest of DPS is funded by Non-General Funds and charges a small administrative overhead fee that offsets the cost of pharmacy operations so that the service operates essentially revenue-neutral.

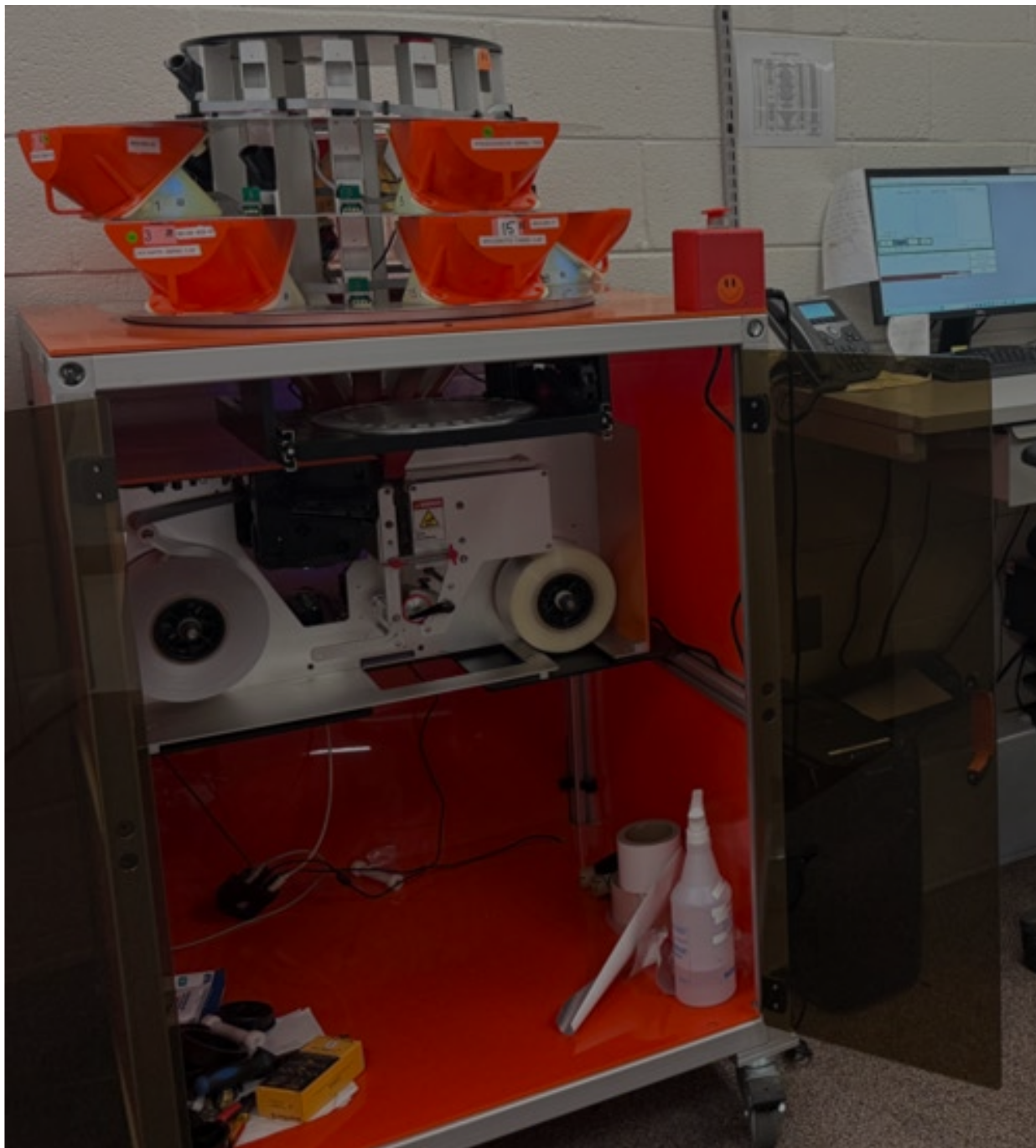
Routine Services:

- Dispense patient-specific prescriptions in support of various VDH programs.
- Provide pharmaceuticals, biologics, and medical supplies to local health departments to support clinic operations.
- Provide vaccines to local health departments for routine vaccinations, outbreaks, foreign travel, flu and COVID clinics, etc.
- Provide clinical and inventory management consultation.
- Provide advice and guidance related to pharmacy laws and regulations.
- Support legislative policy review and response.
- Provide undesignated stock of albuterol and epinephrine to K-12 public schools.
- Properly dispose of expired or returned drugs.
- Assist with Emergency Response and Preparedness, requiring close collaboration with Office of Emergency Preparedness, Divisions within Office of Epidemiology, and Community Health Services.

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Richmond, VA 23219

Phone Number: 804-786-4326

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Staffing Pharmacists:

Lisa Jeannette-Pettaway (Pharmacy Supervisor)

Christie Barret (TB Inventory Manager)

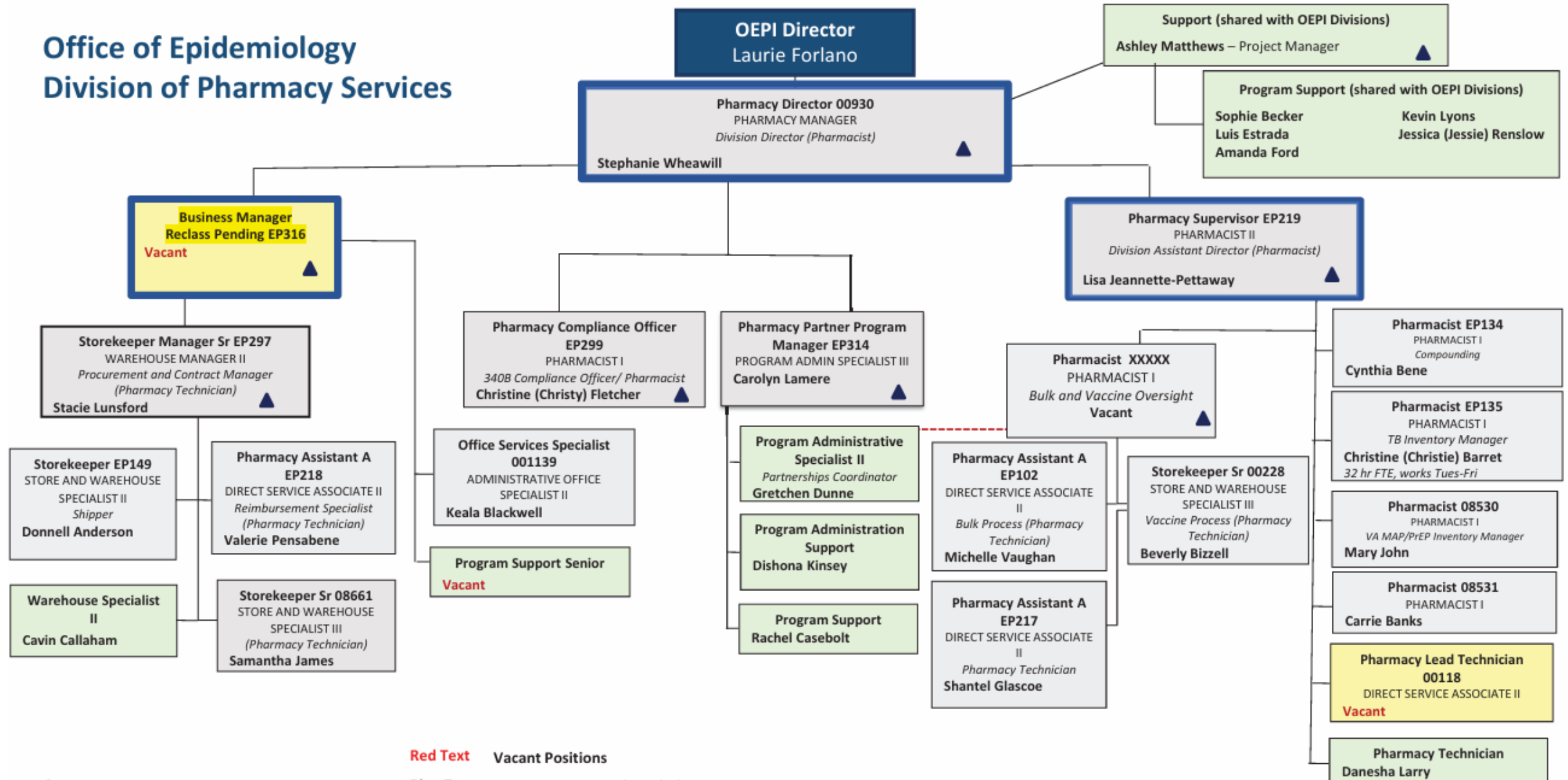
Mary John

Cynthia Bene

Carrie Banks

Office of Epidemiology

Division of Pharmacy Services



- ▲ Supervisor (Pharmacy Leadership Team)
- On-Site Manager
- Cross Management

- Red Text Vacant Positions
- Blue Text Positions Being Onboarded
- Vacant Classified Positions
- Contractors

Inventory Management

DPS helps support pharmaceutical inventory control at VDH by:

- Combined group purchasing and distribution
- Transferring medications among LHDs
- Identifying needs and adjusting inventory levels to respond to needs
- Maintaining sufficient stock within budget
- Maintaining accurate record keeping
- Providing appropriate, safe, and secure storage
- Preventing waste
- Optimizing the investment in inventory
- Increasing collaboration between wholesalers, group purchasing organizations, procurement and programs
- Increasing visibility of practices and inventory
- Oversight of 340 B Program
- Adjudicating and seeking reimbursement from third party insurance



Sufficient stock
without wastage;
forecasting and review

Costs of procurement,
inventory in
accordance with policy
and procedures

First-line TB Drugs

Rifamycins



R

Rifampin
Rifapentine

Isoniazid



I

Pyrazinamide



P

Ethambutol



E

Fluoroquinolones



+/-

Moxifloxacin
Levofloxacin

Second Line TB Drugs

Second Line (Secondary) drugs as listed below must be requested for review and approval by the TB Program before DPS can fill a prescription for these meds:

- Rifabutin
- Linezolid
- Cycloserine
- Pretomanid
- Bedaquiline
- Injectable (amikacin, streptomycin, gentamicin)

What is compliance packaging?

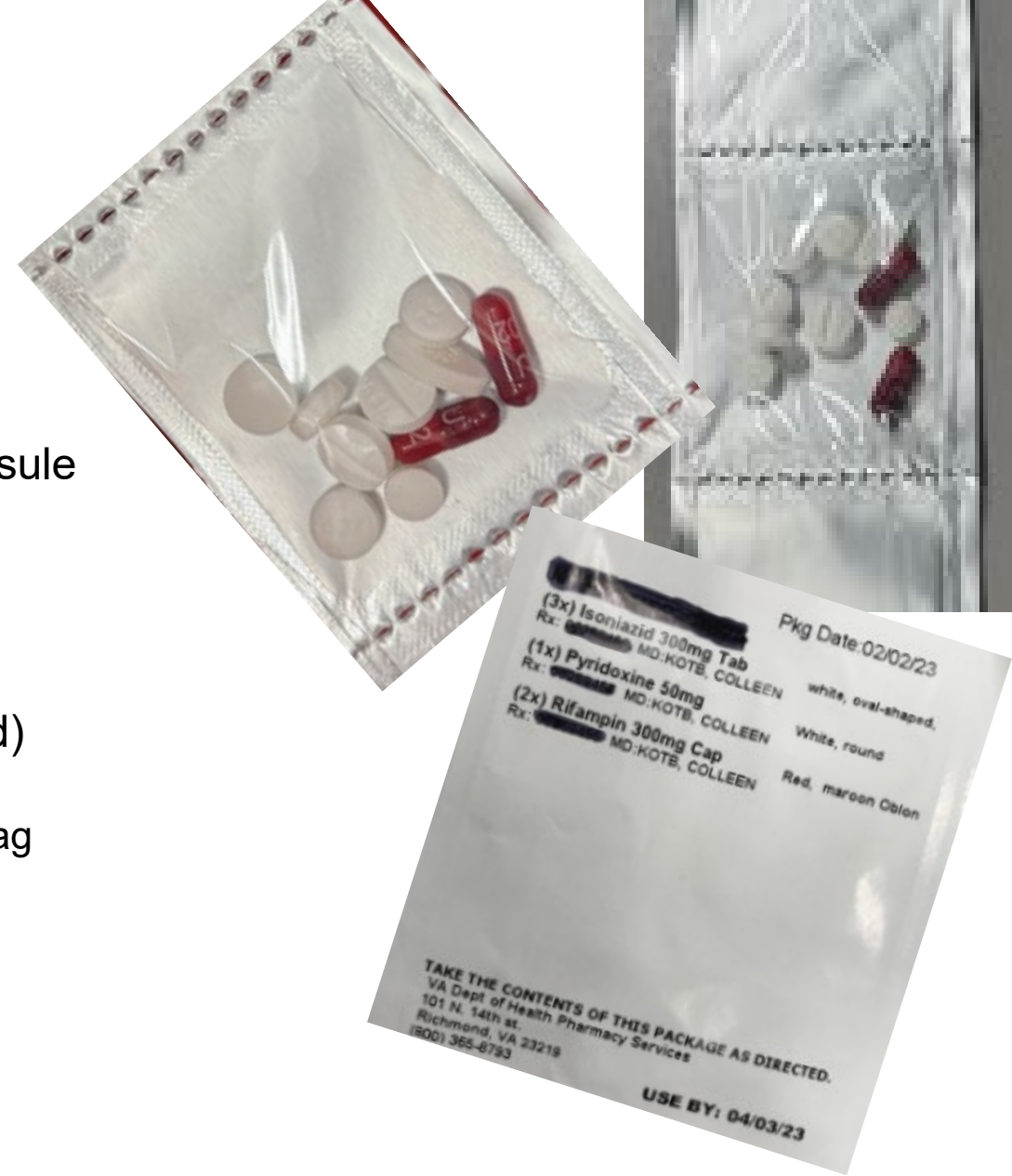
- Board of Pharmacy Definition:
 - Compliance packaging that is comprised of a series of individual containers or pockets labeled with the specific date and time when the contents of that container are to be taken, and which may contain more than one different drug, shall comply with USP-NF standards for customized patient medication packages to include:
 1. If the packaging allows for the separation of the individual containers, the labels for each individual container shall be labeled with the identity of each of the drug products contained within; and
 2. The main packaging label shall contain all the required elements for any outpatient prescription label and shall contain a physical description identifying each solid dosage form contained within the individual containers.
- Medications are packaged in a single one-day supply ("individualized" unit dose compliance packaging) for that patient in the sealed packet for all active and suspect TB cases.
- Use of these packets permits non-licensed outreach staff to assist with the directly observed therapy thereby saving licensed staff time with this task.

Compliance Packaging

Printed on the front of the packet:

- date packaged
- patient name
- medication name and strength and number of pills, tablet/capsule and description of medication (color/shape)
- Prescription number (rx #),
- Prescriber's name
- Instructions (take the contents of this package as directed) ^
- Use by date (60 day beyond use date from the date packaged)

^ The packets are placed in a clear resealable bag. The outside of the bag has a label for each medication and one label with instructions on the frequency (e.g., biweekly, daily, M-F).



Laws and Regulations for Compliance Packaging

DOT Outreach Staff Permissible Acts in Virginia	DOT Outreach Staff Non-Permissible Acts in Virginia
Authorization to possess controlled substances but only in the context of normal business functions and when acting as a designated agent for the prescriber, pharmacy or controlled substance registration certificate holder.	Outreach worker shall not administer drugs to a patient.
Authorization to deliver or distribute controlled substances in the course of your job when acting as an agent for the prescriber, pharmacy or controlled substance registration certificate holder.	Outreach worker shall not dispense drugs to a patient.

State

Code of Virginia Pharmacy Regulations
§ 54.1-3420.2D 18VAC110-20-275. Delivery of dispensed prescriptions
§ 54.1-3420.2 B 18VAC110-20-340. Packaging standards for dispensed prescriptions.

Federal

United States Pharmacopeia–National Formulary (USP–NF) Chapter <659> Packaging and Storage Requirements

Storage and Handling



- **Read** the prescription label for specific instructions **every time**
- Store all medication in original container with original labels as dispensed by Pharmacy.
 - If refrigeration is required, store in refrigerator.
 - If refrigeration is not required, do not place with cold medication.
- Store in an area not accessible for children.
- Pay attention to the **Beyond Use Date** on label affixed to the bottle.

Commonly Prescribed TB Liquid Medications

	Drug	Storage Temp	Stability
Commercial Product(s)	Isoniazid 50mg/5mL	Room temperature Do NOT refrigerate	6-12 months (depends on dating on manufacturer bottle)
	Levofloxacin 25mg/mL	Room temperature	6-12 months (depends on dating on manufacturer bottle)
Special Compound Product(s)	Ethambutol 100mg/mL	Refrigerate (2-8C)	90 days
	Levofloxacin 50mg/mL	Refrigerate (2-8C)	57 days
	Pyrazinamide 10mg/mL or 100mg/mL	Refrigerate (2-8C)	60 days
	Pyridoxine 1mg/mL	Refrigerate (2-8C)	30 days
	Rifampin 10mg/mL or 25mg/mL	Refrigerate (2-8C)	28 days

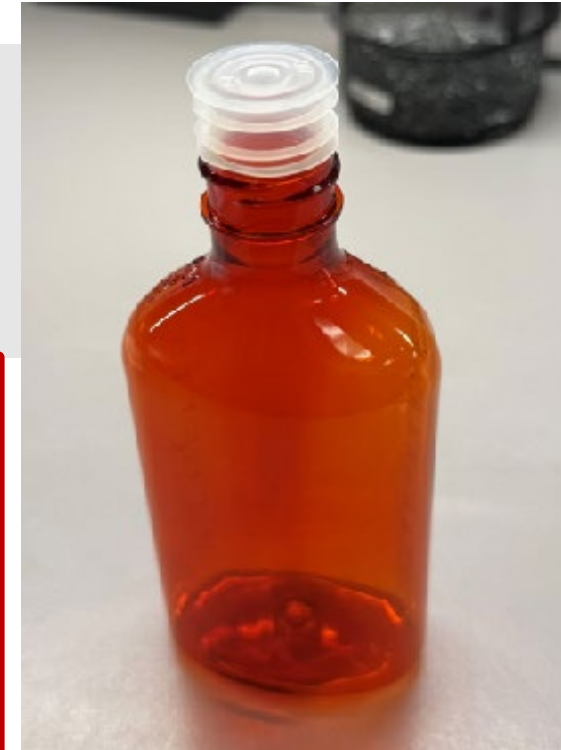
Note: Stability/storage subject to change based on compounding clinical reference material



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**Tip for
LHD
Staff**

Place orders for liquid "Special Compound" medications up to 7 days in advance, preferably by the end of the previous week compound is needed, so Pharmacy staff can plan. Compounds take extra time and are only shipped on Mondays, Tuesdays and Wednesdays.

340B Program Overview

Intent

"To permit covered entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

.R. Rep. No. 102-384(II), at 12 (1992)

VDH 340B Compliance Officer:

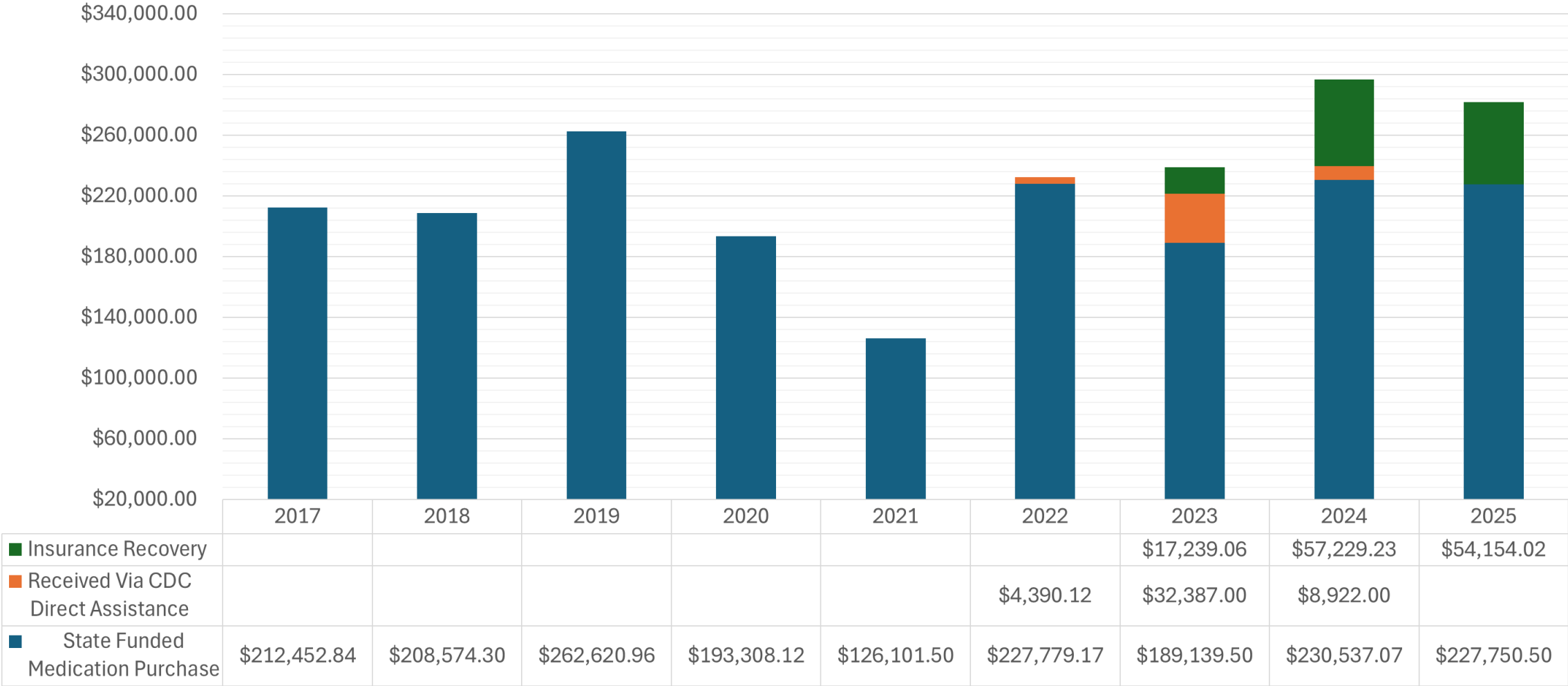
Christy Fletcher, PharmD

340B Tuberculosis (TB) Documentation Requirements

Services must be aligned as specified in the scope of the TB grant.

1. Complete Tuberculosis (TB) Newcomer Health History.
2. Attest "that the TB newcomer health history has been completed, and the client continues to receive TB services throughout the duration of care."

TB Medication Costs FY17-FY25



■ State Funded Medication Purchase ■ Received Via CDC Direct Assistance ■ Insurance Recovery

Preventing Waste

For patients not on stable treatment:

- Day Supply: Consider 2-week supply until treatment/therapy is stable; most orders are for 30-day supply at a time.
- Refill window: Consider fills be limited to no more than 7 days early; pharmacy currently fills 14 days early unless dictated by insurance.
- Medication Returns: LHD staff should return medications not given to patients within 14 days of the date dispensed.
 - Some insurance companies have a return period in the contract and time period is defined by state law. Current policy states to return in 60 days.
- Track medication through client picking up medications; need mechanism to reconcile medications dispensed by Pharmacy but not received by patient.

Frequently Asked Questions

Is there a cut-off for order times to get prescriptions shipped?

Pharmacy makes every effort to process and ship orders received before 1:30pm the same day. Occasionally circumstances will prevent this such as refill too soon, issues with the order that need to be resolved, issues with the packaging machine, heavy volume, etc. If an order is submitted after 1:30pm and is urgent LHD staff should call the pharmacy.

Is the TB Order Form going to be in the EHR?

The goal is that TB workflow, including information currently collected in the [RedCap TB Prescription Order Form](#) will be incorporated within the EHR. The workflow has been discussed in the current design and implementation phase.

How many days supply are allowed to be ordered?

Unless approved by TB, Pharmacy will dispense a maximum of 30 days supply. LHD staff may consider requesting smaller supply until treatment/therapy is stable.

Can LHD relabel medications dispensed by Pharmacy?

No medications that have been dispensed and labeled for a client may be relabeled at the LHD. All unused medications must be returned to the Pharmacy.

Frequently Asked Questions

Is there an available resource on crushing, mixing and administering TB medications to infants and children?

Please utilize the resource created and made available by VDH TB Program: [Window Treatment After Exposure to Tuberculosis -What parents need to know.](#)

Where can I find information regarding drug handling and storage procedures in Health Departments?

Please visit VDH Division of Pharmacy Services Intranet page. See [Drug Handling & Storage Procedures in Health Departments](#). Contact pharmacy@vdh.virginia.gov with specific questions.

Can a nurse or outreach worker repackage medications?

No. Repackaging of medication is legally permitted in a pharmacy under a pharmacist license. Additionally, since the medication was dispensed by the Pharmacy, medication should not be repackaged by anyone at the LHD.

Can a patient repackage their own medications that are in their possession?

Yes, if there is ability to remove a tablet, and substitute, this may be deemed appropriate. If a medication is provided to the patient, staff would be assisting the patient in self-administration and is not considered repackaging.

Frequently Asked Questions

Are there any additional requirements for medications that are left at a patient's home and not in child-proof prescription bottle?

All drugs must be dispensed in tight, light resistant containers with approved child resistant safety closures. If the client requests that his/her drugs not be placed in a child resistant container or receives medication in compliance packets which are not child-proof, the client should sign the back of the prescription blank or some other document indicating such. This documentation should be retained in the client's record.

Where should TB medications dispensed by DPS be stored at the LHD?

These medications should be stored in the locked secure storage area designated on the Controlled Substance Registration (CSR) to await delivery to the client. Access to the locked storage area designated on the CSR may be accessed by the CSR Responsible Party, CSR Supervising Practitioner and others whose names are listed on the Designated Access List when a clinician with prescriptive authority is not onsite. The Designated Access List should be current and maintained in the storage area along with the CSR policy and procedures, agency Memorandum of Understanding (MOU) and other applicable documents.

Frequently Asked Questions

Can a health department keep medication not picked up by a patient to have on site?

All unopened packages of drugs (expired/not expired) including prescriptions for clients that do not get picked up within 60 days from the date of dispensing, are required to be returned to the pharmacy.

How far in advance should LHD submit prescription refill request orders?

It is helpful for LHDs to submit refill orders 7-10 days in advance of when needed to allow for issues such as needing a new prescription or a shipping issue to be resolved or for holiday closures. Current policy is to fill up to 14 days early, except when held to stricter limits by insurance but best practices to avoid wastage is to reorder closer to 7 days early. For special compounded products, LHD staff should try to submit at least 7 days (5 business days) in advance (see slide 14). Compounds require extra time and are only shipped Mondays, Tuesdays and Wednesdays. Utilize the Need By Date field on the RedCap and the Notes section to communicate this information.

Frequently Asked Questions

What is the process for a LHD to route a prescription from an outside provider to VDH Pharmacy?

Normally, a prescription starts as a [written prescription](#) and is faxed from the originating physician's office to a pharmacy. DPS has a "Special Use" pharmacy permit allowing prescriptions to be faxed from the prescriber's office to LHDs then faxed to DPS. Faxed written prescriptions signed by a prescriber coming from LHDs to DPS must contain the following information within the body of the signed prescription per state pharmacy regulations: FAXED TO DPS (Division of Pharmacy Services), THE INITIALS OF THE PERSON FAXING THE DOCUMENT, AND THE DATE THAT THE DOCUMENT IS BEING FAXED. Writing this information within the body of the prescription document serves to cancel the prescription so that it cannot be presented to another pharmacy.

What is needed for pharmacy to bill medications to insurance?

Pharmacy staff will utilize information within the [RedCap TB Prescription Order Form](#) to identify the appropriate fund source for the medication. Information needed for billing pharmacy drug claims includes the Member ID, RxBIN, RxPCN and RxGroup numbers. Without this information pharmacy may not be able to successfully bill insurance. This may be submitted on a copy of the pharmacy prescription card attached in the Redcap, entered manually into the Redcap or faxed to the pharmacy. Pharmacy may be able to find the insurance through look-ups for some patients. Some clients may have separate cards for pharmacy and medical insurance, as this differs by plan. LHDs should train staff doing intake to ensure they obtain the pharmacy drug card in the medical record for LHD staff to include in the order form.

Ongoing Risks

- Increase in TB cases
- Recent supply Issues with first line drugs (INH/RIF)
- Costly second line drugs
- Uncertainty of 340B pricing