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Medication Handling

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Participants will:

- Review safe practices for storing and administering medications
- Discover required policy elements
- Discuss common deficiencies around medications in the RHC

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Medication Rules

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491.6 Physical plant and environment

(a) Construction. The clinic or center is constructed, arranged, and maintained to insure access to and safety of patients, and provides adequate space for the provision of direct services.

(b) Maintenance. The clinic or center has a preventive maintenance program to ensure that:

- All essential mechanical, electrical, and patient-care equipment is maintained in safe operating condition;
- **Drugs and biologicals are appropriately stored;** and
- The premises are clean and orderly.

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The RHC must ensure the appropriate storage of drugs and biologicals which are used in the clinic.

- Drugs and biologicals must be stored and maintained in accordance with the manufacturer's instructions for temperature and other environmental conditions as well as expiration dates, etc.
- They may not be stored in areas that are readily accessible to unauthorized individuals/personnel.
- The clinic's policies and procedures must identify which types of clinic staff are authorized access to drugs and biologicals.
    - For example, if medications are kept in a private office, or other area where patients and visitors are not allowed without the supervision or presence of a health care professional, they are considered secure.
    - If medications are kept in cabinets located in areas where patients, visitors or other unauthorized personnel have ready access when clinic personnel are **not** also present, the cabinets must be locked.

491.9 Provision of services

(b) Patient care policies.
(3) The policies include:

- A description of the services the clinic or center furnishes directly and those furnished through agreement or arrangement.
- Guidelines for the medical management of health problems which include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the clinic or center.
- **Rules for the storage, handling, and administration of drugs and biologicals.**

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Storage of drugs and biologicals
Consistent with accepted professional principles, RHC's must demonstrate appropriate storage and preparation of medications under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security.

Proper environmental conditions
Where the manufacturer's FDA-approved package insert specifies environmental conditions, such as temperature, humidity, exposure to light, etc., for storage of drugs, the RHC is expected to follow the labelled conditions. RHC's must exercise caution in administering any drug or biological that is not labelled to indicate proper storage conditions or that may have been stored under inadequate conditions.

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Security

The RHC must have policies and procedures that are consistent with State and Federal law to address how drugs and biologicals are stored and secured, including who is authorized access to the drug storage area. Drugs and biologicals must be stored in a secure manner to prevent unmonitored access by unauthorized individuals. Drugs and biologicals must not be stored in areas that are readily accessible to unauthorized persons. For example, if medications are kept in a private office, or other area where patients and visitors are not allowed without the supervision or presence of a health care professional, they are generally considered secure. Areas restricted to authorized personnel only would generally be considered "secure areas."

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Security (continued)
RHCs are permitted flexibility in the storage of non-controlled drugs and biologicals when delivering care to patients, and in the safeguarding of drugs and biologicals to prevent tampering or diversion. An area in which staff members are actively providing care to patients or preparing to receive patients, i.e. setting up for injections, would generally be considered a secure area. When a patient care area is not staffed, both controlled and non-controlled substances are expected to be locked, in accordance with state and Federal law.

If the RHC uses cart(s) containing drugs or biologicals, whenever the cart is in use and unlocked, someone with authorized access to the drugs and biologicals in the cart must be within close eyesight of and directly monitoring the cart. That person could be a nurse, a physician, or other individual who in accordance with State and Federal law and RHC policy is authorized access to the drugs and biologicals in the cart. That individual must monitor the cart and be aware of other people's activities near the cart. He/she is responsible for the security of the drugs and biologicals in the cart.

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Security (continued)

Record keeping for the receipt and disposition of all scheduled drugs.

The U.S. Department of Justice Drug Enforcement Administration (DEA) classifies drugs that are controlled in accordance with the Controlled Substances Act into five “schedules,” ranging from Schedule I substances, which have a high potential for abuse and no currently accepted medical use in treatment, to Schedule V substances, which have a low potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics.

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Record keeping for the receipt and disposition of all scheduled drugs.

The RHC is required to accurately track the receipt and disposition of all scheduled drugs used in the RHC. Components of a record system for scheduled drugs would include:

- Locked storage of scheduled drugs when not in use; Accountability procedures to ensure control of the distribution, use, and disposition of all scheduled drugs;
- Tracking movement of all scheduled drugs from the point of entry into the RHC to the point of departure either through administration to the patient, destruction, or return to the manufacturer. This system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.
- Prompt reconciliation of any discrepancies in count. The RHC is capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual loss or diversion to the time of detection and determination of the extent of loss or diversion.

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Handling drugs and biologicals.

“Handling” includes reconstituting or mixing medications in accordance with directions contained in approved labeling provided by the drug’s manufacturer.

Compounding

“Handling” also includes compounding or admixing of sterile intravenous preparations or of other drugs, either on- or off-site, using either facility staff or a contracted pharmacy service.

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Expiration & Beyond Use Dates

A drug or biological is outdated after its expiration date, which is set by the manufacturer based on stability testing under specified conditions as part of the FDA approval process. It should be noted that a drug or biological may become unusable prior to its expiration date if it has been subjected to conditions that are inconsistent with the manufacturer's approved labeling.

A drug or biological is also outdated after its "beyond-use date" (BUD), which may be reached before the expiration date, but never later. The BUD takes into account the specific conditions and potential for deterioration and microbial growth that may occur during or after the original container is opened, while preparing the medication for dispensing and administration, and/or during the compounding process if it is a compounded medication.

The BUD is to be based on information provided by the manufacturer, whenever such information is available.

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Basic safe practices for medication administration within the RHC
The RHC's patient care policies must reflect accepted standards of practice that require the following information be confirmed prior to each administration of medication that takes place in the RHC (such as administration of vaccines or medications via injection):

Right patient: ensuring the patient's identity. Acceptable patient identifiers include, but are not limited to: the patient's full name; an identification number assigned by the RHC; or date of birth. Identifiers must be confirmed by patient identification card, patient statement (when possible), or other means outlined in the RHC's policy. The patient's identification must be confirmed to be in agreement with the medication administration record and medication labeling prior to medication administration to ensure that the medication is being given to the correct patient.

Right medication: the correct medication, to ensure that the medication being given to the patient matches that prescribed for the patient and that the patient does not have a documented allergy to it;

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Basic safe practices for medication administration within the RHC

Right dose: the correct dose, to ensure that the dosage of the medication matches the prescribed dose, and that the prescription itself does not reflect an unsafe dosage level (i.e., a dose that is too high or too low);

Right route: the correct route, to ensure that the method of administration – orally, intramuscular, intravenous, etc. - is the appropriate one for that particular medication and patient; and

Right time: the appropriate time, to ensure adherence to the prescribed frequency and time of administration.

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Basic safe practices for medication administration within the RHC

NOTE: the “5 rights” focus specifically on the process of administering medications. The medication process is generally recognized as consisting of five stages: ordering/prescribing; transcribing and verifying; dispensing and delivering; administering; and monitoring/reporting. Errors may occur in other components of the process, even when there is strict adherence to the “5 rights” of medication administration, for example when there has been a prescribing or a dispensing error.

RHCs are encouraged to promote a culture in which it is not only acceptable, but also strongly encouraged, for staff to bring to the attention of the prescribing practitioner questions or concerns they have regarding medication orders. Any questions about orders for drugs or biologicals are expected to be resolved promptly.

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Frequently Asked Questions (FAQ) And Common Deficiencies

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FAQ

- What is considered secure?
  - Lock vs line of sight
  - Lock the room or lock the stuff
  - Note: Compliance spectrum
- What is considered appropriate infection control protocols?
  - Clean vs dirty
  - Injection safety
  - Aseptic technique
- Where/how/when should meds be drawn up?
  - Avoid cross contamination
  - Use appropriate aseptic technique
  - No pre-filled syringes (unless directly from mfr.)

Common Deficiencies

- Inappropriate storage
  - Single dose
  - Multi dose
  - Expired items
  - Temperature adherence
  - Security
  - Cross contamination
- Inappropriate administration
  - 5 Rs
  - Following mfr. guidance (pre-filled)
- Inappropriate documentation
  - Documentation in patient record
  - Distribution process
  - Temperature logs

Pharmaceutical Policy Content:

- Storage
- Security
- Power outage
- Transport
- Administration
- Recall
- Distribution
- Disposal
- Controlled
- Samples
- Documentation

SDV/MDV Information

Single-Dose Vials	Multi-Dose Vials
Approved for use on single patient for single procedure or injection	Can be used for more than one patient when aseptic technique is followed
Does not have antimicrobial preservative	Contains an antimicrobial preservative to limit growth of bacteria
Harmful bacteria can grow and infect a patient	Preservatives have no effect on bloodborne viruses
Do not assume a vial is SDV or MDV based on size or volume of medication. ALWAYS CHECK THE LABEL	Discard MDVs when the expiration date has been reached or beyond use date has been reached (28 days)
DISCARD AFTER EVERY USE	Discard if sterility of the vial is in question

Survey Readiness:

- If clinic finds a vial out of compliance, pull records of medication lot number to determine patients impacted by deficient practice and to see if record keeping is current
- Staff understanding
  - Observe administration techniques
  - When is a medication no longer considered viable?
  - How does the clinic dispose of medications?
  - What is the difference between single/multi dose vials?
  - Who is responsible for medication storage areas?
  - Does the clinic have pre-made kits? If so, who is responsible to monitor?
    - Overnight bags, emergency kit, personal caddy, etc.
  - Review policy with staff that handle medications and train/test understanding

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Resources

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CDC Training Resources

- **FAQ:**
  - https://www.cdc.gov/injectionsafety/providers/provider_faqs.html
- **Injection Safety Campaign Materials:**
  - https://www.cdc.gov/injectionsafety/1anonly.html
- **Setting-specific Infection Control Assessment Tools:**
  - http://www.cdc.gov/infectioncontrol/tools/index.html
- **Injection Safety On-line Training Module:**
  - https://www.train.org/main/course/1081807/external icon

SAMPLE MEDICATION LOG

DATE	PATIENT NAME	MEDICATION	LOT NO.	DOSE	# of SAMPLES GIVEN	EXP. DATE	SIGNATURE

CONTROLLED SUBSTANCE LEDGER

CONTROLLED SUBSTANCE (MEDICATION NAME)____Strength______________Lot number______________Exp ______________

NOTE: Use one ledger sheet for each individual vial/package of controlled substance medication with same strength, lot and expiration.

DATE	ACTION		AMT RECEIVED (new stock)	AMOUNT USED			BALANCE/ COUNT	PATIENT NAME AND MRN	STAFF NAME (PRINT)		NOTES
	CHECK ONE	FOR AUDIT, CHECK ONE	QUANTITY (tablets, vials, pre-filled syringes)	UNITS ADMINISTERED		UNITS WASTED	QUANTITY REMAINING (tablets, vials, pre-filled syringes)		1st PERSON	WITNESS/ 2nd PERSON	
				Dose in units	Volume if applicable	(volume/ tablets)					
	☐ Receive ☐ Dispense ☐ Audit	☐ AM ☐ PM							1st:	2nd:	
	☐ Receive ☐ Dispense ☐ Audit	☐ AM ☐ PM							1st:	2nd:	
	☐ Receive ☐ Dispense ☐ Audit	☐ AM ☐ PM							1st:	2nd:	
	☐ Receive ☐ Dispense ☐ Audit	☐ AM ☐ PM							1st:	2nd:	
	☐ Receive ☐ Dispense ☐ Audit	☐ AM ☐ PM							1st:	2nd:	
	☐ Receive ☐ Dispense ☐ Audit	☐ AM ☐ PM							1st:	2nd:	
	☐ Receive ☐ Dispense ☐ Audit	☐ AM ☐ PM							1st:	2nd:	
	☐ Receive ☐ Dispense ☐ Audit	☐ AM ☐ PM							1st:	2nd:	
	☐ Receive ☐ Dispense ☐ Audit	☐ AM ☐ PM							1st:	2nd:	
	☐ Receive ☐ Dispense ☐ Audit	☐ AM ☐ PM							1st:	2nd:	
	☐ Receive ☐ Dispense ☐ Audit	☐ AM ☐ PM							1st:	2nd:	

Inventory of this controlled substance MUST be completed twice daily by two authorized personnel and kept on file in hard-copy for 11 years.

Refrigerator & Freezer Temperature Log

Month/Year_____

Refrigerator needs to be at +36° to 46° F (2° to 8° C) **+40° F is the ideal temperature.**

Freezer needs to be at **+5° F** (-15° C) **or colder** **0° F or colder** is ideal.

Record the Time, Temperatures & Initials two times (2) each business day, upon arrival (morning) and when closing the office at the end of the day (evening).

Circle the F or C below to identify whether temperatures are taken in Fahrenheit or Celsius

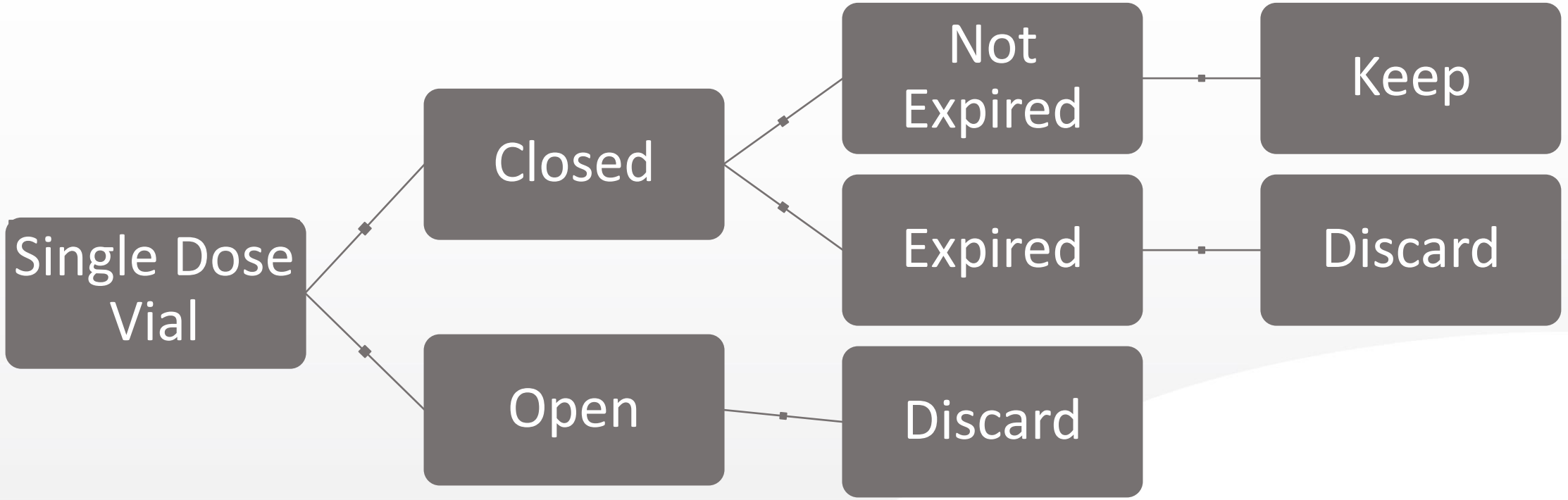
DAY	TIME	REFRIG	FREEZER	INITIALS	DAY	TIME	REFRIG	FREEZER	INITIALS
1st	am	°F °C	°F °C		17th	am	°F °C	°F °C	
	pm	°F °C	°F °C			pm	°F °C	°F °C	
2nd	am	°F °C	°F °C		18th	am	°F °C	°F °C	
	pm	°F °C	°F °C			pm	°F °C	°F °C	
3rd	am	°F °C	°F °C		19th	am	°F °C	°F °C	
	pm	°F °C	°F °C			pm	°F °C	°F °C	
4th	am	°F °C	°F °C		20th	am	°F °C	°F °C	
	pm	°F °C	°F °C			pm	°F °C	°F °C	
5th	am	°F °C	°F °C		21st	am	°F °C	°F °C	
	pm	°F °C	°F °C			pm	°F °C	°F °C	
6th	am	°F °C	°F °C		22nd	am	°F °C	°F °C	
	pm	°F °C	°F °C			pm	°F °C	°F °C	
7th	am	°F °C	°F °C		23rd	am	°F °C	°F °C	
	pm	°F °C	°F °C			pm	°F °C	°F °C	
8th	am	°F °C	°F °C		24th	am	°F °C	°F °C	
	pm	°F °C	°F °C			pm	°F °C	°F °C	
9th	am	°F °C	°F °C		25th	am	°F °C	°F °C	
	pm	°F °C	°F °C			pm	°F °C	°F °C	
10th	am	°F °C	°F °C		26th	am	°F °C	°F °C	
	pm	°F °C	°F °C			pm	°F °C	°F °C	
11th	am	°F °C	°F °C		27th	am	°F °C	°F °C	
	pm	°F °C	°F °C			pm	°F °C	°F °C	
12th	am	°F °C	°F °C		28th	am	°F °C	°F °C	
	pm	°F °C	°F °C			pm	°F °C	°F °C	
13th	am	°F °C	°F °C		29th	am	°F °C	°F °C	
	pm	°F °C	°F °C			pm	°F °C	°F °C	
14th	am	°F °C	°F °C		30th	am	°F °C	°F °C	
	pm	°F °C	°F °C			pm	°F °C	°F °C	
15th	am	°F °C	°F °C		31st	am	°F °C	°F °C	
	pm	°F °C	°F °C			pm	°F °C	°F °C	
16th	am	°F °C	°F °C						
	pm	°F °C	°F °C						

Date Vial Opened _____

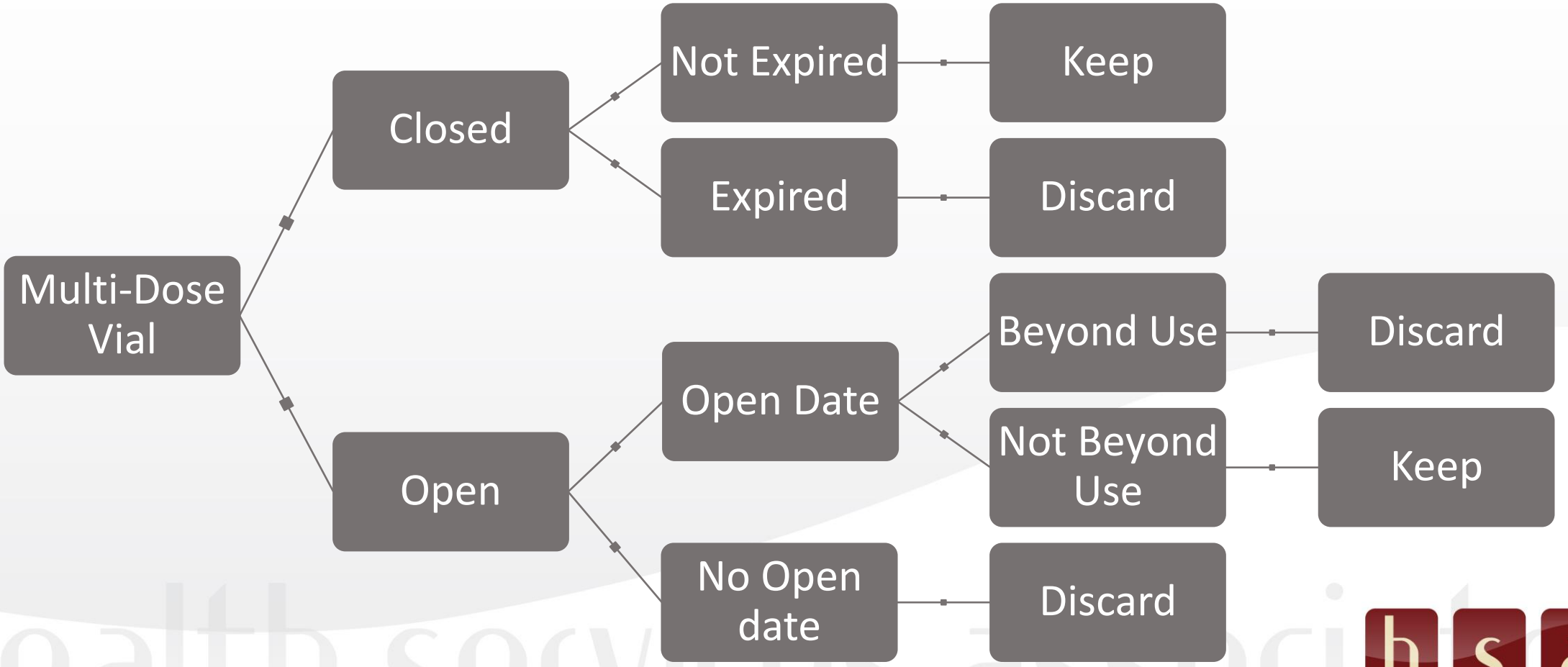
Date Vial Expires _____

Discard After 28 Days

Single Dose Vial Decision Tree



Multi Dose Vial Decision Tree



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