PURPOSE

To promote safe work practices and provide guidelines on safety measures for the receipt, storage, preparation, compounding, dispensing, administration, spill clean-up, waste management, and Employee Medical Surveillance (DHS Policy 925.350). It is important to minimize occupational exposure to these drugs because of the risk of adverse health effects.

SCOPE

All departments that handle hazardous medications will provide guidelines and a training program relevant to the tasks performed by their personnel. These departments will include, but not limited to: Pharmacy, Nursing, Physicians and Environmental services.

DEFINITIONS

See Appendix 1

RESPONSIBILITIES

1. Pharmacist-In-Charge (PIC) is responsible for ensuring overall compliance with the policy and procedure.
2. All trained and authorized personnel handling hazardous medications must abide by the policy and perform the procedure as specified.

FREQUENCY

The policy and procedure will be reviewed at least yearly and/or when a revision is needed.

POLICY

1. Hazardous Drug List:

1.1. Hazardous drug (HD) (include those used for cancer chemotherapy, antiviral drugs, hormones, some bio- engineered drugs, and other miscellaneous drugs) is any drug

identified by at least one of the following six criteria, as defined by National Institute of Occupational Safety and Health (NIOSH): Carcinogenicity, Teratogenicity or other developmental toxicity, Reproductive toxicity, Organ toxicity at low doses, Genotoxicity, Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria

1.2. RLANRC Pharmacy is responsible to maintain a list of hazardous drugs used at RLANRC.

1.3. The list is reviewed and approved by the Pharmacy and Therapeutics Committee

1.4. The RLANRC HD list divides the HD drugs into 4 different subgroups based on the result of their assessment of risk (AoR) of their potential exposures and severity of harm, thus containment requirements for HD handlers to minimize the risks:

1.4.1. **RLANRC HD group 1 (Risk level 1):** Antineoplastic requiring no compounding (ready-to-be-administered)

1.4.2. **RLANRC HD group 2 (Risk level 2):** non-antineoplastic with higher risk (higher probability of occurrence of harm (occupational exposure) and/or greater severity of the harm). Many drugs of this group have reproductive risk.

1.4.3. **RLANRC HD group 3 (Risk level 3):** Reproductive Risk with higher potential of occupational exposure

1.4.4. **RLANRC HD group 4 (Risk level 4):** Non-antineoplastic or Reproductive-risk drugs with lower risk (lower occupational exposure and/or lower severity of the harm). Thus, additional containment is not required for this HD group.

Table 1. RLANRC HD groups vs. probability of exposure and Severity of harm

	Antineoplastic	Manipulation Required?	Probability of Exposure	Severity of Harm due to Exposure
Group 1	Yes	Regardless	Regardless	Regardless
Group 2	No	Yes/No	High	High
Group 3	No	No	High/Low	Low

Group 4	No	No	Lower	Lower

1.5. Refer to Appendix 3 for RLANRC list of hazardous drugs

1.6. Addendum of HD list is a transition list for new drugs to be used at RLANRC but not listed on the approved RLANRC HD list yet.

2. Assessment of Risk (AoR):

2.1. Assessment of Risk is an evaluation of the risk factors related to potential exposure to a hazardous medication, or the blood and body fluids of patients receiving hazardous medications to reduce occupational exposure.

2.2. An assessment of risk is used to establish alternative containment strategies and/or work practices in handling any specific hazardous medications or dosage forms.

2.3. Once the AoR classifies these hazardous drugs based on their risk of direct occupational exposure, alternative procedures for appropriate handling will be explicitly stated and followed.

2.4. Assessment of risk of hazardous drugs must be reviewed annually.

2.5. The AoR of a new drug to be used at RLANRC shall happen as soon as the new drug is brought on board for use.

2.6. If an AOR is not performed and implemented on a specific hazardous drug or dosage form yet, it must be handled according to USP <800> with respect to its original NIOSH listed group/table

3. Review of the RLANRC HD list:

3.1. Since the NIOSH list is published periodically and biannually, during the interim periods between the updates of NIOSH lists, the P&T committee at RLANRC will review newly FDA approved drugs, or established drugs with new safety warnings handled at RLANRC for

3.1.1. Consideration of temporary addition to the list if deemed hazardous or

3.1.2. Deletion from the list if deemed not hazardous.

3.1.3. Such drugs may be removed from the list or remain in the list if they are subsequently not included or included on the next published NIOSH list respectively.

3.2. The hazardous drugs on the addendum list will be reviewed by P&T committees. Upon approval, these drugs will be removed from addendum list and officially added to the Rancho HD list.

3.3. The annual review of the list shall happen at least every 12 months and approved by P&T committee.

4. Handling of Hazardous Medications:

4.1. Exposure:

4.1.1. Occupational exposure to hazardous medication can happen when handling them. Appendix 4 includes common activities at Rancho that may involve exposure to hazardous medications

4.1.2. Personnel who are exposed to a hazardous medication via dermal or mucosal contact, injection, ingestion, inhalation, or other means must immediately take steps to minimize the severity and duration of exposure (e.g., wash or rinse, needle aspiration, removal of saturated materials) and report to an immediate supervisor for evaluation at the employee health center.

4.2. **Personal Protection Equipment (PPE) Use:**

4.2.1. All employees who handle hazardous drugs shall follow the containment requirements outlined in the “Alternative Containment Strategies for Handling Hazardous Drugs” (aka PPE guideline of handling HD) to ensure proper handling of hazardous drugs

4.2.2. PPE that are overtly contaminated or used during antineoplastic spill cleanup must be considered to have more than trace contamination and disposed of as bulk hazardous waste (see disposal section for more details).

4.2.3. Sterile Gloves:

a. Double gloves must be donned unless AoR of the HD specified differently

b. Gloves must be powder-free.

c. Outer gloves must meet **ASTM D-6978** and when handling HD medications.
d. If only one pair of gloves is required per AoR of certain medications, the gloves must also meet **ASTM D-6978** and when handling HD medications.
e. The outer, sterile chemotherapy gloves must be changed every 30 minutes during continuous compounding and immediately if defect, puncture, or tear is suspected.
f. When removing/changing the contaminated outer gloves, they are to be placed in the black RCRA bin inside the BSC or a sealable plastic bag before removal from the BSC and disposed of as hazardous waste

4.2.4. **Gowns**:

a. Double gowns must be worn inside the hazardous buffer rooms. Outer gown must be disposable chemotherapy gown, shown to resist permeability to hazardous drugs. Gowns must be long sleeved, have closed cuffs (either elastic or knit), and close in the back (no open front) to prevent accidental contamination of clothes in the event of a spill.
b. Gowns must be changed every 3 hours during continuous compounding and whenever torn, punctured, or visibly contaminated.
c. Gowns must be worn during compounding, spill control, and during waste management activities to protect the employee from exposure to potential HD residues.
d. Unlike regular compounding gowns, gowns worn for hazardous compounding must be removed carefully, assuming contamination of the exterior portion of the gown and discarded in appropriate contaminated waste container.
e. Gowns used for hazardous compounding may not be retained for later use during that compounding shift or day. They must be removed and discarded in the appropriate hazardous waste container each time the compounder leaves the HD compounding buffer area.

f. Gowns worn in hazardous drug handling areas must not be worn to other areas

4.2.5. **Hair covers** required when handling hazardous medications unless specified differently per AoR

4.2.6. **Shoe covers**: 2 pairs of shoe covers must be donned before entering the buffer room and doffed when exiting. Shoe covers worn in HD handling areas must not be worn to other areas.

4.2.7. **Face masks and goggles**: A full-face piece respirator provides eye and face protection. Goggles must be used when eye protection is needed. Face shields in combination with goggles provide a full range of protection against splashes to the face and eyes.

4.3. Receiving:

4.3.1. Spill kits must be accessible in the pharmacy receiving area in the pharmacy

4.3.2. Hazardous drugs must be unpacked from external shipping containers in a designated area that is neutral or negative in pressure relative to the surrounding areas.

4.3.3. Hazardous drugs must neither be unpacked from their external shipping containers in sterile compounding areas nor in positive pressure areas.

4.3.4. After unpacking from shipping containers, hazardous drugs shall be delivered to their storage area immediately

4.3.5. Antineoplastic hazardous drugs sealed in a plastic bag shall be retained in this bag until delivery to storage area

4.3.6. Receiving personnel must don one pair of ASTM D6978 chemotherapy gloves and must have other PPE available in case of damaged items.

4.3.7. Unless a spill is encountered, only a single pair of "chemo" gloves need be worn by staff receiving and unpackaging HDs.

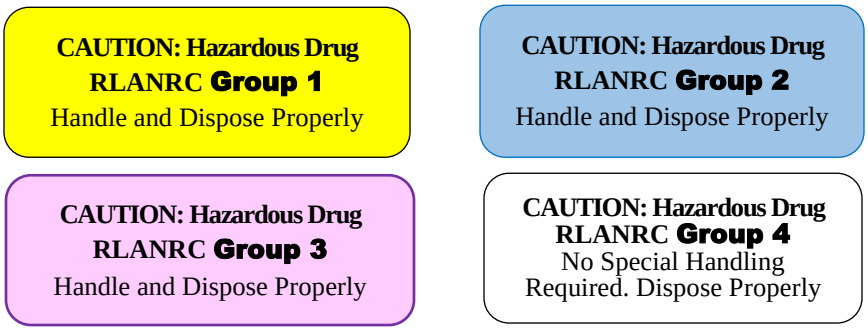
4.3.8. Gloves shall be changed after handling antineoplastic hazardous drugs

4.3.9. Any compromised container (broken vials or ampules) will be quarantined and handled as a spill.

4.4. Storage:

4.4.1. HDs are stored in a manner that prevents spillage or breakage if the container falls. HDs are not stored on the floor.

4.4.2. Non-antineoplastic hazardous medications and final dosage forms requiring no manipulation of antineoplastic hazardous medications may be stored with non-hazardous medication inventory in separate bins with appropriate HD warning labels:



4.4.3. HD medications that will be compounded in hazardous buffer room (“800”) must be stored in negative pressure HD storage room

4.4.4. Refer to appendix 8 for SOP of storing HD medications

4.4.5. Antineoplastic hazardous medications of RLANRC HD group 1 that require compounding prior to administration must be stored

a. Separately from non-hazardous medications.
b. In HD storage room (a negative pressure, externally vented room with at least 12 ACPH)

4.4.6. Patient’s own hazardous medication

a. To be used only if the medication is not immediately available from the pharmacy. Refer to Pharmacy P&P 3.15.0 Medications/Medication containers brought into the facility by patient.
b. Requires a provider’s order.
c. The medication will remain in the original container; it will not be prepacked by the pharmacy.

d. Pharmacy will inspect the medication and place in a plastic bag labeled with appropriate Hazardous Drug auxiliary labels. The medication will be stored in the patient's medication cassette.

4.5. Compounding:

4.5.1. Personnel who prepare unit-dose packages or the repackaging of tablets or capsules of HDs shall wear PPE according to PPE guideline of HD handling

4.5.2. Non-sterile compounding of oral solutions/suspension of HDs is not a permitted activity at Rancho.

4.5.3. NuAire BSC II type B is designated for sterile compounding of hazardous medications

4.5.4. All sterile compounding of hazardous medications must be performed in the BSC unless allowed in LAFW per AoR

4.5.5. A CSTD must be employed when such a device is available for the hazardous medication being compounded.

4.5.6. If non-hazardous medications are compounded in the same C-PEC as hazardous medications, they must be labeled as hazardous.

4.5.7. When compounding HD preparations, a plastic-backed preparation mat should be placed on the work surface of the BSC. The mat should be changed immediately if a spill occurs and regularly during use and should be discarded at the end of the daily compounding activity.

4.6. Dispensing:

4.6.1. **Dispensing Final Dosage Forms**: Hazardous medications must be dispensed as a final product that minimize or eliminates the requirement for further manipulation by nursing staff.

a. Crushing tablets or opening capsules of hazardous medications is not permitted in all pharmacy settings.

b. Preparing half-tablet unit doses by cutting scored tablets is permitted for Rancho HD groups 2, 3, and 4, but must happen in HD storage room with all required PPE and designated tools.

c. Cutting tablets of Rancho HD group 1 is not permitted in all pharmacy settings.

d. Equipment used to dispense (e.g., counting trays and spatula) should be dedicated for use with hazardous drugs in RLANRC HD groups 1, 2, and 3 to prevent cross contamination between groups. Hazardous drugs of RLANRC HD group 4 require no separate spatula.

e. Hazardous drugs of all RLANRC HD groups shall not be placed in repackaging machines.

4.6.2. Dispensing Methotrexate for subcutaneous injection:

a. Methotrexate injection shall be dispensed as prefilled syringes:

- The prefilled syringes of Methotrexate brought into facility by patient will be used first. The patient own methotrexate prefilled syringes must be checked by a physician or a pharmacist for authenticity. Refer to pharmacy policy 3.15.0 of Medications/medication container brought into facility by patient for further details.
- If the patient own medication of methotrexate prefilled syringes is no longer available, pharmacy will need to order it from Cardinal or appropriate vendors and dispense them as is (no manipulation of methotrexate injection is permitted) for administration while the patient is admitted in inpatient setting at Rancho.

b. RN staff will administer the ordered dose and discard the remaining waste appropriately per protocol

4.6.3. **Labeling:** All HD medications of groups 1, 2, and 3 will be placed in regular plastic bags with 2 auxiliary labels on the outside. Group 4 HD medications require 1 auxiliary label. See below for details.

a. **Group 1** – Yellow warning label with the words “CAUTION: Hazardous Drug. RLANRC Group 1. Handle and Dispose properly” ***and*** Red warning label with the words “HD – HAZARDOUS DRUG”

b. **Group 2** – Blue warning label with the words "CAUTION: Hazardous Drug. RLANRC Group 2. Handle and Dispose properly" ***and*** Yellow warning label with the words "HD – Caution: HAZARDOUS DRUG. Observe special handling, administration, and disposal requirement"

c. **Group 3** – Pink warning label with the words "CAUTION: Hazardous Drug. RLANRC Group 3. Handle and Dispose properly" ***and*** Yellow warning label with the words "HD – Caution: HAZARDOUS DRUG. Observe special handling, administration, and disposal requirement"

d. **Group 4** – White warning label with the words "CAUTION: Hazardous Drug. RLANRC Group 4. Handle and Dispose properly"

4.7. Delivery/Transport:

4.7.1. Hazardous medications must be transported in an external container such as a bin or bag indicated for hazardous drug delivery only. Pharmacy delivering staff must remove individual patient medication bags out of the delivery bags and discard the disposable delivery bags or bring back to pharmacy the recyclable delivery bags/bins.

4.7.2. Hazardous medications must be transported in a manner that minimizes potential for falls and spills.

4.7.3. Personnel must wear a single pair of chemotherapy gloves when placing hazardous medications into or removing hazardous medications from an external container for transport.

4.7.4. Chemotherapy spill kit must accompany hazardous medications in liquid dosage forms during transport.

4.8. Administration:

4.8.1. Needleless system must be used to reduce the risk of needle sticks. Antineoplastic hazardous drugs must be administered safely using protective medical devices and techniques when possible (e.g., needleless, and closed systems).

4.8.2. Splitting, crushing, and opening dosage forms of all Rancho HD group 2 & 3 medications must take place in a designated area with required one pair of ASTM 6978 gloves and a N95 respirator or surgical mask.

4.8.3. Splitting, crushing, and opening dosage forms of all Rancho HD group 1 medications is not permitted.

4.8.4. All personnel who administer hazardous drugs must follow all containment requirements outlined in the "PPE Guideline for Hazardous Drugs" chart.

4.8.5. When handling linens, the body wastes and fluids from patients receiving antineoplastic drugs, employees should wear two pairs of chemotherapy gloves and impermeable disposable gown for 48 hours after the drug was administered while caring for the patient.

4.8.6. Nursing staff will post a sign on the outside of the patients' rooms who are receiving chemotherapy to inform team of the necessary precautions. The signs and precautions will remain for 48 hours from the last chemotherapy dose.

4.9. A 4-Step Cleaning Process of HD - Deactivation, Decontamination, Cleaning, and Disinfecting:

4.9.1. All areas where HDs are handled and all reusable equipment and devices must be deactivated, decontaminated, and cleaned. Also, sterile compounding areas and devices must be subsequently disinfected.

4.9.2. Agents used for deactivation, decontamination, and cleaning should be applied through the use of wipes wetted with appropriate solution and NOT delivered by a spray bottle to avoid spreading HD residue

4.9.3. **Deactivation** – Deactivation renders a component inert or inactive (HD residue)

4.9.4. **Decontamination** – Decontamination occurs by inactivating, neutralizing or physically removing HD residue from non-disposable surfaces and transferring it to absorbent, disposable materials (e.g., wipes, pads, towels) appropriate to the area being cleaned.

a. C-PEC must be decontaminated at least daily, when used, any time a spill occurs, before and after certification, any time voluntary interruption occurs and if the ventilation tool is moved
b. Areas under the work tray of the C-PEC where contamination may build – these areas must be deactivated, decontaminated and cleaned at least monthly

4.9.5. **Cleaning** – Cleaning is the process that results in the removal of contaminates (e.g., soil, microbial contamination, HD residue) from objects and surfaces using water, detergent, surfactant, solvents and/or other chemicals.

4.9.6. **Disinfection** – Disinfection is a process of inhibiting or destroying microorganisms.
a. Before disinfection can be adequately performed surfaces must be cleaned
b. Disinfection must be done for areas intended to be sterile, including sterile compounding areas

4.9.7. **PeridoxRTU:**
a. PeridoxRTU is a broad spectrum EPA-Registered sporicide, bactericide, virucide, tuberculocide and fungicide disinfectant and hard surface cleaner with a 3-minute sporicide claim at 99.9999% efficacy.
b. PeridoxRTU is approved and designated for use as a one-step disinfectant and cleaner in Rancho hazardous buffer room and hazardous storage room.
c. PeridoxRTU® contains no alcohol or bleach, requires no rinsing and leaves minimal residue on surfaces.

4.10. Spill Management:

4.10.1. Personnel who clean spills of hazardous drugs must follow all containment requirements outlined in the “Alternative Containment Strategies for Handling Hazardous Drugs” chart (Appendix 6).

4.10.2. American Society of Hospital Pharmacist (ASHP) considers small spills to be less than 5mL (1tsp) or 5gms.

4.10.3. For spill less than 5ml, it is cleaned by the person who caused the spill

4.10.4. For spill larger than 5mL, code orange must be activated (refer to appendix 6)

4.11. Disposal/waste:

4.11.1. Refer to appendix 7 below and Pharmacy Policy and Procedure 7.17.0 [Medical Pharmaceutical/ Hazardous Waste Disposal] for details

4.11.2. In patients' room and/or medication room:

a. All contaminated linen with patient excreta shall be placed into the contaminated linen bag
b. Disposable items contaminated with patient excreta, such as PPE, diapers, or absorbent pads will be placed in the regular trash
c. Trace remainders of HD group 1 (syringes, gloves, and medication wrappers) shall be placed in yellow chemotherapy bins in medication rooms
d. Empty syringes, empty vials, and medication wastes of HD groups 2, 3, and 4 except for Coumadin, Tretinoin must be placed in blue pharmaceutical waste bins in medication room
e. Coumadin, Tretinoin wastes must be placed in black RCRA hazardous bins in medication rooms

4.11.3. Inside and outside of the pharmacy cleanroom (Refer to appendix 5b and appendix 7 for details)

a. **Large black RCRA hazardous bins**: bulk or waste of hazardous drugs such as IV bags, tubing, and visibly soiled PPE and wastes of Warfarin & Tretinoin.
b. **Blue pharmaceutical waste bins** (for compounding process in "797" buffer room): trace remainders of HDs such as empty IV bags, tubing, syringes
c. **Yellow chemotherapy bins for trace remainders of HDs** (for compounding process in "800" buffer room): Empty IV bags, tubing, syringes, and all used PPE unless soiled (significantly contaminated) then place in black bins
d. **Regular trash:** empty packaging and used PPE unless soiled (significantly contaminated) then place in black bins

4.12. Medical surveillance:

4.12.1. Medical surveillance is part of a comprehensive exposure control program complementing engineering controls, safe work processes, and use of PPE:

a. The general purpose of surveillance is to minimize adverse health effects in personnel potentially exposed to HDs. Medical surveillance programs involve assessment and documentation of symptom complaints, physical findings, and laboratory values (such as a blood count) to determine whether there is a deviation from the expected norms.

b. Healthcare workers who handle HDs as a regular part of their job assignment should be enrolled in a medical surveillance program.

c. All medical examinations and procedures are performed by a licensed independent practitioner and provided at a reasonable time and place without cost to the employees. The medical examinations are offered at pre-placement, annually, or more frequently when indicated following acute exposure and at transfer or termination of employment/assignment.

4.12.2. Refer to DHS Hazardous Drug Medical Surveillance Policy and Procedure 925.350

4.13. Training Personnel Handling Hazardous Medications:

4.13.1. **Pharmacy Staff**:

a. Pharmacy staff handling HD medications must be trained how to handle HD medications properly and successfully complete a written competency exam to ensure the effectiveness of training.

b. Personnel knowledge and ability must be re-assessed through written competency exam every 12 months and whenever a new or significantly changed equipment or procedure is implemented.

c. Training records must be maintained for at least 3 years.

d. Training for pharmacy staff who will handle hazardous medications in any capacity must include:

- Review of this Policy and Procedures as it relates to Hazardous Medications
- Proper use of PPEs, engineering controls, and other safety devices
- Spill Management
- Accidental exposure procedure
- Proper disposal of Hazardous medications

4.13.2. **Nursing Staff**:

a. Registered nurses and other ancillary staff who will handle hazardous medications, including all personnel authorized by RLANRC to transport or administer medications, must be fully trained by their respective departments in the handling of hazardous medications.

PROCEDURES

1. Hazardous Drug List:

1.1. Performing an AoR:

1.1.1. An assessment of risk must consider the type, dosage form, risk of exposure, packaging, manipulation, and other exceptional characteristics or likely situations of use.

1.1.2. NIOSH listed hazardous drugs that are exempt from an assessment of risk include active pharmaceutical ingredient (API) of hazardous drugs and any antineoplastic hazardous drug requiring manipulation. These drugs will be handled with full PPE requirement per USP chapter <800>.

1.1.3. The AoR of a new drug to be used at RLANRC shall happen as soon as the new drug is brought on board for use:

a. The initial AoR is performed by Rancho HD taskforce team (a joint team of pharmacy department and clinical professional development department). After the initial AoR of the new drug, a temporary RLANRC HD group number will be assigned.

b. The new temporary additions to the list shall be approved by Med Safety quarterly
c. Once approved by med safety, the new list will then be sent for posting

1.2. Establishing and Maintaining RLANRC HD list: The NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings is the main reference of RLANRC HD list.

1.2.1. All drugs handled at RLANRC found on the NIOSH list of hazardous drugs shall be included on the RLANRC HD list.

1.2.2. The medications on the RLANRC HD list are categorized in 4 different subgroups based on the AoR of their potential exposures and severity of harm, thus containment requirements for HD handlers to minimize the risks.

2. Exposure:

2.1. RLANRC maintains a file containing the SDS or MSDS for each hazardous medication in use. This file must be readily accessible to personnel during each work shift and at each work area.

2.2. Personnel who have contact with a hazardous substance should notify others in the vicinity of the exposure and proceed with decontamination.

2.3. All exposures shall be reported by the employee to their immediate supervisor. The employee and supervisor must complete the Industrial Accident (IA) form. The incident event must be entered into the Safety Intelligence system (SI)

2.4. Employee Health should be contacted for further evaluation during business hours. On weekends, holidays or between 4 pm – 7:30 am, house supervisor must be notified for further instructions.

2.5. Specific procedures of different exposures:

2.5.1. For skin exposure:

a. Remove any contaminated PPEs or clothing.
b. Immediately wash contaminated skin with soap and water.
c. Refer to the Safety Data Sheet (SDS) for agent specific interventions

2.5.2. For eye exposure:

a. Flush the affected eye immediately with saline solution or water for at least 15 minutes.
b. Use eyewash station if available.
c. Refer to the Safety Data Sheet (SDS) for agent specific interventions

2.5.3. For minor cuts: (caused by contaminated broken glass or other sharp objects)
a. The affected area should be immediately washed with soap and water for 15 minutes.
b. The employee should then proceed to the hospital's designated employee health service for further evaluation

2.5.4. For inadvertent injection: If the needle remaining in the injection site, the plunger should be withdrawn to remove as much of the drug as possible. Then needle stick procedure must be followed

2.5.5. For inhalation/Oral exposure: Employee must report to Employee Health

3. General PPE use:

3.1. Nurses to follow PPE guideline of handling HD for Nurses (Appendix 5a)**:**

3.2. Pharmacy to follow PPE guideline of handling HD for Pharmacy (Appendix 5b)

4. Exposure:

4.1. RLANRC maintains a file containing the SDS or MSDS for each hazardous medication in use. This file must be readily accessible to personnel during each work shift and at each work area.

4.2. Personnel who have contact with a hazardous substance should notify others in the vicinity of the exposure and proceed with decontamination.

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a. Remove any contaminated PPEs or clothing.
b. Immediately wash contaminated skin with soap and water.
c. Refer to the Safety Data Sheet (SDS) for agent specific interventions

4.5.2. For eye exposure:
a. Flush the affected eye immediately with saline solution or water for at least 15 minutes.
b. Use eyewash station if available.
c. Refer to the Safety Data Sheet (SDS) for agent specific interventions

4.5.3. For minor cuts: (caused by contaminated broken glass or other sharp objects)
a. The affected area should be immediately washed with soap and water for 15 minutes.
b. The employee should then proceed to the hospital's designated employee health service for further evaluation

4.5.4. For inadvertent injection: If the needle remaining in the injection site, the plunger should be withdrawn to remove as much of the drug as possible. Then needle stick procedure must be followed

4.5.5. For inhalation/Oral exposure: Employee must report to Employee Health

5. General PPE use:

5.1. Nurses to follow PPE guideline of handling HD for Nurses (Appendix 5)**:**

5.2. Pharmacy to follow PPE guideline of handling HD for Pharmacy (Appendix 5)

5.3. Sterile Gloves**:**

5.3.1. Gloves must be powder-free.

5.3.2. Sterile gloves must meet ASTM D-6978 must be worn when compounding.

5.3.3. Double gloves must be donned unless AoR of the HD specified differently

5.3.4. The outer, sterile chemotherapy gloves must be changed every 30 minutes during continuous compounding and immediately if defect, puncture or tear is suspected

5.3.5. When removing/changing the contaminated outer gloves, they are to be placed in the black RCRA bin inside the BSC or a sealable plastic bag before removal from the BSC and disposed of as hazardous waste

6. Receiving:

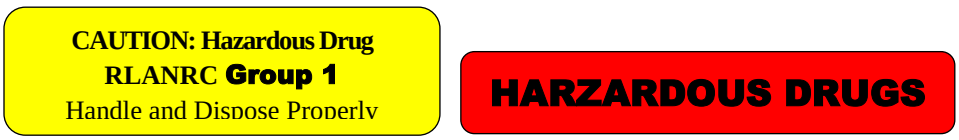
6.1. Handling damaged HD shipping container

If the shipping container appears damaged	1. Seal container without opening and contact the supplier 2. If the unopened package is to be returned to the supplier, enclose the package in an impervious container and label the outer container "Hazardous" 3. If the supplier declines return, dispose of as hazardous waste
If a damaged shipping container must be opened	1. Seal the container in plastic or an impervious container 2. Transport it to a C-PEC and place on a plastic-backed preparation mat 3. Open the package and remove undamaged items 4. Wipe the outside of the undamaged items with a disposable wipe 5. Enclose the damaged item(s) in an impervious container and label the outer container "Hazardous" 6. If the supplier declines return, dispose of as hazardous waste 7. Deactivate, decontaminate, and clean the C-PEC (see Deactivating, Decontaminating, Cleaning, and Disinfecting procedure) and discard the mat and cleaning disposables as hazardous waste

7. Dispensing:

7.1. Dispensing with hazardous warning auxiliary stickers: HD medications must be dispensed with appropriate auxiliary stickers

7.1.1. **RLANRC HD Group 1**:



7.1.2. **RLANRC HD Group 2**:

CAUTION: Hazardous Drug
RLANRC Group 2
Handle and Dispose Properly

Caution: Hazardous Drug
Observe special Handling, Administration, and Disposal Requirements

7.1.3. **RLANRC HD Group 3**:

CAUTION: Hazardous Drug
RLANRC Group 3
Handle and Dispose Properly

Caution: Hazardous Drug
Observe special Handling, Administration, and Disposal Requirements

7.1.4. **RLANRC HD Group 4**:

CAUTION: Hazardous Drug
RLANRC Group 4
No Special Handling Required.
Dispose Properly

7.2. Workflow of obtaining chemotherapy consent:

7.2.1. Hazardous drugs listed on RLANRC Group 1 that are used for non-cancer treatment will not need the consent form

7.2.2. Chemotherapy consent will be obtained by the provider prior to initiating oral chemotherapy treatment. If the treatment is continuing therapy from a DHS facility, the provider will verify that consent is in the medical record. If unable to verify, or if admitted from a Non-DHS facility, a new consent will be obtained. Workflow delineation of chemotherapy consent is listed as below

a. **Physician**:

- ✓ Obtain informed consent (if used to treat Cancer)
- ✓ Input medication order in Orchid

b. **Pharmacy**:

- ✓ Verify with nurse that informed consent has been completed (Do not delay treatment while waiting for consent)
- ✓ Deliver medication appropriately labeled
- ✓ Provide Spill Kit if needed

c. **Nurses**:

- ✓ Verify that informed consent has been completed when it is for the treatment of Cancer
- ✓ Administer the medication following appropriate precautions

7.3. Delivery/Transport:

7.3.1. Hazardous medications must be transported in an external impervious plastic bag to prevent contamination in the event of leakage. And the external bag must bear the indication warning on the outside “For Hazardous Drug Delivery Only”.

7.3.2. Personnel must wear a single pair of chemotherapy gloves when placing hazardous medications into or removing hazardous medications from the external bag or container for delivery.

7.3.3. The external plastic bag for delivery must be completely sealed transported in a manner that minimizes potential for falls and spills.

7.3.4. The pharmacy technician shall carry a Chemotherapy Spill kit when delivering oral hazardous drugs of liquid formulation.

7.4. Spill Management:

7.4.1. Refer to appendix 6 for the procedure to handle hazardous spill.

7.5. **Procedure of HD Cleaning Process**:

7.5.1. **Hazardous buffer room and Hazardous storage room**:

a. All areas of the rooms must be cleaned using PeridoxRTU

b. Refer to appendix 4 of the policy of “Cleaning and Disinfecting of cleanroom suite - 5.03.9N” for specific areas to be cleaned daily, weekly, and monthly

7.5.2. **Biological Safety Cabinet**:

a. Must be decontaminated at least daily, any time a spill occurs, before and after certification, any time voluntary interruption occurs, and if the ventilation tool is moved.
b. The work surface of the BSC must be decontaminated between compounding of different hazardous drugs.
c. Area under the work tray must be deactivated, decontaminated, and cleaned at least monthly.
d. Refer to appendix 4 of the policy of “Cleaning and Disinfecting of cleanroom suite - 5.03.9N” for order of cleaning inside BSC

REFERENCES

1. Board of Pharmacy - Section 1735, Article 4.5 of Division 17 of Title 16 of the' California Code of Regulations
2. Board of Pharmacy - Section 1751, Article 7 of Division 17 of Title 16 of the California Code of Regulations
3. American Society of Health-System Pharmacists. ASHP Guidelines on Compounding Sterile Preparations. Am J Health-Syst Pharm. 2014; 71:145–66.
4. USP General Chapter <800> June 2019 Revision.
5. CSHP compounding grids, 2016

ATTACHMENTS / APPENDICES

1. **Appendix 1** - Definitions
2. **Appendix 2** - Abbreviations Used in Policy
3. **Appendix 3** - RLANRC List of hazardous drugs (by HD groups and by generic names)
4. **Appendix 4** – Potential Routes of Exposure Based on Activity
5. **Appendix 5** - Alternative Containment Strategies for Handling Hazardous Drugs (PPE Guideline When Handling HD drugs for nurses and pharmacy staff)
6. **Appendix 6** - Hazardous Spill Management
7. **Appendix 7** - Disposal/Waste of HD medications
8. **Appendix 8 –** SOP of storing HDs

APPENDIX 1: Definitions

1. **Anteroom**: An ISO Class 8 or cleaner room with fixed walls and doors where personnel hand hygiene, garbing procedures, and other activities that generate high particulate levels may be performed. The anteroom is the transition room between the unclassified area of the facility and the buffer room.
2. **Biological safety cabinet (BSC), Class II**: A ventilated cabinet with an open front and inward and downward unidirectional HEPA-filtered airflow and HEPA-filtered exhaust. A BSC used to prepare a CSP must be capable of providing an ISO Class 5 or better environment for preparation of the CSPs.
3. **Biosafety cabinet (BSC):** A ventilated cabinet used for the preparation of hazardous drugs, having an open front with inward airflow for personnel protection, downward HEPA-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection.
4. **BUD** (Beyond Use-Date): Either the date, or hour and date, after which a CSP must not be used. The BUD is determined from the date/time that preparation of the CSP is initiated.
5. **Buffer room**: An ISO Class 7 or cleaner room with fixed walls and doors where PEC(s) that generate and maintain an ISO Class 5 environment are physically located. The buffer room may only be accessed through the ante-room.
6. **Chemotherapy Gloves:** Tested for used with Chemotherapy Drugs per ASTM D6978. Note: all references to gloves in this policy will be referring to ASTM approved.
7. **Cleaning agent:** An agent for the removal of residues (e.g., dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
8. **CSTD**: Closed-system transfer device
9. **Deactivation:** Rendering a compound inert or inactive
10. **Decontaminate:** Decontamination occurs by inactivating, neutralizing, or physically removing hazardous drug residue from non-disposable surfaces and transferring it to absorbent, disposable materials
11. **First air:** The air exiting the HEPA filter in a unidirectional air stream.
12. **Formulation:** The specific qualitative and quantitative composition of the final CSP.

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13. **Garb:** Items such as gloves, garments (e.g., gowns, coveralls), shoe covers, head and facial hair covers, masks, and other items designed to reduce particle-shedding from personnel and minimize the risk of contamination of CSP(s).
14. **Hazardous drug (HD)** (include those used for cancer chemotherapy, antiviral drugs, hormones, some bio- engineered drugs, and other miscellaneous drugs): Any drug identified by at least one of the following six criteria, as defined by National Institute of Occupational Safety and Health (NIOSH): Carcinogenicity, Teratogenicity or other developmental toxicity, Reproductive toxicity, Organ toxicity at low doses, Genotoxicity, Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria.
15. **High-efficiency particulate air (HEPA) filtration**: Being, using, or containing a filter designed to remove 99.97% of airborne particles measuring 0.3-micron or greater in diameter passing through it.
16. **ISO Class 5:** An atmospheric environment that contains not more than 3520 particles 0.5 mm and larger size per cubic meter of air for any LAFW, BSC, CAI, and CACI
17. **ISO Class 7:** An atmospheric environment that contains not more than 352,000 particles of 0.5 mm size and larger per cubic meter of air for any buffer area
18. **Line of demarcation**: A visible line on the floor that separates the clean and dirty sides of the ante-room.
19. **N-95 respirator:** A respiratory protective device designed to achieve a very close facial fit and very efficient filtration of airborne particles
20. New drugs may be defined as hazardous if they have structural similarities to drugs that are already designated as hazardous.
21. **NIOSH** lists hazardous medications in 3 different groups:
    - **NIOSH Group 1:** Cytotoxic drugs that exhibit one or more of the six characteristics of hazardous drugs. Many of these drugs may pose an occupational hazard to males or females who are actively trying to conceive, women who are pregnant, may become pregnant or breast feeding.
    - **NIOSH Group 2:** Drugs that exhibit one or more of the six characteristics of hazardous drugs but not by a cytotoxic mechanism. Some of these drugs may represent an occupational hazard to males and females who are actively trying to conceive, women who are pregnant or breastfeeding because they may be present in the breast milk
    - **NIOSH Group 3:** Drugs that primarily pose a reproductive risk to males and females who are actively trying to conceive, women who are pregnant or breastfeeding because they may be present in the breast milk.
22. **One-step disinfectant cleaner:** A product with an EPA-registered (or equivalent) claim that it can clean and disinfect a non-porous surface in the presence of light to moderate organic soiling without a separate cleaning step.

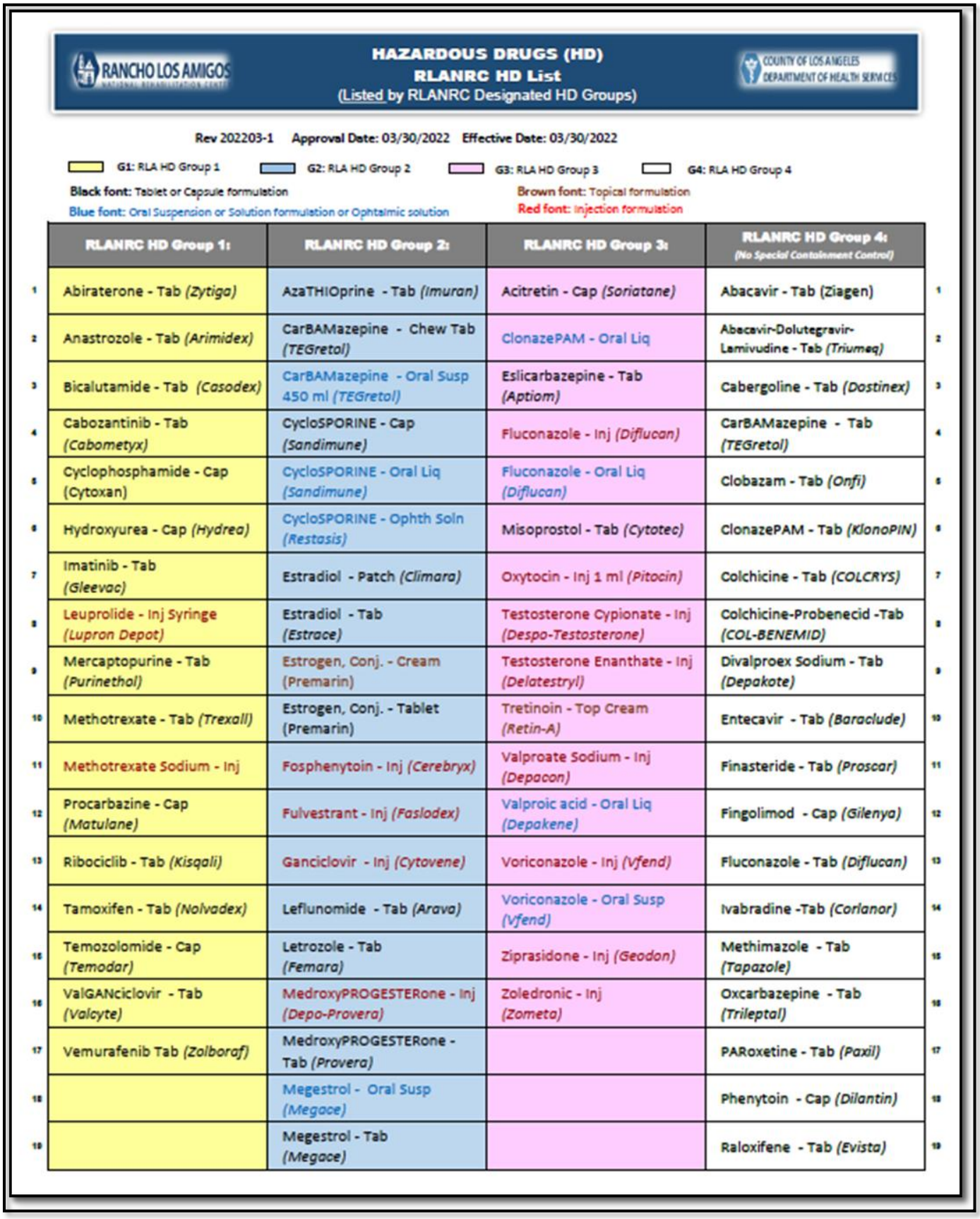
23. **Pass-through chamber:** An enclosure with sealed doors on both sides that should be interlocked. The pass-through is positioned between two spaces for the purpose of minimizing particulate transfer while moving materials from one space to another.
24. **Personal protective equipment (PPE):** Items such as gloves, gowns, respirators, goggles, face shields, and others that protect individual workers from hazardous physical or chemical exposures.
25. **Positive-pressure room**: A room that is maintained at higher pressure than the adjacent spaces, and therefore the net airflow is out of the room.
26. **Primary Engineering Control (PEC):** PEC is a device that provides an ISO Class 5 environment for the exposure of critical sites when compounding hazardous and non-hazardous CSPs. Such devices include PECs (Class II BSCs and CACIs) for hazardous CSPs and PECs (LAFWs and CAIs) for non-hazardous CSPs.
27. **RLANRC HD list:** List of hazardous medications used at Rancho Los Amigos National Rehabilitation Center. The medications on the RLANRC HD list are categorized in 4 different sub-lists (groups) based on their containment requirement for HD handlers to minimize risks of potential exposures.
28. **Safety Data Sheets (SDS):** An informational document (previously known as a Material Safety Data Sheet (MSDS) that provides written or printed material concerning a hazardous chemical that is prepared in accordance with the HCS).
29. **Secondary engineering control (SEC):** The area where the PEC is placed (e.g., a cleanroom suite or an SCA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area.
30. **Sporicidal agent:** A chemical or physical agent that destroys bacterial and fungal spores when used in sufficient concentration for a specified contact time. It is expected to kill all vegetative microorganisms.
31. **Stability:** The extent to which a product or preparation retains physical and chemical properties and characteristics within specified limits throughout its expiration or BUD.
32. **The National Institute for Occupational Safety and Health (NIOSH):** The United States federal agency responsible for conducting research and making recommendations for the prevention of work-related injury and illness.
33. **USP <800>** "Hazardous Drugs – Handling in Healthcare Settings" by United States Pharmacopeia: Standards for cleanroom design, environmental monitoring, cleaning of primary and secondary engineering controls, and the core competencies for personnel involved in the processes of compounding sterile preparations.

APPENDIX 2 – Abbreviations Used in Policy

ACPH	Air changes per hour

BLA	Biological License Application
BSC(s)	Biological safety cabinet(s)
BUD(s)	Beyond-use date(s)
CETA	Controlled Environment Testing Association
cfu	Colony-forming units
COA(s)	Certificate(s) of analysis
CSP(s)	Compounded sterile preparation(s)
DCA(s)	Direct compounding area(s)
ECV(s)	Endotoxin challenge vial(s)
HD(s)	Hazardous drug(s)
HEPA	High-efficiency particulate air
HVAC	Heating, ventilation, and air conditioning
IPA	Isopropyl alcohol
ISO	International Organization for Standardization
LAFS	Laminar airflow system
LAFW(s)	Laminar airflow workbench(es)
PEC(s)	Primary engineering control(s)
PPE	Personal protective equipment
QA	Quality assurance
QC	Quality control
SAL	Sterility assurance level
SCA	Segregated compounding area
SEC(s)	Secondary engineering control(s)
SOP(s)	Standard operating procedure(s)
TSA	Trypticase soy agar
“ wc	Inch of water column (unit used to measure differential pressure)

APPENDIX 3a – RLANRC List of hazardous drugs – by Groups



HAZARDOUS DRUGS (HD)
RLANRC HD List
(Listed by RLANRC Designated HD Groups)

RANCHO LOS AMIGOS

COUNTY OF LOS ANGELES DEPARTMENT OF HEALTH SERVICES

Rev 202203-1 Approval Date: 03/30/2022 Effective Date: 03/30/2022

G1: RLA HD Group 1 G2: RLA HD Group 2 G3: RLA HD Group 3 G4: RLA HD Group 4

Black font: Tablet or Capsule formulation
Blue font: Oral Suspension or Solution formulation or Ophtalmic solution
Brown font: Topical formulation
Red font: Injection formulation

	RLANRC HD Group 1:	RLANRC HD Group 2:	RLANRC HD Group 3:	RLANRC HD Group 4: (No Special Containment Control)	
1	Abiraterone - Tab *(Zytiga)*	AzaTHIOprine - Tab *(Imuran)*	Acitretin - Cap *(Soriatane)*	Abacavir - Tab (Ziagen)	1
2	Anastrozole - Tab *(Arimidex)*	CarBAMazepine - Chew Tab *(TEGretol)*	ClonazePAM - Oral Liq	Abacavir-Dolutegravir-Lamivudine - Tab *(Triumeq)*	2
3	Bicalutamide - Tab *(Casodex)*	CarBAMazepine - Oral Susp 450 ml *(TEGretol)*	Eslicarbazepine - Tab *(Aptiom)*	Cabergoline - Tab *(Dostinex)*	3
4	Cabozantinib - Tab *(Cabometyx)*	CycloSPORINE - Cap *(Sandimune)*	Fluconazole - Inj *(Diflucan)*	CarBAMazepine - Tab *(TEGretol)*	4
5	Cyclophosphamide - Cap (Cytoxan)	CycloSPORINE - Oral Liq *(Sandimune)*	Fluconazole - Oral Liq *(Diflucan)*	Clobazam - Tab *(Onfi)*	5
6	Hydroxyurea - Cap *(Hydrea)*	CycloSPORINE - Ophth Soln *(Restasis)*	Misoprostol - Tab *(Cytotec)*	ClonazePAM - Tab *(KlonoPIN)*	6
7	Imatinib - Tab *(Gleevac)*	Estradiol - Patch *(Climara)*	Oxytocin - Inj 1 ml *(Pitocin)*	Colchicine - Tab *(COLCRYS)*	7
8	Leuprolide - Inj Syringe *(Lupron Depot)*	Estradiol - Tab *(Estrace)*	Testosterone Cypionate - Inj *(Despo-Testosterone)*	Colchicine-Probenecid -Tab *(COL-BENEMID)*	8
9	Mercaptopurine - Tab *(Purinethol)*	Estrogen, Conj. - Cream (Premarin)	Testosterone Enanthate - Inj *(Delatestryl)*	Divalproex Sodium - Tab *(Depakote)*	9
10	Methotrexate - Tab *(Trexall)*	Estrogen, Conj. - Tablet (Premarin)	Tretinoin - Top Cream *(Retin-A)*	Entecavir - Tab *(Baraclude)*	10
11	Methotrexate Sodium - Inj	Fosphenytoin - Inj *(Cerebryx)*	Valproate Sodium - Inj *(Depacon)*	Finasteride - Tab *(Proscar)*	11
12	Procarbazine - Cap *(Matulane)*	Fulvestrant - Inj *(Faslodex)*	Valproic acid - Oral Liq *(Depakene)*	Fingolimod - Cap *(Gilenya)*	12
13	Ribociclib - Tab *(Kisqali)*	Ganciclovir - Inj *(Cytovene)*	Voriconazole - Inj *(Vfend)*	Fluconazole - Tab *(Diflucan)*	13
14	Tamoxifen - Tab *(Nolvadex)*	Leflunomide - Tab *(Arava)*	Voriconazole - Oral Susp *(Vfend)*	Ivabradine -Tab *(Corlanor)*	14
15	Temozolomide - Cap *(Temodar)*	Letrozole - Tab *(Femara)*	Ziprasidone - Inj *(Geodon)*	Methimazole - Tab *(Tapazole)*	15
16	ValGANciclovir - Tab *(Valcyte)*	MedroxyPROGESTERone - Inj *(Depo-Provera)*	Zoledronic - Inj *(Zometa)*	Oxcarbazepine - Tab *(Trileptal)*	16
17	Vemurafenib Tab *(Zolboraf)*	MedroxyPROGESTERone - Tab *(Provera)*		PARoxetine - Tab *(Paxil)*	17
18		Megestrol - Oral Susp *(Megace)*		Phenytoin - Cap *(Dilantin)*	18
19		Megestrol - Tab *(Megace)*		Raloxifene - Tab *(Evista)*	19

APPENDIX 3a – RLANRC List of hazardous drugs – by Groups (cont.)

Reviewed: 4/19/22 TT

RANCHO LOS AMIGOS NATIONAL REHABILITATION CENTER

HAZARDOUS DRUGS (HD)
RLANRC HD List
(Listed by RLANRC Designated HD Groups)

COUNTY OF LOS ANGELES DEPARTMENT OF HEALTH SERVICES

Rev 202203-1 **Approval Date: 03/30/2022** **Effective Date: 03/30/2022**

G1: RLA HD Group 1 G2: RLA HD Group 2 G3: RLA HD Group 3 G4: RLA HD Group 4

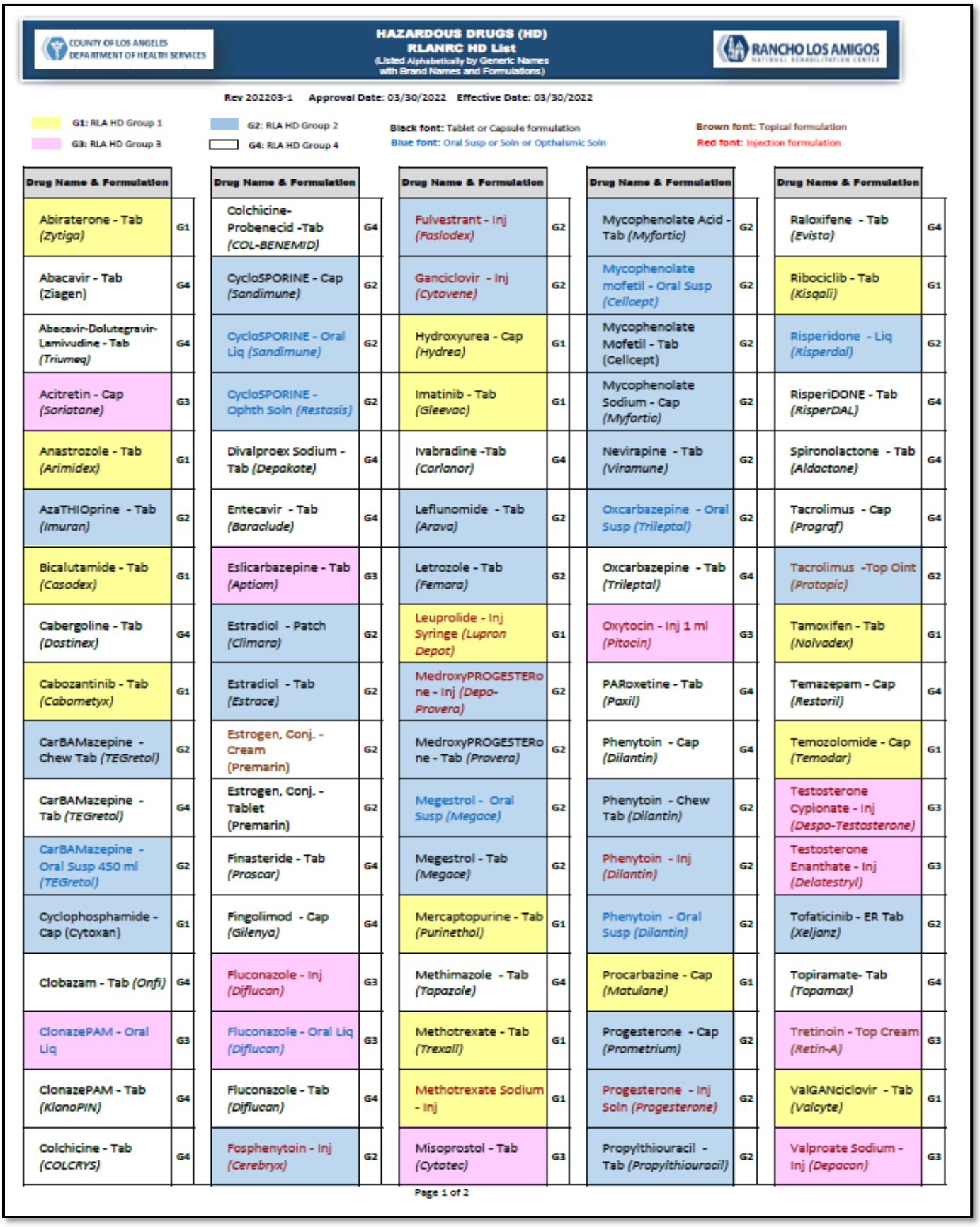
Black font: Tablet or Capsule formulation
Brown font: Topical formulation
Blue font: Oral Suspension or Solution formulation or Ophtalmic solution
Red font: Injection formulation

	RLANRC HD Group 1:	RLANRC HD Group 2:	RLANRC HD Group 3:	RLANRC HD Group 4: (No Special Containment Control)	
20		Mycophenolate mofetil - Oral Susp *(Cellcept)*		RisperiDONE - Tab *(RisperDAL)*	20
21		Mycophenolate Mofetil - Tab *(Cellcept)*		Spironolactone - Tab *(Aldactone)*	21
22		Mycophenolate Sodium - Cap *(Myfortic)*		Tacrolimus - Cap *(Prograf)*	22
23		Mycophenolate Acid - Tab *(Myfortic)*		Temazepam - Cap *(Restoril)*	23
24		Nevirapine - Tab *(Viramune)*		Topiramate- Tab *(Topamax)*	24
25		Oxcarbazepine - Oral Susp *(Trileptal)*		Valproic acid - Cap *(Depakene)*	25
26		Phenytoin - Chew Tab *(Dilantin)*		Voriconazole - Tab *(Vfend)*	26
27		Phenytoin - Inj *(Dilantin)*		Warfarin - Tab *(Coumadin)*	27
28		Phenytoin - Oral Susp *(Dilantin)*		Zidovudine - Cap *(Retrovir)*	28
29		Progesterone - Cap *(Prometrium)*		Ziprasidone - Cap *(Geodon)*	29
30		Progesterone - Inj Soln *(Progesterone)*		Zonisamide - Cap *(Zonegran)*	30
31		Propylthiouracil - Tab *(Propylthiouracil)*			31
32		Risperidone - Liq *(Risperdal)*			32
33		Tacrolimus -Top Oint *(Protopic)*			33
34		Tofaticinib - ER Tab *(Xeljanz)*			34
35		Zidovudine - Oral Liq *(Retrovir)*			35
36		Zidovudine_Lamivudine Tab *(Combivir)*			36
37		Zidovudine_Abacavir_Lamivudine -Tab (Trizivir)			37

Revision date: 06262020 jpp, 09162020 jpp, 09232020 jpp, 09302020 jpp, 10072020 jpp,10282020 jpp, 12092020 jpp, 03302022 jpp, 04252022 jpp, 05092022 jpp

Reviewed: 4/19/22 TT

APPENDIX 3b – RLANRC List of hazardous drugs – by Generic N



COUNTY OF LOS ANGELES DEPARTMENT OF HEALTH SERVICES

HAZARDOUS DRUGS (HD)
RLANRC HD List
(Listed Alphabetically by Generic Names with Brand Names and Formulations)

RANCHO LOS AMIGOS NATIONAL REHABILITATION CENTER

Rev 202203-1 **Approval Date:** 03/30/2022 **Effective Date:** 03/30/2022

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Black font: Tablet or Capsule formulation
Blue font: Oral Susp or Soln or Opthalmic Soln
Brown font: Topical formulation
Red font: Injection formulation

Drug Name & Formulation		Drug Name & Formulation		Drug Name & Formulation		Drug Name & Formulation		Drug Name & Formulation	
Abiraterone - Tab *(Zytiga)*	G1	Colchicine-Probenecid -Tab *(COL-BENEMID)*	G4	Fulvestrant - Inj *(Faslodex)*	G2	Mycophenolate Acid - Tab *(Myfortic)*	G2	Raloxifene - Tab *(Evista)*	G4
Abacavir - Tab (Ziagen)	G4	CycloSPORINE - Cap *(Sandimune)*	G2	Ganciclovir - Inj *(Cytovene)*	G2	Mycophenolate mofetil - Oral Susp *(Cellcept)*	G2	Ribociclib - Tab *(Kisqali)*	G1
Abacavir-Dolutegravir-Lamivudine - Tab *(Triumeq)*	G4	CycloSPORINE - Oral Liq *(Sandimune)*	G2	Hydroxyurea - Cap *(Hydrea)*	G1	Mycophenolate Mofetil - Tab (Cellcept)	G2	Risperidone - Liq *(Risperdal)*	G2
Acitretin - Cap *(Soriatane)*	G3	CycloSPORINE - Ophth Soln *(Restasis)*	G2	Imatinib - Tab *(Gleevac)*	G1	Mycophenolate Sodium - Cap *(Myfortic)*	G2	RisperiDONE - Tab *(RisperDAL)*	G4
Anastrozole - Tab *(Arimidex)*	G1	Divalproex Sodium - Tab *(Depakote)*	G4	Ivabradine -Tab *(Corlanor)*	G4	Nevirapine - Tab *(Viramune)*	G2	Spironolactone - Tab *(Aldactone)*	G4
AzaTHIOprine - Tab *(Imuran)*	G2	Entecavir - Tab *(Baraclude)*	G4	Leflunomide - Tab *(Arava)*	G2	Oxcarbazepine - Oral Susp *(Trileptal)*	G2	Tacrolimus - Cap *(Prograf)*	G4
Bicalutamide - Tab *(Casodex)*	G1	Eslicarbazepine - Tab *(Aptiom)*	G3	Letrozole - Tab *(Femara)*	G2	Oxcarbazepine - Tab *(Trileptal)*	G4	Tacrolimus -Top Oint *(Protopic)*	G2
Cabergoline - Tab *(Dostinex)*	G4	Estradiol - Patch *(Climara)*	G2	Leuprolide - Inj Syringe *(Lupron Depot)*	G1	Oxytocin - Inj 1 ml *(Pitocin)*	G3	Tamoxifen - Tab *(Nolvadex)*	G1
Cabozantinib - Tab *(Cabometyx)*	G1	Estradiol - Tab *(Estrace)*	G2	MedroxyPROGESTERone - Inj *(Depo-Provera)*	G2	PARoxetine - Tab *(Paxil)*	G4	Temazepam - Cap *(Restoril)*	G4
CarBAMazepine - Chew Tab *(TEGretol)*	G2	Estrogen, Conj. - Cream (Premarin)	G2	MedroxyPROGESTERone - Tab *(Provera)*	G2	Phenytoin - Cap *(Dilantin)*	G4	Temozolomide - Cap *(Temodar)*	G1
CarBAMazepine - Tab *(TEGretol)*	G4	Estrogen, Conj. - Tablet (Premarin)	G2	Megestrol - Oral Susp *(Megace)*	G2	Phenytoin - Chew Tab *(Dilantin)*	G2	Testosterone Cypionate - Inj *(Despo-Testosterone)*	G3
CarBAMazepine - Oral Susp 450 ml *(TEGretol)*	G2	Finasteride - Tab *(Proscar)*	G4	Megestrol - Tab *(Megace)*	G2	Phenytoin - Inj *(Dilantin)*	G2	Testosterone Enanthate - Inj *(Delatestryl)*	G3
Cyclophosphamide - Cap (Cytoxan)	G1	Fingolimod - Cap *(Gilenya)*	G4	Mercaptopurine - Tab *(Purinethol)*	G1	Phenytoin - Oral Susp *(Dilantin)*	G2	Tofaticinib - ER Tab *(Xeljanz)*	G2
Clobazam - Tab *(Onfi)*	G4	Fluconazole - Inj *(Diflucan)*	G3	Methimazole - Tab *(Tapazole)*	G4	Procarbazine - Cap *(Matulane)*	G1	Topiramate- Tab *(Topamax)*	G4
ClonazePAM - Oral Liq	G3	Fluconazole - Oral Liq *(Diflucan)*	G3	Methotrexate - Tab *(Trexall)*	G1	Progesterone - Cap *(Prometrium)*	G2	Tretinoin - Top Cream *(Retin-A)*	G3
ClonazePAM - Tab *(KlonoPIN)*	G4	Fluconazole - Tab *(Diflucan)*	G4	Methotrexate Sodium - Inj	G1	Progesterone - Inj Soln *(Progesterone)*	G2	ValGANciclovir - Tab *(Valcyte)*	G1
Colchicine - Tab *(COLCRYS)*	G4	Fosphenytoin - Inj *(Cerebryx)*	G2	Misoprostol - Tab *(Cytotec)*	G3	Propylthiouracil - Tab *(Propylthiouracil)*	G2	Valproate Sodium - Inj *(Depacon)*	G3

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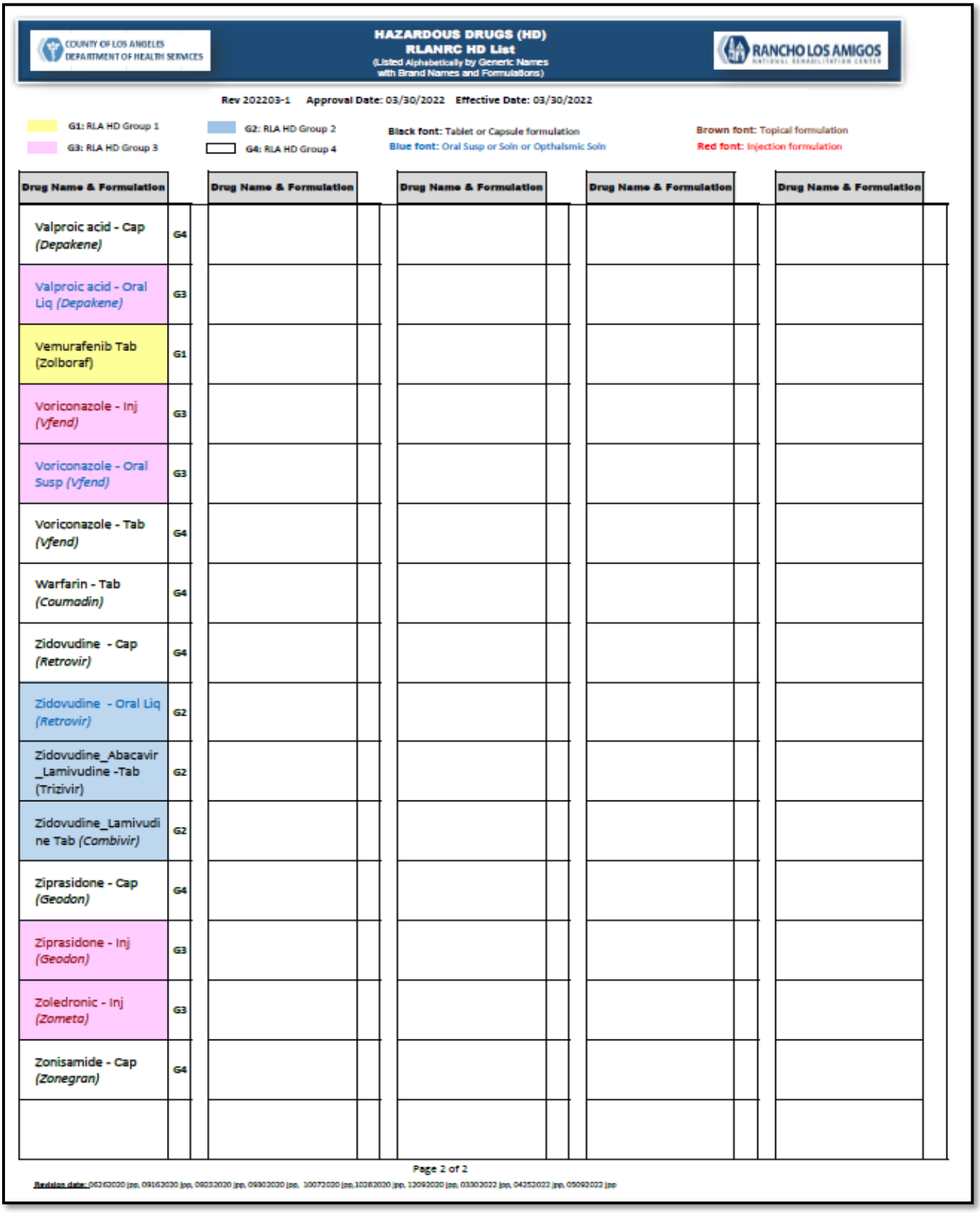
Reviewed: 4/19/22 TT

APPENDIX 3b – RLANRC List of hazardous drugs – by Generic Names (cont.)



COUNTY OF LOS ANGELES DEPARTMENT OF HEALTH SERVICES

HAZARDOUS DRUGS (HD)
RLANRC HD List
(Listed Alphabetically by Generic Names with Brand Names and Formulations)

RANCHO LOS AMIGOS NATIONAL REHABILITATION CENTER

Rev 202203-1 **Approval Date:** 03/30/2022 **Effective Date:** 03/30/2022

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Black font: Tablet or Capsule formulation
Blue font: Oral Susp or Soln or Opthalmic Soln
Brown font: Topical formulation
Red font: Injection formulation

Drug Name & Formulation		Drug Name & Formulation		Drug Name & Formulation		Drug Name & Formulation		Drug Name & Formulation	
Valproic acid - Cap *(Depakene)*	G4								
Valproic acid - Oral Liq *(Depakene)*	G3								
Vemurafenib Tab (Zolboraf)	G1								
Voriconazole - Inj *(Vfend)*	G3								
Voriconazole - Oral Susp *(Vfend)*	G3								
Voriconazole - Tab *(Vfend)*	G4								
Warfarin - Tab *(Coumadin)*	G4								
Zidovudine - Cap *(Retrovir)*	G4								
Zidovudine - Oral Liq *(Retrovir)*	G2								
Zidovudine_Abacavir _Lamivudine -Tab (Trizivir)	G2								
Zidovudine_Lamivudine Tab *(Combivir)*	G2								
Ziprasidone - Cap *(Geodon)*	G4								
Ziprasidone - Inj *(Geodon)*	G3								
Zoledronic - Inj *(Zometa)*	G3								
Zonisamide - Cap *(Zonegran)*	G4								

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Revision date: 06262020 jpp, 09162020 jpp, 09232020 jpp, 09302020 jpp, 10072020 jpp,10282020 jpp, 12092020 jpp, 03302022 jpp, 04252022 jpp, 05092022 jpp

Reviewed: 4/19/22 TT

APPENDIX 4 – Potential Routes of Exposure Based on Activity

Activity	Potential Route of Exposure
Dispensing	• Counting tablets and capsules from bulk containers • Contacting with HD residues present on drug container, individual dosage units, and outer containers
Compounding	• Pouring oral or topical liquids from one container to another • Constituting or reconstituting powdered or lyophilized HDs • Withdrawing or diluting injectable HDs from parenteral containers • Expelling air or HDs from syringes • Contacting with HD residue present on PPE or other garments • Deactivating, decontaminating, cleaning, and disinfecting areas contaminated with or suspected to be contaminated with HDs • Maintenance activities for potentially contaminated equipment and devices
Administration	• Generating aerosols during administration of HDs by various routes (e.g. injection, irrigation, oral, inhalation, or topical application) • Performing certain specialized procedures (e.g., intraoperative intraperitoneal injection or bladder instillation) • Priming an IV administration set
Patient-care activities	Handling body fluids (e.g., urine, feces, sweat, or vomit) or body-fluid-contaminated clothing, dressings, linens, and other materials
Spills	Spill generation, management, and disposal
Receipt	Contacting with HD residues present on drug container, individual dosage units, outer containers, work surfaces, or floors
Transport	Moving HDs within a healthcare setting

APPENDIX 5a – Alternative Containment Strategies for Handling Hazardous Drugs (PPE Guideline When Handling HD drugs) - **For NURSES**

Activities \ PPE	Gloves	Gown	Respiratory Protection	Eye/Face Protection	Hair cover
RLANRC HD GROUPS 1, 2, and 3					
1. Administration * if there is a chance of spills or splashing					
Capsules/Tablets	2 Pairs	No	No	No	No
Liquid (Injection/Suspension) and topical formulation	2 Pairs	Yes*	Yes*	Yes*	No
2. Spill Management					
• Staff will isolate the contaminated area. • Spill Kit: obtain from Pharmacy • Small Spills (< 5mL or 1 tsp): Cleaned by the person who caused the spill (Follow spill kit instruction) • Large Spills (> 5mL or 1 tsp): See instructions from code orange. Operator will contact ANS/ House Supervisor					
3. Handling of Waste of RLA Hazardous Drug Groups					
HD Group 1					
In patients' room and/or medication room	2 Pairs of Gloves	• **Yellow chemotherapy bins** for trace remainders of HDs: for example, syringes or gloves, medication wrappers			
HD Group 2 and Group 3					
In patients' room and/or medication room	2 Pairs of Gloves	• **Black RCRA hazardous bins** Coumadin, Tretinoin • **Blue pharmaceutical waste bins**: empty syringes, empty vials, and medication wastes except for Coumadin, Tretinoin • **Regular trash**: empty packaging and used PPE			
RLANRC HD GROUP 4					
Under the current workflow of hazardous drugs at Rancho, all medication formulations of group 4 are exempt from all special handling precautions					

Reviewed: 4/19/22 TT

APPENDIX 5b – Alternative Containment Strategies for Handling Hazardous Drugs (PPE Guideline When Handling HD drugs) - **For PHARMACY**

Activities \ PPE vs. HD Group	RLANRC HD Groups	ASTM 6978 Gloves	Chemo Gown	Respiratory Protection	Eye/Face Protection	Hair cover	Shoe cover
1. Receiving, Unpacking and Stocking in Pharmacy: In a normal (neutral) or negative pressure							
UNDAMAGED parcels	**1, 2, 3, 4**	1 Pair					
DAMAGED medication parcels	**1, 2, 3, 4**	2 Pairs	Chemo Gown	Surgery Mask, N95 or CAPR	Goggles or Face Shield	Bouffant	2 Pairs
2. Delivery Within Facility (From Pharmacy): In sealed plastic bags with appropriate auxiliary labels corresponding to RLANRC HD groups of the medications							
Delivery to patient care areas	**1**	1 Pair					
	2, 3, 4						
3. Packaging and Labeling of Non-Sterile Preparations: For inpatient settings, these activities of group 1, 2, and 3 MUST be take place in HD storage room with dedicated tools and PPE. Group 4 can be prepared outside of HD storage room.							
• Repackaging using a manual packaging system (e.g., blister-pack) • Counting with tray and spatula (e.g., tablets, capsules) • Pouring from bulk bottle to unit-dose bottle (i.e. liquid suspension)	**1, 2, 3**	2 Pairs	Double (Chemo Gown outside)	Surgical Mask, N95 or CAPR	If splash potential	Bouffant	2 Pairs
	4 Must Not Use IPack	1 Pair *					
4. Preparing Non-Sterile HD Dosage Forms (Cutting tablets): MUST be prepared in HD storage room using dedicated tools. Activities such as crushing tablets or opening a dosage form are NOT PERMITTED in Pharmacy settings.							
Preparing half-tablet unit dose	**1**	Not Permitted					
	2, 3, 4	2 Pairs	Chemo Gown	Surgical Mask, N95 or CAPR	If splash potential	Bouffant	2 Pairs
5. **Preparing Compounded Sterile Preparations:** MUST be prepared in BSC unless specified differently in specific AoR of each hazardous medication and its dosage forms							
IV, SC, IM injectable preparations, etc.	**1**	Not Permitted					
	2, 3 In BSC if LAFW not permitted per AoR	2 Pairs sterile	Double (Chemo Gown outside)	Surgical Mask, N95 or CAPR	If splash potential	Bouffant	2 Pairs
	4	n/a					

***** For pregnant/lactating staff or male/female staff who are trying to conceive, double chemo gloves must be used

Reviewed: 4/19/22 TT

APPENDIX 5b – Alternative Containment Strategies for Handling Hazardous Drugs (PPE Guideline When Handling HD drugs) (cont.) - **For PHARMACY**

Activities / PPE vs. HD Group	RLANRC HD Groups	ASTM 6978 Gloves	Chemo Gown	Respiratory Protection	Eye/Face Protection	Hair cover	Shoe cover
6. Spill Management in Pharmacy • **Small Spills (< 5mL or 5g):** Cleaning by pharmacy staff if in pharmacy and by Nursing staff if in nursing unit • **Large Spills (> 5mL or 5g):** Cleaning by EVS Department. Dial 57291 and 0; after hours dial 0 then code ORANGE will be activated							
Intact dosage form spill (e.g., tablets, capsule) - *Spill Kit Not Required*	**1, 2**	2 Pairs					
	3	1 Pair *					
	4	1 Pair *					
Spill inside the BSC & HD buffer room	**1, 2**	2 Pairs sterile	Double (Chemo outside)	N95 or CAPR	Goggles and Face Shield	Bouffant	2 Pairs
Spill outside the HD buffer room *Don PPE from Spill Kit*	**1, 2, 3**	2 Pairs sterile	Chemo Gown	N95 or CAPR	Goggles and Face Shield	Bouffant	2 Pairs
Spill outside the HD buffer room	**4**	1 Pair					
7. Cleaning of Areas in Pharmacy:							
Cleaning of preparation areas (e.g., countertops in dispensary, HD shelves and bins)	**1, 2, 3, 4**	1 Pair *		N95 or CAPR if risk of inhalation	Goggles if Risk of Splash		
Hazardous buffer environment Daily clean of BSC Decontamination of BSC	**1, 2, 3**	2 Pairs sterile	Double (Chemo gown outside)	N95 or CAPR	Goggles and Face Shield	Bouffant	2 Pairs
8. Handling of Waste of RLA Hazardous Drug							
Inside and Outside of the cleanroom including general pharmacy areas	**1, 2, 3**	2 Pairs (sterile if inside cleanroom)	**Large black RCRA hazardous bins:** bulk or waste of Hazardous Drugs such as IV bags, tubing, and visibly soiled PPE. Warfarin & Tretinoin **Small blue pharmaceutical waste bins:** trace remainders of HDs: empty IV bags, tubing, syringes **Regular trash** empty packaging and used PPE unless soiled (significantly contaminated) then place in black bins **Yellow chemotherapy bins** for trace remainders of HDs: Empty IV bags, tubing, syringes, and all used PPE unless soiled (significantly contaminated) then place in black bins				

Reviewed: 4/19/22 TT

	4	1 Pair	

* If pregnant/lactating or male/female trying to conceive, double chemo gloves must be used

REVISED: 10/22/2020, 03/23/2021, 03/25/2022

APPENDIX 6 – Hazardous Spill Management

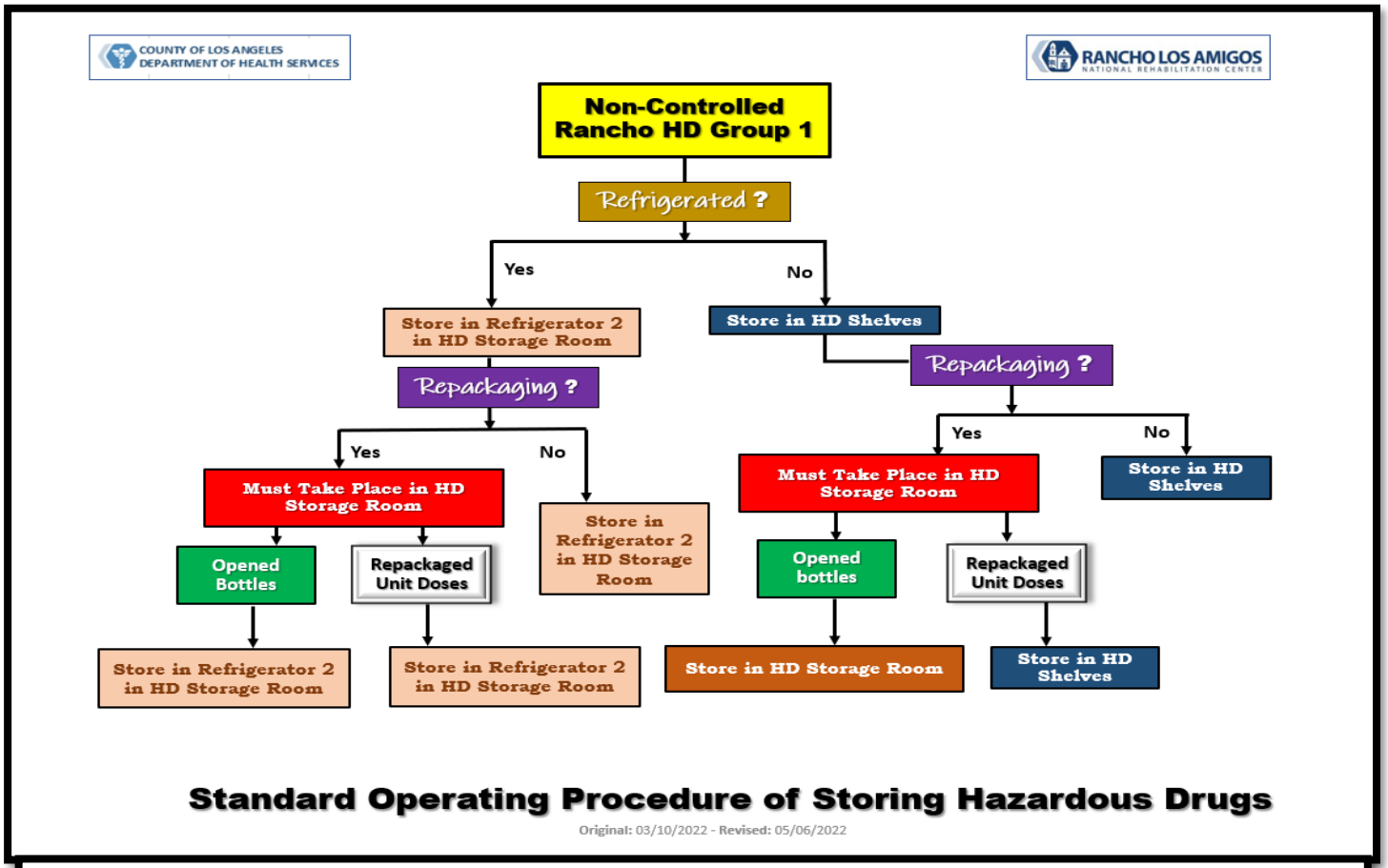
Spill Management	
• Staff will isolate the contaminated area. • Spill Kit: obtain from Pharmacy • Small Spills (< 5mL or 1 tsp): Cleaned by the person who caused the spill (Follow spill kit instruction) • Large Spills (> 5mL or 1 tsp): See instructions from code orange listed below, then operator will contact ANS/ House Supervisor	
CODE ORANGE	
During Working Hours (M – F: 08:00 - 16:30)	**After Hours (16:30 – 08:00, weekends and holidays)**
❖ Staff dials x **57291** AND **0** ❖ Safety Officer and Facilities staff: • Respond to area • Evaluate the spill • Review SDS sheet (located in NRO) • Determine who cleans the spills ✓ EVS or ✓ Hazmat Team from Downey Fire Department	❖ Staff dials **0** ❖ Administrative Nursing Supervisor (aka House supervisor) • Respond to area • Evaluate the spill • Review SDS sheet (located in NRO) • Determine who cleans the spills ✓ EVS or ✓ Hazmat Team from Downey Fire Department

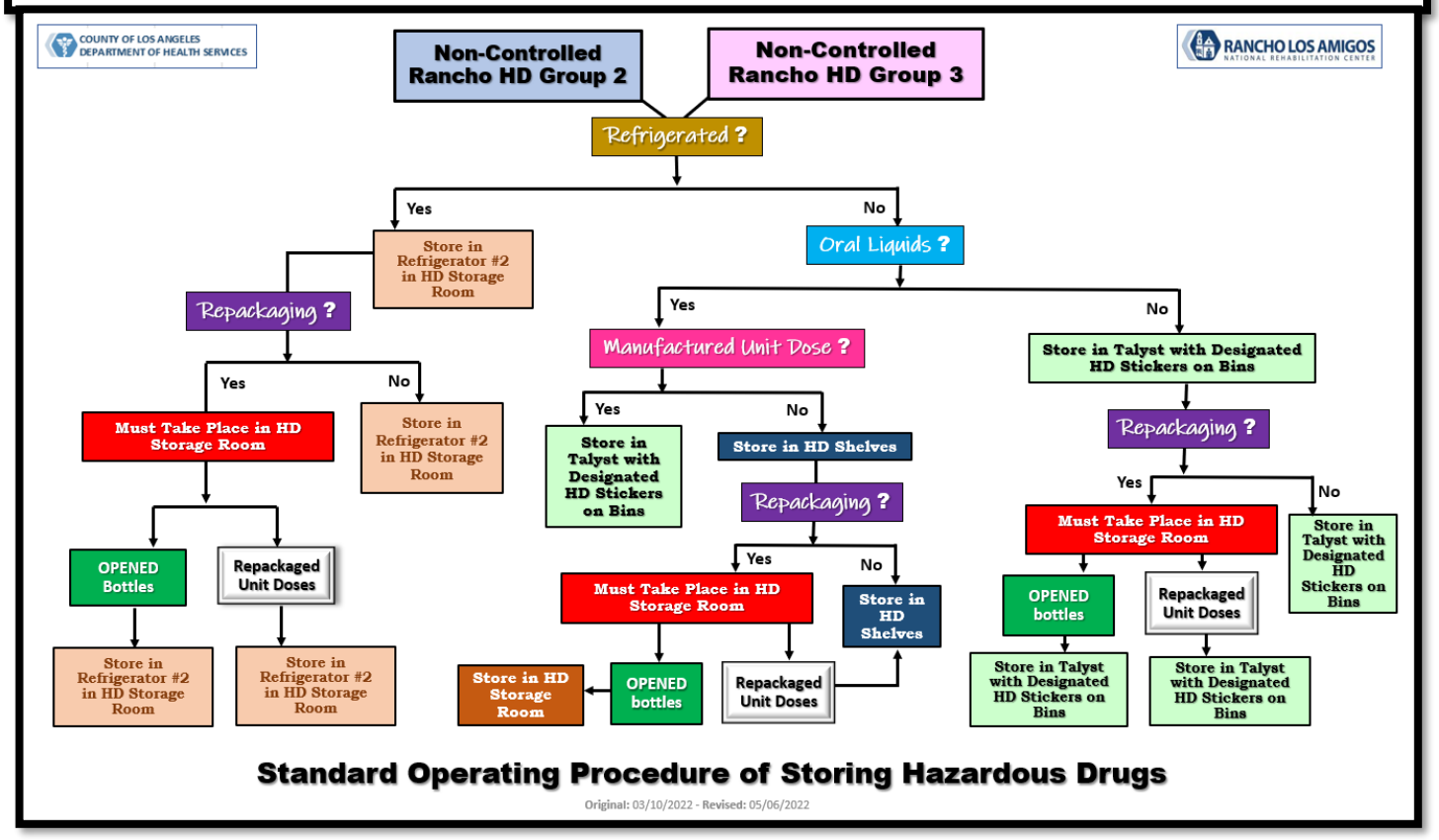
APPENDIX 7 – Disposal/Waste of HD medications

Handling of Waste of RLA Hazardous Drug Groups
HD Group 1
• **Yellow chemotherapy bins** for trace remainders of HDs: for example, syringes or gloves, medication wrappers • **Black RCRA hazardous bins** for bulk waste of HDs
HD Group 2, Group 3, and 4
• **Black RCRA hazardous bins** Coumadin, Tretinoin • **Blue pharmaceutical waste bins**: empty syringes, empty vials, and medication wastes except for Coumadin, Tretinoin • **Regular trash**: empty packaging and used PPE

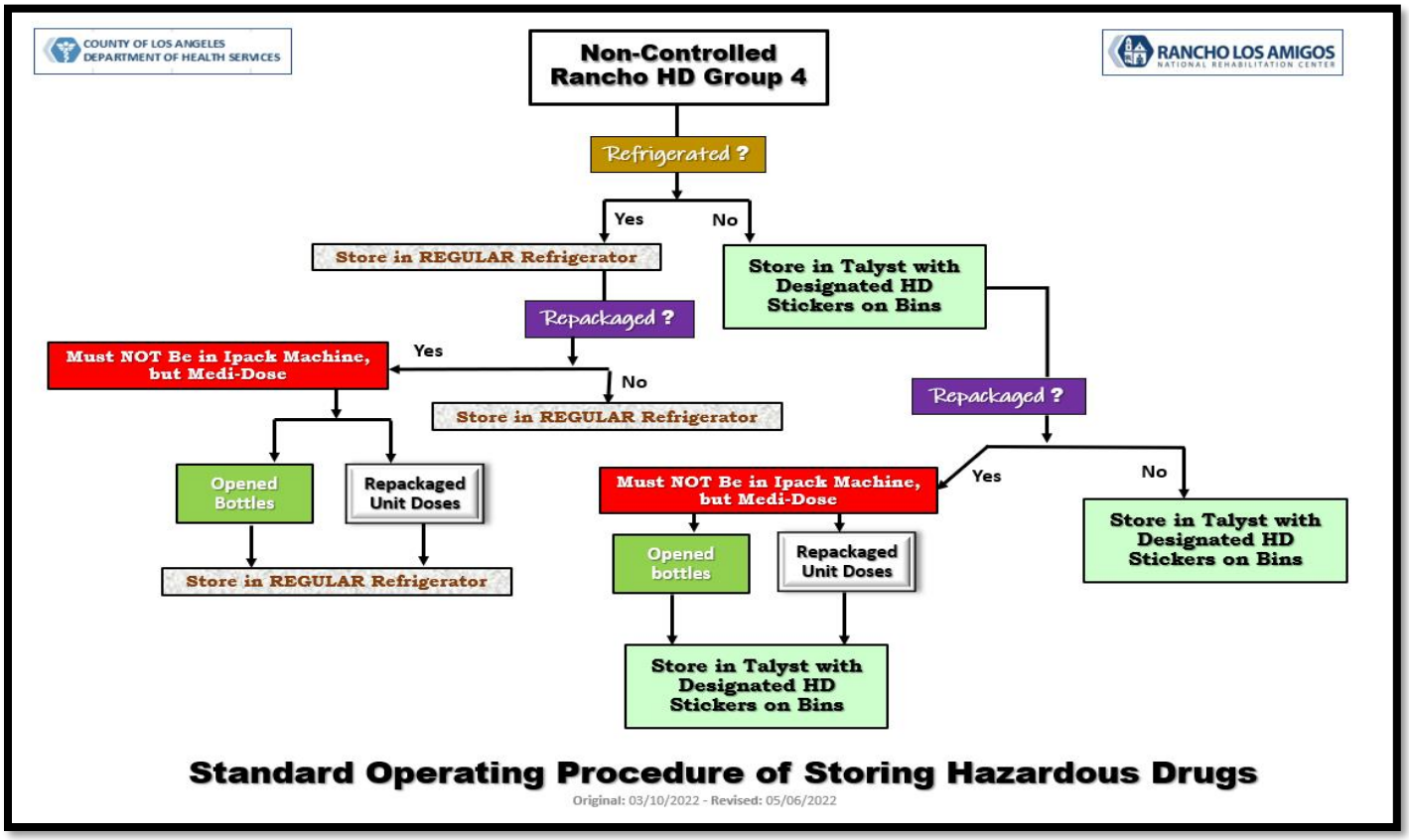
Reviewed: 4/19/22 TT

APPENDIX 8 – SOP of Storing Hazardous Drugs





Reviewed: 4/19/22 TT



APPENDIX 8 – SOP of Storing Hazardous Drugs (cont.)

DOCUMENT HISTORY

1. **Record of Original**

POLICY AND PROCEDURE MANUAL - PHARMACY SERVICES				Section: DEPARTMENT OF PHARMACY			
Subject: *HAZARDOUS MEDICATIONS*				Policy Code *1.50.0*	Most Recent Revision Version N1	Replaces Code *n/a*	Code Status: Active
Original Written by:	**Brian Kakehashi** (Name)	**Brian Kakehashi** (Signature)	Date *05/24/2016*	Original Approved by:	**Brian Kakehashi** (Name)	**Brian Kakehashi** (Signature)	Date *05/24/2016*
							Original Effective Date *05/24/2016*

2. **Record History of Reviewing and Revising**

Revised/Reviewed by	Signature	Title	Date	Approved by	Signature	Title	Date
JUSTIN PHAN		*Pharmacist*	*03/01/2020*	*DAO TANG*		*Pharmacist In Charge*	*03/02/2020*
Summary of Revision/Review Description	• Major revision of the policy to prepare for the new cleanroom suite • Adapting some recommendations from most revision of USP <800> (June 2019)						
JUSTIN PHAN	*Justin Phan*	*Pharmacist*	*02/07/2021*	*DAO TANG*		*Pharmacist In Charge*	*03/02/2021*
Summary of Revision/Review Description	• Updating Designated Viable sampling locations for CEPA test						

Reviewed: 4/19/22 TT

Revised/Reviewed by	Signature	Title	Date	Approved by	Signature	Title	Date
JUSTIN PHAN	*Justin Phan*	*Pharmacist*	*03/01/2022*	*Thinh Tran*		*Director of Pharmacy*	*03/01/2022*
Summary of Revision/Review Description	• Updating Methotrexate Injection Dispensing Procedure • Updating list of Rancho Hazardous list • Updating the procedure of half-tablet preparation and crushing/opening a dosage form of HD • Adding SOP flow chart of storing HD in pharmacy						

Reviewed: 4/19/22 TT

RANCHO LOS AMIGOS
NATIONAL REHABILITATION CENTER

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POLICY AND PROCEDURE MANUAL - PHARMACY SERVICES				Section: DEPARTMENT OF PHARMACY			
Subject: *HAZARDOUS MEDICATIONS*				Policy Code *1.50.0*	Most Recent Revision Version N1	Replaces Code *n/a*	Code Status: Active
Original Written by:	**Brian Kakehashi** (Name)	**Brian Kakehashi** (Signature)	Date *05/24/2016*	Original Approved by:	**Brian Kakehashi** (Name)	**Brian Kakehashi** (Signature)	Date *05/24/2016*
							Original Effective Date *05/24/2016*

Most Recent Reviewed Date	Next Review Due Date	Revised ☒ (Check the box if revised) Reviewed ☒ (Check the box if reviewed)	Assigned Revision Version	Active or Retired?	Effective Date
03/01/2022	*03/01/2023*		*N1*	*Active*	*03/14/2021*

Revised / Reviewed by	Signature	Title	Revised / Reviewed Date	Approved by	Signature	Title	Date
JUSTIN PHAN	*Justin Phan*	*Pharmacist*	*03/01/2022*	*Thinh Tran*		*Director of Pharmacy*	*03/01/2022*
Summary of Revision Description	• Updating Methotrexate Injection Dispensing Procedure • Updating list of Rancho Hazardous list • Clarifying half-tablet preparation and crushing/opening a dosage form of HD						

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Reviewed: 4/19/22 TT