RIVERSIDE UNIVERSITY HEALTH SYSTEM - MEDICAL CENTER
HOUSEWIDE

	Document No: 836	Page 1 of 3
Title: Look-Alike/Sound-Alike Medication Error Prevention	**Effective Date:** 12/10/2018	☐ RUHS – Behavioral Health ☐ RUHS – Care Clinics ☒ RUHS – Medical Center ☐ RUHS – Public Health ☐ Departmental
Approved By: Jennifer Cruikshank CEO/ Hospital Director		☐ Policy ☐ Procedure ☒ Guideline

1. SCOPE

1.1 Drug names can look or sound like other drug names, which may lead to potentially harmful medication errors. This policy is designed to provide guidance in preventing medication errors due to these Look-Alike/Sound-Alike Medications.

2. DEFINITIONS

2.1 **Look-Alike/Sound-Alike Medications.** The Joint Commission defines Look-Alike/Sound-Alike Medications as medications with similar medication names, either written or spoken, which may lead to potentially harmful medication errors when confused with each other. In practice, Look-Alike/Sound-Alike Medications are commonly referred to as LASA (Look-Alike/Sound-Alike) or SALA (Sound-Alike/Look-Alike) Medications.

3. GUIDELINES

3.1 The hospital develops and maintains a list of Look-Alike/Sound-Alike Medications

3.2 The hospital annually reviews and, as necessary, revises its list of Look-Alike/Sound-Alike Medications.

a. Reported medication errors involving confusion of similar medication names will be reviewed and considered for addition to the list of Look-Alike/Sound-Alike Medications.

b. New formulary additions will be reviewed for Look-Alike/Sound-Alike concerns and considered for addition to the list of Look-Alike/Sound-Alike Medications.

3.3 The hospital takes actions to prevent errors involving the interchange of medications on its list of Look-Alike/Sound-Alike Medications, including:

a. The Look-Alike/Sound-Alike Medications list will be readily available (in either electronic or hard copy format) in pharmacy and patient care areas where medications are stored, dispensed, or administered.

b. Maintain awareness of Look-Alike/Sound-Alike Medications

c. When unclear, determine the indication of the medication before dispensing or administering.

d. Accept verbal or telephone orders only when truly necessary, and NEVER for chemotherapy. Read back and verify all orders, spell product name, and state its indication.

e. Use standardized order sets or pre-printed prescription forms if available.

f. Change appearance of product names on computer screens, storage bins, pharmacy product labels, and medication administration records when possible by changing font appearance to draw attention to the parts of the names that differ. Strategies can include:
   - Use of tall man lettering as recommended by the Institute for Safe Medication Practices (e.g. hydrOXYzine and hydrALAzine).
   - Use of highlighting
   - Use of boldface type
   - Use of different colors

g. Set computerized alerts to help clinicians differentiate Look-Alike/Sound-Alike Medications.

h. Judiciously use Look-Alike/Sound-Alike Medications auxiliary stickers.

i. Consider storage of Look-Alike/Sound-Alike Medications in different locations.

j. Encourage reporting of errors due to Look-Alike/Sound-Alike Medications.

4. REFERENCES

4.1 The Joint Commission standards MM.01.02.01 and MM.04.01.01 EP4 - Effective date July 1, 2018

4.2 Centers for Medicare & Medicaid Services §482.25(a) Standard: Pharmacy Management and Administration

4.3 Institute for Safe Medication Practices: List of Confused Drug Names - Published 2015

4.4 Institute for Safe Medication Practices: Look-Alike Drug Names with Recommended Tall Man Letters - Published 2016

5. ATTACHMENTS

5.1 APPENDIX A

Document History:

Prior Release Dates: 12/28/2015	**Retire Date:** N/A
Document Owner: Pharmacy Department	**Replaces Policy:** Pharmacy Department Policy F623: Look-Alike, Sound-Alike Medications

Date Reviewed	Reviewed By:	Revisions Made Y/N	Revision Description
08/14/2018	Pharmacy Review Committee	Yes	Updated to new policy template Added Scope section Added Definitions section Minor Wording changes Updated References Updated APPENDIX A
09/19/2018	Nursing Policy & Procedure Committee	No	No changes
10/01/2018	P&T Committee	Yes	Bold new medications on the list moving forward.
10/02/2018	Policy Approval Committee	No	
11/8/18	MEC	*No*	

RUHS MEDICAL CENTER: LOOK-ALIKE/ SOUND-ALIKE DRUG LIST

Drug names can look or sound like other drug names, which may lead to potentially harmful medication errors. Measures that can help prevent drug mix-ups of Look-Alike/ Sound-Alike Medications include: Confirm indication * Include both brand and generic names * Use tall man lettering as suggested by the Institute for Safe Medication Practices * Judiciously use Look-Alike/ Sound-Alike Medications auxiliary stickers * Encourage reporting of errors due to Look-Alike/ Sound-Alike Medications

DRUG NAME	CONFUSED WITH	EXPLANATION
Adacel® (Tdap)	Daptacel® (DTaP)	Both Adacel® (Tdap) and Daptacel® (DTaP) are vaccines that contain diphtheria and tetanus toxoids as well as acellular pertussis, but each brand contains different amounts of antigens, have different frequencies, and are used for different age ranges.
ALPRAZolam	LORazepam	ALPRAZolam and LORazepam are two different medications in the same drug class (benzodiazepines) used for similar indications.
amphotericin B *(liposomal)* Ambisome®	amphotericin B *(conventional)*	Ambisome® is the brand name for amphotericin B (liposomal) and can be confused with conventional amphotericin B which is dosed differently and has more toxic side effects.
amphotericin B *(conventional)*	amphotericin B *(liposomal)* Ambisome®	
ceFAZolin	cefTRIAXone	Both ceFAZolin (Ancef®) and cefTRIAXone (Rocephin®) are cephalosporin antibiotics. ceFAZolin (Ancef®) is a first-generation cephalosporin typically dosed THREE times a day, while cefTRIAXone (Rocephin®) is a third-generation cephalosporin typically dosed ONCE a day.
ceftriaxone	ceFAZolin	
cloNIDine	clonazepam (KlonoPIN®)	KlonoPIN® is the brand name for clonazePAM which is typically used for anxiety. cloNIDine is in a completely different drug class and typically used for blood pressure control.
clonazepam (KlonoPIN®)	cloNIDine	
Daptacel® (DTaP)	Adacel® (Tdap)	Both Adacel® (Tdap) and Daptacel® (DTaP) are vaccines that contain diphtheria and tetanus toxoids as well as acellular pertussis, but each brand contains different amounts of antigens, have different frequencies, and are used for different age ranges.
Depo-Medrol®	Solu-MEDROL®	Depo-Medrol® and Solu-MEDROL® are different parenteral formulations of methylprednisolone. Depo-Medrol® should only be given IM.
DOBUTamine	DOPamine	Both DOBUTamine and DOPamine are continuous infusions commonly used in critically ill patients. DOBUTamine is typically used more for inotropic support while DOPamine is typically used for hemodynamic support.
DOPamine	DOBUTamine	
EPINEPHrine	ePHEDrine	ePHEDrine and EPINEPHrine are both adrenergic agonists. ePHEDrine is typically used for anesthesia-induced hypotension. EPINEPHrine is typically used in a variety of indications including hypotension/shock, hypersensitivity reactions, or in certain ACLS pathways.
ePHEDrine	EPINEPHrine	
HBIG (hepatitis B immune globulin)	hepatitis B vaccine	Hepatitis B vaccine is a vaccine which stimulates the immune system to make antibodies and provides long term protection against the hepatitis B virus, but does not work immediately. HBIG is hepatitis B immune globulin (not a vaccine). It contains large amounts of hepatitis B antibodies when immediate protection against hepatitis B is needed, but the protection is only short-term.
hepatitis B vaccine	HBIG (hepatitis B immune globulin)	
HBIG (hepatitis B immune globulin)	Hib (*Haemophilus Influenzae* Type b Vaccine	HBIG is hepatitis B immune globulin (not a vaccine) and is used when immediate protection against the hepatitis B virus is needed. Hib (*Haemophilus influenzae* Type b Vaccine) is a vaccine to protect against the bacteria *Haemophilus influenza*.
Hib (*Haemophilus Influenzae* Type b Vaccine	HBIG (hepatitis B immune globulin)	
hepatitis B vaccine	Hib (*Haemophilus Influenzae* Type b Vaccine	Hepatitis B vaccine is a vaccine to protect against the hepatitis B virus. Hib (*Haemophilus influenzae* Type b Vaccine) is a vaccine to protect against the bacteria *Haemophilus influenza*.
Hib (*Haemophilus Influenzae* Type b Vaccine	hepatitis B vaccine	
HumuLIN®	HumaLOG®	HumaLOG® is the brand name for insulin lispro and is considered a rapid-acting insulin. HumuLIN® is a brand name for insulin regular which is considered a short-acting insulin. HumaLOG® (insulin lispro) has a faster onset compared to HumuLIN® (insulin regular).
HumaLOG®	HumuLIN®	
HumuLIN®	NovoLIN®	Both NovoLIN® and HumuLIN® are different brand names for insulin regular.
HumaLOG®	NovoLOG®	Both NovoLOG® (insulin aspart) and HumaLOG® (insulin lispro) are rapid-acting insulins, but are not interchangeable without a physician order/prescription or therapeutic interchange process in place.
hydrALAZINE	hydrOXYzine	hydrOXYzine is typically used for anxiety or itching. hydrALAZINE is in a completely different drug class and typically used for blood pressure control.
hydrOXYzine	hydrALAZINE	
HYDROmorphone	morphine	HYDROmorphone (commonly referred to by its brand name Dilaudid®) and morphine are both opioids used to control pain but are dosed differently.
lamiVUDine	lamoTRIgine	lamiVUDine (Epivir® or Epivir HBV®) is typically used in the treatment of hepatitis B or as part of an HIV regimen. lamoTRIgine (Lamictal®) is a completely different drug typically used to manage seizures or certain psychiatric conditions.
lamoTRIgine	lamiVUDine	
LORazepam	ALPRAZolam	ALPRAZolam and LORazepam are two different medications in the same drug class (benzodiazepines) used for similar indications.
metoprolol succinate	metoprolol tartrate	Metoprolol succinate (brand name Toprol XL®) is the extended release version of metoprolol which is typically dosed ONCE a day while metoprolol tartrate (Lopressor®) is the immediate release version of metoprolol which is typically dosed TWICE a day.
metoprolol tartrate	metoprolol succinate	
morphine	HYDROmorphone	HYDROmorphone (commonly referred to by its brand name Dilaudid®) and morphine are both opioids used to control pain but are dosed differently.
NovoLIN®	HumuLIN®	Both NovoLIN® and HumuLIN® are different brand names for insulin regular.
NovoLIN®	NovoLOG®	NovoLOG® is the brand name for insulin aspart and is considered a rapid-acting insulin. NovoLIN® is a brand name for insulin regular which is considered a short-acting insulin. NovoLOG® (insulin aspart) has a faster onset compared to NovoLIN® (insulin regular).
NovoLOG ®	NovoLIN®	
NovoLOG ®	HumaLOG®	Both NovoLOG® (insulin aspart) and HumaLOG® (insulin lispro) are rapid-acting insulins, but are not interchangeable without a physician order/prescription or therapeutic interchange process in place.
oxyCODONE	OxyCONTIN®	oxyCODONE is available in either immediate release tablets or extended release tablets. OxyCONTIN® is the brand name for oxyCODONE extended release tablets.
OxyCONTIN®	oxyCODONE	
rifabutin	riFAMpin	Both rifabutin and riFAMpin are antitubercular agents, but have different indications and are dosed differently. Rifabutin is only available orally, while riFAMpin is commercially available in both parenteral and oral formulations.
riFAMpin	rifabutin	
risperiDONE (RisperDAL®)	rOPINIRole	RisperDAL® is the brand name for risperiDONE which is a second-generation antipsychotic typically used in certain psychiatric disorders. rOPINIRole anti-Parkinson agent typically used in Parkinson disease or Restless Leg Syndrome.
rOPINIRole	risperiDONE (RisperDAL®)	
Solu-MEDROL®	Depo-Medrol®	Depo-Medrol® and Solu-MEDROL® are different parenteral formulations of methylprednisolone. Depo-Medrol® should only be given IM.
sulfADIAZINE	sulfaSALAzine	sulfADIAZINE is an antibiotic typically used in certain infections. sulfaSALAzine is a medication typically used in certain autoimmune diseases.
sulfaSALAzine	sulfADIAZINE	

RIVERSIDE UNIVERSITY HEALTH SYSTEM - MEDICAL CENTER
Housewide

	Document No: 842	Page 1 of 4
Title: Drug Formulary and Non-Formulary Process	**Effective Date:** 5/6/2019	☐ **RUHS – Behavioral Health** ☐ **RUHS – Care Clinics** ☒ **RUHS – Medical Center** ☐ **RUHS – Public Health** ☐ **RUHS – Hospital Clinics** ☐ **Departmental**
Approved By and Date Approved: Jennifer Cruikshank CEO/ Hospital Director		☒ **Policy** ☐ **Procedure** ☐ **Guideline**

1. SCOPE

1.1. This policy applies to the Riverside University Health System – Medical Center.

2. DEFINITIONS

2.1. Active Ingredient: A chemical compound that provides pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body.

2.2. Closed Formulary: A limited list of medications. A closed formulary limits drugs to specific physicians, patient care areas, or disease states via formulary restrictions.

2.3. Dosage Form: The physical form of a dose of a chemical compound used as a medication intended for administration. Examples of dosage forms include tablet, capsule, and injectable.

2.4. Drug: A drug is defined as:

a. A substance recognized by an official pharmacopoeia or formulary.

b. A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.

c. A substance (other than food) intended to affect the structure or any function of the body.

d. A substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device.

e. Biological products are included within this definition and are generally covered by the same laws and regulations, but differences exist regarding their manufacturing processes (chemical process versus biological process.)

2.5. Drug Monograph: Drug Monograph is a document supporting the use of a medication with the goal of optimal patient outcomes. The Department of Pharmacy will maintain a template of the Drug Monograph, which will be provided upon request. At the minimum, the Drug Monograph will contain the following elements:

a. Indications for Use

b. Effectiveness

c. Drug Interactions

d. Potential for Errors and Abuse

e. Adverse Drug Events

f. Sentinel Event Advisories

g. Other Risks

h. Costs

i. Population(s) served (for example, pediatrics, geriatrics, etc.)

2.6. Fact Sheet: A summary of the drug monograph that serves as an educational aid.

2.7. Formulary: An approved list of active ingredient medications, including medication strength and dosage form, available for use by RUHS - Medical Center. Active ingredients, specific dosage forms, and strengths on this list are procurable by Department of Pharmacy.

2.8. Non-Formulary: Medications is not on the approved list of formulary medications.

2.9. Non-Formulary Request: A request to use a medication not on the approved list of formulary medications. The request is required for active ingredients not on formulary and/or routes not approved by Pharmacy & Therapeutics Committee (P&T).

3. POLICY

3.1. A closed formulary **will be** maintained with active ingredient names, strengths, and dosage forms, in electronic format.

3.2. The number of drug concentrations are standardized and limited, while meeting patient care needs.

3.3. Only medications from the RUHS - Medical Center Drug Formulary and pharmacy approved non-formulary medications will be dispensed.

3.4. Additions, deletions, and/or changes to formulary medications, including SAMPLE medications, will be reviewed periodically and as needed through the Pharmacy Review Committee. These will be submitted to P&T and Medical Executive Committee (MEC) for approval. A comprehensive review of the formulary will occur no less frequently than every 3 years.

3.5. P&T and MEC reviews and approves changes to formulary active ingredients and routes of administration of formulary active ingredients.

3.6. The Department of Pharmacy reviews and approves changes to medication strength and/or dosage forms of formulary active ingredients and approved routes.

3.7. Emerging safety and efficacy information will be discussed by Pharmacy Review Committee for consideration of formulary revision.

4. PROCEDURES

4.1. Adding or Deleting Active Ingredients to Formulary

a. Adding: The requestor must be a Chief of Service, Director of the Department of Pharmacy, or designee. The requestor must complete and submit a Formulary Addition Request form, Drug Monograph, and Fact Sheet (or equivalent) to the

Department of Pharmacy. The requestor is invited to appear at P&T meeting to present the addition to the RUHS - Medical Center formulary.

b. Deleting: The requestor must communicate to the Department of Pharmacy regarding recommendation to delete an active ingredient from formulary. The recommendation must be accompanied with an explanation.

c. Submissions are reviewed by the Department of Pharmacy and a recommendation will be presented to P&T.

d. The recommendations of P&T will be submitted to the MEC for final approval.

e. For all new active ingredients and/or new usage to an existing ingredient that are added to formulary, if there is a potential for an increased risk for a medication error, a hospital-wide surveillance must be in place to monitor for compliance and success with established safeguards for at least 6 months from the time the medication is added to the formulary. This medication use evaluation will be conducted by the Department of Pharmacy and will be reviewed by P&T.

f. Pharmacy systems will be updated to reflect additions/deletions approved by MEC.

g. If a request is denied, the requestor may ask to appear before the P&T to appeal the decision. Appealing a decision does not guarantee formulary addition or deletion.

4.2. Adding or Deleting Dosage Forms and/or Strengths of Active Ingredients on Formulary

a. The Department of Pharmacy will review and approve 1) Additions or deletions of dosage forms and strengths of active ingredients on formulary, and 2) Changes to restrictions or comments of formulary active ingredients.

b. The additions, deletions, and/or changes to the formulary will be submitted to P&T and MEC for retrospective review.

4.3. Non-Formulary Process for Inpatient Use and Clinic Use

a. Active Ingredients Not On Formulary

i. Attending Physician, Senior Resident Physician, Director of Pharmacy or designee must complete and submit the non-formulary request.

ii. Approval is dependent upon medical necessity with the following criteria:

- Use of the medication for the specified indication is supported by medical literature (clinical guidelines, FDA approval, clinical trials, etc.), AND
- Use of formulary alternative(s) are inappropriate for the specific patient (hypersensitivity reactions, treatment failure at maximum tolerated doses, etc.), AND
- No significant interactions between the requested medication and other medications are present, AND
- The patient has the means to obtain and continue the medication on an outpatient basis if chronic, ongoing use is indicated.

iii. Submissions are reviewed by the Department of Pharmacy.

iv. Approvals: The medication will be procured (ordered or borrowed, if possible) by the pharmacy staff upon receipt of approved non-formulary request. Because the Department of Pharmacy does not stock non-formulary medications, an extended turnaround time might be expected.

v. Denials: The prescriber will be communicated to regarding the denial.

b. Active Ingredient on Formulary, but Dosage Form and/or Strength Not on Formulary

i. The Department of Pharmacy will approve or deny a request to procure and dispense dosage forms and/or strengths not listed on the formulary of approved active ingredients and approved routes.

ii. The approved usage of these dosage forms and/or strengths will be considered for addition to formulary.

c. Non-Formulary Process for Outpatient Use

i. The Department of Pharmacy may review non-formulary requests for outpatient use.

5. REFERENCES

5.1. TJC, Revision to: Elements of Performance for Medication Management, MM.02.01.01

6. ATTACHMENTS

6.1. Formulary Addition Request Form

6.2. Inpatient & Clinic Use Non-Formulary Medication Request Form

Document History:

Release Dates: 12/28/15	**Retire Date:**
Sponsored by: Pharmacy Department	**Replaces Policy:**

Date Reviewed	Reviewed By:	Revisions Made?	Revision Description
12/11/18	PRC	Yes	Minor clarifications. Added closed formulary and fact sheet definitions. Updated formatting. Removed P&T and MEC definition.
2/4/19	P&T	No	
3/5/19	PAC	Yes	Clarified the following: definition of active ingredient, pharmacy approves non-formulary medication, medication use evaluations (if conducted) on new medications/usage will be presented at P&T. Deleted redundant sentence on process to formulary changes and non-formulary medications.
4/11/19	MEC	No	

Riverside University Health System - Medical Center
Department of Pharmacy Services
Formulary Addition Request

TO: Pharmacy and Therapeutics Committee
(951) 486-4529 or Fax (951) 486-4540

Date:_____

It is requested that the following medication be added to the hospital formulary:
GENERIC NAME:_____ TRADE NAME:_____
DOSAGE FORM:_____ STRENGTH:_____
Comparable Formulary Medications:_____
Indications or situations in which requested medication is superior to formulary choices:
_____
Therapeutic effectiveness compared to existing formulary medications:
_____
Risks (including propensity for medication errors, abuse potential, and sentinel events):
_____
Current formulary medications which may be deleted upon addition of the medication requested:
_____
Requested for use in the following settings:
_____
Conditions or restrictions (more than one may apply):
☐ Inpatient ☐ Outpatient ☐ Specialty
☐ Chief of Service, Attending Staff Physician, or Senior Resident.

Potential conflict of interest disclosure:
I received financial or research support from the manufacturer: ☐Yes ☐No
I have a consulting agreement with the manufacturer: ☐Yes ☐No
I, my spouse, or dependent(s) have a financial interest in the manufacturer of this agent: ☐Yes ☐No
Please list all references or studies that support the addition of this agent to the current formulary:
_____
_____

Request must be made by one of the following:
Chief of Service, Attending Staff Physician, or Director of Department of Pharmacy

_____ Print Name
_____ Department
_____ Signature
_____ Phone/Pager Number

PLEASE NOTE:
A representative of the requesting service will be invited to attend the Pharmacy & Therapeutics Committee meeting to discuss the addition of this medication to the formulary. If there is a potential for an increased risk for a medication error, a hospital-wide surveillance process must be in place to monitor for compliance and success with established safeguards for at least 6 months from time the medication is added to the formulary.

FOR PHARMACY USE BELOW THIS LINE:

Cost:_____

Action:_____

Comments:_____

Recommended Coverage: ☐Inpatient ☐Outpatient: ☐MISP

Drug Plan Coverage: Medi-Cal ☐Yes ☐No **IEHP** ☐Yes ☐No **Molina** ☐Yes ☐No Revision (12/18)

RIVERSIDE UNIVERSITY HEALTH SYSTEM-MEDICAL CENTER
DEPARTMENT OF PHARMACY SERVICES

NON-FORMULARY MEDICATION REQUEST FORM

☐ INPATIENT USE ☐ CLINIC USE

(Does NOT replace the physician order)

*Required Fields

*Medication, Dose, Route, Frequency: _____

*Indication for use: _____ *Estimated Duration of Therapy: _____

*Formulary alternatives and why inappropriate: _____

Evidence to support use of requested medication in lieu of formulary alternatives for this indication (treatment guidelines, clinical trial(s), FDA approval, etc.): _____

_____

*Has the FDA imposed a Risk Evaluation and Mitigation Strategy (REMS) program for this medication?
Searchable REMS database on FDA website: http://www.accessdata.fda.gov/scripts/cder/rems/index.cfm

(Circle One)
NO YES → Medication requires communication to the Medication Safety Officer or Designee.

Attending Staff Physician, or Senior Resident Physician:

_____ _____ _____
*Printed Name *Signature *Date

RETURN TO THE PHARMACY AS SOON AS POSSIBLE TO REDUCE ANY DELAY IN PRESCRIPTION ORDER PROCESSING.
Please note that if request is approved, it may take more than 24 hours for pharmacy to acquire the medication.

FOR PHARMACY USE ONLY:

Approval is dependent upon medical necessity with the following criteria:

1. Use of the medication for the specified indication is supported by medical literature (clinical guidelines, FDA approval, clinical trials, etc.), AND
2. Use of formulary alternative(s) are inappropriate for the specific patient (hypersensitivity reactions, treatment failure at maximum tolerated doses, etc.), AND
3. Use outweighs any interactions between the requested medication and current medications, AND
4. The patient has the means to obtain and continue the medication on an outpatient basis if chronic, ongoing use is indicated.

Reviewing Pharmacist (Antimicrobials, pediatric/neonatal medications, and chemotherapy shall be communicated to the corresponding clinical pharmacist.):

_____ _____ _____
*Printed Name *Signature *Date

Corresponding Clinical Pharmacist:

_____ _____ _____
Printed Name Date Method of Communication

Approving Senior Pharmacist:

_____ _____ _____
*Printed Name *Signature *Date

NON-FORMULARY MEDICATION REQUEST **For communication purposes only. NOT a part of the patient's medical record.**	[PLACE PATIENT LABEL HERE]

Last Updated: 2/4/19

RIVERSIDE UNIVERSITY HEALTH SYSTEM - MEDICAL CENTER

HOUSEWIDE

	Document No: 851	Page 1 of 14
Title: Handling of Hazardous Medications	**Effective Date:** 5/6/2019	☐ RUHS – Behavioral Health ☐ RUHS – Care Clinics ☒ RUHS – Medical Center ☐ RUHS – Public Health ☐ Departmental
Approved By: Jennifer Cruikshank CEO/ Hospital Director		☐ Policy ☒ Procedure ☐ Guideline

1. DEFINITIONS

1.1 *Contaminated:* Material that has been in direct contact with a hazardous drug. Urine, fecal matter, vomit, blood, or body fluids from patients receiving a hazardous drug are considered contaminated for a minimum of 48 hours after administration. Containers that have held contaminated urine, fecal matter, vomit, blood, or other body fluids are considered contaminated until emptied.

1.2 *Exposure:* Physical contact with a hazardous drug, such as during preparation or administration or unprotected contact with a hazardous drug.

1.3 *Hazardous Drug Waste:* An unused or partially used hazardous drug that has not been used for its intended purpose or material that has been contaminated with a hazardous drug.

1.4 *Manipulation/manipulated:* Repackaging of a medication from the original dose form supplied by the manufacturer for patient administration to another dose form.

1.5 *Closed-system drug transfer device (CSTD)*: A drug transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of HD or vapor concentrations outside the system.

1.6 *Chemotherapy glove*: A medical glove that meets the ASTM Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs (D6978) of its successor.

1.7 *Protective gown:* Gowns must be disposable and shown to resist permeability by HDs. Gowns must close in the back (i.e., no open front), be long sleeved, and have closed cuffs that are elastic or knit. Gowns must not have seams or closures that could allow HDs to pass through.

1.8 *Respiratory protection*: a fit-tested NIOSH-certified N95 or more protective respirator is sufficient to protect against airborne particles.

1.9 *Hazardous Drugs (HDs)*: Hazardous drugs include those used for cancer chemotherapy, antiviral drugs, hormones, some bioengineered drugs, and other miscellaneous drugs. Drugs considered hazardous include those that exhibit one or more of the following six characteristics in humans or animals:

a. Carcinogenicity

b. Teratogenicity or other developmental toxicity

c. Reproductive toxicity

d. Organ toxicity at low doses

e. Genotoxicity

f. Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria

1.10 *NIOSH approach involves three groups of drugs*:

a. Tier 1: Antineoplastic hazardous drugs. Many of these drugs may also pose a reproductive risk for susceptible populations (Attachment A and B).

b. Tier 2: Non-antineoplastic hazardous drugs that meet one or more of the NIOSH criteria for a hazardous drug. Some of these drugs may also pose a reproductive risk for susceptible populations (Attachment C).

c. Tier 3: Reproductive risk, hazardous drugs that primarily pose a reproductive risk to men and women who are actively trying to conceive and women who are pregnant or breast feeding, because some of these drugs may be present in breast milk (Attachment D).

1.11 *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.

1.12 *Chemo certified nurse:* Nurse holds a current Oncology Nursing Society (ONS) provider card.

2. PROCEDURES

2.1 This procedure describes the general aspects of handling hazardous drugs (HDs): receipt, storage, labeling, transport and administration that are not directly associated with compounding activities.

a. Preparation and compounding are addressed in separate pharmacy procedure.

b. HD and chemotherapy spill and waste handling are addressed in separate procedure.

2.2 HD will be handled using methods that protect employees, the surrounding environment and others who may encounter them in the healthcare environment.

2.3 Potential Routes of Exposure Based on Activity- Table 1

Activity	Potential Route of Exposure
Dispensing	Counting tablets and capsules from bulk containers
Compounding	• Crushing tablets or opening capsules • Pouring oral or topical liquids from one container to another • Weighing or mixing components • Constituting or reconstituting powdered or lyophilized HDs • Withdrawing or diluting injectable HDs from parenteral containers • Expelling air or HDs from syringes • Contacting 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

2.4 **General Handling of HDs**

a. Appropriate PPE must be worn when handling HDs including during: receipt, storage, transport, compounding, administration, deactivation, decontamination, cleaning, disinfecting and spill control. .

b. Chemotherapy gloves are always worn for handling hazardous medications including non-antineoplastic (Tier 2) and for reproductive risk only HDs (Tier 3). Two pairs of Chemotherapy gloves are required for administering antineoplastic HDs (Tier 1).

c. Gowns are required when administering antineoplastic HDs except for intact tablet or capsule. Gowns worn in HD handling areas must not be worn to other areas in order avoid spreading HD contamination and exposing other healthcare workers.

d. When there is a risk of respiratory exposure to HDs, including 1) spills larger than what can be contained with a spill kit 2) deactivating, decontaminating, cleaning of HDs hood 3) suspected airborne exposure to powders or vapors, an appropriate full-face piece chemical cartridge-type respirator should be worn.

e. Antineoplastic HDs shall be handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparation for administration and disposal.

f. Hands should be washed before and after the use of gloves.

g. HD vials are considered contaminated with HD, any personnel handling these vials will wear chemotherapy gloves.

h. Double gloves and protective gown are required when handling bodily fluids.

2.5 **Receipt of HDs**

a. Antineoplastic HDs (Tier 1) will be unpacked in an area that is neutral/normal or negative pressure relative to the surrounding areas.

b. Antineoplastic HDs will not be unpacked from their shipping containers in sterile compounding areas or in positive pressure areas.

c. Pharmacy personnel responsible for Antineoplastic HD inventory receiving functions will receive training on hazardous drug handling and spill procedures.

d. Should a package of HD be received which is suspected of being damaged, the following will occur:

- The HDs in question will be received and opened in an isolated area.
- In addition to the double chemotherapy gloves, additional PPE will be worn which will include: a coated chemotherapy gown, disposable utility gloves, eye shield and an OSHA-certified N-95 fit tested respirator.
- If a container is broken, the procedure on HD Spills will be followed.

2.6 **Storage of HDs**

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

b. Refrigerated antineoplastic HDs are stored in a dedicated refrigerator, separate from non-hazardous medications, in bins that will contain leakage, in a negative pressure area with at least 12 air changes per hour (ACPH).

c. Non-antineoplastic (Tier 2), reproductive risk only (Tier 3), and final dosage forms of antineoplastic HDs may be stored with other inventory.

d. Antineoplastic HDs requiring manipulation other than counting final dosage forms are stored separately from non-HDs in a manner that prevents contamination and personnel exposure. These HDs must be stored in a negative-pressure room with at least 12 air changes per hour (ACPH).

e. Sterile and non-sterile HDs may be stored together.

f. Specific labels that have been adopted by the organization to be used to designate HDs will be affixed to shelves, or drawers or bins as appropriate where HDs are stored.

2.7 Transport of HDs

a. Compounded HDs in final containers for patient administration will be placed inside of sealed transport bags that are labeled prominently using labels and identifying stickers.

b. Antineoplastic drugs are prepared for transport by individually wrapping each dose in an impervious, sealed plastic bag (1 dose per bag) to prevent contamination in the event of leakage. If the bottle is glass, it must be wrapped in shock absorbent material before being placed in the bag.

c. Pneumatic tubes must not be used to transport any liquid HDs or antineoplastic HDs (Tier 1).

d. Personnel involved in the transport of HDs will be trained in transport and spill procedures.

e. Chemo Spill Kit will be kept in main pharmacy, infusion center and nursing units where chemotherapy is given.

f. HDs that are shipped outside of the facility will be shipped in accordance with local and state Department of Transportation regulations.

2.8 Labeling

a. All packages, containers, prepared syringes, intravenous (IV) bottles, or other devices containing antineoplastic drugs (Tier 1) shall be marked with "CHEMOTHERAPY" sticker to alert personnel that the contents involve antineoplastic drug. Chemotherapy Drug Delivery bags (if applicable) may also be used for transportation of antineoplastic drugs.

b. All packages, containers, prepared syringes, intravenous (IV) bottles, or other devices containing hazardous drugs (Tier 2) shall be marked with "HAZARDOUS DRUG" stickers in a manner sufficient to alert personnel that the contents involve a hazardous drug. Delivery bags are also labeled with "HAZARDOUS DRUG" sticker for hazardous drugs.

c. All packages, containers, prepared syringes, intravenous (IV) bottles, or other devices containing hazardous drugs-reproductive risk (Tier 3) shall be marked with "REPRODUCTIVE RISK" stickers in a manner sufficient to alert personnel that the contents involve a hazardous reproductive risk drugs. Delivery bags are also labeled with "REPRODUCTIVE RISK" sticker for hazardous reproductive risk drugs.

3. ADMINISTRATION AREAS

3.1 Engineering Controls

a. Closed-system transfer devices must be used for administration of antineoplastic HDs. Needleless system is used to reduce the risk of needle sticks.

b. Infusion and Intravenous sets should be attached and primed with base solution in the pharmacy department under the proper engineering control for antineoplastic HDs.

3.2 Worker's Apparel and Protection (See table 6)

a. Appropriate PPE must be worn when administering HDs. After use, PPE must be removed and disposed of in an approved HD waste container at the site of drug administration. Equipment (such as tubing and needles) and packaging materials must be disposed in HD waste containers after administration. Apparel used when hazardous drugs in any category are administered may not be worn out of the administration area.

b. When handling the body wastes and fluids of patients receiving antineoplastic drugs, employees should wear appropriate personal protective equipment for 48 hours after the drug was administered while caring for the patient.

c. Protective goggles, if used, should be cleaned with detergent and thoroughly rinsed.

d. Employees must wash their hands thoroughly with soap and water before and after administering hazardous drugs and whenever gloves are changed.

3.3 Respiratory Therapy

The respiratory therapy department should maintain a standard operating procedure for each specific hazardous drug administered as an aerosol. The treatment area should be posted during administration, and nonessential personnel should not be admitted.

3.4 Environmental Services

a. Environmental services staff must wear appropriate protective gloves when working in any area where HDs are compounded or administered. They must also be trained in spill response and clean-up procedures.

b. Wear two pairs of chemotherapy gloves and impermeable disposable gown if handling linens, feces, or urine from patients who have received antineoplastic HDs within the last 48 hours.

c. Masks are required for reproductive category employees.

d. Further efforts to limit employee exposure are defined by specific policies set by environmental services department.

3.5 **Patient Signage**

Nursing staff member will post a sign on the door to the room and on the chart of every inpatient who has received antineoplastic drugs within the past 3 days (including those from prior admissions or those transferred from other institutions). The sign will note that medication exposure precautions exist and specify the date when the signage can be removed (a minimum of 48 hours after the completion of the last administration of the antineoplastic drug).

3.6 **Patient Transport**

Patients receiving antineoplastic drugs are considered a moderate risk for transport. These patients should be identified to the transporter in accordance with local policy. Employees must wear nitrile gloves when transporting a patient receiving an antineoplastic drug and must be trained in spill response procedures.

3.7 **Laundry**

It is standard procedure to treat all laundry as if it is contaminated with hazardous material. All items are prewashed before being washed. Employees must wear latex or nitrile gloves when handling laundry.

3.8 **Investigational Drugs**

A large number of investigational hazardous drugs are under clinical study in health care facilities. Personnel not directly involved in the investigation should not administer these drugs unless they have received adequate instruction on safe handling procedures.

3.9 **Contaminations and Spills** – Refer to Housewide policy 865 "Hazardous Drug Spill Deactivation and Waste Management"

4. DOCUMENTATION AND TRAINING

4.1 All personnel working with HDs must receive training on the possible health risks associated with exposure to these agents and be instructed on their safe handling and disposal. Employees must have access to this plan.

4.2 Employees who handle HDs or HDs waste should receive initial hazard communication training during new employee orientation. They must also receive additional specific training from their department on the drugs they will be exposed to. Before working with hazardous drugs, they must demonstrate their understanding of and competence in safe and proper drug handling procedures to their supervisor. The department must verify staff competency annually.

4.3 Training must include all aspects of the work involving HDs; the potential exposure involved and the steps necessary to prevent exposure, including the availability and location of Safety Data Sheets; the physical and health risks of the hazardous drugs used in the department; and the content of local policies and of other department policies dealing with hazardous drugs.

5. EXPOSURE REPORTING AND MEDICAL SURVEILLANCE

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

5.2 For eye exposure, the eyes should be immediately flushed with water or an approved saline eye wash for 15 minutes. During this treatment, others in the area should

assist and should also contact the hospital's employee health service for further instructions.

5.3 For skin exposure, the affected area should be immediately washed with soap and water for 15 minutes. Following washing, the employee should proceed to the hospital's designated employee health service for further evaluation.

5.4 For inadvertent injection with the needle remaining in the injection site, the plunger should be withdrawn to remove as much of the drug as possible. If the needle has already been withdrawn, a new, sterile 1-cc syringe with needle should be inserted into the site to aspirate as much drug as possible. The employee should then proceed to the hospital's employee health service for further evaluation and treatment.

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

5.6 The employee should notify his or her supervisor about the incident.

5.7 Medical surveillance programs are designed and implemented by Occupational Health. Surveillance programs involve assessment and documentation of symptom complaints, and physical findings. To determine whether there is a deviation from the expected norms, laboratory analysis, such as complete blood count or urinalysis may be done. Occupational Health will develop a follow-up plan for employees who have shown health changes suggesting toxicity or who have experienced an acute exposure.

6. RESPONSIBILITIES AND ACTIONS: Table 2

Responsible Entity	Action
Department of Pharmacy	• Provides oversight for HDs used at hospital
Departments	• Provides appropriate education and training for all personnel working with or having contact with HDs and all personnel who may be exposed to such drugs during the normal course of their work. • Ensures that training occurs before any employee begins working with these drugs. • Provides the required personal protective equipment. • Verifies staff competency annually. • Verifies periodically that employees are handling hazardous drugs in accordance with local policy. • Ensures that employees know about and have access to this plan at all times.
Employee	• Demonstrates competence in safe and proper handling procedures to the unit supervisor before working with HDs. • Administers hazardous drugs in accordance with this and other applicable policies. • Stores, transports, and otherwise handles hazardous drugs in accordance with local policy. • Cleans up spills properly. • Disposes of hazardous drugs and hazardous drug waste properly.
Employee health services	• Manages the medical surveillance program.
Safety	• Provides assistance to departments implementing local policy.

7. WORKER'S APPAREL AND PERSONAL PROTECTION:

Table 3- Worker's Apparel and Personal Protection

Tier 1- Antineoplastic HDs	Formulation / All Employees	Chemo gloves	Protective gown	Eye Protection	Respiratory protection (N95/ Respirator)	Chemo Nurse needed
	Intact tablet or capsule	single	no	no	no	no
	Cut Tablet	double	yes	no	no	no
	Oral liquid drug	double	yes	yes	no	no
	Topical drug	double	yes	**yes	yes	no
	Subcut, IM, IV, irrigation, inhalation.	double	yes	**yes	***yes	*Yes
Tier 2- Non-Antineoplastic HDs (all dosage formulations)	Employee	single	no	no	no	n/a
	Reproductive Employee	double	yes	no	***yes	n/a
Tier 3- Reproductive risk HDs (all dosage formulations)	Employee	single	no	no	no	n/a
	Reproductive Employee	double	yes	no	yes	n/a

*No Chemo nurse required for antineoplastic HD with NO manipulation (e.g. pre-filled syringe/kit – Lupron Depot)"

yes for splash risk * yes for aerosols

More PPE can be worn out of precaution, this is minimum required PPE

8. ATTACHMENTS

8.1 Attachment A- Tier 1 Antineoplastic HDs Injectable: IVPB, IVP,IM

8.2 Attachment B- Tier 1 Antineoplastic HDs Oral: Capsule, Tablet

8.3 Attachment C- Tier 2 Non-antineoplastic HDs

8.4 Attachment D- Tier 3 Reproductive risk HDs

9. REFERENCES

9.1 NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016. DHHS (NIOSH) Publication Number 2016-161 (Supersedes 2014-138).

9.2 2013 Updated American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety Standards Including Standards for the Safe Administration and Management of Oral Chemotherapy. Oncology Nursing Forum; Vol. 40, No. 3, May 2013.

9.3 USP <800> Hazardous Drugs – Handling in Healthcare Settings.

9.4 Relevant Policy- Nursing 703.01 Chemotherapy (Tier 1-Antineoplastic HDs) and Biotherapy Administration.

Document History:

Prior Release Dates: 2/15/17, 3/12/18		**Retire Date:** N/A	
Document Owner: Pharmacy Department		**Replaces Policy:** F618 6/11, F621 12/13	
Date Reviewed	**Reviewed By:**	**Revisions Made Y/N**	**Revision Description**
1/24/2019	Cancer Quality of Care Committee	Yes	Update tables 3, 4, 5 (Tier 1, 2 and 3) with new approval medications and non-formulary medications. Also added brand name to table 3, 4, 5.
2/19/2019	Pharmacy Review Committee	No	
3/20/2019	Nursing Policy and Procedure	Yes	Move HDs tables 3,4,5 to attachments.
3/4/19	P&T	No	Not Patient care does not need to go to MEC.

ATTACHMENTS

Attachment A- Tier 1 Antineoplastic HDs Injectable: IVPB, IVP,IM			
Adotrastuzumab (Kadcyla)	Dacarbazine	Histrelin (Supprelin LA; Vantas)	Pemetrexed (Alimta)
Amsacrine		Idarubicin (Idamycin PFS)	Pentostatin (Nipent)
Arsenic trioxide (Trisenox)	Dactinomycin (Cosmegen)	Ifosfamide (Ifex)	Pertuzumab (Perjeta)
Azacitidine (Vidaza)	Daunorubicin	Inotuzumab ozogamicin (Besponsa™)	Pralatrexate (Folotyn)
Bacillus Calmette Guerin (BCG)	Decitabine (Dacogen)	Irinotecan (Camptosar)	Romidepsin (Istodax)
Belinostat (Beleodaq)	Degarelix (Firmagon)	Ixabepilone (Ixempra Kit)	Streptozocin (Zanosar)
Bendamustine (Bendeka; Treanda)	Docetaxel (Taxotere)	Larotrectinib (Vitrakvi)	Temozolomide (Temodar)
Bleomycin	Doxorubicin (Adriamycin)	Leuprolide (Lupron; Eligard)	Temsirolimus (Torisel)
Bortezomib (Velcade)	Epirubicin (Ellence)	Mechlorethamine	Teniposide
Brentuximab vedotin (Adcetris)	Eribulin (Halaven)	Melphalan (Alkeran; Evomela)	Thiotepa (Tepadina)
Busulfan (Busulfex)	Etoposide (Toposar)	Methotrexate (Otrexup; Rasuvo)	Topotecan (Hycamtin)
Cabazitaxel (Jevtana)	Floxuridine	Mitomycin (Mutamycin)	Trabectedin (Yondelis®)
Carboplatin	Fludarabine	Mitoxantrone	Trimetrexate (Neutrexin)
Carfilzomib (Kyprolis)	Fluorouracil (Adrucil)	Moxetumomab pasudotox-tdfk (LUMOXITI)	Triptorelin (Trelstar Mixject; Triptodur)
Carmustine (BiCNU; Gliadel Wafer	Fulvestrant (Faslodex)	Nelarabine (Arranon)	Valrubicin (Valstar)
Cisplatin	Gemcitabine (Gemzar)	Nilotinib (Tasigna)	Vinblastine
Cladribine	Gemtuzumab ozogamicin (Mylotarg)	Olaratumab (Lartruvo)	Vincristine (Vincasar PFS)
Clofarabine (Clolar)	Glasdegib (Daurismo)	Omacetaxin (Synribo)	Vinorelbine (Navelbine)
Cyclophosphamide	Goserelin (Zoladex)	Oxaliplatin	Ziv-aflibercept (Zaltrap)
Cytarabine		Paclitaxel	

Attachment B-Tier 1 Antineoplastic HDs Oral: Capsule, Tablet			
Abiraterone (Yonsa; Zytiga)	Dacomitinib (Vizimpro)	Ivosidenib (Tibsovo)	Ponatinib (Iclusig) (TKI)
Afatinib (Gilotrif)	Dasatinib (Sprycel) (TKI)	Ixazomib (Ninlaro)	Procarbazine (Matulane)
Altretamine (Hexalen)	Enzalutamide (Xtandi)	Lapatinib (Tykerb) (TKI)	Regorafenib (Stivarga)(TKI)
Anastrozole (Arimidex)	Encorafenib (Braftovi)	Larotrectinib (Vitrakvi)	Ruxolitinib (Jakafi) (TKI)
Apalutamide (Erleada)	Erlotinib (Tarceva) (TKI)	Lenvatinib (Lenvima) (TKI)	Sonidegib (Odomzo)
Axitinib (Inlyta) (TKI)	Estramustine (Emcyt)	Letrozole (Femara)	Sorafenib (Nexavar) (TKI)
Baricitinib (Olumiant)	Etoposide	Lomustine (Gleostine)	Sunitinib (Sutent) (TKI)
Bexarotene (Targretin)	Everolimus (Afinitor; Afinitor Disperz; Zortress)	Lorlatinib (Lorbrena)	Talazoparib (Talzenna)
Bicalutamide (Casodex)	Exemestane (Aromasin)	Megestrol (Megace)	Tamoxifen (Soltamox)
Binimetinib (Mektovi)	Flutamide	Melphalan (Alkeran)	Temozolomide (Temodar)
Bosutinib (Bosulif) (TKI)	Fostamatinib (Tavalisse)	Mercaptopurine (6-MP; purinethol)	Thioguanine (Tabloid)
Busulfan (Myleran)	Gefitinib (Iressa) (TKI)	Methotrexate (Trexall; Xatmap)	Topotecan (Hycamtin)
Cabozantinib (Cometriq; Cabometyx) (TKI)	Gilteritinib (Xospata)	Mitotane (Lysodren)	Toremifene (Fareston)
Capecitabine (Xeloda)	Glasdegib (Daurismo)	Nilotinib (tasigna) (TKI)	Trametinib (Mekinist)
Ceritinib (Zykadia) (TKI)	Hydroxyurea (Hydrea; Droxia; Siklos)	Olaparib (Lynparza)	Trifluridine/Tipiracil (Lonsurf)
Chlorambucil (Leukeran)	Ibrutinib (Imbruvica) (TKI)	Palbociclib (Ibrance)	Vandetanib (Caprelsa) (TKI)
Crizotinib (Xalkori) (TKI)	Idelalisib (Zydelig)	Panobinostat (Farydak)	Vemurafenib (Zelboraf)
Cyclophospha mide (cytoxan)	Imatinib (Gleevec) (TKI)	Pazopanib (Votrient) (TKI)	Vismodegib (Erivedge)
Dabrafenib (Tafinlar)	Isotretinoin (Absorica; Amnesteem; Claravis; Myorisan; Zenatane)	Pomalidomide (Pomalyst)	Vorinostat (zolinza)

Attachment C- Tier 2 Non-antineoplastic HDs			
Abacavir (Ziagen)	Estrogen/Progesterone combinations	Mipomersen (Kynamro) (SQ)	Propylthiouracil
Alefacept (Amevive) (IV)	Estrogens esterified (Menest)	Mycophenolate mofetil (CellCept)(IV, PO)	Raloxifene (Evista)
Apomorphine (Apokyn) (subq)	Estropipate	Mycophenolic acid (Myfortic)	Rasagiline (Azilect)
Azathioprine (Azasan; Imuran) (PO, IV)	Fingolimod (Gilenya)	Nevirapine (Viramune)	Sirolimus (Rapamune)
Carbamazepine (TEGretol)	Fluoxymesterone	Ospemifene (Osphena)	Spironolactone (Aldactone)
Chloramphenicol (IV)	Ganciclovir (Cytovene) (IV)	Oxcarbazepine (Trileptal)	Tacrolimus (Prograf)
Cidofovir (IV)	Leflunomide (Arava)	Palifermin (Kepivance) (IV)	Teriflunomide (Aubagio)
Cyclosporine (Gengraf; Neoral; SandIMMUNE) (IV,PO)	Lenalidomide (Revlimid)	Phenoxybenzamine (Dibenzyline)	Thalidomide (Thalomid)
Deferiprone (Ferriprox)	Liraglutide recombinant (Saxenda; Victoza)(IM)	Porfimer (Photofrin)	Tofacitinib (Xeljanz)
Dexrazoxane (Totect; Zinecard) (IV)	Medroxyprogesterone acetate (IM,subq, PO)	Progesterone (PO, IM)	Valganciclovir (Valcyte)
Entecavir (Baraclude)	Methimazole (Tapazole)	Progestins	Zidovudine (Retrovir) (PO,IV)
Estradiol (PO, IM, transdermal, vaginal)			

Attachment D- Tier 3 Reproductive risk HDs

Acitretin (Soriatane)	Dronedarone (Multaq)	Macitentan (Opsumit)	Ribavirin (Copegus)
Alitretinoin	Dutasteride (Avodart)	Menotropins (Menopur)	Riociguat (Adempas)
Ambrisentan (Letairis)	Duvelisib (Copiktra)	Mifepristone (Mifeprex)	Topiramate (Topamax)
Bosentan (Tracleer)	Ergonovine/ methylergonovine (IM, IV)	Misoprostol (Cytotec)	Tretinoin
Cabergoline	Eslicarbazepine (Aptiom)	Mogamulizumab-kpkc (Poteligeo)	Ulipristal (Ella)
Cemiplimab-rwlc (Libtayo) (IV)	Finasteride (Proscar)	Nafarelin (Synarel) (nasal)	Vigabatrin (Sabril)
Cetrorelix (Cetrotide) (subq)	Ganirelix (subq)	Pasireotide (Signifor)	Warfarin (Coumadin)
Clomiphene (Clomid)	Gonadotropin,chorionic (Novarel) (IM)	Pentetate calcium trisodium (IV, inhalation)	Ziprasidone (Geodon) (IM,PO)
Choriogonadotropin (Ovidrel)(subq)	Icatibant (Firazyr) (subq)	Peginesatide	Zoledronic acid (Reclast) (IV)
Dinoprostone (Cervidil; Prostin E2)	Iobenguane (AdreView) (IV)	Plerixafor (Mozobil) (subq)	Zonisamide (Zonegran)
	Lomitapide (Juxtapid)		

RIVERSIDE UNIVERSITY HEALTH SYSTEM – MEDICAL CENTER
Housewide

	Document No: 867	Page 1 of 5
Title: Treatment of Gastrointestinal C. Difficile Infection in Adult Patients	**Effective Date:** 3/4/2019	☐ RUHS – Behavioral Health ☐ RUHS – Care Clinics ☒ RUHS – Medical Center ☐ RUHS – Public Health ☐ Departmental
Approved By:  Jennifer Cruikshank CEO/ Hospital Director		☐ Policy ☐ Procedure ☒ Guideline

1. DEFINITIONS

1.1 CDI. *Clostridioides difficile* infection.

1.2 HAI. Hospital-associated infection.

1.3 HO. Hospital onset.

1.4 ACG. American College of Gastroenterology.

1.5 PCR. Polymerase chain reaction

1.6 ID. Infectious disease

1.7 IDSA. Infectious Disease Society of America

1.8 HIV. Human Immunodeficiency Virus

1.9 ANC. Absolute neutrophil count

1.10 ICU. Intensive care unit

2. BACKGROUND

2.1 *Clostridioides difficile* infection (CDI) is a major concern for community hospitals and medical centers everywhere. Nationally, there has been a focus on antimicrobial stewardship programs to help minimize healthcare acquired infections by optimizing antimicrobial use. One of the major outcomes targeted by antimicrobial stewardship programs is the reduction of CDIs.

2.2 Adherence to treatment guidelines has shown significant improvement in CDI recurrence and mortality, and has been associated with a shorter length of stay in previous studies (5.2, 5.3). Unfortunately, adherence is inconsistent and standardized treatment is fairly uncommon. In one study, in the absence of a standardized treatment protocol or algorithm, only 51.7% of providers followed the 2010 IDSA guidelines (5.2)

3. PURPOSE

3.1 To provide guidance for the management of gastrointestinal *Clostridioides difficile* infections (CDI) in adult patients at RUHS-Medical Center.

3.2 To optimize and decrease variations in treatment through adherence to guideline-driven treatment.

3.3 To reduce CDI-related length of stay, recurrence, mortality and drug cost

4. GUIDELINE

4.1 Diagnosis

a. Confirm diagnosis via stool culture and glutamate dehydrogenase (GDH), C. diff toxin immunoassay and/or PCR.

b. CDI testing should only be performed on a patient with diarrhea (unformed stool).

c. A positive test for C. difficile without symptoms should not be treated.

d. Determine CDI severity as follows:

- Initial episode, non-severe
  - i. Diarrhea + Leukocytosis with WBC $\leq$ 15000 cells/mL AND SCr < 1.5mg/dL
- Initial episode, Severe
  - ii. Diarrhea + Leukocytosis with WBC $\geq$ 15,000 cells/mm^3 OR SCr > 1.5mg/dL
- Initial episode, fulminant
  - i. Any of the following attributable to CDI: Hypotension/shock, ileus or significant abdominal distention, mental status changes or end organ failure
- Recurrent CDI
  - i. Recurrence within 8 weeks of completion of therapy

4.2 Other considerations

a. Re-evaluate the need for antibiotics unless medically necessary as the use of antibiotics is associated with prolonged time to resolution and recurrence. Avoid the use of high-risk antibiotics such as clindamycin, fluoroquinolones, cephalosporins and broad spectrum penicillins.

b. Discontinue the use of acid suppressive medications especially proton pump inhibitors due to an increase in risk of recurrence associated with their use.

c. Avoid pro-motility and anti-peristaltic agents such as loperamide, diphenoxylate/atropine, etc.

d. After an initial positive result, repeat testing should NOT be performed to monitor treatment response or carriage.

e. Consider this a recurrence if it occurs within 8 weeks of completion of therapy for the previous occurrence.

4.3 Treatment. CDI Severity Treatment Chart

CDI TREATMENT CHART

RUHS Algorithm
Initial episode, NON-SEVERE
Vancomycin PO 125mg four times daily x 10 days
Initial episode, SEVERE
Vancomycin PO 125mg four times daily x 10 days
Initial episode, FULMINANT
Absence of ileus: Vancomycin 500 mg PO or NG tube QID **In the presence of ileus or toxic colon: Above + rectal instillation of Vancomycin 500 mg/100 mL QID + metronidazole 500 mg IV TID** **Surgical consultation**
Recurrent
First recurrence: Pulse/taper Vancomycin PO (*High risk patients – Consult ID) **Vanc 125 mg PO QID x 14 days (week 1 and 2)** **Vanc 125 mg PO BID x 7 days (week 3)** **Vanc 125 mg PO daily x 7 days (week 4)** **Vanc 125 mg PO every other day x 14 days (week 5 & 6), may extend up to 8 weeks.** **Second recurrence: ID Consult (for Fidaxomicin)** **Three or more recurrences: ID Consult and consider fecal transplant**

RUHS Treatment Algorithm for CDI
Initial episode, NON-SEVERE Leukocytosis with WBC ≤ 15000 cells/mL AND SCr < 1.5mg/dL
Vancomycin PO 125mg four times daily x 10 days
Initial episode, SEVERE Leukocytosis with WBC ≥ 15,000 cells/mm^3 OR SCr > 1.5mg/dL
Vancomycin PO 125mg four times daily x 10 days
Initial episode, FULMINANT Hypotension/shock, ileus or significant abdominal distention, mental status changes or end organ failure
Absence of ileus: Vancomycin 500 mg PO or NG tube QID In the presence of ileus or toxic colon: Above + rectal instillation of Vancomycin 500 mg/100 mL QID + metronidazole 500 mg IV TID Mandatory Surgical consultation
Recurrent
First recurrence: Pulse/taper Vancomycin PO (*High risk patients – Consult ID for Fidaxomicin) Vanc 125 mg PO QID x 14 days (week 1 and 2) Vanc 125 mg PO BID x 7 days (week 3) Vanc 125 mg PO daily x 7 days (week 4) Vanc 125 mg PO every other day x 14 days (week 5 & 6), may extend up to 8 weeks. Second recurrence: ID Consult (for Fidaxomicin) Three or more recurrences: ID Consult and consider fecal transplant *High risk patients – Immunocompromised – HIV (CD4 < 200 cells/mm3), ANC < 1000 cells/mm3, active chemotherapy, and organ or bone marrow transplant.

5. REFERENCES

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Document History:

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Date Reviewed	**Reviewed By:**	**Revisions Made Y/N**	**Revision Description**
5/21/2018	Antimicrobial Stewardship Subcommittee	Yes	Updated entire treatment section based on IDSA 2018 *C. difficile* treatment guidelines. Added other considerations section.
11/13/2018	Pharmacy Review Committee	No	
12/3/18	P&T	No	
1/22/19	PAC	No	
2/14/19	MEC	No	

RIVERSIDE UNIVERSITY HEALTH SYSTEM – MEDICAL CENTER
Housewide

	Document No: 869	Page 1 of 9
Title: Antimicrobial Prophylaxis for Surgery	**Effective Date:** 3/4/2019	☐ RUHS – Behavioral Health ☐ RUHS – Care Clinics ☒ RUHS – Medical Center ☐ RUHS – Public Health ☐ Departmental
Approved By:  Jennifer Cruikshank CEO/ Hospital Director		☐ Policy ☐ Procedure ☒ Guideline

1. PURPOSE

1.1 The purpose of these institutional guidelines is to establish evidence-based standards for surgical prophylaxis at RUHS Medical Center. The recommendations in this document are based on the 2013 consensus guidelines from American Society of Health-System Pharmacists (ASHP), the Infectious Diseases Society of America (IDSA), the Surgical Infection Society (SIS) and the Society for Healthcare Epidemiology of America (SHEA).

2. GUIDELINES

2.1 **Timing of administration** – Antibiotics should be administered to achieve highest tissue concentrations at the time of initial incision and throughout the duration of the surgery. Intra-operative redosing may be required to ensure adequate tissue concentrations if the duration of the procedure exceeds two half-lives of the drug, or if there is excessive blood loss (> 1500 mL) during the procedure.

a. Infusion of the prophylactic antibiotics must be initiated within 60 minutes of the procedure and completed prior to the first surgical incision.
b. Vancomycin and fluoroquinolone infusions should begin within 60-120minutes prior to the incision and completed prior to the first incision.
c. Redosing intervals should be measured from the time of administration of the pre-operative dose and not from the beginning of the procedure (refer to Table 2).
d. Redosing may not be needed in renal failure.

2.2 **Discontinuation of surgical prophylaxis**

a. Contaminated or dirty procedures – discontinue within 24 hours of surgical end time.
b. Clean and clean-contaminated procedures – discontinue after the surgical incision is closed in the operating room, even in the presence of a drain (exceptions include implant-based breast reconstruction, joint arthroplasty, and cardiac procedures).
c. Continuation of antibiotics beyond these recommended durations requires documentation of reason for continuation such as in the case of an active or suspected infection.

2.3 Use of Vancomycin

a. Routine use of vancomycin prophylaxis is not recommended for any procedure.
b. Vancomycin may be included in the regimen of choice when a cluster of MRSA cases (e.g., mediastinitis after cardiac procedures) or methicillin-resistant coagulase-negative staphylococci SSIs have been detected at an institution. Based on review of SSIs at RUHS Medical Center we do not recommend routine use of Vancomycin.
c. At this time we recommend the use of Vancomycin as an alternative for patients with a beta-lactam allergy.
d. The Infection Prevention Committee and Antimicrobial Stewardship Subcommittee will review hospital-specific surveillance data and update these guidelines on an annual basis to reflect changes in hospital flora based on these surveillance data.

Table 1: Antimicrobial choices

Procedure Type	Antimicrobials	Alternatives for a Beta-lactam Drug Allergy	Notes
Thoracic (non-cardiac)	Cefazolin	Vancomycin	
Vascular	Cefazolin	Vancomycin or Clindamycin	
Gastrointestinal Surgery			
Appendectomy	Cefoxitin	Clindamycin + Gentamicin[1] OR Ciprofloxacin + Metronidazole	Cefazolin + Metronidazole is another alternative
Colorectal (ex: APR, colon resection, colostomy)	Cefoxitin	Clindamycin + Gentamicin[1] OR Ciprofloxacin + Metronidazole OR	Alternatives: Cefazolin + Metronidazole, OR Ertapenem[2]
Hepatobiliary	Cefoxitin	Clindamycin + Gentamicin[1] OR Ciprofloxacin + Metronidazole	

Hernia repair with/without mesh	Cefazolin	Clindamycin	
PEG placement or revision	Cefazolin	Clindamycin or Vancomycin + Gentamicin or Ciprofloxacin	
Laparoscopy (diagnostic)	No antibiotics indicated unless high risk for infection		
Rectal exam/hemorrhoid surgery	No antibiotics indicated		
Urological Procedures			
Lower tract instrumentation with risk factors for infection (includes transrectal prostate biopsy)	Ciprofloxacin or Cefazolin	Clindamycin + Gentamicin[1]	
Clean without entry into the urinary tract or clean with entry into the urinary tract	Cefazolin (the addition of a single dose of an aminoglycoside may be recommended for placement of prosthetic material [e.g., penile prosthesis])	Clindamycin + Gentamicin[1]	
Clean-contaminated	Cefazolin + metronidazole OR cefoxitin	Ciprofloxacin + Metronidazole OR Gentamicin[1] + Clindamycin	
OB/Gyn			
Hysterectomy (vaginal or laparoscopic), pubovaginal sling	Cefazolin	Clindamycin or Vancomycin + Gentamicin[1]or Ciprofloxacin	
Cesarean delivery	Cefazolin		

PPROM (preterm premature rupture of membranes)	Ampicillin 2g IV Q 6h x 48h and Azithromycin 1g PO x 1 dose	Clindamycin + Gentamicin[1]	
Induced abortion/dilation and evacuation (D&C)	Doxycycline 100mg po 1 hour before procedure and 200mg after procedure and metronidazole 500mg po BID x 5 days		
Hysteroscopy (diagnostic, operative, endometrial ablation)	No antibiotics indicated		
Laparoscopy (diagnostic, operative, tubal sterilization)	No antibiotics indicated		
IUD Insertion	No antibiotics indication		
Neurosurgery	Cefazolin	Clindamycin or Vancomycin	

Cardiac Pacemakers AICD	Cefazolin	Clindamycin or Vancomycin	
Head & Neck Parotidectomy, thyroidectomy, tonsillectomy Clean with placement of prosthesis (excludes tympanostromy tubes) Clean-contaminated or Contaminated	 Prophylaxis not recommended Cefazolin Cefazolin + metronidazole	 Clindamycin Clindamycin	
Spine Surgery With or without instrumentation	Cefazolin	Clindamycin or Vancomycin	MRSA risk: Vancomycin + Cefazolin Beta-lactam allergy and MRSA risk: Vancomycin + Ciprofloxacin OR Clindamycin + Ciprofloxacin

Orthopedic Surgery			
Clean operations involving hand, knee, or foot and not involving implantation of foreign material	None		
Total Joint Replacement	Cefazolin	Vancomycin or clindamycin	MRSA risk: Add Vancomycin to Cefazolin
Open reduction of fracture/internal fixation	Cefazolin	Vancomycin or clindamycin	Beta-lactam allergy and MRSA risk: Vancomycin + Cipro OR Clindamycin + Cipro
Open Fractures			
Grade I	Cefazolin	Vancomycin	Duration of prophylaxis – 24 hours
Grade II	Cefazolin	Vancomycin	Duration of prophylaxis – 48 hours
Grade III (A,B,C)	Cefazolin + Gentamicin[1] For contamination with soil, water or fecal matter: Piperacillin/tazobactam	Vancomycin Levofloxacin + metronidazole If patient is intoxicated: Clindamycin + levofloxacin (metronidazole must not be used if patient is intoxicated due to risk for disulfiram reaction)	Duration of prophylaxis – 72 hours
Plastic Surgery Skin biopsy, mass excision	Cefazolin	Clindamycin or Vancomycin	

Notes:

1. Gentamicin for surgical antibiotic prophylaxis should be limited to a single dose given preoperatively. Dosing is based on the patient's actual body weight. If the patient's actual weight is more than 20% above ideal body weight (IBW), the dosing weight (DW) can be determined as follows: DW = IBW + 0.4(actual weight – IBW).
2. Routine use of ertapenem for surgical prophylaxis is controversial due to concerns over increase in resistant organisms. Recommended based on clinician or surgeon judgment as clinically indicated, OR if a patient is likely to be colonized by an ESBL-producing organism.

Table 2: Adults - Pre- and Intraoperative Antibiotic Dose and Redosing Intervals
NOTE: Many procedures require no post-op doses of antimicrobials. If desired, limit duration to < 24 hours post-closure.

Antibiotic	Adult Dose	Dosing in Renal Dysfunction	Redosing Interval in Hours	Maximum dose in a 24-hour period
Cefazolin	<120kg – 2 grams IV q 8h ≥ 120kg – 3 grams IV q 8h	CrCl < 30ml/min – 2g IV q 12h 3g IV q 12h CrCl < 10ml/min – Administer only pre-op dose	4	12 grams
Clindamycin	900mg IV q 8h	No adjustment	6	2700mg
Vancomycin	<80kg – 1 gram IV q 12h 80-99kg – 1.25 grams IV q 12h 100-120kg – 1.5 grams IV q 12h >120kg – 2 grams IV q 12h	CrCl < 50ml/min – administer pre-op dose x 1 only (Do not redose)	12	4 grams
Ampicillin/Sulbactam	3 grams IV q6h	CrCl < 30ml/min – 3g Q 12h CrCl < 10ml/min – 3g Q 24h	2	12 grams
Aztreonam	2 grams IV q 8h	CrCl < 30ml/min – 2g Q 12h CrCl < 10ml/min – 2g Q 24h	4	8 grams
Cefoxitin	2 grams IV q 6h	CrCl < 30ml/min – 2g IV q 12h CrCl < 10ml/min – 2g IV q 24h	2	8 grams
Ciprofloxacin	400 mg IV q 12h	CrCl < 30ml/min – 400mg q 24h	8	1200mg
Levofloxacin	500mg IV q 24h	CrCl < 30ml/min – Administer only pre-op dose	N/A (dosed q 24h)	
Metronidazole	500mg	No adjustment	8	1500 mg

Gentamicin[1]	5mg/kg (single dose)	If CrCl < 20ml/min – 2mg/kg as a single dose	N/A (dosed q 24h)	

1. Gentamicin for surgical antibiotic prophylaxis should be limited to a single dose given preoperatively. Dosing is based on the patient's actual body weight. If the patient's actual weight is more than 20% above ideal body weight (IBW), the dosing weight (DW) can be determined as follows: DW = IBW + 0.4(actual weight – IBW)

Table 3. Pediatric Dosing Intervals and Doses

PEDIATIC DOSING			
Antibiotic	Pediatric Dose	Maximum Dose	Re-dosing Interval
Ampicillin	50 mg/kg	2 g	2 hr
Ampicillin/ sulbactam	50 mg/kg ampicillin	3 g	2 hr
Cefazolin	30 mg/kg	< 120 kg: 2 g ≥ 120 kg: 3 g	4 hr
Cefoxitin	40 mg/kg	2 g	2 hr
Clindamycin	10 mg/kg	900 mg	6 hr
Gentamicin	2.5 mg/kg	120 mg	8 hr
Metronidazole	15 mg/kg	500 mg	6 hr
Vancomycin	15 mg/kg	1 g	n/a

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10/18/18	OR Committee	Yes	Changes based on CDC and SIS guidelines. Added pediatric dosing section
5/21/18	Antimicrobial Stewardship Subcommittee	No	
11/13/18	Pharmacy Review Committee	No	Update Peds dosing on ampicillin/sulbactam
12/3/18	P&T Committee	Yes	Changes to surgical prophylaxis discontinuation times – included section on dirty/contaminated procedures. Also addressed need to document continuation of antibiotics if extended beyond recommended durations. Updated OB/GYN section based on recommendations from the chair of OB. Ortho open fracture section updated to match Ortho's protocol. Other minor changes determined after P&T was adjourned.
1/22/19	PAC	No	
2/14/19	MEC	No	

RIVERSIDE UNIVERSITY HEALTH SYSTEM – MEDICAL CENTER

HOUSEWIDE

	Document No: 875	Page 1 of 10
Title: Penicillin Allergy Skin Testing Procedure (Pre-Pen®) for Inpatients	**Effective Date:** 3/4/2019	☐ RUHS – Behavioral Health ☐ RUHS – Care Clinics ☒ RUHS – Medical Center ☐ RUHS – Public Health ☐ Departmental
Approved By:  Jennifer Cruikshank CEO/ Hospital Director		☐ Policy ☒ Procedure ☐ Guideline

1. SCOPE

1.1 This procedure is applicable to adult patients admitted to RUHS Medical Center's Moreno Valley campus.

2. BACKGROUND

2.1 The reported rate of penicillin allergy is approximately 10%. Although, 80-90% of patients who report a penicillin allergy will have negative skin tests and are not at a risk of an IgE-mediated allergic reaction. True hypersensitivity to penicillin wanes with time, with more than half of skin test positive patients losing sensitivity by 5 years, and 80% by 10 years.

2.2 Patients labeled with a Penicillin allergy end up requiring alternatives that are broader spectrum with more adverse effects and may require more monitoring (ex: Vancomycin, fluoroquinolones, and aminoglycosides). Additionally, these patients end up being exposed to greater doses of these alternative antibiotics over time leading to an increased risk of multi-drug resistant pathogens (*C. difficile*, MRSA, VRE).

3. DEFINITIONS

3.1 EMR. Electronic medical record.

3.2 ID. Infectious Diseases service.

3.3 Pre-Pen©. Benzylpenicilloyl polylysine injection, a skin test antigen used in the assessment of sensitization to penicillin in patients suspected to have clinical penicillin hypersensitivity. Pre-Pen© (major determinant) identifies up to 90% of patients with an IgE-mediated penicillin allergy. When combined with Penicillin G K (minor determinant) testing the sensitivity increases to 97%. Pre-Pen© has a high negative predictive value. Less than 5% of patients who test negative to Pre-Pen© will develop a systemic reaction following penicillin administration. This risk is not higher than in patients without a history of penicillin allergy.

3.4 Pre-Pen© Kit. Prepared by dispensing RUHS Pharmacy, includes testing supplies and reagents.

3.5 PAST. Penicillin Allergy Skin Test.

3.6 Testing Team –Attending physicians who have been trained on penicillin allergy testing procedures. Vascular access nurses who are trained on penicillin allergy testing procedures.

a. Training and competency to perform this test includes: completion of mandatory didactic training -- a video presentation, and a practical training.

4. GUIDELINES

4.1 Ordering

a. PAST ordering is restricted to the attending physician, ID attending or antimicrobial stewardship pharmacist.

b. The ordering provider will assess patient eligibility prior to requesting the procedure.

4.2 Hours of service:

a. PAST is only available Monday – Friday between 8am – 4pm.

4.3 Patient eligibility:

a. Penicillin skin testing is not meant to delay antibiotic therapy in seriously ill patients requiring immediate treatment. For seriously ill patients, initial treatment with a non-penicillin alternate regimen should begin immediately if needed.
b. Assuming the patient is hemodynamically stable, penicillin skin testing may be initiated after the patient receives an initial dose of the alternate regimen.
c. Informed consent must be obtained from the patient/patient's representative prior to administration of the test.

d. Inclusion Criteria:

- Patients who report a penicillin allergy, but cannot recall their reaction and there is no objective data confirming the allergy.
- Patients receiving aztreonam instead of a beta-lactam for an infection.
- Patients have a documented or suspected allergy to penicillin class of antibiotics and are receiving alternate antibiotics where penicillin is the preferred class.
- Patient has amenable skin surface on the arms to perform the test accurately.
- Informed consent has been obtained from the patient or patient's representative and documented for the testing procedure.
- IgE mediated reactions typically occur within one hour of exposure to the offending agent, but may be delayed by several hours in rare cases. Patients should remain under observation for 24 hours post-test.

e. **Exclusion Criteria:**

- Patients who have demonstrated a systemic or marked local reaction to previous administration of Pre-Pen©.

- Patient known to be extremely hypersensitive to penicillin in less than or equal to (<) 5 years, i.e. anaphylactic reaction
- Recent anaphylaxis in the past 4 weeks to any cause.
- Use of antihistaminergic agents in the past 48 hours to 7 days (depends on agents – consult clinical pharmacist). This is not an absolute contraindication if the patient is able to mount a histamine response during scratch test.
  - i. 24 hours for chlorpheniramine maleate or fexofenadine
  - ii. 4 days for diphenhydramine hydrochloride
  - iii. 3 weeks for hydroxyzine or phenathiazines
- Use of systemic steroids in the past 7 days is not an absolute contraindication to PAST as long as patient is able to mount a histamine response during scratch test.
- Patients with clear histories of severe skin reactions such as Stevens-Johnson syndrome or toxic epidermal necrolysis.
- Patients where allergy is an adverse effect such as GI intolerance, and not a true allergy. There is no indication to perform PAST.
- Pregnant or nursing patients unless recommended for testing by Obstetrics/Gynecology Attending physician.

5. Procedure

5.1 The testing team will utilize the PAST order set to order all necessary supplies.

5.2 Pre-Pen® Kit and Supplies

- The following supplies are necessary for performing the penicillin skin test.
- Pre-Pen© (benzylpenicilloyl polylysine injection USP), 0.25 mL ampule
- Histamine control (1 mg/mL), 5 mL vial
- Sodium chloride 0.9% Preservative Free control, 10 mL vial
- Reconstituted penicillin G K 10,000 units/mL solution
- Duo-Tip® Test II device
- 0.5-1 mL syringes, 26-28 g needle
- Alcohol swabs, reaction ruler, timer, and pen

a. All major/minor penicillin determinants, positive controls, and negative controls will be compounded in the pharmacy under sterile conditions.
b. The necessary reagents will be sent together as a kit. The Pre-Pen© kit will be dispensed from the inpatient pharmacy and contain the following components:

- 0.1 mL Pre-Pen© (benzylpenicilloyl polylysine injection USP) in 2 separate 1 mL tuberculin syringes, 27 g needle

- 0.1 mL normal saline in 2 separate 1 mL tuberculin syringes, 27 g needle
- 0.1 mL penicillin G K 10,000 units/mL solution in 2 separate 1 mL tuberculin syringes, 27 g needle
- 0.1 mL Histamine control (Histatrol) in 1mL tuberculin syringe, 27 g needle
- Amoxicillin 250mg capsule

c. Rescue medications Kit – will be prepared by Pharmacy.

- EPINEPHrine 0.3 mg/0.3 mL autoinjection (Epi-Pen®)
- DiphenhydrAMINE 50 mg/mL vial 1 mL
- MethylPREDNISolone 40 mg/mL vial 1 mL

5.3 Precautions: Although rare, the Pre-Pen© does carry a risk of anaphylaxis. Prior to initiating the skin testing procedure, rescue medications including epinephrine, an injectable antihistamine, and a systemic corticosteroid must be ordered. This must remain an active order for 48 hours beginning at the time the Pre-Pen© order is entered.

5.4 See Appendix for procedures for performing PAST.

5.5 Post-Procedure Nursing Management

a. The patient's primary nurse should monitor the patient's vital signs every 30 minutes for the first hour, or per medication administration guidelines when the initial therapeutic dose of penicillin is given.

b. The primary nurse should also be informed to continue closely monitoring the patient for any clinical signs or symptoms of a possible adverse drug reaction as long as the patient is receiving penicillin treatment.

c. Any signs of a reaction should be reported to the ordering physician.

d. Completed documentation form with test results will be placed in the "Progress Notes" section of the patient's chart by the individual performing the test.

5.6 Reporting of Results & Documentation

a. The testing team member will chart the administration of the penicillin skin test on the MAR (medication administration record).

b. The results will be recorded in a progress note, which will include the skin prick and intradermal test date, time, and results as appropriate.

c. After consulting with the attending physician, the individual performing the test will modify the documented allergies in the EMR. The documented penicillin allergy will be removed and replaced with either "Negative Penicillin Skin Test," or "Positive Penicillin Skin Test," with a comment of who conducted the test, when it was conducted, and any details regarding the results of the test.

5.7 Patient Education

a. Upon completion of skin testing, each patient will receive education from a clinical pharmacist surrounding the results and significance of the test, including a standard patient result card to demonstrate to the primary care physician and preferred outpatient pharmacy.

b. Completion of education must be documented in the patient's EMR.

6. Pharmacy Preparation and Compounding

6.1 Penicillin G K Preparation

a. Reconstitute Penicillin G K to 1 million units per mL following the manufacturer's labeling.
b. Transfer 1 mL of the Penicillin G K solution to a sterile empty vial. Add 9 mL of normal saline to make a 100,000 unit/mL solution.
c. Transfer 1 mL of the Penicillin G K 100,000 units/mL solution to a sterile empty vial and add 9 mL of normal saline to make a 10,000 unit/mL solution. This is the solution to be used for both the prick (0.1mL) and intradermal testing (0.1mL).

6.2 Histamine Control (Histatrol©), Pre-Pen© Preparation, Normal Saline

a. Using 1 mL 27 g needle tuberculin syringes, withdraw ordered amount of Pre-Pen© (0.25 mL ampule), normal saline (10 mL vial), histamine control solution (Histatrol©), reconstituted Penicillin G K solution 10,000 units/mL into separate syringes. Label each syringe.

7. REFERENCES

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8. ATTACHMENT

8.1 Performing Test Procedures

Document History:

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Document Owner: Antimicrobial Stewardship Program	**Replaces Policy:** N/A

Date Reviewed	**Reviewed By:**	**Revisions Made?**	**Revision Description**
11/13/18	Pharmacy Review Committee	Yes	Updated testing team section.
12/3/18	P&T Committee	Yes	Changed PO Amoxicillin challenge to mandatory. Updated guidance on use of steroids and antihistamines. Updated anaphylaxis history section. Updated section on pregnant patients and other minor changes.
1/22/19	PAC	No	
2/14/19	MEC	No	

Performing Testing Procedure:

1. **STEP 1: Prick/Scratch Test**
   a. Sequential tests, spaced about 1 inch apart shall be made on either the volar surface of the forearm or the lateral aspect of the upper arm. Clean designated area with an alcohol swab and let dry.

   b. Using an ink pen, draw 3 vertical lines about 1 inch apart on the designated testing area of the arm, labeling the following in each of the 4 sections in order from left to right: "**PG**" (Penicillin G), "**PRP**" (PRE-PEN®), "**-**" (normal saline), "**+**" (histamine).

   c. Gather labeled syringes of the 4 solutions – Pre-pen©, diluted Penicillin G and saline negative control, and histamine positive control

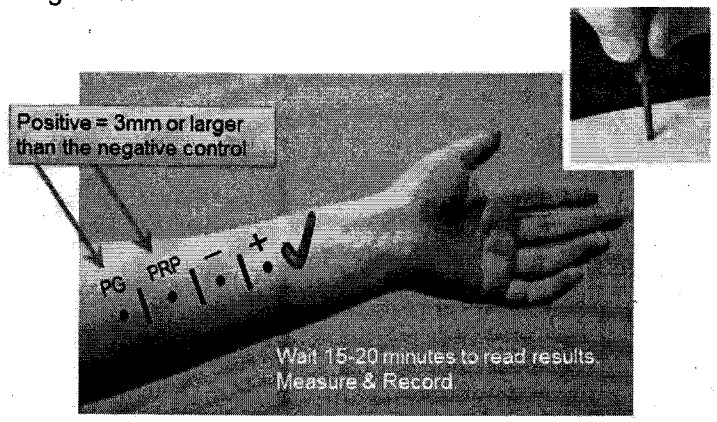
   d. Apply a small drop of each solution to the separate pre-marked sites on the testing arm (see Figure 1 below)

   e. Puncture the epidermis using a twisting motion at each drop site using the Duotip-Test II® device. Do not draw blood.

   f. Read the test in 15-20 minutes:

      - **Negative**: Change in diameter of wheal is **less than 3 mm** than that observed with the negative control. **Proceed to intradermal test.**
      - **Positive:** Change in diameter of wheal is **greater than 3 mm** that that observed with the negative control. As soon as a positive response is observed, the solution should be wiped off the skin. Stop. **Do not proceed to intradermal test.**
      - The **positive** control (histamine skin test) should be positive to ensure the results are not falsely negative **(wheal at least 5mm)**.
      - The **negative** control (saline skin test) should be negative. If a **wheal > 2-3mm** develops after 20 minutes, repeat prick skin test. Upon re-testing, if control still creates a wheal > 2-3mm after 20 minutes, discontinue test and notify the ordering physician.

      See Figure 1.



2. STEP 2: INTRADERMAL TEST

a. DO NOT PERFORM IF PUNCTURE TEST IS POSITIVE

b. Select 5 sites on either the volar surface of the forearm or the lateral aspect of the upper arm for intradermal testing. These sites should be on the opposite arm as the prick test, if possible.

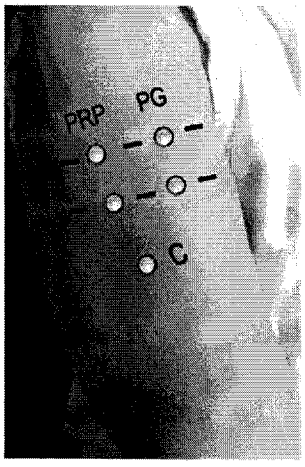
c. Using a 26-30 gauge, short bevel needle, intradermally inject 0.02 mL of Pre-Pen© solution twice (separate at least 2 cm apart). Mark the margins of the initial blebs with an ink pen.

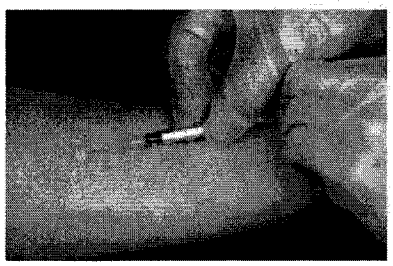
d. Using separate needles and syringes, intradermally inject diluted Penicillin G (0.02 mL = 200 units of penicillin) twice (separate at least 2 cm apart) and 0.02 mL of saline (separate at least 5 cm apart from other sites).

e. Read the test in 15 – 20 minutes:

- **Negative:** No increase in the original bleb and no greater reaction than the negative control site.
- **Positive:** Bleb or wheal increases > 2 mm from its original size or is > 2 mm larger than the negative controls. **Stop. Patient is NOT to receive penicillin.**
- If the negative control (saline) site exhibits a wheal > 2-3 cm, repeat the test. If the same reaction is observed, do not proceed further and consult an allergist.
- Indeterminate - wheal only slightly larger than initial injection bleb, with or without accompanying erythematous flare and slightly larger than the control site; OR discordance between duplicates. Intradermal test may be repeated.
- See Figure 2.

Figure 2:





- **Create bleb of 2-3 mm under skin (similar to PPD)**
- **Circle the perimeter of the bleb**

Wait 15-20 minutes to read results. Measure & Record.

Positive = Original bleb has GROWN 3mm or larger

3. **STEP 3: Oral Penicillin Challenge - Mandatory**

   a. Oral amoxicillin 250 mg PO dose x 1 administered in a monitored setting for 45-60 minutes if both puncture and intradermal tests are negative.

4. **Management of Reactions**

   a. Resuscitative equipment and rescue medications will be made available. Rescue medications will remain available at all times including the 15 minute post-administration observation period.
   b. Rescue medications– will be prepared by Pharmacy

      - EPINEPHrine 0.3 mg/0.3 mL autoinjection (Epi-Pen®)
      - DiphenhydrAMINE 50 mg/mL vial 1 mL
      - MethylPREDNISolone 40 mg/mL vial 1 mL

   c. For **mild reactions**: In case of isolated itching, flushing, hives, mild chest tightness, nausea, abdominal pain, or back pain, with normal vital signs, treat with IV diphenhydramine 50 mg.
   d. For **severe reactions**: In case of hypotension, throat swelling, wheezing/respiratory distress, or decreased oxygen saturation, **immediately alert the Rapid Response Team and supervising physician.** Treat with epinephrine 0.3 mg IM x 1, diphenhydramine 50 mg IV and methylprednisolone 40 mg IV.
   e. Patients who have either a mild or severe immediate allergic reaction to a penicillin skin test will be considered to have a positive test result. All penicillin drug allergies will remain active in their medication history.
   f. Report any adverse drug reactions via the online incident reporting system after the patient has stabilized and the physician has been made aware

5. **Interpretation of Test**

   a. Positive or indeterminate response to benzylpenicilloyl polylysine (Pre-Pen©) or Penicillin G:

      - If a patient has a positive response to benzylpenicilloyl polylysine, Penicillin G he/she should not receive any penicillin antibiotics unless given via a desensitization protocol.
      - Patients with indeterminate responses should also not receive penicillin antibiotics, although this may change based on a repeat test result.
      - Consider a graded challenge with a cephalosporin or carbapenem as the cross sensitivity rate is extremely low. Cephalosporins with side chains common to penicillin and aminopenicillins should still be cautiously avoided (i.e. cephalexin, cefadroxil, cefaclor).

   b. Indeterminate control response:

      - If patient has indeterminate control site reactions on two consecutive intradermal tests, the patient will be ineligible for further penicillin skin testing. Patient has a likely dermatographic reaction making interpretation of penicillin skin test results difficult. Any allergic history to a penicillin class drug will remain on the patient's profile. They should not receive any penicillin antibiotics unless given via a desensitization protocol.

- Consider a graded challenge with a cephalosporin or carbapenem as the cross sensitivity rate is extremely low. Cephalosporins with side chains common to penicillin and aminopenicillins should still be cautiously avoided (i.e. cephalexin, cefadroxil, cefaclor).

c. Negative response to benzylpenicilloyl polylysine or Penicillin G (and amoxicillin oral challenge if given):

- If the results of the benzylpenicilloyl polylysine or Penicillin G are negative, proceed with treatment with a penicillin agent.
- The patient may also receive other cephalosporins and carbapenems as long as they do not have a pre-existing documented allergy to these medications.

RIVERSIDE UNIVERSITY HEALTH SYSTEM– MEDICAL CENTER
Housewide

	Document No: 877	Page 1 of 3
Title: Immediate – Use Compounded Sterile Preparation (CSP)	**Effective Date:** 2/11/2019	☐ **RUHS – Behavioral Health** ☐ **RUHS – Care Clinics** ☒ **RUHS – Medical Center** ☐ **RUHS – Public Health** ☐ **Departmental**
Approved By:  Jennifer Cruikshank CEO/ Hospital Director		☒ **Policy** ☐ **Procedure** ☐ **Guideline**

1. SCOPE

1.1 This policy applies to any non-hazardous compounded sterile preparation (CSP) that is compounded outside of an ISO class 5 environment.

1.2 The immediate-use provision is intended only for those situations where there is a need for emergency or immediate patient administration of a CSP.

2. DEFINITIONS

2.1 CSP: Compounded sterile preparation

2.2 ISO Class 5: not more than 3520 particles 0.5mm and larger size per cubic meter of air. Primary Engineering Control (PEC) is a device that provide an ISO Class 5 or better. Examples of PEC devices include, but are not limited to, laminar airflow workbenches, biological safety cabinets, compounding aseptic isolators and compounding aseptic containment isolators.

2.3 Beyond-use date (BUD): hour and date after which a CSP must not be used or administration must not begin. The BUD is determined from the date/time that preparation of the CSP is initiated.

2.4 Hazardous drug: Any drug identified by at least one of the following six criteria:

- Carcinogenicity
- Teratogenicity or developmental toxicity
- Reproductive toxicity in humans
- Organ toxicity at low doses in humans or animals
- Genotoxicity
- New drugs that mimic existing hazardous drugs in structure or toxicity

Refer to HW 851 policy for list of hazardous drugs.

3. POLICY

3.1 The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile non-hazardous products from the manufacturers' original containers and not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/ device.

3.2 The compounding procedure is a continuous process not to exceed 1 hour, unless required for the preparation.

3.3 During preparation, aseptic technique is followed and, if not immediately administered, the CSP is under continuous supervision to minimize the potential for contact with non-sterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces. (Refer to Elsevier Performance Manager-Clinical Skills for how to prepare CSP outside of ISO class 5 environment.)

3.4 Administration begins not later than 1 hour following the start of the preparation of the CSP.

3.5 For single patient use

3.6 Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing:

a. patient identification information

b. names and amounts of all ingredients

c. name or initials of the person who prepared the CSP

d. 1-hour BUD and time.

3.7 If administration has not begun within 1 hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded.

4. REFERENCES

4.1 Board of Pharmacy, California Code of Regulation, Title 16, Article 4.5, Section 1751.8

4.2 Elsevier Performance Manager-Clinical Skills

4.3 HW 852 Medication Administration

4.4 HW 851 Handling of Hazardous Medications

Document History:

Prior Release Dates: 6/93, 4/97, 9/97, 3/00, 3/03, 12/07, 12/10, 1/14	**Retire Date:** N/A
Document Owner: Pharmacy	**Replaces Policy:** B213

Date Reviewed	Reviewed By:	Revisions Made Y/N	Revision Description
9/11/2018	Pharmacy Review Committee	Y	Changed to House-wide. Changed policy name. Added definitions. Deleted procedures, use Elsevier for clinical skills, Revised policy according to current practices and regulations. Added references.
10/9/2018	Nursing P&P	Y	Approved on e-vote
11/5/2018	P&T	Y	Added for single patient use (3.5)
12/4/18	PAC	N	
1/10/19	MEC	N	

RIVERSIDE UNIVERSITY HEALTH SYSTEM – MEDICAL CENTER
Housewide

	Document No: 900	Page 1 of 1
Title: EPOC Blood Analysis System Downtime Guidelines for Testing Blood Glucose	**Effective Date:** 2/11/2019	☐ **RUHS – Behavioral Health** ☐ **RUHS – Care Clinics** ☒ **RUHS – Medical Center** ☐ **RUHS – Public Health** ☐ **Departmental**
Approved By:  Jennifer Cruikshank CEO/ Hospital Director		☐ **Policy** ☐ **Procedure** ☒ **Guideline**

1. DEFINITIONS

1.1 STAT: STAT is used as a directive by medical personnel during an emergency situation; meaning, immediately.

2. GUIDELINES

2.1 This guideline will serve as a quick reference guide when requesting "Stat" Laboratory testing when the EPOC Blood Analysis System cannot be used for patient testing of blood glucose.

2.2 Collect venous or arterial blood in a green top tube.

2.3 Complete request for "STAT" random glucose using Lab requisition Form # 78.

2.4 Deliver the specimen and requisition directly to the Chemistry Department in the lab and give directly to the Clinical Lab Scientist (CLS) in the chemistry department.

2.5 Do not deliver the specimen to the main lab accessioning area.

2.6 The blood specimen will be immediately accessioned by the Chemistry CLS into the Lab computer, tested and upon completion the Glucose result will immediately be called to the requesting nursing unit.

3. ATTACHMENTS

3.1 General Lab Form #78

Document History:

Prior Release Dates: 5/4/2016	**Retire Date:** N/A
Document Owner: Laboratory	**Replaces Policy:** N/A

Date Reviewed	Reviewed By:	Revisions Made Y/N	Revision Description
1/16/2019	Director, Lab	N	
1/17/2019	Point of Care Coordinator, Lab	N	

UNLISTED TESTING

Do Not Use the space below for Blood Bank, Microbiology or Path Requests. Use appropriate forms. DO NOT ABBREVIATE .

The above area is for ADDRESSOGRAPH use only. PLEASE do not write or stamp over Patient Information.

PRIMARY ICD	SECONDARY ICD

RIVERSIDE COUNTY REGIONAL MEDICAL CENTER
Department of Clinical Lab & Anatomic Pathology
John W. Koett, MD, PhD, Chairman
Moogil Choe, MD, Assoc Chairman
Gary R. Strickland, MD, Staff
26520 Cactus Avenue
Moreno Valley, Ca. 92555
Phone: 951/486-5300
Fax: 951/486-5270

DR LAST NAME PLEASE PRINT REQUIRED

DR FIRST NAME PLEASE PRINT REQUIRED

PERSON FILLING OUT FORM PLEASE PRINT REQUIRED

Ord Date:	Clinic or Unit/Room:
Draw/Collection Date:	
Draw/Collection Time:	Collected by:

PANELS

- **Electrolyte** (CO2, Cl, Na, K)
- **Basic Metabolic Panel** (Ca, CO2, Cl, Creat, Glu, Na, K, BUN)
- **Comp Met Panel** (Cl, Na, K, Gluc, Bun, Creat, TP, Alb, Ca, Alk Phos, AST, ALT, T. Bili)
- **Hepatic Function Panel** (TProt, Alb, T. & D. Bili, Alk Phos, ALT, AST)
- **Renal Panel** (Alb, Ca, CO2, Cl, Creat, Gluc, Phos, K, Na, BUN)
- **Acute Hepatitis Panel** (Hep B Surf Ag, Hep C Ab, Hep A Ab IgM, Hep B Core Ab IgM)
- **Lipid Panel** (Chol, Trig, HDL, LDL, VLDL) **14 Hrs Fasting**

CARDIAC PANEL

- Includes CK, Total; CK-MB, Relative Index, Troponin I
  Requires Gold or Red plus a Green Top

One form #630 for each unit of blood requested (4) MUST accompany each of the panel orders below.

- **TRAUMA BASIC** (BasicMetPanel, CBC, Alcohol, PT, PTT, Serum Osmolality, Patient ABORh, Antibody Screen)
- **TRAUMA A** (BasicMetPanel, CBC, Alcohol, PT, PTT, Serum Osmolality, Patient ABORh, Antibody Screen, Crossmatch 4 Units)

PreNatal Panel A Requires BB Form #630

- **PreNatal Panel A** (ABORh, Antibody Screen, CBC, Rubella, RPR, HBSAg
- **PreNatal Panel B** (HIV Screen, Sickle Cell Screen)

Diabetic Panels - PATIENTS MUST BE FASTING 14 HOURS

- **FASTING Comp** - CompMetPanel w FBS, Hemoglobin A1c, Lipid Panel, Urine Microalbumin
- **FASTING Basic** - BasicMetPanel w FBS, Hemoglobin A1c, Lipid Panel, Urine Microalbumin

THE TWO PANELS BELOW ARE TO BE ORDERED ONLY ON INFANTS LESS THAN 3 MONTHS OLD

- **CompInfPanel** (CO2, Cl, Na, K, Gluc, Bun, Creat, Ca, TP, Alb, Ca, Alk Phos, ALT, AST, Neonate Bili which inc D.Bilirubin)
- **HepInfFunctPanel** (T Prot, Alb, Neo Bili, Alk Phos, ALT, AST)

CHEMISTRY

- Amylase
- Lipase
- Ck-Total
- CK-MB *(Green Top)*
- Troponin I *(Green Top)*
- Random Glucose
- Fasting Glucose
- 2 hr PP Glucose
- 1 Hr Glucose Chall
- CO_2
- Chloride
- Na, Sodium
- K, Potassium
- BUN
- Creatinine
- Bilirubin, Total
- Bilirubin, Direct
- Bilirubin, T. Cord
- **Bili, Neonate (T&D)**
- Alk Phos
- AST (SGOT)
- ALT (SGPT)
- GGT
- LDH
- Calcium
- Phos
- Magnesium
- Uric Acid
- T. Protein
- Albumin
- Alcohol, Ethyl
- Ferritin
- **Iron, Total**
- **TIBC (Inc % Sat)**
- Ammonia
  Green in ice & water
- Osmolality, Serum
- Osmolality, Urine
- Acetone, Qual
- ß Oxybutyrate
- Lactic Acid
  Gray in ice & water
- Hemoglobin A_1C
- Cholesterol (Total)
- Triglyceride
- HDL Cholesterol
- LDL Cholesterol
- VLDL Cholesterol

URINE DRUG SCREEN

- Drug Screen Panel, EIA

TOLERANCES

- *3* (Hour Glucose Tol)
- *5* (Hour Glucose Tol)

HEMATOLOGY

- CBC (Includes Diff)
- CBC with Retic (Includes Diff)
- Hemogram
- H & H
- Platelet Count
- Retic Count
- Sed Rate (ESR)
- Eosinophil Count
- Malaria Smear
- Kleihauer-Betke
- Sickle Cell Screen
- Blood Smr Path Revw

COAGULATION

- PT, Protime and INR
- PTT
- Fibrinogen
- D-dimer, Quant
- Mixing Studies
- Ivy Bleeding Time

URINALYSIS

- Screen
- Urine Pregnancy Test
- Microalbumin
- Myoglobin Screen
- Spec Grav Only, Urine

THERAPEUTIC DRUGS

- Acetaminophen
- Carbamazepine
- Digoxin (Dig)
- Depekene (Valproic Acid)
- Gentamicin, Peak
- Gentamicin, Random
- Gentamicin, Trough
- Lithium
- Phenobarb
- Phenytoin (Dilantin)
- Salicylate
- Theophylline
- Tobramycin, Peak
- Tobramycin, Random
- Tobramycin, Trough
- Vancomycin, Peak
- Vancomycin, Random
- Vancomycin, Trough

HEPATITIS

- Hep B Surf Ag
- Hep B Surf Ab
- Hep B Core Ab, Total
- Hep B Core Ab, IgM
- Hep A Ab, IgM Acute
- Hep A Ab, Total Conv
- Hepatitis C Ab

THYROID / ENDOCRINE

- T4, Total
- T4, Free
- TSH (Ultra-Sensitive)
- T3, Total
- ß HCG, Quant
- ß HCG, Qual (Pregnancy)
- PSA (Total)

SEROLOGY / IMMUNO

- ANA (Anti-Nuclear Ab)
- Anti-DNA DS
- Anti-Mitochondrial
- Anti-Smooth Muscle
- C3 Complement
- C4 Complement
- C Reactive Protein
  Green Top
- HIV Screen
- Monospot
- Prealbumin
- Rheumatoid Factor, Qual
- RPR
- Rubella, Manual
- Rubeola
- Varicella

BODY FLUID STUDIES

SPECIMEN TYPE:

Timed for: Hours

24° Vol:

- Amniostat
- Creat, Ur, Rand
- Creat, Ur, Timed
- Fetal Fibronectin
- K, Ur, Rand
- K, Ur, Timed
- Na, Ur, Rand
- Na, Ur, Timed
- T. Prot, Ur, Rand
- T. Prot, Ur, Timed
- CSF Cell Count
- CSF Glucose
- CSF Protein
- Cell Count, Body Fluid
- TP Body Fluid
- Semen Analysis, Fertility
  Requires additional form
- Semen Analysis, Post
- Crystal ID
- Reducing Sub-Stool
- pH, Body Fluids
- pH, Stool
- pH, Urine Only
- Sp Grav, Body Fluid Only

RIVERSIDE UNIVERSITY HEALTH SYSTEM – HOSPITAL BASED CLINICS
Housewide

	Document No: 1101	Page 1 of 5
Title: Practitioner Notification and Accountability of Incomplete and/or Delinquent Medical Records in Ambulatory Care	**Effective Date:** 3/4/2019	☐ **RUHS – Behavioral Health** ☒ **RUHS – Hospital Clinics** ☐ **RUHS – FQHC's** ☐ **RUHS – Medical Center** ☐ **RUHS – Public Health** ☐ **Departmental**
Approved By:  Jennifer Cruikshank CEO/Hospital Director		☒ **Policy** ☐ **Procedure** ☐ **Guideline**

1. SCOPE

1.1 To define the expectations for completion of ambulatory clinic, including hospital based specialty clinic, medical records for Riverside University Health System providers.

1.2 To specify the conditions under which reasonable and appropriate sanctions may be taken for failure to complete medical records as required by federal, state, and RUHS requirements.

1.3 To establish a procedure for corrective action when a member of the Medical Staff, including Licensed Independent Practitioners (LIP), has become delinquent in completion of medical records.

2. DEFINITIONS

2.1 EHR – Electronic Health Record

2.2 HIM – Health Information Management

2.3 LIP - An individual as permitted by law and regulation and also by the organization, to provide care and services without direction or supervision within the scope of the individual's license and consistent with the privileges granted by the organization. Ex: Physician, licensed physician resident, physician assistant, and/or advanced practice nurse.

2.4 MSO – Medical Staff Office

2.5 Day – For the purpose of this policy, "day" is a calendar day.

3. POLICY

3.1 The patient's clinic medical record should be completed and signed electronically in the Electronic Health Record (EHR), or signed legibly in ink during EHR down-time, by those providers involved in the patient's care within 72 hours of each encounter. The Medical Center will enforce consequences if encounters are not closed at 14 days.

3.2 The ambulatory clinic record should include:

a. Updated demographic data;

b. Clinical notes, including the dates and time of visit(s), with the patient's history, physical examination, and all information necessary to support a well-informed assessment and treatment plan;

- Treatment recommendations should include any notation of prescriptions and/or diet instructions given, if applicable, and self-care instructions;

c. Summary list, as appropriate, including chronic problems, medications, and allergy documentation;

d. Consultation reports;

e. Reports of all ancillary services, including laboratory tests, medical imaging examinations, and pathology reports;

f. If a procedure was performed, a well-documented note summarizing the essential details of the procedure, including the techniques used, the findings, and tissue removed or altered, as appropriate, and medications given;

g. Referral information from other providers;

h. Consent forms.

i. Resident notes associated with the encounter.

j. Telemedicine encounters and electronic consults

3.3 RUHS will utilize standardized Health Information Management (HIM) procedures for determining incomplete medical records, for determining when an incomplete medical record has reached a delinquent status, and for documentation requirements.

4. PROCEDURE

4.1 Medical Records are expected to be completed in accordance with policy to facilitate care coordination.

4.2 Members of the Medical Staff (including all LIP) shall be responsible for completion of the medical record documentation for the clinic visit.

4.3 Ambulatory clinic encounter documentation:

a. An ambulatory clinic note is required for each patient encounter by:

- Direct entry into the EHR, or
- Handwritten, if during EHR down-time, by the use of an approved clinic form, which can be scanned into the EHR.

b. For each patient encounter, a licensed provider's documentation must be in the record and closed within 14 days of the encounter.

- Clinic notes forwarded for an Attending physician's co-signature, also require closure 14 days after the encounter.

4.4 Members of the Medical Staff (including all LIP) shall receive notification from the Health Information Management (HIM) Department of medical records deficiencies prior to the time the records will be considered delinquent.

4.5 If at any time the practitioner contests the incomplete or delinquent medical record, it is the responsibility of the practitioner to contact the HIM Department promptly. HIM representatives will investigate the practitioners claim(s), taking into consideration any mitigating circumstances, and make a final determination. The timeline for pending disciplinary action of the provider will be stopped until such determination is made.

4.6 When a provider is identified as out of compliance with respect to completion of clinic notes (including progress notes and ambulatory clinic procedure notes) the enforcement process with proceed as follows:

a. **Time = day 1:** The encounter is marked as incomplete by HIM. No specific notification of the provider is provided beyond flagging the electronic medical record (within EPIC in-basket).

b. **Time = day 3:** Medical staff expectation is to have the medical record completed by this time.

c. **Time = day 10:** after the provider is identified as non-compliant with medical records completion, HIM will evaluate the medical record to confirm responsibility and, if appropriate, will establish contact with the provider via email, pager, text messaging or phone call, as well as contact the Nursing Coordinator and/or Department Secretary, Clinic Physician Lead and/or Department Chair via email, to inform them of the delinquent medical record and potential for suspension if the medical record is not completed within 4 days from notification by HIM. HIM may reassign the delinquent medical record to an appropriate Medical Director, Department Chair (or Vice Chair), or another provider for administrative closure.

d. **Time = day 14:** after the provider is identified as non-compliant and delinquent with medical records completion, HIM will notify the provider, Clinic Physician Lead, Ambulatory Quality Director and/or the provider's Department Chair (and/or Vice Chair) of the eminent suspension. If the medical record is not immediately completed, HIM will notify the MSO suspension should be enacted.

4.7 Once the suspension of privileges for delinquent medical records has been initiated, the Medical Staff Administration (MSA) will:

a. Contact the provider via phone call

b. Forward a suspension letter to the provider via email

c. Send a certified copy of the suspension letter to the provider via USPS.

d. Notify the provider's Department Chair (and/or Vice Chair).

e. Notify the Clinic Physician Lead (if different than above)

f. Notify the Ambulatory Quality Director

g. Notify the President of the Medical Staff,

h. Notify the Credentials Committee Chair,

i. If applicable, notify the Perioperative Associate Chief Nursing Officer.

j. If applicable, unless directed otherwise by the medical staff president all elective surgeries scheduled by the provider for the day after the suspension begins will be cancelled.

4.8 While under suspension of privileges for delinquent medical records, no new non-emergent procedures or clinic days will be allowed. However, the provider may finish current clinic day if there is no the provider to cover.

4.9 The medical staff president may, on a case by case basis, decide to withhold suspension for delinquent records in emergent situations as necessary. No suspension shall compromise patient safety.

4.10 The practitioner will remain on suspension until the practitioner has completed all his/her delinquent medical records.

4.11 Once all delinquent records are completed, a monetary fine will be applied prior to reinstatement of privileges. Fine amounts payable to the Medical Staff Administration (MSA), on a rolling calendar year:

a. 1st suspension: $50

b. 2nd suspension: $100

c. 3rd suspension: $200

d. Fine continues to double

4.12 Upon completion of all delinquent records and fine has been paid, the Medical Staff Administration (MSA) will notify the provider and personnel listed in section 4.7, via email, pager, text messaging, or phone call, of reinstatement.

4.13 Exceptions may be made by the Medical Executive Committee for providers with delinquent medical records who are ill, on vacation, sabbatical, or another excused absence. In the providers absence, the delinquent medical records shall be re-assigned to the Department Chair (or Vice Chair) or another provider within the providers Department for administrative closure

5. MONITORING

5.1 The Health Information Management Department shall conduct a monthly review encompassing all clinical services to ascertain chart completion compliance. Results shall be reported to the Medical Informatics Committee, Professional Practice Evaluation Committee, and Medical Executive Committees for action.

6. DISCIPLINARY SANCTIONS

6.1 Enforcement of sanctions will be under the direction of the Department Chair (and/or Vice Chair), President of the Medical Staff, and Medical Executive Committee (MEC)

Document History:

Prior Release Dates: Dec 2018	**Retire Date:** N/A
Document Owner: Ambulatory Care Committee Co-Chairs	**Replaces Policy:** N/A

Date Reviewed	Reviewed By:	Revisions Made?	Revision Description
12/18/18	Ambulatory Care Committee	Yes	Added "for administrative closure to 4.8
1/10/19	Medical Executive Committee	Yes	Adjusted 4.7-4.12 to mirror the inpatient policy already in place
2/5/19	Policy Approval Committee	Yes	Correct allied health professionals to LIP; make scope Hospital based clinics; define "day"