SUBMITTAL TO THE RIVERSIDE UNIVERSITY HEALTH SYSTEM MEDICAL CENTER GOVERNING BOARD COUNTY OF RIVERSIDE, STATE OF CALIFORNIA

ITEM: 18.1
(ID # 27300)
MEETING DATE:
Tuesday, March 18, 2025

FROM : RUHS-MEDICAL CENTER

SUBJECT: RIVERSIDE UNIVERSITY HEALTH SYSTEM – MEDICAL CENTER: Approve Policies, All Districts. [Total Cost $0]

RECOMMENDED MOTION: That the Board of Supervisors:

1. Review and approve the attached Medical Center and Clinics Policies.

ACTION:Consent

Jennifer Cruikshank
Jennifer Cruikshank, Chief Executive Officer – Health System 3/5/2025

MINUTES OF THE GOVERNING BOARD

On motion of Supervisor Spiegel, seconded by Supervisor Gutierrez and duly carried by unanimous vote, IT WAS ORDERED that the above matter is approved as recommended.

Ayes:	Medina, Spiegel, Washington, Perez and Gutierrez
Nays:	None
Absent:	None
Date:	March 18, 2025
xc:	RUHS-MC

Kimberly A. Rector
Clerk of the Board
By: _____
Deputy

SUBMITTAL TO THE RIVERSIDE UNIVERSITY HEALTH SYSTEM MEDICAL CENTER GOVERNING BOARD OF DIRECTORS COUNTY OF RIVERSIDE, STATE OF CALIFORNIA

FINANCIAL DATA	Current Fiscal Year:	Next Fiscal Year:	Total Cost:	Ongoing Cost
COST	$ 0	$ 0	$ 0	$ 0
NET COUNTY COST	$ 0	$ 0	$ 0	$ 0
SOURCE OF FUNDS: N/A			Budget Adjustment: No	
			For Fiscal Year: 24/25	

C.E.O. RECOMMENDATION: Approve

BACKGROUND:

Impact on Citizens and Businesses

The Riverside University Health System Medical Center (RUHS MC) is a licensed and accredited acute care hospital serving the needs of County residents since 1893. RUHS MC currently has two campuses – one in Moreno Valley and one on County Farm Road in the City of Riverside.

As an acute care hospital RUHS MC is required by the State of California to have a "governing body" separate from its administrative leaders and medical staff leadership. The "governing body" is "the person, persons, board of trustees, directors or other body in whom the final authority and responsibility is vested for conduct of the hospital." 22 CCR §70035. (See also 42 CFR 482.12 and Joint Commission Standard LD.01.03.01) The Board of Supervisors serves as the "governing body" for the hospital.

Various regulatory requirements mandate that the Governing Board participate in the leadership and decision-making of the Medical Center by reviewing and approving its policies relating to certain topics.

RUHS-MC is committed to furnishing a safe, accessible, effective and efficient environment consistent with its mission, services and applicable governmental mandates. This includes fostering the protection, safety and well-being of patients, employees, staff and visitors during natural or man-made disasters and ensuring to the greatest extent possible, adherence to our social responsibility and commitment to the community.

Impact on Residents and Businesses

The RUHS Medical Center offers a 439-bed providing adult, Pediatric and Neonatal Services, including a Level 1 Trauma Center, the county's only Pediatric Intensive Care Unit, a Stroke Center, with over 40 specialty care clinics, as well as a Medical and Surgical Center featuring state-of-the-art Outpatient Surgical, Diagnostic and Imaging Equipment, Rehabilitation Services,

and an Outpatient Pharmacy. The RUHS Emergency Treatment Services/Inpatient Treatment Facility at the Arlington Campus located in Riverside is a 77-bed inpatient Psychiatric Treatment Facility. The integrated healthcare continuum is fortified with 14 RUHS-CHCs conveniently located throughout the county which work in close partnership with RUHS-BH and RUHS-PH to offer access to comprehensive high-quality and integrated primary, Behavioral Health, Specialty Care, Dental Care and Health Promotion services.

Training future healthcare leaders is fundamental to our commitment to serving our community as well as our mission as a safety net institution. An efficient, well-functioning medical center providing care of high quality creates many positive benefits for Riverside County citizens and its businesses.

ATTACHMENTS:
Attachment A: RUHS Policy List 10.01.24 to 12.31.24
Attachment B: RUHS Policies 10.01.24 to 12.31.24

Jacqueline Ruiz, Principal Analyst 3/11/2025 Gregg Gu, Chief Deputy County Counsel 3/5/2025

RUHS Medical Center Policies Approved 10/1/2024 through 12/31/2024

#	Name	Version Effective Date
1	HW 101 Just Culture.pdf	11/22/2024
2	HW 105 Policy Program Management Guidelines.pdf	12/12/2024
3	HW 1304 Transfer and Repatriation Agreement for Higher Level of Care HLOC Trans	12/5/2024
4	HW 456 Care for the Caregiver after an Adverse or Harm Event.pdf	11/4/2024
5	HW 505 Incarcerated Patient Guidelines for Staff.pdf	12/10/2024
6	HW 600.1 Pediatric Patient Admission.pdf	12/10/2024
7	HW 603.7 Regional Analgesia Care via Catheter.pdf	11/22/2024
8	HW 613 Methotrexate Administration and Management for Treatment of Ectopic Pre	12/6/2024
9	HW 626 Abuse Neglect Violence Assessment Reporting.pdf	12/10/2024
10	HW 630 Restraints and Seclusion.pdf	12/6/2024
11	HW 668 Suicide Prevention.pdf	12/6/2024
12	HW 804 High Alert Medication.pdf	11/22/2024
13	HW 811 Automated Dispensing System Pyxis.pdf	11/22/2024
14	HW 820 Inpatient Penicillin and Cephalosporin Direct Oral or Graded Oral Challeng	11/22/2024
15	HW 828 Smart Infusion Pump System.pdf	11/22/2024
16	HW 836 Look Alike Sound Alike Medication Error Prevention.pdf	11/22/2024
17	HW 874 Hand Hygiene and Garbing for Sterile Compounding.pdf	11/22/2024
18	HW 877 Immediate Use Compounded Sterile Preparation CSP.pdf	11/22/2024
19	HW 893 Therapeutic Use of Hypertonic Saline.pdf	12/6/2024
20	HW 894 Pending Pharmacotherapeutic Management of Patients with AWS.pdf	11/22/2024

RIVERSIDE UNIVERSITY HEALTH SYSTEM –

MEDICAL CENTER, COMMUNITY HEALTH CLINICS, AND HOSPITAL BASED CLINICS

House wide

	Document No: 101	Page 1 of 11
Title: Just Culture	**Effective Date:** 11/22/2024	☐ **RUHS – Behavioral Health** ☒ **RUHS – Community Health Centers** ☒ **RUHS – Hospital Based Clinics** ☒ **RUHS – Medical Center** ☐ **RUHS – Public Health** ☐ **Departmental**
Approved By:  Jennifer Cruikshank CEO/Hospital Director		☐ **Policy** ☐ **Procedure** ☒ **Guideline**

1. SCOPE

1.1 Just Culture guidelines for determining culpability apply to all Riverside University Health System (RUHS) Employees, Licensed Practitioners, Students, Trainees, Contractors, and Volunteers.

1.2 Where Riverside University Health System is stated, the entities referred to include RUHS Medical Center, Hospital Based Clinics and Community Health Centers.

2. POLICY STATEMENT

2.1 Riverside University Health System is committed to promoting a culture of safety and designing systems of accountability that are fair and just, with a mission to build a system of workplace justice that produces better outcomes.

2.2 Riverside University Health System is committed to organizational learning through leadership that supports trust, transparency, fairness, patient safety in an event investigation.

2.3 Riverside University Health System supports staff who report adverse events, near misses, hazardous or unsafe conditions, and intolerance of retaliation for said reporting.

2.4 Riverside University Health System expects each employee to model behaviors that supports our mission and values to promote patient safety and will not tolerate intentionally unsafe actions, reckless actions, disregard for the welfare of patients or staff, or other willful misconduct and or misbehavior.

3. DEFINITIONS:

3.1 **At – Risk Behavior:** describes conduct that is intended, but this not recognized or is mistakenly believed to be justified. At risk behavior includes the tendency to drift even when knowing the right thing to do.

3.2 **Coaching:** Supportive discussion(s) with an employee to provide guidance and feedback to proactively address areas for improvement, including but not limited to safe behavioral choices.

3.3 **Counseling:** First step in correcting performance or behavior concerns. The counseling serves to put the employee on notice that their performance or behavior is unacceptable or at risk.

3.4 **Culture of Safety:** The extent to which the organization's culture supports and promotes patient safety. It refers to the values, beliefs, and norms that are shared by healthcare

practitioners and other staff throughout
the organization that influence their actions and behaviors.

3.5 **Disciplinary Sanction:** punitive deterrent to encourage an individual or group to refrain from undesired behavioral choices.

3.6 **Duties in the Just Culture Algorithm:** employees have three main duties in a workplace for just culture and safety.

3.7 **Duty to avoid causing unjustifiable risk or harm**: the highest duty, what we all owe each other – the duty to not cause unjustifiable risk or harm to one another. Conduct that insults organizational values—including trust, patient-centeredness, collaboration, and stewardship are evaluated in this duty (example: (opening a medical record without a business need, not using a checklist to save time, scanning a patient label not affixed to the patient, disruptive behavior)

3.8 **Duty to Follow Procedural Rules**: describes actions or series of actions as failure to comply with what is required by the organization (example: verifying two patient identifiers, performing hand hygiene, pre-procedure time-out).

3.9 **Duty to Produce Outcomes**: applies when workforce member is largely in control of the system by which an outcome is produced (example; high readmission rate, high hospital acquired infections, being to work on time)

3.10 **Event Reporting System:** A risk management information system to collect and manage data on safety events, systems failures, organizational risks, break downs in communication and teamwork, equipment failures that directly impact patients or staff, near misses, or other risks.

3.11 **Fitness for Duty:** activities performed on or off the job that influence an individual's ability to perform their work safely.

3.12 **Five Behaviors in Just Culture Model**: represents the five intentions towards harm to others, these precise terms are used to determine whether sanction is appropriate or if the underlying cause worthy of investigation. (See Appendix)

3.13 **Human Error:** describes conduct that is not intended, and often referred to as inadvertently doing other than what was intended (e.g., an inescapable human fallibility, a slip, mistake.)

3.14 **Just Culture Algorithm:** an algorithmic process to guide department leaders through the decision-making process when an employee breaches a duty. The algorithm provides managers and supervisors with a repeatable, reliable, fair and just guide in determining culpability. (See attachment 7.1 to 7.6)

3.15 **Just Culture:** A system of shared accountability in which the organization is responsible for the systems they have designed and for responding to the behaviors of their employees in a fair and just manner. The just culture process allows for individual accountability and promotes an organizational learning culture where honest human mistakes are seen as a learning opportunity for the organization and its employees.

3.16 **Knowledge or knowingly causing harm:** describes a behavioral choice made knowing that harm is virtually certain to occur. It is often referred to as "me first" while knowingly causing harm to others.

3.17 **Medical Condition**: A health problem with certain characteristics or symptoms that may or may not require medications as part of the treatment plan.

3.18 **Performance Shaping Factors**: Attributes that impact the likelihood of human errors or behavioral drift.

3.19 **Purpose to cause harm:** describes a conscious objective or intention to cause harm.

3.20 **Reckless Behavior:** describes a behavioral choice to consciously disregard a substantial and unjustifiable risk. The risk of harm is seen to be significant and unjustifiable, but the person chooses to disregard that risk. Reckless behavior is often referred to as “the gamble.”

3.21 **Remediation:** Actions taken to aid employee including, but not limited to, education, training, assignment to task appropriate to knowledge and skill, assign a Quality Assurance and Performance Improvement (QAPI) project.

3.22 **Repetitive Error Algorithm**: assessment of repetitive errors and repetitive at-risk behaviors. It is used when circumstances that are seen as an outlier causes concern. The algorithm goes through a process of elimination through the factors that may lead to repetitive error.

3.23 **Safety Event:** A variance not consistent with the desired, normal, or usual operations of the organization. Safety events can involve patients, employees, visitors or other individuals. An injury does not have to occur.

3.24 **Substitution Test:** A process to assess how another competent individual in a similar situation could be vulnerable to the same error.

3.25 **Unauthorized Substance:** Non-medically prescribed substances capable of altering the mood, perception, behavior or judgement of the individual consuming it or any improper substance obtained with improper prescription.

4. RESPONSIBILITIES

4.1 Department Leader Responsibilities:

a. Completing Just Culture Training provided by RUHS.

b. Implement high reliability communication strategies within the departments to achieve the trust/rapport within teams and with patients (e.g., safety huddles)

c. Encourage staff to identify and submit event reports for system deficiencies, safety events, near misses and hazardous conditions and recognize staff members who do report.

d. Participate in leadership rounding, root cause analysis and support the development of safety systems and processes.

e. Reinforce safe behavioral choices and continually teach staff about the importance of safety systems to counter normalized deviance.

f. Hold individuals accountable for their actions based on the quality of decision making rather than the severity of outcomes. Utilize the Just Culture Algorithm for evaluation of staff actions when reviewing events and near-misses.

4.2 Staff/Individual Responsibilities:

a. Report safety events, near misses, work arounds and hazardous conditions by utilizing direct communication, safety huddles, leadership rounding, and online event reporting system.

b. Participate in the development of safe systems and model behaviors to promote trust/reporting/improvement cycles of safety improvement.

c. Exercise good judgment in the performance of their job duties; ask questions when something is unfamiliar, or when unsure of what needs to be done.

5. GUIDELINES

5.1 Events and safety concerns should be reported through the event reporting system.

5.2 Managers shall follow policies regarding patient safety event reporting and sentinel event reporting for classification and investigation.

5.3 A Leader should identify all duty breaches (see definition) and take each breach through the respective algorithm.

5.4 The just Culture Algorithm will be used to evaluate individual behaviors and culpability. (See definition)

5.5 If the outcome is a determination of willful misconducts, concern for fitness for duty, or unsafe/reckless/negligent behavior, then the manager involved must advise Human Resources and participate in subsequent Human Resources (HR) processes. Leaders will review applicable reporting standards and will report, as needed, to external oversight agencies.

5.6 If the outcome is a determination of unintended human error or system failure then the Leadership team will console the involved staff, encourage peer support resources, and communicate system improvements to all staff and ensure that staff to help prevent future events.

5.7 If there are repeated errors, or occurrences of at-risk behavior, further evaluation is warranted to determine if the root cause is related to system design or individual performance factors. (Attachment 7.6).

5.8 All participants will maintain the confidentiality of the review process.

5.9 If an employee believes he or she has been subjected to inappropriate punitive measures because of self-disclosure, the individual should report the concern to their department leadership, if appropriate, or to Human Resources.

6. REFERENCES

6.1 Connor M., et al.: Creating a fair and just culture: One institution's path toward organizational change. The Joint Commission Journal on Quality and Patient Safety 33:10, 617-624, October 2007

6.2 Frankel A., et al.: Improving patient safety across a large integrated health care delivery system. Int J Qual Health Care 12 (suppl. 1):i3l-i40, De. 2003

6.3 Institute of Medicine: To Err is Human: Building a Safer Health System. Washington, DC: National Academy Press, 2000.

6.4 Marx D.: Patient Safety and the "Just Culture"; A primer for Health Care Executives. New York City: Columbia University, 2001.

6.5 Marx, D. (2018). Culture as Choice. In: Gilbert, C., Journé, B., Laroche, H., Bieder, C. (eds) Safety Cultures, Safety Models. Springer Briefs in Applied Sciences and Technology. Springer, Cham. https://doi.org/10.1007/978-3-319-95129-4_7Meadows S, Baker K, Butler J. The Incident Decision Tree: Guidelines for action Following Patient Safety Incidents. In: Henriksen K, Battles JB, Marks ES, et al., editors. Advances in Patient Safety: From Research to Implementation (Volume 4: Programs, Tools, and Products). Rockville (MD): Agency for Healthcare Research and Quality (US); 2005 Feb. https://www.ncby.nlm.nih.gov/books/NBK20586/

6.6 Reason J, Hobbs A. Managing maintenance error: a practical guide. Aldershot: Ashgate Publishing Group; 2003

7. ATTACHMENTS

7.1 Three Duties and Five Behaviors in Just Culture Model

7.2 Just Culture Algorithm: The Duty to Avoid Causing Unjustifiable Risk or Harm

7.3 Just Culture Algorithm: The Duty to Follow a Procedural Rule

7.4 Just Culture Algorithm: The Duty to Produce an Outcome

7.5 Just Culture Algorithm: Repetitive Human Error

7.6 Just Culture Algorithm: Repetitive At-Risk Behavior

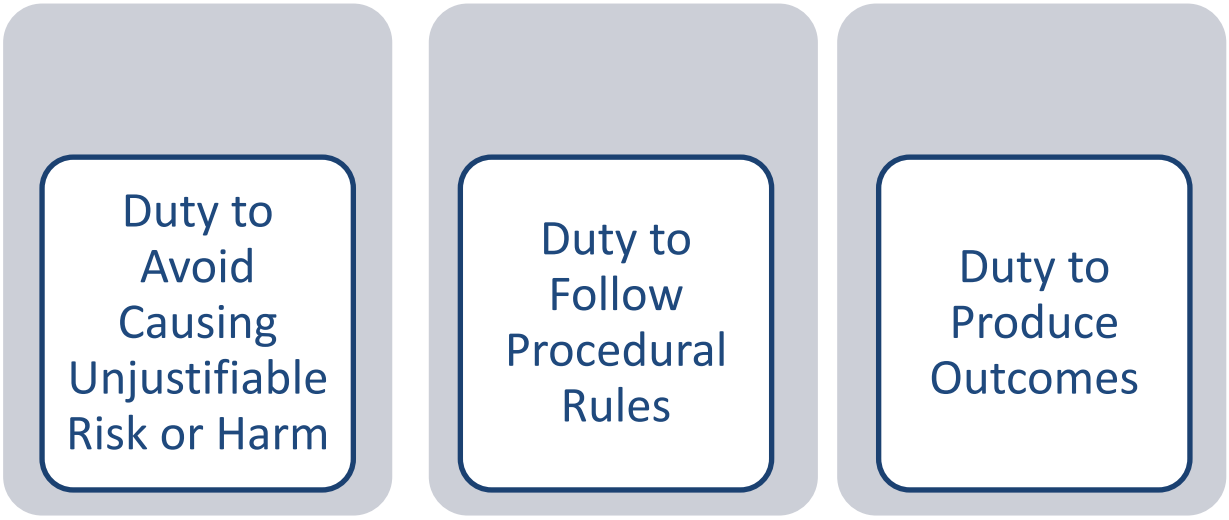
Document History:

Prior Release Dates: New	**Retire Date:** N/A
Document Owner: Patient Safety Officer	**Replaces Policy:** N/A

Date Reviewed	Reviewed By:	Revisions Made Y/N	Revision Description
04/26/2024	Just Culture Steering Group (Patient Safety Officer, Medical Program Director, Executive Director, Critical Care Services, HR Business Partner)	Y	Created Guideline
5/16/2024	Nursing P&P	Yes	Needs an owner and update to document history
5/20/2024	PAC	Yes	Scope to define Med Center, Clinics, Community Health
10/10/2024	MEC	Yes	Minor wording change, remove event investigation questions.

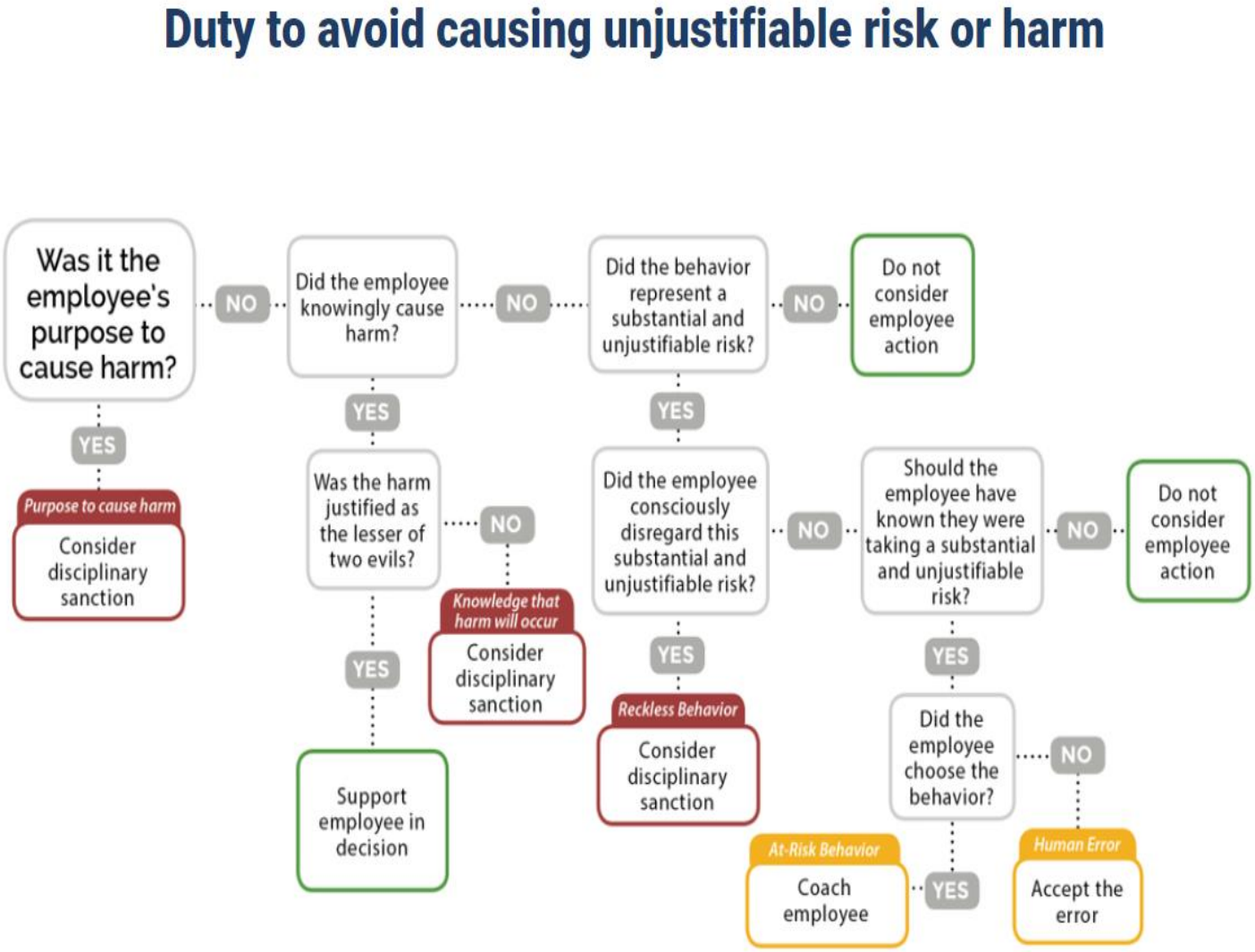
ATTACHMENT 7.1 Three Duties and Five Behaviors in Just Culture Model
Adopted from David Marx, J.D., 2021

The Three Duties

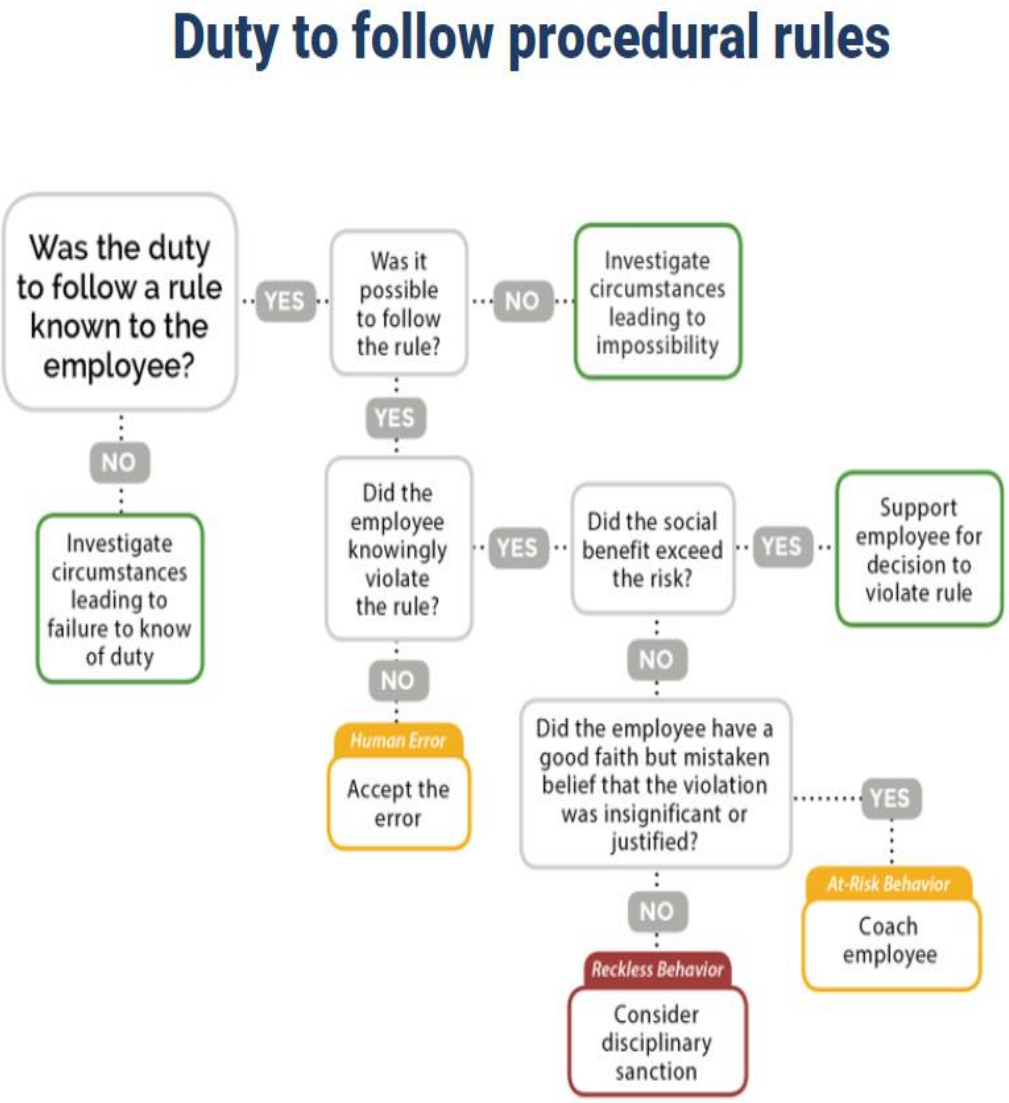


The Five Behaviors

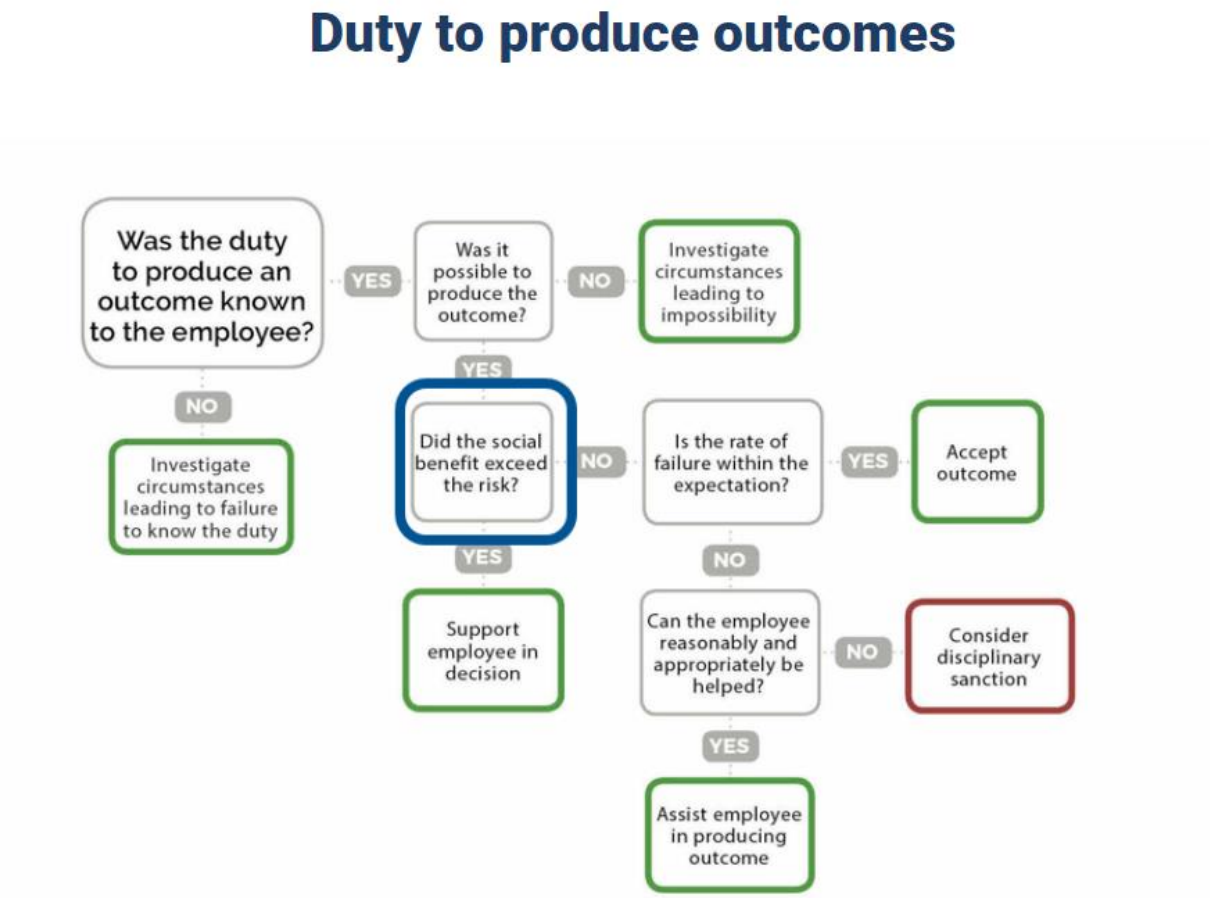
ATTACHMENT 7.2 Just Culture Algorithm:
The Duty to Avoid Causing Unjustifiable Risk or Harm *Adopted from David Marx, J.D., 2021*



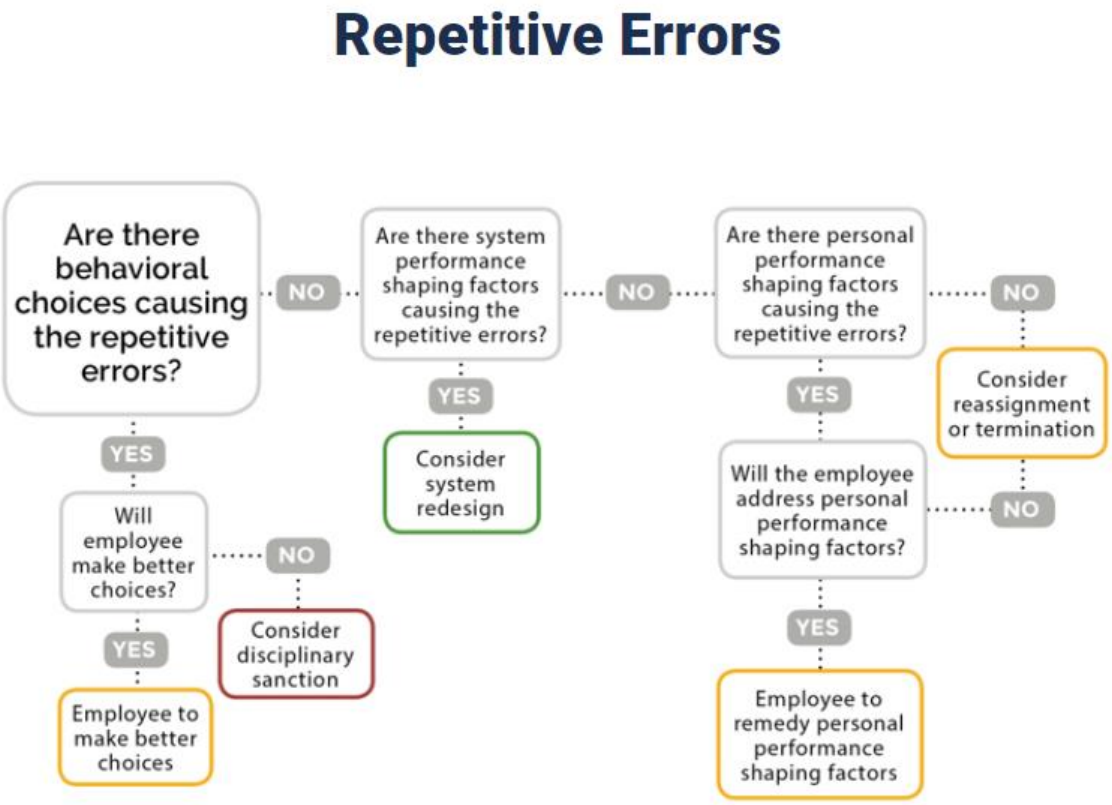
ATTACHMENT 7.3 Just Culture Algorithm: The Duty to Follow a Procedural Rule
Adopted from David Marx, J.D., 2021



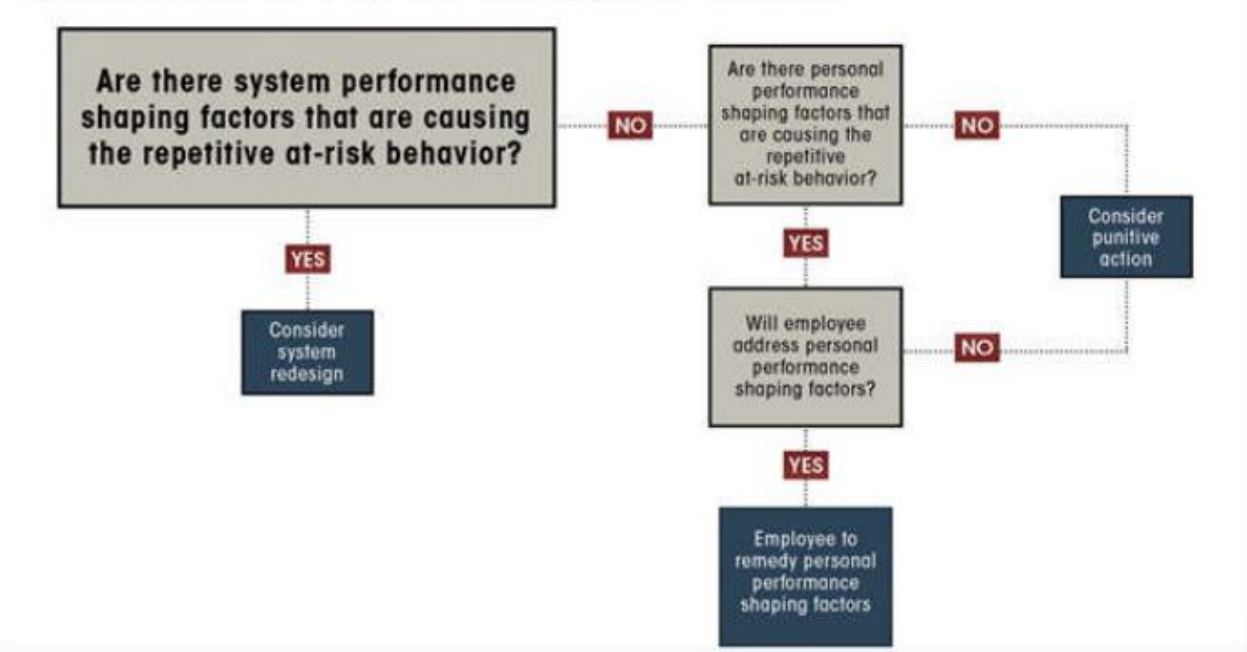
ATTACHMENT 7.4 Just Culture Algorithm: The Duty to Produce an Outcome
Adopted from David Marx, J.D., 2021



ATTACHMENT 7.5 Just Culture Algorithm: Repetitive Human Error
Adopted from David Marx, J.D., 2021



ATTACHMENT 7.6 Just Culture Algorithm: Repetitive At-Risk Behavior
Adopted from David Marx, J.D., 2021



RIVERSIDE UNIVERSITY HEALTH SYSTEM – MEDICAL CENTER, COMMUNITY HEALTH CENTERS, AND HOSPITAL BASED CLINICS

Title:	Effective Date:	☒ Medical Center* ☒ Community Health Centers ☒ Hospital Based Clinics
Policy Program Management	12/12/2024	
Approved By:  Jennifer Cruikshank CEO / Hospital Director		☐ Housewide ☐ Departmental
		☐ Policy ☒ Guideline ☐ Procedure

1. SCOPE

1.1 This document governs policies, procedures, and guidelines. It does not govern standardized procedures. Standardized procedures provide the legal mechanism for nurses/health care professionals to perform functions that would otherwise be considered the practice of medicine. Standardized Procedures are governed by separate policies, created by the Interdisciplinary Practice Committee.

2. DEFINITIONS

2.1 Clinical. Based on or involving medical treatment, practice, observation, or diagnosis.

2.2 Departmental. Departmental policy documents (policies, procedures, guidelines, protocol, etc.) that apply to only one or two services or departments.

2.3 Guidelines. A guideline details steps usually taken to fulfill an objective. It is acceptable for a hospital representative to occasionally deviate from a Guideline due to a unique clinical consideration and with clinical justification.

2.4 Housewide. Policy documents that involve three or more services or departments are referred to as housewide.

a. Exception: Nursing Department. If a policy applies to multiple individual nursing units, but is still contained within the nursing service, it may be treated as a departmental policy (Nursing Department), as opposed to a housewide policy. The Nursing Department approval process is governed by Nursing Administration.

2.5 Medical Executive Committee (MEC). The MEC is the executive committee charged with carrying out the functions of the medical staff. It is composed of the Chief of Medical Staff, the Medical Director, and the Chairs and Vice Chairs of clinical departments, among others.

2.6 Nursing Policies and Procedures Committee (Nursing P&P). Nursing P&P is the committee charged with reviewing and approving all policy documents governing the administration of nursing units.

2.7 Pharmaceuticals and Therapeutics Committee (P&T). P&T is the executive committee charged with reviewing all policy documents with pharmaceutical or therapeutic content.

2.8 Policies. Expressions of intent, normally required by external statuses, regulations or standards. Deviation(s) from a policy are prohibited.

2.9 Policy Approval Committee (PAC). PAC is an administrative committee. It ensures that all housewide policy documents follow a common standard of format, quality, and review.

**RUHS - Medical Center designation includes Arlington Campus, unless Arlington Campus is specifically excluded in the scope section in the body of the policy document.*

2.10 Policy Document. A document developed by a multidisciplinary group of hospital staff, convened for the purpose of influencing and determining all major decisions and actions, and ensuring that all activities take place within the boundaries set by them. Common policy documents include but are not limited to policies, procedures, and guidelines.

2.11 Policy Program. A set of policy documents that govern a common entity, and the processes, tools, and rules in place to manage them.

2.12 Procedures. Steps that must be followed to carry out a policy. Deviation(s) from a procedure are prohibited.

3. POLICY STANDARDS

3.1 All policies documents written and approved across the organization are required to be:

a. Accessible. All policy documents must be directly accessible to staff.

b. Current. All policy documents must be reviewed according to the timeline set by regulatory and/or accrediting body requirements. At minimum, they must be reviewed at least once every third calendar year.

c. Common template. All policy documents must utilize a common RUHS template.

d. Oversight. Each department must have a staff member identified to manage and monitor their policies.

e. Survey ready. All department/unit leadership must maintain policy documents required of their service areas by regulatory and accrediting bodies.

f. Retention. All policies must be retained according to the County of Riverside Retention Schedule.

g. Most Current Version Usage. Before sharing or using policy documents, staff must access the online version to ensure that they have the most updated version of the policy document.

h. Monitoring and Enforcement. All policy documents must be applied consistently.

3.2 Collaboration Requirement

a. If a unit policy mentions another unit or area of the hospital, it must receive review by the area. If, for example, a policy mentions pharmacy, nursing, or infection control, it must request review from the area before approval and posting online

3.3 Human Resources

a. Even if a policy relates only to the department that owns the policy, if it deals with human resources matters, the policy must be reviewed by Human Resources to ensure it is consistent with employment law, union MOUs, and existing County of Riverside Human Resources policy.

3.4 Nursing Skills and Procedural Standards:

a. Elsevier Clinical Skills (formerly known as Mosby's Clinical Skills) will be utilized as the Department of Nursing's primary source for nursing skills and procedures. The resource is available through the hospital intranet on each nursing unit for easy reference. The Nursing Supervisor and Nursing Administration office maintain a compact disc (CD) of the clinical skill information. The Nursing Department manual will contain procedures and protocols that outline additions and exceptions to Elsevier Clinical Skills. Should a difference in practice arise between the two manuals the Riverside University Health System – Medical Center manuals will be followed.

4. APPROVAL PROCESS

4.1 All policies must be maintained by document owner, this includes:

a. Submitting policies for review and approval no later than every 3 years.

b. Updating policy to current practices when appropriate.

c. Ensuring policies do not expire and understanding it may take up to six (6) months for a policy to complete the approval process.

d. Creating an education strategy at the appropriate level for the policy.

4.2 Policy owners must indicate which location applies to the policy via the policy template check boxes. Then they must follow the applicable approval process.

4.3 Medical Center Approval Process: see Attachment 5.1

4.4 Ambulatory Approval Process (Community Health Clinics and Hospital Based Clinics): see attachment 5.2.

5. POLICY TEMPLATE

5.1 All policies must use the approved template (See Attachment 5.3), this includes indentation labels, document history, and document headers.

5.2 Policy Header must be completed in its entirety, including a selection of designation, document applicability, and document type.

5.3 Document History must be completed in its entirety and should reflect the review process of document, including a summary of content changes. (You may omit minor changes to grammar and format)

5.4 References shall be up to date and in AMA formatting.

a. Refer to any other policies that are applicable to the document in this section.

6. ATTACHMENTS

6.1 RUHS – Medical Center Housewide Policy Approval Process

6.2 RUHS – Community Health Centers and Hospital Based Clinics process

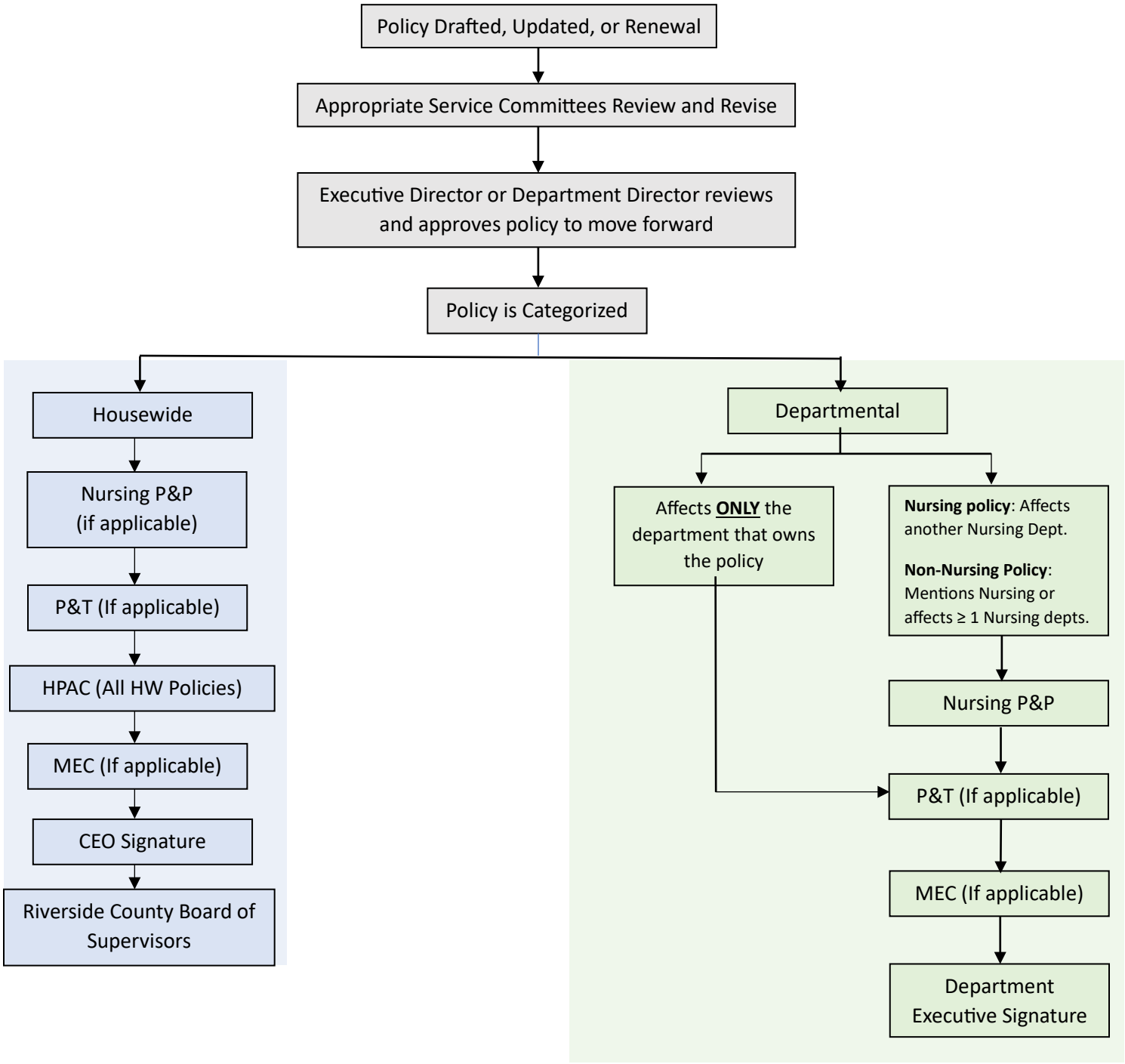
6.3 Policy Template

Document History:

Prior Release Dates: 10/2017, 3/2021,	**Retire Date:** N/A
Document Owner: Policy Program Administrator	**Replaces Policy:** NURS 116.01 Policies, Procedures, and Protocols: Nursing Department.

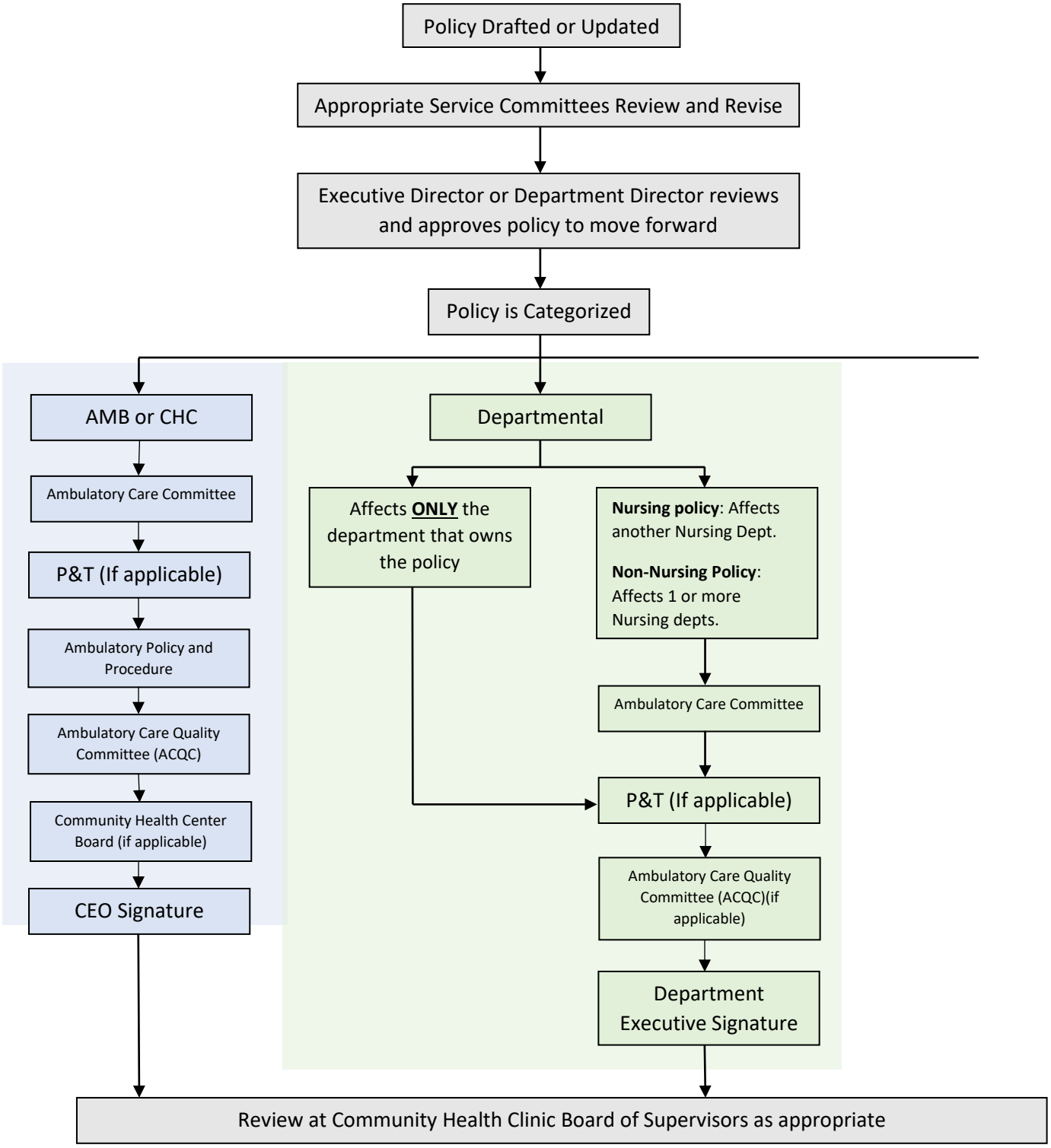
Date Reviewed	Reviewed By:	Revisions	Summary of Revisions Accepted by Owner
12/7/2023	Policy Program Admin	Y	Major changes to template, addition to departmental guidelines, requirement to consult with outside departments.
1/7/2024	Nursing Policies and Procedures Chair	Y	Clarification of policy owner responsibilities, changes to template, expansion of review flowchart, new attachment, edits to Nursing section, reordering flow.
1/11/2024	Chief Clinical Integration Officer, Ambulatory Care Services	Y	Addition of Ambulatory review process
7/2/2024	Policy Approval Committee	Y	Approval of template changes, clarification of Arlington and Correctional Health
8/6/2024	Policy Approval Committee	Y	Approval of changes, except for the attachment outlining accountability workflow, as this is more appropriately a workflow rather than a policy.

Attachment 5.1 - RUHS – Medical Center Policy Approval Process



NOTE: It can take up to **6 months** for a policy to complete the approval process. It is the document owner's responsibility to ensure the policy does not lapse.

Attachment 5.2 - RUHS Ambulatory (CHC's and Hospital Based Clinics) Approval Process



NOTE: It can take up to 6 months for a policy to complete the approval process. It is the document owner's responsibility to ensure the policy does not lapse.

RIVERSIDE UNIVERSITY HEALTH SYSTEM (– ENTITY NAME IF NOT GLOBAL)
(DEPARTMENTAL OR HOUSEWIDE DESIGNATION)

	Document No: XX.XXXX	Page 1 of
Title: Title	**Effective Date:** MOST RECENT EFFECTIVE DATE	☐ **RUHS – Community Health Centers** ☐ **RUHS – Hospital Based Clinics** ☐ **RUHS – Medical Center**
Approved By: Name of Approving Director Title of Approving Director		☐ **Housewide** ☐ **Departmental**
		☐ **Policy** ☐ **Procedure** ☐ **Guideline**

1. **PURPOSE** (This section is a brief explanation of why we have this policy)

2. **SCOPE** (The Scope is already defined in the check boxes and heading in the template. Only use the Scope section here in the body if an additional, more limited scope is required, such as to exclude Arlington, or to exclude a specific type of patient. Usually, this is not needed, but it can be used if appropriate.)

3. **DEFINITIONS** (Please define any jargon, acronyms, or specialized terms)

   3.1 Word or phrase. Definition.

   3.2 Word or phrase. Definition.

4. **POLICY/PROCEDURE/GUIDELINE** (choose one)

   4.1 Heading Title

   a. Subheading

   i. Subheading 2

   - Subheading 3

5. **REFERENCES** (Please list any relevant regulations, laws, or standards in this section. Also include any related RUHS policies)

   5.1 Heading Title

   a.

6. **ATTACHMENTS** (If applicable)

**RUHS - Medical Center includes Arlington Campus, unless Arlington Campus is specifically excluded in the scope section.*

Document History:

Prior Release Dates: (Dates of previously released versions if applicable)	**Retire Date:** (Insert the retirement date if applicable. If not, write N/A)
Document Owner: (Department;Committee;or job title of the owner/sponsor. Do not enter specific names)	**Replaces Policy:** (Insert any previous versions of this policy that have a different name and/or number. If none exists, write N/A)

Date Reviewed	Reviewed By:	Suggested Revisions Y/N	Summary of Owner Accepted Revisions
Mm/dd/yy	(ABC Committee or title (not name) individual subject expert)	(Yes/No)	(Fill in descriptions of revisions requested)

RIVERSIDE UNIVERSITY HEALTH SYSTEM – MEDICAL CENTER

Housewide

	Document No: 1304	Page 1 of 3
Title: Transfer and Repatriation Agreement for Higher Level of Care (HLOC) Transfers from Outside Facilities	**Effective Date:** 11/22/2024	☐ **RUHS – Behavioral Health** ☐ **RUHS – Community Health Centers** ☐ **RUHS – Hospital Based Clinics** ☒ **RUHS – Medical Center** ☐ **RUHS – Public Health** ☐ **Departmental**
Approved By: Jennifer Cruikshank CEO/Hospital Director		☐ **Policy** ☒ **Procedure** ☐ **Guideline**

1. **SCOPE.** This procedure applies only to patients from a Referring Facility that is requesting admission into RUHS for a non-emergent HLOC transfer from an inpatient setting. For patients who are experiencing a medical emergency, please refer to HW 656 Screening, Stabilizing Treatment and Transfer of Patients with Emergency Medical Conditions.

2. DEFINITIONS

2.1 Higher Level of Care (HLOC) – When a clinically stable patient needs a service not provided by the Referring Facility, patient needs to be transferred to another facility that can provide service, referred to as higher level of care transfer.

2.2 Repatriation - – The process of sending the patient back to the Referring Facility after the reason for HLOC transfer has been addressed by RUHS.

3. PROCEDURE.

3.1 When a referral packet is received for non-emergent HLOC transfer, RUHS Transfer Center will check for completeness. The packet must have the appropriate medical records including doctor's notes stating stability for transfer, diagnostics, and procedures related to the needed services. Note: The hard copy of the medical record, disks, and films must be with the patient on arrival.

3.2 RUHS Transfer Center must confirm the patient's insurance coverage prior to physician review.

3.3 RUHS Transfer Center will contact Specialty Physician during regular business hours (8 am to 5 pm) if services needed can be provided at RUHS. Once confirmed, RUHS Transfer Center to contact assigned admitting physician to review and discuss case.

3.4 RUHS Transfer Center will notify referring facility of the intent to accept and facilitate physician to physician discussion.

3.5 RUHS Specialty Attending Physician will notify RUHS Transfer Center if case will be accepted or declined.

a. An accepting primary team (Internal medicine, family medicine or surgery) must be identified for transfers needing specialty care/physician.

b. RUHS Specialty Attending Physician must confirm appropriate initial level of care (intensive care, telemetry, medical surgical). This may change after the patient is

in-house and can be adjusted accordingly after assessment by a RUHS Admitting Physician on the primary team.

3.6 If case is accepted, RUHS Transfer center will initiate an event in EPIC then notify the Patient Access team to complete the registration process. RUHS Transfer Center to provide Attending physician the medical record number.

a. For adult patients, RUHS Admitting physician can enter an admit order (inpatient or observation) prior to arrival.
b. For pediatric patients, RUHS Admitting physician will enter an admit order after patient has arrived.

3.7 RUHS Transfer Center will notify referring facility of acceptance and request for the insurance authorization to transfer as well as the following completed forms.

a. Transfer and Return Agreement – This is a RUHS form required on all transfers and must be signed by the referring facility's administrator.

b. Letter of Agreement for Hospital Services – This is a RUHS form for uninsured and underinsured patients. This must be signed by the referring facility's administrator, preferably the Chief Financial Officer.

c. Copy of the referring facility's Patient Acknowledgement of Transfer signed by the patient or designee. If referring facility do not have such form, documentation regarding explanation and verbal agreement on the referring facility's electronic medical record (EMR) will be accepted.

3.8 RUHS Transfer Center to secure bed from RUHS bed placement team and provide information to the referring facility. RUHS Transfer Center will obtain transportation information (ambulance, pick up time, and estimated arrival) and inform RUHS House Supervisor.

3.9 RUHS primary team Attending Physician will inform the patient's assigned RUHS case manager or the RUHS Transfer Center when the patient is clinically stable. Patient may be discharged from RUHS or there may be a request for repatriation if there are long term clinical needs.

3.10 If the request is for repatriation, RUHS Transfer Center to contact referring facility to request for bed. RUHS Transfer Center will send appropriate medical records as needed.

a. If bed capacity is not available at the time RUHS requests for return transfer, RUHS will confirm acceptance of the patient with the first bed available as a priority admission. RUHS Transfer Center to contact referring facility regularly to check for bed availability.

3.11 RUHS Transfer center, in coordination with the referring facility, will facilitate transportation back. The referring facility is responsible for the cost of transferring or transporting patients to or from RUHS.

4. REFERENCES

4.1 HW 656 Screening, Stabilizing Treatment and Transfer of Patients with Emergency Medical Conditions

5. ATTACHMENTS

5.1 Transfer and Return Agreement

5.2 Letter of Agreement for Hospital Services

Document History:

Prior Release Dates: New	**Retire Date:** N/A
Document Owner: Integrated Care Management	**Replaces Policy:** N/A

Date Reviewed	**Reviewed By:**	**Revisions Accepted**	**Revision Description**
9/18/2023	Assistant Director for Integrated Care Management	New	New
11/16/2023	Director Integrated Care Management	New	New
11/2023	Chief Compliance and Privacy Officer, Executive Director		
6/4/2024	County Counsel	Yes	Focus on procedures for RUHS staff, not on sending facilities procedures or commitments, as that is covered in the transfer agreement.
8/6/2024	Policy Approval Committee	No	
9/12/2024	Medical Executive Committee	Yes	
9/27/2024	Pediatrics	Yes	
10/2/2024	Gastroenterology	Yes	
10/10/2024	Medical Executive Committee	No	

RIVERSIDE UNIVERSITY HEALTH SYSTEM -

Medical Center, Community Health Centers and Hospital Based Clinics

	Document No: 456	Page 1 of 15
Title: RUHS CARES: Care for the Caregiver (C4C) after an Adverse or Harm Event	**Effective Date:** 11/4/2024	☐ **RUHS – Behavioral Health** ☒ **RUHS – Community Health Centers** ☒ **RUHS – Hospital Based 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 all workforce members.

2. POLICY STATEMENT

2.1 Riverside University Healthcare System (RUHS) – Medical Center, Community Health Centers, and Hospital Based Clinics recognize the potential emotional and psychological impact adverse harm and emotionally traumatic events can have on employees and physicians. To that end, RUHS is committed to providing support and care for our caregivers; staff and physicians, impacted by emotionally traumatic events.

2.2 The Peer Support process is part of the Patient Safety and Risk Management Program. As such, all program related referrals and encounters are maintained in a confidential manner. The effectiveness and evaluation of the Peer Support program is reported to the RUHS Cares Steering Committee, Medical Executive Council, Nursing Executive council, the Performance Improvement and Patient Safety Committee and Physician Wellness Committee.

3. PURPOSE

3.1 To provide guidelines and structure for offering emotional first aid and support of workforce members after a harm/adverse or traumatic event.

4. DEFINITIONS

4.1 **Adverse/Harm event:** an unanticipated event that may have or did result in harm. The event may or may not have resulted in an error.

4.2 **Automatic Deployment:** Tier 2 Peer Support will be deployed in an event of patient harm or harm from experiencing a traumatic event meeting Tier 2 Activation. Behavioral Health Crisis team will be available to provide emergent intervention as needed.

4.3 **Critical Incident Stress Debriefing:** additional group debriefing provided by RUHS-Behavioral Health trained staff that will require staff coverage to allow attendees to be

present for the group for 1-2 hours uninterrupted. Groups are conducted consistent with the Mitchel Model for crisis debriefing which consist of (7) structured phases.

4.4 **Care for the Caregiver (C4C) Activation:** activation is triggered when an unexpected emotionally traumatizing event occurs. (see Appendix A)

4.5 **Harm:** any measurable amount of physical, psychological, or financial injury.

4.6 **Peer Supporter:** a trained member of the Peer Support Team who is available to respond to physicians or personnel to offer and provide emotional first aid following a harm, adverse or emotionally traumatic event.

4.7 **Peer support:** emotional first aid provided to a person who is involved in an unexpected health care or other emotionally traumatic event.

4.8 **Emotional First Aid:** evidence informed approach to reduce stress symptoms to assist in healthy recovery following a traumatic event, The aim to reduce stress symptoms and assist in a healthy recovery following a traumatic event, natural disaster, public health emergency, or even a personal crisis in a less structured manner.

4.9 **Initial Unit Debriefing:** process of holding a post-event discussion about what happened during the event. The discussion may include input from participants regarding what occurred, what worked well, what could be improved upon, or personal feelings associated with the event. The scope and purpose of the debriefing should be established in the opening comments. A debriefing is not an investigation and is separate and apart from a peer supporter interaction.

4.10 **Traumatic Event:** an experience that causes emotional upheaval or has the potential to impact the well-being of workforce member(s) in the work environment. Examples of a traumatic event include but are not limited to the following:

a. Workplace violence event

b. Severe injury or death

c. Medical error

d. Unanticipated patient harm or death (especially when the age or other characteristics remind the individual of a family member or loved one)

e. Sudden loss of a co-worker

f. Collective, significant personal loss

g. Multiple deaths in a clinical area

h. Seriously disruptive or troubled employee

i. Actual suicide or homicide attempts by a patient, employee, or visitor

4.11 **Tier 1 Peer Support Activation:** initial support and check-in is provided by Department /Unit manager, supervisor, or department chair. During this initial team debriefing, unit supervisor/manager and/or department chair will assess for additional need of peer support or critical incident stress debriefing groups. (Appendix B)

4.12 **Tier 2 Trained Peer Supporter Activation:** if unit supervisor/manager and or department chair identifies additional support is needed, a referral is made to the Peer Support

Coordination Team. Tier 2 activation will include peer support provided by trained peer supporters who are colleagues from all areas of the organization and/or critical incident stress debriefing by RUHS-Behavioral Health trained staff, who have completed the required training to administer psychological first aid while monitoring the need to expedite referral to professional assistance. (Appendix B)

4.13 **Tier 3 Activation of Expedited Referral Network**: some workforce members involved in a patient harm or other emotionally traumatizing event will require additional help from other trained professionals, inside and outside of the organization. Some may benefit from talking to the in-house chaplain or a social worker while others would best benefit from a referral to the Employee Assistance Program or an external therapist or psychologist. (Appendix B)

4.14 **Workforce Members**: is defined as any regular employee, temporary assistance employee (TAP), per diem employee, contract employee, volunteer, trainee, residents, medical students, and/or any other persons whose conduct, in the performance of work for RUHS – Medical Center or ambulatory clinics, is under the direct control of RUHS – Medical Center or ambulatory clinics, whether or not they are paid by Riverside University Health System.

5. PROCEDURES

5.1 A referral to the Peer Support program can be made by anyone in response to a harm or emotionally traumatic event that triggers the need for emotional support of workforce member(s). The referral is then reviewed by the Peer Support coordination team to follow up and coordinate support.

5.2 Activation of the Peer Support program is managed by the House Supervisors:

a. The House Supervisor Team will oversee the activation and intake process. The house supervisor team oversees the (a) completion of the intake form and coordinate dispatch for peer support.

b. The House Supervisor Team can be reach at extension 18660.

c. Upon activation, C4C steering team assigned lead may need to contact the involved individual or their supervisor/manager to evaluate the level of post-event support and resources needed. Resources and referrals may include but are not limited to a trained Peer Support Team member, escalation to Tier three support such as the Employee Assistance Program, Chaplain/Pastoral Services, or external access to a higher level of psychological support.

5.3 Guidelines for Activation (see Appendix A)

a. <u>Tier 1 Activation:</u> Department /Unit level support will be provided by the unit manager, supervisor, or department chair. Support may be provided any time workforce member(s) are experiencing levels of stress that exceed their ability to cope, whether it is due to a patient harm event, emotionally traumatizing experience, or cumulative stress. Support includes:

i. Connect with affected workforce member(s).

ii. Provide one on one reassurance.

iii. Reaffirm confidence in the workforce member.

iv. Assist with contacting the Peer Support Intake coordinators to determine if additional resources are needed.

v. Assist the workforce member to temporarily leave the unit and go to a 'safe space' to emotionally process the event.

vi. Consider relieving involved workforce members of duties for the balance of the shift or longer, if necessary, through collaboration with the Human Resources or staffing office; call in flex staff if available and/or request oncoming employees to come in early, etc.

vii. Check in on workforce member regularly after initial interaction.

viii. Notify workforce member of next steps, if any.

b. Tier 2 Activation: Upon receipt of notification, the intake house supervisor will gather initial information, triage the call, and provide a handoff report to a trained peer supporter or resource as needed.

i. Intake information includes date and time of the triggering event or request, name of involved workforce member, unit, type of event, exposure level to incident (direct vs indirect), effectiveness of tier one support, any special concerns, etc.

ii. All requests or referrals for Peer Support Program shall be provided to RUHS Cares C4C assigned lead for review, to gather additional information as needed, and coordinate dispatch if appropriate.

iii. Peer Support staff shall be available via phone or email during their assigned work hours to provide support to the involved workforce member when necessary; and be prepared to respond to the unit if immediate personal response is needed.

iv. Peer supporter will (in addition to support provided in Tier One):

- Provide one-on-one crisis intervention or group support. Group support may include critical incident stress debriefing with trained RUHS-Behavioral Health staff members.
- Maintain confidentiality of information shared both during individual and group sessions. Avoid writing or keeping any notes regarding the encounter other than name, contact information and date/time of any agreed upon follow-up contact. Demonstrate active listening techniques.
- Offer support and re-direct conversation as needed to focus on the individual rather than the event.
- Be attentive and “in the moment” with the workforce member.
- Evaluate and determine the need for referral to Tier 3 support for additional assistance as needed.
- Document in the Peer Support Log.
- Participate in ongoing team meetings and education.

c. Tier 3 Activation: Expedited referral network may be triggered by the peer supporter, supervisor, a colleague or the individual when needed. Added resources include but are not limited to:

   i. Employee Assistance Program (EAP)

   ii. Private Insurance Provider (e.g., psychiatrist, psychologist, therapist, etc.)

   iii. Chaplain

   iv. Other as appointed by organization

d. Expedited access to external resources is provided through the County of Riverside Human Resources at https://rc-hr.com/benefits/employee-assistance-program.

6. PEER SUPPORT STRUCTURE

6.1 The role of peer supporter is to assist the workforce member with normalizing the feelings and emotions that results from stress or traumatic event while being mindful of not trying to "fix" the workforce member, situation, or event.

a. Tier 1 Peer Supporters consist of individuals whom others just naturally turn to for advice and solace within their department, they can provide day to day encouragement to their peers.

b. Tier 2 Peer supporters are considered trained peer supporters that consist of colleagues from all areas of the organization who have completed the required training necessary to administer emotional first aid while monitoring for the need to expedite referral assistance (Tier Three Activation).

c. Tier 3 Peer Supporters are trained, experienced or qualified professionals inside and outside of the organization. This may include but not limited to the following specialist.

   i. Chaplain

   ii. Social Worker

   iii. Program therapist or Psychologist

   iv. Outside referral to Employee Assistance program

6.2 Training for Tier 1 and Tier 2 Peer Supporter

a. Tier 1 Peer Supporters will participate in a formalized training. Targeted topics include but not limited to the following:

   i. Purpose of the "care for the care giver" program

   ii. Care for the Care Giver program structure

   iii. Role of the Peer Supporter and the importance of confidentiality

   iv. Accessing the different levels of peer support

a. Tier 2 Peer Supporters will participate formalized comprehensive training that may include Regional Training and Workshop**.** In addition to Tier One training requirements, targeted topics include but not limited to the following:

i. Basic concepts and background of the "Second Victim Phenomenon" and the emotional impact on caregivers involved in an event that resulted in patient's harm

ii. High risk clinical teams, areas and scenarios within the organization

iii. Identification of individuals experiencing or is at risk of experiencing emotional trauma

iv. Six Stages of Recovery

v. Strategies for providing Support to caregivers

vi. Peer Support interventions available at the organization

7. PROGRAM EVALUATION

7.1 Peer supporters will complete a confidential Peer Support Log "debriefing summary form" within 24- hours of interaction.

7.2 Invitations to provide feedback will be sent out electronically to all providers and staff every month, requesting participants in the Peer Support program provide feedback about their experience and include any recommendations for improvement.

7.3 Evaluation of the program will be achieved through volume statistics (number and frequency of deployments over the number of patient harm events) as well as qualitative analysis through post-encounter surveys.

a. Program statistics will be reported up through the organization's reporting structure.

b. Data detailing the effectiveness of the Peer Support program will be shared via a dashboard.

8. QUALITY MEASURES

8.1 Measurements of outcomes and processes may include, but not limited to, the following:

a. Outcome Measures:

i. Number of activated peer support calls activated per month or quarterly

ii. Number of peer support interactions by unit or department

iii. Type of referrals made

b. Process Measures

i. Effectiveness and timeliness of responses

ii. Timeliness of access to higher level of support

9. CROSS REFERENCE

9.1 Peer Support Standard Operating Procedure

10. REFERENCES

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11. APPENDICES

11.1 A: RUHS Cares Event Activation Algorithm

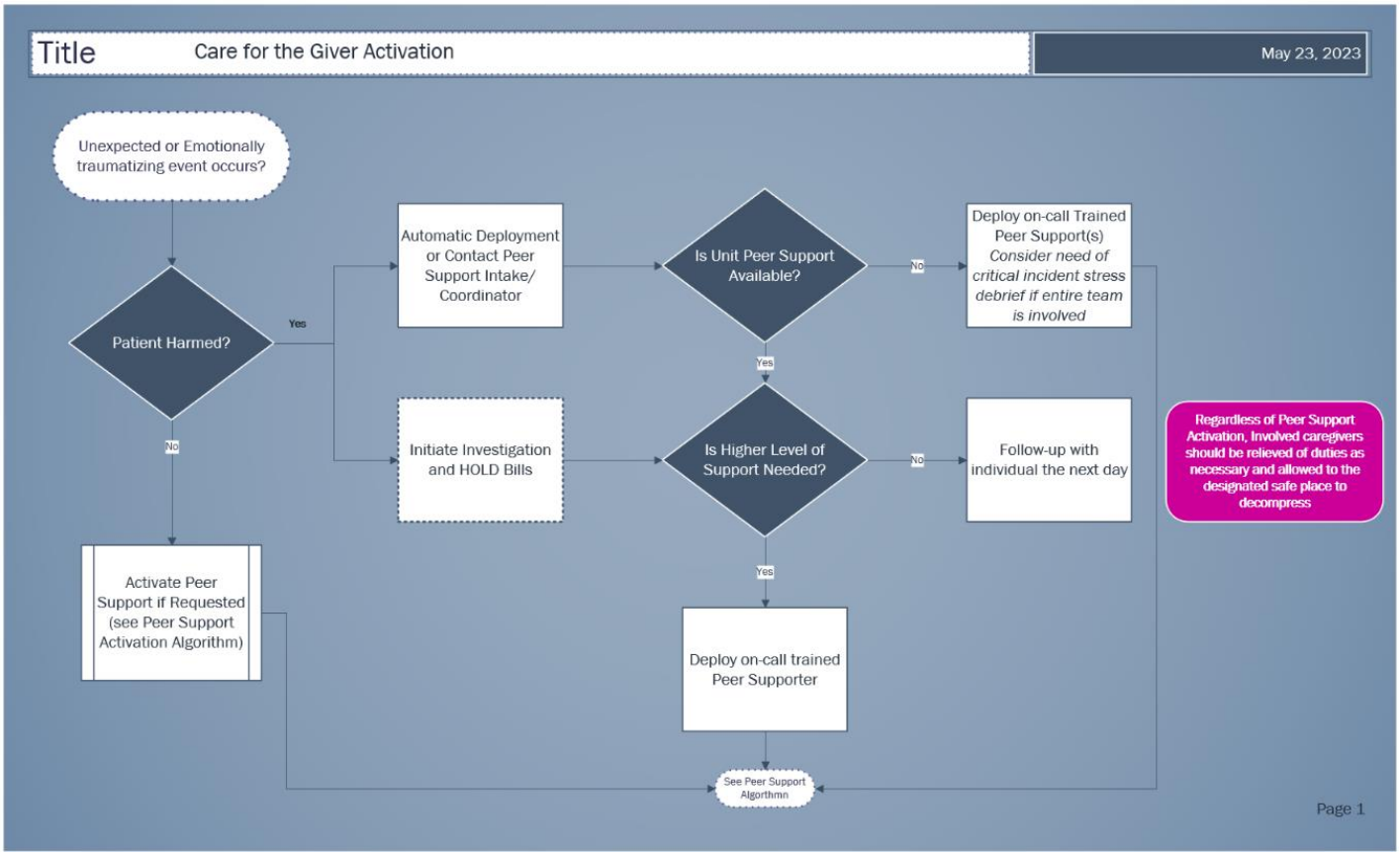
11.2 B: The Scott Three-Tiered Interventional Mode of Second Victim Support

11.3 C: Peer Support Activation Algorithm

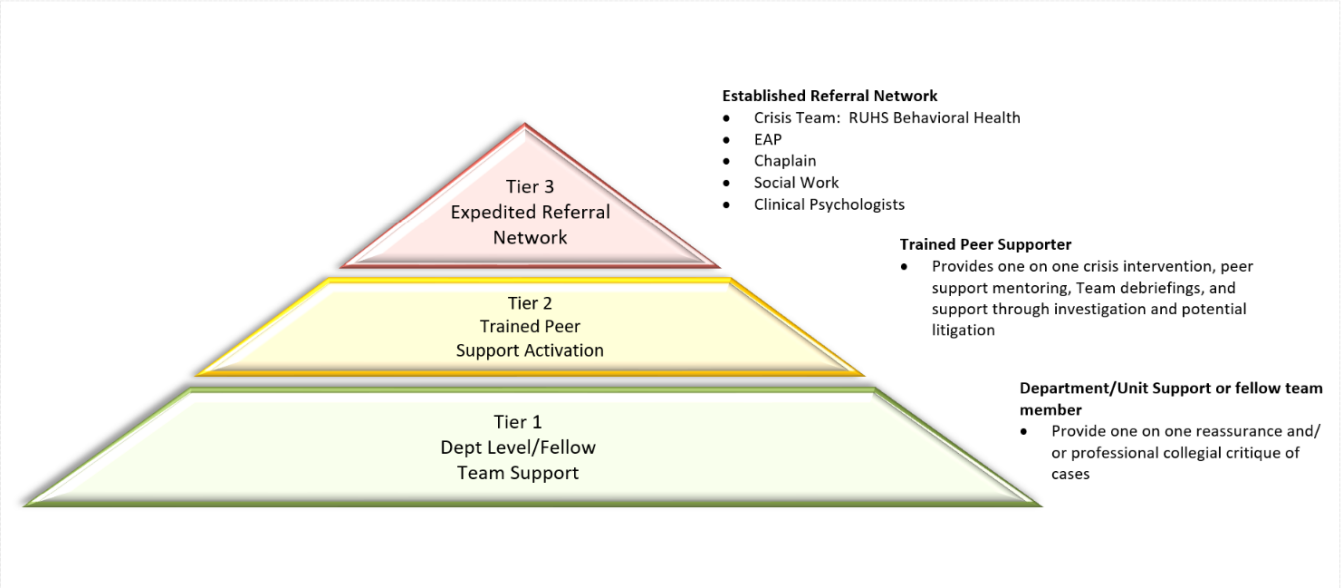
11.4 D: Peer Support Recruitment Letter

11.5 E: Peer Supporter Application

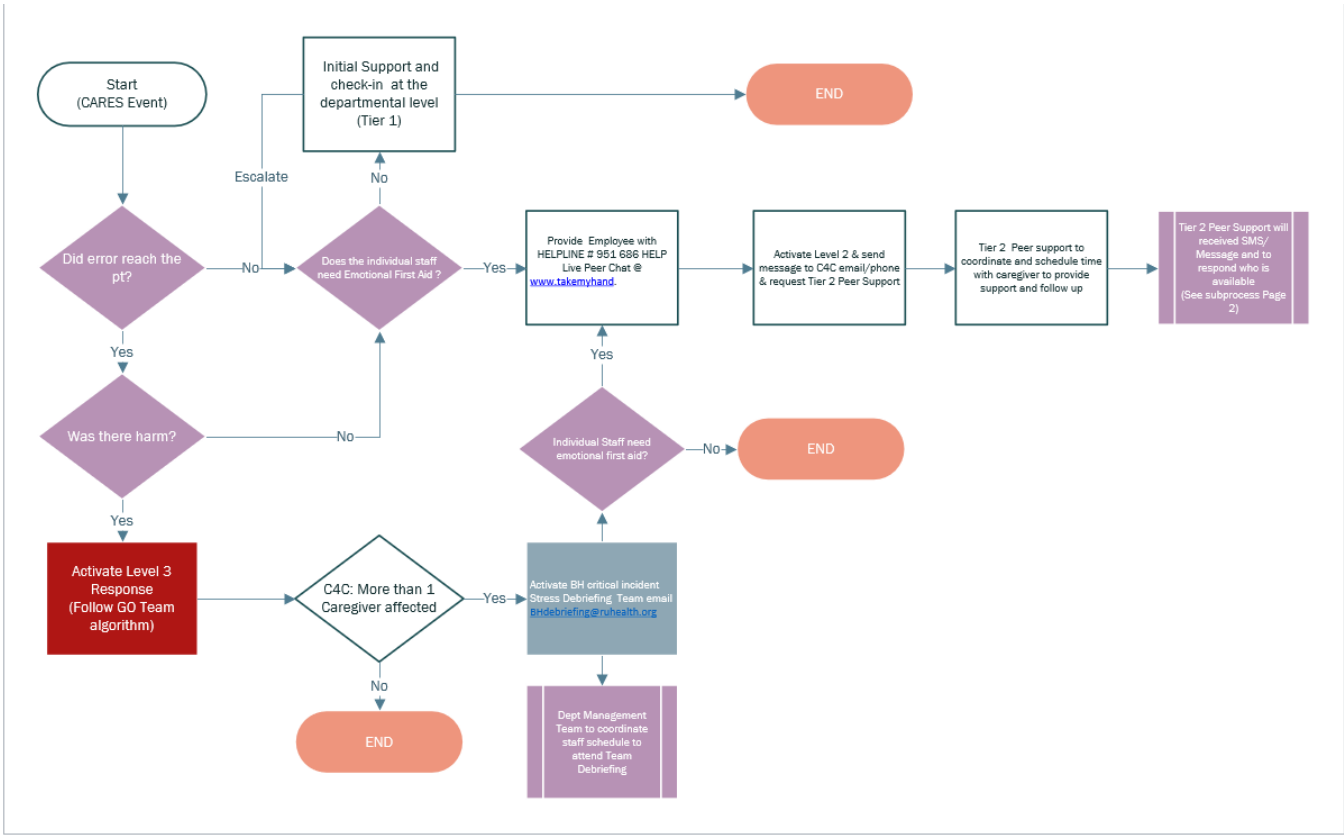
Appendix A
Care for the Care Giver Activation
Adopted from BETA HEART Algorithm



Appendix B
Adopted from : The Scott Three-Tiered Interventional Mode of Second Victim Support
JT COMM JQual Patient Saf. 2010 NavL36(5)L233-40



Appendix C
Activating the Peer Support
Adopted from BETA HEART Algorithm



Appendix D
Example Physician Peer Support Recruitment Letter
Adopted from BETA HEART C4C tools

Physician Recruitment Letter

[date]

[Type the sender company name]
Address
City, State, Zip Code

Physicians Name
Address
City, State, Zip Code

Dear Dr. [Name of Doctor],

We are writing to inform you that [Hospital Name] is embarking on a new program called Care for the Caregiver. The goal of the program is to provide timely emotional support to providers directly involved in a patient harm event; sometimes referred to as the "second victim." As you may already be aware, direct involvement in a patient harm event can be emotionally devastating; causing depression, questioning one's knowledge and skill as a clinician, lack of sleep and withdrawal from social interaction with colleagues further heightening the sense of isolation. This emotional phenomenon frequently results in shaking the provider's confidence, resulting in a loss of professional fulfillment and sometimes to the point of leaving the profession altogether.
Our belief is that a fellow physician is best positioned to provide peer support with a greater depth of empathy and understanding of the broad array of emotions and frustrations the provider may be experiencing. It is our hope that the peer supporter will help to normalize those emotions and serve as a mentor to assist the provider through his/her emotional recovery. It is for this reason that we are writing to you and inquiring if you would be interested in learning more about volunteering as a Peer Supporter to those physicians involved in a patient harm or other emotionally traumatizing event.

As a volunteer Peer Supporter, you would provide emotional support and resources to help the physician process the event in a healthy and lasting manner while teaching skills to build resilience. We anticipate that the time commitment for our peer supporters will be approximately XX hours for the initial training, participation in monthly debrief sessions and that you are available to respond between X to X hours per month.

Care for the Caregiver is a wonderful opportunity for you to provide a level of emotional support and understanding that can only come from one who has experienced similar thoughts and feelings. We need you to help heal our healers. If you are interested in learning more about serving as a Peer Supporter please contact (Name), at (Phone). We thank you for your time and hope that you will consider being a part of this integral program.

[Type the sender title]
[Type the sender company name]

Appendix E
Peer Support Application
Adopted from BETA HEART C4C tools

Peer Supporter Application
Tier Two (2)

Individuals interested in joining the Care for Caregiver team and supporting their colleagues as trained peer supporter are requested to complete this application for review by the Team Steering Committee for final approval by the RUHS Cares Steering Committee.

Personal Information

Name:		
Address		
City:	**State:**	**ZIP Code**
Phone (Mobile)	**Phone: (Work)**	

Employment Information

Current Dept.:		**Current Title**
Primary Shift worked	**Years of Clinical Experience:**	
Phone Mobile)	**Phone: (Work)**	

Clinical Experience

Do you have any experience providing any of the following ? (Check all that apply)

- Individual Counseling/Coaching
- Small Group Work
- Stress Management
- Leading Debriefing
- **Other: Please Specify**

How did you hear about the Peer Support Team?

Why would you like to become a member of this team?

Additional Information would like for us to know about you

I would like to be considered for the role of peer supporter

Applicant's Signature Date:

I endorse this applicant's request to join the peer support team

Manager Signature: **Date**

Please submit completed application to :
RUHS Cares: Care For the Caregiver
Steering Committee

Document History:

Prior Release Dates: New	**Retire Date:** N/A
Document Owner: Patient Safety Officer	**Replaces Policy:** N/A

Date Reviewed	Reviewed By:	Revisions Made Y/N	Revision Description
11/21/2024	Nursing Policies and Procedures Committee	N	
11/27/2024	PAC Evote	Y	Standardize the term used to refer to staff needing support.
11/3/2024	MEC	Y	Grammar, formatting, clarify safe space

RIVERSIDE UNIVERSITY HEALTH SYSTEM – MEDICAL CENTER

Housewide

	Document No: 505	Page 1 of 3
Title: Care of Incarcerated Patients	**Effective Date:** 12/10/2024	☐ **RUHS – Behavioral Health** ☐ **RUHS – Community Health Centers** ☐ **RUHS – Hospital Based Clinics** ☒ **RUHS – Medical Center** ☐ **RUHS – Public Health** ☐ **Departmental**
Approved By:  Jennifer Cruikshank CEO/ Hospital Director		☐ **Policy** ☐ **Procedure** ☒ **Guideline**

1. DEFINITIONS

1.1 Deputy: law enforcement personnel employed by the Riverside County Sheriff's Department (RSD).

1.2 Officer: law enforcement personnel employed by the California Department of Corrections and Rehabilitation (CDCR).

2. GUIDELINES

2.1 Riverside University Health Systems – Medical Center (RUHS-Medical Center) staff guidelines:

a. Incarcerated patients are not subject to receiving and/or signing acknowledgement of the Notice of Privacy Practices (NPP) or Hospital Conditions of Admission.

b. Staff must not divulge any information about incarcerated patients to anyone other than those directly involved in the patient's medical care. Exchange of information shall be limited to that which is of medical necessity.

c. All public calls or inquiries (e.g. family or friends) regarding incarcerated patients must be referred to correctional personnel within the Detention Care Unit (DCU) Control Pod.

d. No appointments, visitation information, location within the hospital or discharge times will be released to anyone except to the correctional officer/deputy providing security.

e. Visitation for inmates not housed on the DCU will follow our Visiting Hours and Visitor Safety Policy HW 614.

f. All incoming and outgoing mail, messages, etc. for the incarcerated patient shall be routed through the correctional officer/deputy.

g. Upon discharge, staff shall place the incarcerated patient's discharge documentation in a sealed envelope and give to the deputy or officer providing transportation back to the correctional facility.

h. Discharge medications should be sealed in a bag and given to the deputy or officer for transportation back to the correctional facility.

i. When interacting with the incarcerated patient, staff members shall maintain a helpful and professional demeanor and shall not discuss their own or any staff member's personal business with the incarcerated patient.

j. Staff members shall not engage in a social relationship with the incarcerated patients or their families.

k. Staff members shall never accept gifts or money from incarcerated patients or their families.

l. Staff members shall never bring any gifts, food, or clothing from anyone to the incarcerated patient. Examples include pens, pencils or magazines. Any such request from an incarcerated patient should be made directly to the correctional officer or deputy providing security.

m. Any request from an incarcerated patient for RUHS-Medical Center staff to communicate with anyone who is not directly involved in their medical care must be reported to the correctional officer or deputy immediately.

n. When attending to an incarcerated patient, staff members shall not keep valuables, personal or other unnecessary items in their pockets or on their person. These items may not be secured and can be considered as a weapon or unauthorized item if taken by an inmate.

o. The incarcerated patient may only have personal items necessary for their medical care and personal hygiene.

p. Coffee, soda, candy, ice cream, extra food, ear plugs, and eye shades are prohibited unless deemed a medical necessity by the attending physician.

q. Any questions or concerns related to safety and security should be directed to the Deputy or Officer in attendance or the Control Pod within the DCU.

r. Due to the interactive nature and information available on the SONIFI health television system, incarcerated patients shall not have access to the in-room television. Any exception for comfort care or end of life must be approved by the unit director or hospital administration.

2.2 Deputy / Officer Responsibilities

a. Security concerns are the sole responsibility of the officer and/or deputy monitoring the incarcerated patient and correctional personnel are responsible for the security of the incarcerated patient at all times. Correctional personnel will:

i. Escort incarcerated patients to and from treatment locations in the Medical Center.

ii. Ensure safe access to the patient while medical staff is conducting treatment, exam and/or evaluation.

iii. Remove forensic restraints at the request of medical staff in order to conduct examinations or procedures that are medically necessary.The decision to remove the forensic restraints will ultimately be at the discretion of the officer and/or deputy providing security in compliance with RUHS Policy HW 630 Restraints and Seclusion.

iv. Respect privacy during obstetrics or gynecology examinations. Correctional personnel shall give considerations to the privacy of the incarcerated patient. Correctional personnel should stand outside the privacy curtain unless security concerns dictate other arrangements are made.

v. Carry out daily activities not directly related to the incarcerated patient's care (e.g., visiting, phone, mail).

vi. Provide security of the incarcerated patient at all times, including during

patient exams and evaluations.

2.3 Concerns with RSD or CDCR correctional personnel will be reported to the supervisor of their respective agency.

3. REFERENCES

3.1 California Penal Code, Section 4570

3.2 RUHS Policy HW 614 Visiting Hours and Visitor Safety

3.3 RUHS Policy HW 630 Restraints and Seclusion

Document History:

Prior Release Dates: 6/1987, 8/2014, 11/13/2017, 3/18/2021	**Retire Date:** N/A
Document Owner: Security	**Replaces Policy:** N/A

Date Reviewed	**Reviewed By:**	**Revisions Made Y/N**	**Revision Description**
5/14/2024	Security	Y	Reference visiting hours policy
8/22/2024	Nursing P&P	Y	Update Scope
11/5/2024	PAC	Y	Add information on television, add reference to restraints policy

RIVERSIDE UNIVERSITY HEALTH SYSTEM – MEDICAL CENTER

Housewide

	Document No: 600.1	Page 1 of 2
Title: Pediatric Patient Admissions	**Effective Date:** 12/10/2024	☐ **RUHS – Behavioral Health** ☐ **RUHS – Community Health Centers** ☐ **RUHS – Hospital Based Clinics** ☒ **RUHS – Medical Center** ☐ **RUHS – Public Health** ☐ **Departmental**
Approved By:  Jennifer Cruikshank CEO/ Hospital Director		☒ **Policy** ☐ **Procedure** ☐ **Guideline**

1. DEFINITION

1.1 Pediatric Unit: Acute Care Pediatrics, Pediatric Intensive Care Unit (PICU) and/or Neonatal Intensive Care Unit (NICU)

2. POLICY

2.1 Patients 17 years of age and younger shall be admitted to a Pediatric Unit at Riverside University Health System - Medical Center (RUHS-Medical Center) for management of acute medical conditions, unless there are extenuating circumstances necessitating admission to a non-pediatric unit of RUHS-Medical Center.

2.2 The NICU should be the first choice of location for admissions for infants less than or equal to 30 days of life and preterm infants up to 44 weeks corrected gestational age. Patients with fewer than 30 days of life may be deferred to the Pediatrics or PICU at the discretion of the attending neonatologist.

a. At no time will a patient under age 14 be admitted to anywhere other than a pediatric unit unless the condition is pregnancy-related.

2.3 Patients between 18 and 21 years of age being admitted for treatment of California Children's Services (CCS) eligible conditions may be admitted to the pediatric unit or the applicable non-pediatric unit of the hospital.

a. Patients with CCS-eligible conditions shall be under the care of a CCS-paneled attending or sub-specialist.

2.4 Notifications:

a. The Case Manager and/or Nursing House Supervisor shall notify the pediatric attending or designee any time a pediatric patient is admitted to a non-pediatric unit of RUHS – Medical Center.

3. REFERENCES

3.1 California Code of Regulations , Title 22, Division 2, Subdivision 7, Chapter 3, Article 2, Sections 41515.1-41518.9

3.2 Title 22, Div. 9, Chapter 7, Article 3

3.3 Title 22, Div. 5, Chapter 1, Article 6, Section 70537.

3.4 RUHS NICU Guideline 1.3: NICU Admission, Observation, Transfer, and Discharge.

3.5 RUHS PICU Guideline 1.1: PICU Admission, Transfer, and Discharge

3.6 "California Children's Services Eligible Medical Conditions." dhcs.ca.gov, 1 Sept. 2024, dhcs.ca.gov/provgovpart/Documents/CCS%20eligible%20medical%20conditions.pdf

Release Dates: 01/26/01, 04/03/07, 3/10/2021	**Retire Date:** N/A
Document Owner: Peds	**Replaces Policy:** N/A

Date Reviewed	Reviewed By:	Revisions Made Y/N	Revision Description
3/9/2021	Nursing Admin	N	
9/10/24	Pediatrics & NICU Leadership Team	Y	Minor grammar updates. Removed list of CCS Eligible conditions. Added Eligible conditions in the reference and added PICU & NICU admission reference
11/5/2024	Policy Approval Committee	N	

RIVERSIDE UNIVERSITY HEALTH SYSTEM – MEDICAL CENTER
Housewide

	Document No: 603.7	Page 1 of 10
Title: Regional Analgesia Care via Catheter	**Effective Date:** 11/22/2024	☐ **RUHS – Behavioral Health** ☐ **RUHS – Community Health Centers** ☐ **RUHS – Hospital Based Clinics** ☒ **RUHS – Medical Center** ☐ **RUHS – Public Health** ☐ **Departmental**
Approved By: Jennifer Cruikshank CEO / Hospital Director		☐ **Policy** ☐ **Procedure** ☒ **Guideline**

1. SCOPE

1.1 Applies to the management of regional analgesia care via catheters for admitted adult and pediatric patients at the Medical Center Main Campus. Describes interdisciplinary care roles and includes anesthesia care providers and critical care surgeons.

1.2 Patient care will be assigned to designated units and staff who have completed training and competency evaluation.

1.3 Surgical Critical Care attendings may only perform ESP (erector spinae plane) blocks with tunneled catheter placement. See Appendix 9.3

1.4 Provide guidelines and standards in conjunction with RUHS approved Online Learning System topics including: 1) Regional Anesthesia; 2) Local Anesthesia: Patient Monitoring, 3) Regional Blocks

1.5 Epidural Analgesia, and Care of the Laboring patient is covered in separate policy.

2. DEFINITIONS

2.1 Infusion device: an external or implanted pump used to administer analgesia

2.2 Dermatomes: specific skin surface areas innervated by a single spinal nerve or group of nerves

2.3 Regional anesthetic infusion (peripheral nerve block): administration of local anesthetic through a catheter in proximity to a specific nerve or nerve bundle to produce sensory and motor blockade to a specific region of the body. The purpose of the infusion is to produce blockade of nerve(s) and produce analgesia.

2.4 Local Anesthetic Systemic Toxicity (LAST): symptoms of toxicity from overdose of local anesthetics that affect the cardiovascular system, central nervous system, or both. LAST occurs due to excessive systemic uptake of local anesthetic. Onset of symptoms typically occurs between 1 and 5 minutes after local anesthetic injection but may be delayed more than 15 minutes. Symptoms include: hemodynamic instability, cardiovascular collapse, seizures, and cardiac arrest. LAST is rare but is life-threatening without the use of specific, rapidly administered treatment and requires alterations from standard advanced cardiovascular life support.

3. GUIDELINES

3.1 Indications for short-term regional analgesia and / or regional anesthesia

a. Postoperative pain

b. Procedural pain

c. Trauma pain

d. Some nonsurgical pain (e.g. sickle cell-related lower extremity pain)

e. Cancer pain

f. Chronic nonmalignant pain

3.2 A patient will always have intravenous (IV) access when regional infusions are being administered.

3.3 Education and Competency: Nursing

a. Review RUHS Online Learning System for guidelines for nursing care. The primary-care provider and/or the anesthesia team may determine that regional anesthesia is contraindicated in certain conditions.

b. Review RUHS Online Learning System for guidelines for nursing care related to Local Anesthesia: Patient Monitoring.

c. Review RUHS Online Learning System for guideline for nursing care related to Regional Blocks.

d. The RN will complete initial and ongoing institution-established educational requirements related to administration of regional analgesia including the use of designated infusion device

3.4 Qualified Anesthesia Care Providers –

a. Attendings, residents, CRNAs

3.5 Qualified Surgeons –

a. Surgical Critical Care trained Attendings

b. Surgical Critical Care Fellows under direct supervision

3.6 Responsibilities: Anesthesia-Care Provider, Surgeons

a. Complete training requirements related to the use of designated medication infusion device

b. Perform history, physical examination and review of relevant laboratory studies prior to performing regional anesthesia procedures.

c. Develop a plan of care through review of patient health and medication history, including anticoagulants, assessment and evaluation of current pain state, the patient's understanding of their pain, and establishment of goals for pain management.

d. Obtain patient informed consent for the procedure.

e. Use sterile technique to place the regional catheter.

f. Apply sterile occlusive dressing at the catheter insertion site.

g. Verify correct catheter placement and appropriate dosing.

h. Assess the patient's vital signs after catheter placement.

i. Write or enter orders.

   i. Appropriate medication(s), dosages, and concentrations to be infused

   ii. Manage side effects and complications

   iii. Monitoring parameters and frequency

   iv. Contact information (e.g., pager, phone number)

j. When using an infusion pump, the provider programs and initiates the infusion.

k. Providers make dose and rate changes to the infusion pumps.

l. Perform initial injection and/or initiation of a continuous infusion of analgesia.

m. Perform dermatome assessment and confirmed desired goal is met as needed.

n. Providers write or enter new orders to increase or decrease the rate of infusion. Orders are not titratable.

o. Communicate with the RN regarding patient status or changes in patient status during treatment.

p. Assess the patient's pain daily and as clinically indicated by the managing service (anesthesia, or surgery) provider.

q. Coordinate and remove catheters upon discontinuation of therapy.

3.7 Responsibilities: Registered Nurse (RN), qualified

After verification of the correct catheter placement and assessment of the patient's vital signs by surgeon or anesthesia care provider, the RN may be responsible for the following aspects of patient care:

a. Monitor the catheter insertion site

b. Monitor the patient for analgesic efficacy and side effects

c. Treat analgesic related side effects under physician direction.

d. Recognize potential complications of regional analgesia and initiate emergency therapeutic measures accordingly if complications arise including stopping infusion therapy.

e. Monitor the patient's vital signs, level of consciousness (RASS), mobility, and pain level, sensory block and motor function per Provider order.

f. Troubleshoot infusion devices consistent with infusion pump training. If troubleshooting requires disconnection of the infusion tubing from catheter connection, pause infusion and notify managing provider (anesthesia, surgery) to assess.

g. May replace new, pre-packaged or prepared drug when the dose, concentration, and rate remain the same.

i. Always trace a tube or catheter from the patient to the point of origin before connecting any new device or infusion or adjusting the infusion rate.

ii. Always hang infusion bag/syringe with the label facing out so it can be read.

h. Provide patient and family education.

4. PROCEDURES: Regional Catheter

4.1 Nursing staff will use the process guidelines in the Regional Catheter Checklist when monitoring patients with a regional peripheral nerve catheter (see Appendix B). The checklist includes but not limited to the following:

a. Anesthesia or Surgery provider to attach a *Regional Only* label to the end of the tubing near catheter hub, and the regional tubing and pump. Nursing shall support the integrity of labeling and infusion safety thereafter.

b. Implement the monitoring parameters and alarm notification to providers protocol as outlined in Appendix A

4.2 Regional Catheter Monitoring (Appendix B)

a. Obtain and document in health record at least Q4H vital signs including Temp, HR, RR, B/P, SpO_2, pain, and motor status to extremity with regional catheter.

4.3 **Administration of regional analgesia by continuous infusion is to be delivered via dedicated smart infusion pump for regional catheter use.** Use distinctly different pumps for intravenous (IV) applications and place the regional catheter infusion pump on one side of the patient's bed and all other pumps on the other side of the bed when possible.

4.4 The provider will manage the pump, make any rate changes to the pump, and place new orders

4.5 Nursing shall record administration actions in the medication administration record using "Document for Another" functionality and enter the managing providers username.

4.6 Do <u>not</u> use tubing that has injection ports in conjunction with regional catheters to limit the risk of inadvertently administering a medication intended for IV injection into the site.

4.7 Notify the provider if the patient is experiencing unrelieved or excessive pain.

4.8 Limit the disconnection and reconnection of regional delivery systems in order to minimize the risk of infectious complications.

a. Assess catheter connections and the regional site. If disconnected at any point, apply an empty sterile syringe to end of catheter and contact managing provider.

4.9 Monitor for signs and symptoms of complications including inadequate analgesia, hypotension and bradycardia, respiratory depression, nausea and vomiting, seizures or altered mental status. Nursing <u>may stop</u> the administration of analgesia / anesthesia if the patient exhibits symptomatic hypotension, or any signs Local Anesthetic System Toxicity (LAST).

a. Signs and symptoms of LAST include dizziness, tinnitus, dysphoria, circumoral numbness, metallic taste, agitation, seizures, confusion, auditory changes and dysrhythmias.

b. **If LAST is suspected, stop the medication infusion and Call Anesthesia provider**.

c. Call Rapid Response Team (RRT), Code Blue, Code White as per indication.

d. *Do not reinitiate medication infusion. Acute Pain consult must occur before further therapy.

5. DOCUMENTATION

5.1 Blood pressure, oxygen saturation, heart rate, respiratory rate, RASS, pain intensity score, and motor block level as indicated by provider order.

5.2 Document rate of regional or epidural infusion rate and volume.

5.3 Visual inspection of insertion site.

5.4 Side effect management.

5.5 Patient/family education.

5.6 Complications and emergency recognition and management.

6. PRECAUTIONS

6.1 Universal precautions and sterile technique.

6.2 Fall precautions should be assessed and implemented.

6.3 Anticoagulation

a. Anticoagulation does not have to be withheld or can be at provider discretion

6.4 Assess for pressure injury from points of tubing connection.

a. **Due to sensory changes, patient position changes may be necessary to prevent pressure sores from developing.**

6.5 A resuscitation bag, mask and medications must be readily available in the patient care area where epidural medication is administered.

7. LOCAL ANESTHETIC SYSTEM TOXICITY

7.1 Notify Anesthesia provider for suspected or actual adverse reaction or toxicity.

7.2 LAST is rare, but is life-threatening without the use of specific, rapidly administered treatment and requires alterations from standard Advanced Cardiovascular Life Support (ACLS).

7.3 Intravenous fat emulsion, or lipid emulsion 20%, is used for therapeutic intervention and reversal. Refer to hospital policy for lipid rescue.

8. REMOVAL OF THE CATHETER

8.1 Catheters will only be removed by Anesthesia Providers or surgeons

8.2 Ensure step-down analgesia has been established and pain is under control

8.3 Explain the procedure to the patient.

9. ATTACHMENTS

9.1 Attachment 1: Regional Anesthesia Sign

9.2 Appendix A: Peripheral Nerve Catheter Check List

9.3 Surgeons: Continuous Intercostal Rib Block Guideline

10. REFERENCES

10.1 American Association of Nurse Anesthesiology (AANA). (2017). Care of patients receiving analgesia by catheter techniques: Position statement and Policy Considerations.

10.2 Baker, D.W. (2016). The Joint Commission statement on pain management. Healthcare Quality Evaluation, The Joint Commission.

10.3 Chumbley G, Thomas S. Care of the patient receiving epidural analgesia. Nurs Stand. 2010 Nov 3-9;25(9):35-40. doi: 10.7748/ns2010.11.25.9.35.c8075. PMID: 21141166.

10.4 DeCicco, M. et al., (1995) Time D

10.5 HW 603.6 Epidural Analgesia Care via Catheter (non- Obstetric)

10.6 HW 830 Administration of Parenteral medications for Adult Patients

10.7 HW 819 Pediatric and Neonatal Parenteral Medication Administration

10.8 HW 880 Lipid Rescue Therapy for Amide Anesthetics

10.9 Johnson RL, Kopp SL, Hebl JR, Erwin PJ, Mantilla CB. Falls and major orthopaedic surgery with peripheral nerve blockade: a systematic review and meta-analysis. Br J Anaesth. 2013 Apr;110(4):518-28. doi: 10.1093/bja/aet013. Epub 2013 Feb 24. PMID: 23440367; PMCID: PMC3600943.

10.10 Neal JM, Neal EJ, Weinberg GL. American Society of Regional Anesthesia and Pain Medicine Local Anesthetic Systemic Toxicity checklist: 2020 version. Reg Anesth Pain Med. 2021 Jan;46(1):81-82. doi: 10.1136/rapm-2020-101986. Epub 2020 Nov 4. PMID: 33148630.zzz

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10.12 Practice Advisory for the Prevention, Diagnosis, and Management of Infectious Complications Associated with Neuraxial Techniques: An Updated Report by the American Society of Anesthesiologists Task Force on Infectious Complications Associated with Neuraxial Techniques and the American Society of Regional Anesthesia and Pain Medicine. *Anesthesiology* 2017; 126:585–601.

10.13 Practice Guidelines for Acute Pain Management in the Perioperative Setting: An Updated Report by the American Society of Anesthesiologists Task Force on Acute Pain Management. *Anesthesiology* 2012; 116:248-273.

Document History:

Prior Release Dates: N/A	**Retire Date:** N/A
Document Owner: Nursing	**Replaces Policy:** N/A

Date Reviewed	Reviewed By:	Revisions Made?	Revision Description
12/2023	Interdisciplinary subcommittee – Anesthesia, Nursing, Pharmacy, Surgery	Yes	Create new policy – separate from epidural policy with addition of Surgeon management
7/3/2024	Pre Nursing P&P	N	No recommended changes, move to NPP for consent agenda item.
7/18/2024	Nursing P&P	N	Consent agenda item
08/05/2024	Pharmacy & Therapeutics Committee	Y	Updated Attach 1 – add language to contact MRI dept
9/3/2024	PAC	Y	Add reference to related policy
9/12/2024	MEC	Y	Post MEC discussion to specify the ESP intercostal rib block only for critical care surgeons (1.1 and 1.3). Specified SCC trained faculty only in 3.5 a and b.

9.1 Attachment 1: Regional Anesthesia Sign

REGIONAL CATHETER

IF MRI ORDERED, CONTACT MRI DEPARTMENT

Date placed _____ *in Right/Left* _____

Assess motor/sensory functions prior to getting patient out of bed

9.2 Appendix A: Regional Peripheral Nerve Catheter Checklist

Upon Receiving the Patient:

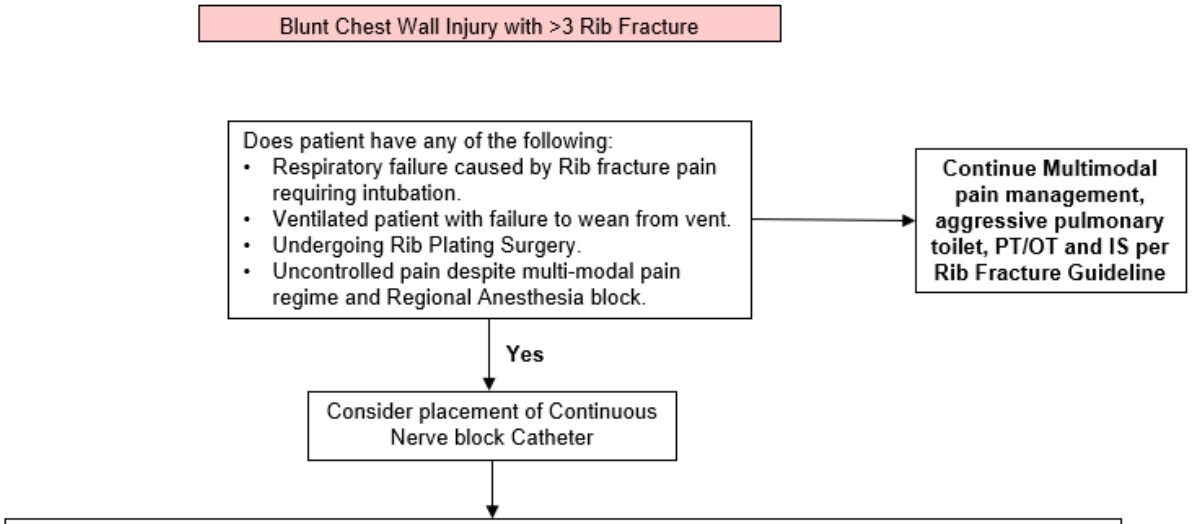
Receive handoff from responsible care team member

- Verify regional medication orders and nursing orders
- Verify regional catheter and regional tubing is labeled
- Assess regional site for bleeding or drainage
- Obtain and document in medical record at least Q4H vital signs including:
    - Temp, HR, RR, B/P, SpO_2, pain, and motor status to extremity with regional catheter.
- Assess regional catheter site each shift
- Assess and ensure IV is patent.

9.3 Appendix Surgeons: Continuous Intercostal Rib Block Guideline

The division does not intend these guidelines to supplant clinical judgment, and we note that specific patient nuances may require modification of the approach.

Numbers in (red parentheses) reference further literature and guidance in the attached reference sheets.



1. Obtain informed consent for paravertebral nerve block.
2. Avanos On-Q Silversoaker 5in catheter for ≤3 Rib fracture, 7.5-10in for >3 rib fractures.
3. Order "2% Lidocaine w/ Epinephrine 1:200,000".
4. Order "Ropivacaine 0.2% local anesthetic infusion".
    1. Set "Dose" 10mL/hr, "Route" Peripheral Nerve Block, "Frequency" Continuous, "For" 5 days.
    2. Enter contact information (phone) of the provider managing the infusion.
5. Obtain Sapphire pump with epidural line from central supply or ~~OB suite.~~
6. Use sterile technique for placement of ON-Q catheter using On-Q Tunneler & Sheaths.
7. Inject 2% Lidocaine w/' Epi through the catheter to access patient's vital sign change.
8. Apply sterile occlusive dressing with Bio-patch and Tegaderm at catheter insertion site.
9. Connect catheter to Sapphire pump using epidural line and set initial basal rate at 10 ml/hr, no bolus.
10. Write/enter new order when changing rate of infusion.
11. Communicate with RN regarding change in infusion rate.
12. Daily assessment of patient's pain:
    1. Surgeon provider programs and initiates the infusion.
    2. Surgeon provider make dose and rate changes to the infusion pumps based on q6hr PIC score.
        1. If patient have PIC score of 1 in any category, increase the rate by 2 ml/hr up to max 14m ml/hr.
        2. Keep the rate same if the PIC score 3-7.
    3. Surgeon provider determines the timing and coordinate removal of catheter
        1. If PIC Score ≥7 consider removing the catheter.
        2. Max On-Q catheter is 5 days, remove catheter regardless of PIC score.
        3. Titration is not necessary prior to removal.

RIVERSIDE UNIVERSITY HEALTH SYSTEM – MEDICAL CENTER
HOUSEWIDE

	Document No: 613	Page 1 of 4
Title: Methotrexate Administration and Management for Treatment of an Ectopic Pregnancy	**Effective Date:** 12/6/2024	☐ **RUHS – Behavioral Health** ☐ **RUHS – Community Health Clinics** ☒ **RUHS – Medical Center** ☐ **RUHS – Public Health** ☐ **Departmental**
Approved By:  Jennifer Cruikshank CEO/ Hospital Director		☐ **Policy** ☒ **Procedure** ☐ **Guideline**

1. **SCOPE:** The purpose of this procedure is to define the administration of Methotrexate to adult female patients who have been diagnosed with ectopic pregnancy and are outpatients at Riverside University Health Systems – Medical Center, Emergency Department (ED).

2. DEFINITIONS:

2.1 Methotrexate: Methotrexate is a chemotherapeutic agent for use as a medical therapy for unruptured ectopic pregnancies. Its mechanism of action is competitive inhibition of folate-dependent steps in nucleic acid synthesis, which effectively kills the rapidly dividing ectopic trophoblast.

2.2 Ectopic pregnancy: A fertilized egg that implants in any location other than the inner lining of the uterus. The majority (95%) of ectopic pregnancies occur in the fallopian tube. However, they can occur in other locations, such as the ovary, cervix, and abdominal cavity.

2.3 Chemotherapy Nurse: A RN who has completed 1) Oncology Nursing Society (ONS) provider course; 2) completed training/certification; and 3) education to administer chemotherapy, antineoplastic hazardous drugs.

3. PRECAUTIONS

3.1 Renal dysfunction does not preclude the use of methotrexate for ectopic pregnancy. Complications from low dose methotrexate are extremely rare.

a. Exclusions may apply for high dose methotrexate or chronic low dose use of methotrexate, none of which apply to the therapeutic regimens for ectopic pregnancy

b. The issue is not that methotrexate is going to cause severe renal failure but that the half-life may be prolonged in renal deficiency as this is where it is excreted.

c. The dose of methotrexate for etopic pregnancy is so low that prolonged half life does not significantly increase any risk to the patient. Even with renal dialysis you would just need to be aware of when the medication was given in relation to her next dialysis to estimate the efficacy of the dose that you are giving.

4. EXCLUSION CRITERIA:

4.1 Viable intrauterine pregnancy.

4.2 Clinically significant abnormalities of hematologic, renal or hepatic laboratory values. Blood dyscrasias, chronic liver disease, chronic renal disease (dialysis) – discuss with provider.

4.3 Breastfeeding (discontinue for 72 hours - methotrexate will not be given if patient refuses to stop breastfeeding).

4.4 Hypersensitivity to methotrexate.

4.5 Immunodeficiency, active pulmonary disease or peptic ulcer disease.

4.6 Hemodynamically unstable.

4.7 Patient is not able to participate in follow-up.

4.8 Concurrent intrauterine pregnancy (heterotopic pregnancy).

4.9 No signed informed consent by patient for the use of methotrexate in the treatment of ectopic pregnancy.

5. INCLUSION CRITERIA:

5.1 Hemodynamically stable.

5.2 No contraindications to methotrexate therapy.

5.3 Serum beta-human chorionic gonadotropin (hCG) ≤ 5000 mIU/ml.

5.4 Lack of fetal cardiac motion detected on transvaginal ultrasound.

5.5 Ectopic mass < 4 cm.

5.6 Willing and able to comply with post-treatment follow-up with access to emergency medical services.

a. Failure of the hCG level to decrease by at least 15% from day 4 to day 7 after methotrexate administration may require a repeat dose on day 7.

6. CLINICAL PROTOCOL:

6.1 ED Nurse must validate that an order for methotrexate for ectopic pregnancy has been placed by an OB Attending Provider to proceed with protocol and checklist.

6.2 Utilize Methotrexate Administration Checklist for Ectopic Pregnancy to guide nursing practice. See Attachment.

6.3 The informed consent must be completed prior to the administration of methotrexate.

6.4 Patient teaching should be provided prior to methotrexate administration.

6.5 Pharmacy Services will attempt to procure the most ready-to-use methotrexate product, e.g. pre-filled syringes.

6.6 **Pre-filled methotrexate syringes, pre-attached fixed needle**

a. Dose: 50mg/m2 to be administered using the patient's actual body weight. Dose will be rounded to meet the available concentrations of the pre-filled syringes. See Attachment.

b. Route: administered **subcutaneously**, will need to administer two or more syringes

i. Do not administer intramuscularly

ii. Do not attempt to remove pre-attached needle

c. Pre-filled methotrexate syringes may be administered by a non-chemotherapy nurse as per policy

d. Don appropriate PPE as per policy

6.7 **When pre-filled syringe is not available, pharmacy will compound methotrexate syringe(s):**

a. Dose: 50mg/m2 to be administered using the patient's actual body weight

b. Route: administered **intramuscularly**

c. The ED charge nurse or designee will notify the house supervisor to assign a chemo nurse to come to the ED to administer the compounded methotrexate.

d. Don appropriate PPE as per policy.

e. The chemo nurse will administer the IM injection of methotrexate as per physician order.

f. The ED and/or chemo nurse will follow the administration checklist (Attachment A) and sign and date when completed.

6.8 The ED and/or chemo nurse will document the care provided in the medical record.

6.9 The ED nurse will conclude the visit and provide the discharge instructions and follow up care.

7. ATTACHMENT

7.1 Methotrexate Pre-filled Syringe Dose Rounding Table

7.2 Methotrexate Administration Checklist for Ectopic Pregnancy

8. REFERENCES

8.1 Chi, T, Pritcharrd T., J.,Syah, A.,: Emergency management of ectopic pregnancy. Medscape Jan.10, 2021. Retrieved on March 14, 2024 from https://emedicine.medscape.com/article/796451-overview#showall

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8.3 Kurt T. Barnhart, MD; MSCE; and Jason M. Franasiak. MD, TS (ABB). Tubal Ectopic Pregnancy. Am J Obstet Gynecol ACOG Practice Bulletin Number 193, March 2018.

8.4 National Institute for Health and Care Excellence (NICE). (2019, April 17). Ectopic pregnancy and miscarriage: Diagnosis and initial management. Retrieved from https://www.clinicalkey.com/#!/content/nice_guidelines/65-s2.0-NG126?scrollTo=%23update-information

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06/2024	Cancer Quality of Care Committee/Hazardous Drug Subcommittee	Yes	Revisions to include pre-filled syringe / chemo RN not needed. Updated checklist for procedure, updated references
08/13/2024	Pharmacy Review Committee	No	Approved
9/5/2024	Pre-Nursing Policy and Procedure Committee	No	Approved to consent agenda
09/09/24	Pharmacy & Therapeutics Committee	No	
10/28/2024	PAC	No	
11/14/2024	MEC	No	

7.1 Methotrexate Pre-filled Syringe Dose Rounding Table

50 mg/m^2 BSA	DOSE (MG)	SYRINGE DOSES TO BE DISPENSED
1.4	70	2x (25 mg) + 1x (20 mg)
1.5	75	3x (25 mg)
1.6	80	2x (25 mg) + 1x (30 mg)
1.7	85	2x (30 mg) + 1x (25 mg)
1.8	90	3x (30 mg)
1.9	95	3x (25 mg)+ 1x (20 mg)
2	100	4x (25 mg)
2.1	105	3x (25 mg) + 1x (30 mg)
2.2	110	2x (30 mg) +2x (25 mg)
2.3	115	3x (30 mg) + 1x (25 mg)
2.4	120	4x (30 mg)
2.5	125	5x (25 mg)
2.6	130	4x (25 mg) + 1x (30 mg)
2.7	135	2x (30 mg) + 3x(25 mg)

7.2 Methotrexate Administration Checklist

SECTION A:	**ED RN VERIFICATION**	
DATE / Time		**VALIDATOR INITIALS**
	1. Verify patient does not meet any exclusion criteria, (see Policy 613), if met, notify OB Physician.	
	2. Verify MTX order has been placed in EPIC by the OB Physician.	
	3. Verify MTX Dose (circle) 1st 2nd 3rd	ED RN Initial
	4. Verify baseline labs ordered and resulted for **first dose** (CBC, CMP, LFTs, quantitative beta-hCG. Labs do not need to be repeated for 2nd and 3rd dose unless ordered by MD).	ED RN Initial
	5. Verify transvaginal ultrasound completed. (Not needed for 2nd or 3rd dose unless ordered by MD).	ED RN Initial
	6. Verify Physician Progress Note in EPIC includes ectopic mass < 4cm. (Not needed for 2nd or 3rd dose unless ordered by physician).	ED RN Initial
	7. Verify H&P in EPIC includes: Last menstrual period (LMP). (Not needed for 2nd or 3rd dose unless ordered by physician).	ED RN Initial
	8. Verify informed consent obtained, copy of record is available to the patient. Must be completed for each dose.	ED RN Initial
	9. Verify actual height and weight are documented in EPIC.	ED RN Initial
	10. Verify with Pharmacy if the ordered MTX product is compounded for IM administration or pre-filled with affixed needle for subcutaneous administration. a. If compounded product for IM administration, **go to Section B**. b. If a pre-filled syringe or autoinjector with affixed subcutaneous needle, go to **Section C.**	
	11. ED to notify NHS of need for Chemo RN to administer compounded MTX injection (***Do not call until 1 through 10 above have been completed)***.	ED RN Initial
SECTION B:	**CHEMO RN & PHARMACY VERIFICATION**	
	1. Chemo RN to call main pharmacy to confirm order in EPIC and time for pick-up. Chemo RN to call ED with ETA.	Chemo RN Initial
	2. Chemo RN to obtain MTX checklist from ED RN prior to picking up MTX from Pharmacy.	Chemo RN Initial
	3. Chemo RN to pick up medication from main pharmacy and verify with the pharmacist the following: right medication, dose, route time, and expiration date and time.	Chemo RN Initial / Pharmacist
	4. Chemo RN to bring MTX to the ED for administration.	Chemo RN Initial
SECTION C:	**CHEMO RN & ED or ED & ED RN VERIFICATION**	
	1. Compounded MTX product requires both ED and Chemo RN verification. Commercially prepared syringe with affixed needle only requires ED verification.	
	2. Review patient does not meet any exclusion criteria, (see Policy 613), if met, notify OB physician.	
	3. Review MTX order has been placed in EPIC by the OB Physician.	
	4. Review MTX Dose (circle) 1st 2nd 3rd	ED RN Initial
	5. Review baseline labs ordered and resulted for first dose (CBC, CMP, LFTs, quantitative beta-hCG. Labs *do not* need to be repeated for 2nd and 3rd dose unless ordered by physician).	
	6. Review transvaginal ultrasound completed. (Not needed for 2nd or 3rd dose unless ordered by physician).	
	7. Review Physician Progress Note in EPIC includes ectopic mass < 4cm. (Not needed for 2nd or 3rd dose unless ordered by physician).	

	8. Review H&P in EPIC includes: LMP. (Not needed for 2nd or 3rd dose unless ordered by physician).	
	9. Verify informed consent obtained, copy of record is available to the patient. Must be completed for each dose.	
	10. Review actual height and weight are documented in EPIC.	Chemo RN Initial

Riverside University Health System – Medical Center

METHOTREXATE (MTX) ADMINISTRATION CHECKLIST FOR ECTOPIC PREGNANCY

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SECTION: D	COMPOUNDED MTX ADMINISTRATION BY CHEMO RN	
	1. Perform hand hygiene, use of proper PPE for hazardous drug handling (double gloves, protective gown, eye, and respiratory protection).	Chemo RN Initial
	2. Inspect the medication, checking that it does not have particulates or discoloration. Do not use any medication that is cloudy or precipitated unless manufacturer information states that this is acceptable.	Chemo RN Initial
	3. Explain the procedure to the patient and verify patient has consented to treatment.	Chemo RN Initial
	4. Verify the following: right patient, using two patient identifiers, the right medication, the right dose, the right route, and the right time.	ED RN Initial / Chemo RN
	5. Utilize BCMA (Bar Code Medication Administration) scanning at the patient's bedside, dual signatures are required in EPIC from the Chemo RN and ED RN.	ED RN Initial / Chemo RN
	6. Administer the medication **intramuscularly** (IM) into the right and/ or left ventrogluteal site using a 22g 1 ½" needle. (The dorsogluteal site is not recommended for IM injections due to the risk of sciatic nerve damage).	Chemo RN Initial
	7. Dispose of the syringe, supplies, and PPE into the chemo waste container, and perform hand hygiene.	Chemo RN Initial
	8. Chemo RN and ED RN will monitor and assess the patient for adverse and allergic reactions to MTX, such as dyspnea, wheezing, or circulatory collapse. In the event of an adverse reaction, the RNs will follow RUHS practice for emergency response.	ED RN Initial / Chemo RN
	9. Once steps 1-8 are complete, **go to section F**.	
SECTION E:	**PRE-FILLED MTX ADMINISTRATION BY ED RN**	
	1. Perform hand hygiene, use of proper PPE for hazardous drug handling (double gloves, protective gown, eye, and respiratory protection).	
	2. Inspect the medication, checking that it does not have particulates or discoloration. Do not use any medication that is cloudy or precipitated unless manufacturer information states that this is acceptable.	
	3. Explain the procedure to the patient and verify patient has consented to treatment.	
	4. Verify the following: right patient, using two patient identifiers, the right medication, the right dose, the right route, and the right time.	
	5. Utilize BCMA (Bar Code Medication Administration) scanning at the patient's bedside, dual signatures are required in EPIC by 2 ED RNs.	
	6. Administer the medication subcutaneously (SQ) into the abdomen or right and/ or left thigh using the commercially prepared prefilled syringe or autoinjector. For administration into the abdomen, avoid 2 inches of the navel.	
	7. Dispose of the syringe, supplies, and PPE into the chemo waste container, and perform hand hygiene.	
	8. The ED RN will monitor and assess the patient for adverse and allergic reactions to MTX, such as dyspnea, wheezing, or circulatory collapse for X time. In the event of an adverse reaction, the RNs will follow RUHS practice for emergency response.	
	9. Once steps 1-8 are complete, **go to section F.**	

SECTION F:	ED RN ASSESSMENT AND TEACHING AFTER MTX ADMINISTRATION	
	1. Will assess and treat the patient's pain as needed.	ED RN Initial
	2. Will provide education for the patient via the EPIC Discharge Instruction handout, to include any follow-up visits with the physician, consultation (in office or via phone), or additional lab appointment. Discharge instructions will also include signs and symptoms of complications which will require immediate return to the ED.	ED RN Initial

	3. Will provide a copy of the completed MTX Checklist to the ED Director or designee for auditing purposes.	ED RN Initial

Print	Signature	Initials	Credentials	Date/Time

RIVERSIDE UNIVERSITY HEALTH SYSTEM

– MEDICAL CENTER, COMMUNITY HEALTH CENTERS, AND HOSPITAL BASED CLINICS

	Document No: 626	Page 1 of 5
Title: Abuse, Neglect, and/or Intimate Partner Violence Assessment and Reporting	**Effective Date:** 12/10/2024	☐ **RUHS – Behavioral Health** ☒ **RUHS – Community Health Centers** ☒ **RUHS – Hospital Based 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 suspected or alleged abuse or assault on a patient before arrival at RUHS. To respond to any suspected or alleged abuse or assault of a patient occurring on the RUHS facility premises, please refer to RUHS policy HW 514.2 Response to Allegations of Assault on a Patient.

2. DEFINITIONS

2.1 Child Abuse or Neglect. "Includes physical injury or death inflicted by other than accidental means upon a child by another person, sexual abuse…neglect… willful harming or injuring of a child or endangering of the person or health of the child, and unlawful corporal punishment…"[4.7]

2.2 Domestic Violence. Abuse perpetrated against any of the following persons: (a) a spouse or former spouse. (b) A cohabitant or former cohabitant. (c) A person with whom the [perpetrator] is having or has had a dating or engagement relationship. (d) A person with whom the [perpetrator] has had a child, where the presumption applies that the male parent is the father of the child of the female parent. (e) A child of a party or a child who is the subject of an action under the Uniform Parentage Act, where the presumption applies that the male parent is the father of the child to be protected. (f) Any other person related by consanguinity or affinity within the second degree.[4.8]

2.3 Elder/ Dependent Adult Abuse. "Elder means any person who is 65 years of age or older".[4.9] "Dependent adult means a person, regardless of whether the person lives independently, between the ages of 18-64 years who resides in this state and who has physical or mental limitations that restrict his or her ability to carry out normal activities or to protect his or her rights, including, but not limited to, persons who have physical or developmental disabilities, or whose physical or mental abilities have diminished because of age.[4.10] "Abuse of an elder or dependent adult" means any of the following: (1) Physical abuse, neglect, abandonment, isolation, abduction, or other treatment with resulting physical harm or pain or mental suffering. (2) The deprivation by a care custodian of goods or services that are necessary to avoid physical harm or mental suffering. (3) Financial abuse."[4.11]

2.4 Mandated Reporting. "Any health practitioner employed in a health facility, clinic, physician's office, local or state public health department, or a clinic or other type of facility operated by a local or state public health department who, in his or her professional capacity or within the scope of his or her employment, provides medical services for a physical condition to **a patient** whom he or she knows or reasonably

suspects is a [victim of abuse,
neglect, or exploitation], shall immediately make a report" to the appropriate agency.[3.2]

2.5 Mandated Reporters. Include, but are not limited to: "A physician and surgeon, psychiatrist, psychologist, dentist, resident, intern, podiatrist, chiropractor, licensed nurse, dental hygienist, optometrist, marriage and family therapist, clinical social worker, professional clinical counselor, or any other person who is currently licensed under Division 2 (commencing with Section 500) of the Business and Professions Code. An emergency medical technician I or II, paramedic, or other person certified pursuant to Division 2.5 (commencing with Section 1797) of the Health and Safety Code. A psychological assistant registered pursuant to Section 2913 of the Business and Professions Code. A marriage and family therapist trainee, as defined in subdivision (c) of Section 4980.03 of the Business and Professions Code. An unlicensed marriage and family therapist intern registered under Section 4980.44 of the Business and Professions Code. A state or county public health employee who treats a minor for venereal disease or any other condition."[3.3]

2.6 Reasonably Suspects. "It is objectively reasonable for a person to entertain a suspicion, based upon facts that could cause a reasonable person in a like position, drawing, when appropriate, on his or her training and experience, to suspect."[3.4]

2.7 Intimate partner - refers to both current and former spouses and dating partners.

3. GUIDELINES

3.1 All Riverside University Health System (RUHS) – Medical Center staff will, to the best of their ability, protect patients from real or perceived abuse, neglect, or exploitation from anyone, including staff, students, volunteers, other patients, visitors, family members, or strangers.

3.2 All allegations, observations, reports or suspected cases of abuse, neglect, intimate partner violence, or exploitation will be reported immediately to the appropriate agency (ies).

3.3 Obligation to Report:

a. Nothing in these guidelines will be interpreted to relieve the *Mandated Reporter* of his or her obligation to promptly report to authorities their reasonable suspicion that an individual (especially a child, elder, a dependent adult, a spouse, or an intimate partner) has been a victim of abuse or neglect as required under California law. *Mandated Reporters* may report independently of the hospital, with or without disclosing the fact of their report to hospital representatives.

b. Cross-reporting may be required where multiple agencies may need to be informed of the suspected abuse. For example, the employee may need to call both law enforcement and Child Protective Services (CPS) or Adult Protective Services (APS).

3.4 Screening for Abuse or Neglect:

a. The suspicion that someone has been the victim of abuse or neglect is rarely based on a single observation or statement. For example, a patient's response to a question upon entrance to the organization (such as "do you feel safe at home?") is insufficient to conclude that the person may have been abused or neglected.

b. As with any diagnosis or assessed need, a reasonable suspicion of abuse or neglect is raised in the mind of the competent healthcare practitioner based on the patient's history and the integration of physical and psychological assessments and observations.

c. Therefore the hospital's approach to screening for abuse and neglect is embedded in the overall process of care and does not rely on the answer to a set of questions or a "screener's" conclusion at a single point in the healthcare process.

3.5 Social Service Referral

a. Patient and Family Services is a resource to hospital personnel and a department representative is on call at all times to 1) assist caregivers in their assessment of suspected abuse or neglect, and 2) for assistance in reporting and patient support.

3.6 Documentation

a. Any observations (including statements made by any individual) or clinical findings suggesting a patient may have been abused or neglected must be documented in their medical record.

- It is recommended that the mandated reporter document in EPIC.

b. However, a caregiver's conclusion as to the presence or absence of abuse or neglect will NOT be documented in the medical record unless the provider arrives at a diagnosis which, by definition, meets the legal definition of abuse or neglect.

3.7 Internal Reporting

a. Any RUHS- Medical Center staff who suspects that a patient, is a victim of abuse or neglect **must** immediately report their suspicion through the chain of command verbally followed by the completion of an incident report using the Datix Incident Reporting System (http://datixapp01/datix/live/index.php).

b. Such internal reporting does not relieve the individual of any obligation he or she must report their suspicion to law enforcement authorities according to California law.

3.8 External Reporting

a. Any RUHS-Medical Center staff who suspects that a patient may be a victim of abuse or neglect must immediately report their suspicions via telephone to the appropriate law enforcement agency.

b. Any RUHS-Medical Center staff, after reporting to the appropriate agencies, will also complete the required written report and forward such report to the appropriate agency within the specified timeframe:

- For law enforcement: CalOES 2-920 California Suspicious Injury Report
- For Child Protective Services: California Suspected Child Abuse Report
- For Adult Protective Services: Report of Suspected Elder/Dependent Abuse

3.9 Education

All clinical employees will receive education (at the time of hire and regularly thereafter) about the criteria for identifying, and the procedures for handling, patients who has injuries or illnesses are attributable to:

a. Intimate partner violence;

b. Elder or dependent adult abuse or neglect;

c. Sexual assault/ rape; or

d. Child physical and/or sexual abuse or neglect.

3.10 Patient/ Family Education

a. Patients exhibiting signs of spousal or intimate partner violence will be offered with crisis intervention services, including access to a forensic examination to document injuries, Danger Assessment, and Safety Planning.

b. They will be provided a list of private and public community agencies that provide, or arrange for, evaluation and care for persons experiencing spousal and intimate partner violence, including, but not limited to, hotlines, local shelters, legal services, and information about temporary restraining orders.

c. Such resource lists are maintained by Patient and Family Services, the Sexual Assault and Forensic Evaluation (SAFE) Clinic, The Riverside County Child Assessment Team (RCCAT), and shall be immediately available through the emergency department.

4. REFERENCES

4.1 California Penal Code §11160(a-b). Last amended 2021.

4.2 California Penal Code §11165.7(a). Last amended 2011.

4.3 California Penal Code §11160(b)(4). Last amended 2021.

4.4 California Penal Code §11161.2. Last amended 2022.

4.5 California Penal Code §11165.9. Last amended 2006.

4.6 California Penal Code §11162.5(d). Last amended 2006.

4.7 California Penal Code §11165.6 Last amended 2007.

4.8 California Family Code §6211. Last amended 1993.

4.9 California Penal Code §11174.4(a). Last amended 2002.

4.10 California Welfare and Institutions Code §15610.23. Last amended 2018.

4.11 California Welfare and Institution Code §15610.07. Last amended 2016.

4.12 RUHS Housewide Policy 514.2 Response to Allegations of Assault on a Patient.

4.13 RUHS Housewide Policy 645 Strangulation Evaluation

Document History:

Release Dates: 04/01/90, 04/21/06,1/15/09, 8/25/2016, 8/31/2017. 8/31/2019, 3/18/2021	**Retire Date:** N/A
Document Owner: Regulatory Compliance	**Replaces Policy:** N/A

Date Reviewed	Reviewed By:	Revisions Y/N	Revision Description
05/18/2023	SAFE Clinic Coordinator	Yes	Definitions added for abuse References update Moved 2.3 to 'scope'
08/20/2023	Regulatory Compliance	No	
12/7/2023	Pre-Nursing P&P	Y	Minor formatting changes
1/2/2024	Nursing P&P	Y	Review of comments and address language
7/22/2024	Nursing P&P	No	
9/3/2024	Policy Approval Committee		Revise and return
11/5/2024	Policy Approval Committee	Yes	Minor wording changes

RIVERSIDE UNIVERSITY HEALTH SYSTEM – MEDICAL CENTER

Housewide

	Document No: 630	Page 1 of 7
Title: Restraints and Seclusion	**Effective Date:** 12/6/2024	☐ **RUHS – Behavioral Health** ☐ **RUHS – Community Health Centers** ☐ **RUHS – Hospital Based Clinics** ☒ **RUHS – Medical Center** ☐ **RUHS – Public Health** ☐ **Departmental**
Approved By: Jennifer Cruikshank CEO/ Hospital Director		☒ **Policy** ☐ **Procedure** ☐ **Guideline**

1. DEFINITIONS

1.1 **Restraint** is any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely.

1.2 **Seclusion** is the involuntary confinement of a person alone in a room or an area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior. Time out is not considered seclusion.

1.3 **Violent Behavior** is violent or self-destructive behavior that jeopardizes the immediate safety of the patient, a staff member or others.

1.4 **Non-Violent Behavior** is the behavior that interferences with medical treatments, lifesaving interventions or ambulating before medically appropriate.

1.5 **Chemical Restraint** is the use of a medication used to restrict the patient's freedom of movement that is not a standard treatment for the patient's new or continuing medical or behavioral condition

2. GENERAL GUIDELINES FOR ALL RESTRAINT/SECLUSION USE

2.1 Indications

a. Restraint or seclusion may be used when least restrictive measure is not sufficient to protect the physical safety of patients, staff members or others.

b. Seclusion may only be used for the management of violent or self-destructive behavior that jeopardizes the immediate safety of the patient, a staff member, or others.

2.2 Initiation: Each episode of restraint or seclusion shall be initiated:

a. Upon the order of a physician or licensed practitioner who is responsible for the patient or

b. In an Emergency situation where the need for restraint or seclusion may occur so quickly that an order cannot be obtained prior to initiation, a registered nurse may initiate if he/she determines it is necessary to protect the patient. An order from a physician or licensed practitioner who is responsible for the patient shall be obtained as soon as clinically appropriate to pause in the process of providing care.

2.3 Use of Antipsychotic Medications to Manage Violent Behavior

a. Antipsychotic medications shall be used in doses consistent with the community standard, to protect the patient or others and to allow the patient to more effectively interact with their environment. Such use is not considered Chemical Restraint.

2.4 Notification

a. Notification to the Attending Physician: If the restraint was not ordered by a physician with attending responsibility for the patient, an attending physician shall be notified that restraint was applied within 24 hours following initiation.

b. Documentation anywhere within the medical record by an attending physician, whether or not it addresses restraint, is considered evidence that the physician was notified of the restraint episode.

2.5 Orders for the use of restraint or seclusion shall never be written as a standing order or on an as needed basis (PRN).

2.6 Duration of the Order

a. **Non-Violent Restraint**

- Orders for restraint for the management of **Non-Violent Behavior** shall remain in effect until the patient's behavior or situation no longer requires restraint. *The restraint order expires at the end of the next calendar day.*

b. **Violent or Self-Destructive Restraint or Seclusion**

- Orders for restraint or seclusion applied to manage Violent Behavior or Self-Destructive Behavior shall remain in effect until the patient's behavior or situation no longer requires restraint or seclusion, in accordance to the following limits up to a total of 24 hours.

    i. 4 hours for adults 18 years of age or older;

    ii. 2 hours for children and adolescents 9 to 17 years of age;

    iii. 1 hour for children under 9 years of age.

- Continuation / renewal of restraint or seclusion order for the management of Violent Behavior for longer than 24 hours shall be based on an in-person evaluation “face to face assessment” by a responsible physician or licensed practitioner.

2.7 Assessment and Monitoring

a. **Non-Violent Restraint**

- Restraint used for the management of Non-Violent Behavior shall be subject to ongoing monitoring and assessment as specified in the patient's plan of care. Monitoring and assessments shall occur at least every two hours, however, concurrent documentation of the monitoring/assessment with unchanged findings is not required.

b. **Violent or Self-Destructive Restraint or Seclusion**

- **One-hour Face-to-face Assessment**

    i. A responsible physician or licensed practitioner shall perform a face-to-face assessment of the patient's physical and psychological status within one hour of the *initiation* of restraint or seclusion.

        A. Person conducting assessment shall evaluate

            1. The patient's immediate situation
            2. The patient's reaction of the intervention
            3. The patients' medical and behavioral conditions; and
            4. The need to continue or terminate the restraint or seclusion.

- **Monitoring of patients requiring Violent or Self Destructive Restraints**

    i. Restrained or secluded patients shall be carefully monitored and observed at least every 15 minutes.

        A. Trained, unlicensed staff with demonstrated competency may perform components of monitoring (e.g. checking the patient's vital signs, hydration and circulation, the patient's level of distress and agitation, and skin integrity), and may also provide for general care needs (e.g. eating, hydration, toileting and range of motion exercises).

    ii. Simultaneously restrained and secluded patients shall be continuously monitored by a trained staff.

- **Assessment of patients requiring Violent or Self Destructive Restraints**

    i. Assessments by a registered nurse, physician assistant or physician shall occur as often as indicated by the patient's condition, behavior, and environmental considerations or at least every two hours.

2.8 Documentation

a. Episodes of restraint shall be documented as indicated on currently approved assessments, monitoring and ordering forms and computerized flowsheets.

2.9 Care Plan

a. The restrained or secluded patient's written plan of care shall be modified to address appropriate interventions implemented and encourage the least restrictive means of protecting the patient.

2.10 Restraint and Seclusion Training (Please refer to Attachment 4.3)

2.11 Reporting Restraint Related Deaths

a. Hospital personnel shall promptly contact hospital administration whenever a patient expires:

- While restrained;

- Within 24 hours after being released from restraint; or
- As the result of a restraint-related condition within 7 days after restraint removal.

b. Designated hospital representatives shall notify the Centers for Medicare and Medicaid Services (CMS) Regional Office of such deaths within one business day of their discovery. Such notification shall be documented in the patient's medical record.

- EXCEPTION: Such deaths may be recorded in a log rather than being reported to CMS if a) the death was not a result of or related to the restraint and b) only soft wrist ties were used to restraint the patient most proximate to death.
- Log is maintained with Nursing House Supervisor in Decedent Affairs Book | Mortuary Log

3. REFERENCES

3.1 42 CFR § 482.13 Condition of participation: Patient's Rights. (e)(f)(g)

3.2 The Joint Commission. (2018). *Provision of Care, Treatment and Services.*

3.3 Rules and Regulations (2019). *Federal Register* Vol. 84, No. 189.

4. ATTACHMENTS

4.1 Examples of Restraints

4.2 Antipsychotic Medications Used to Manage Violent Behavior

4.3 Restraint and Seclusion Training Plan

Document History:

Prior Release Dates: 3/1994, 8/2007, 12/2013, 10/2/2016, 5/6/2019, 1/25/2021, 12/6/2021			**Retire Date:** N/A
Document Owner: Restraints Committee			**Replaces Policy:** 630.1, 630.2, 630.3
Date Reviewed	**Reviewed By:**	**Revisions Made Y/N**	**Revision Description**
12/2024	Policy Owner	N	Re-sign

ATTACHMENT 4.1
Examples of Physical Restraint

Device	Not Restraint	Restraint
Devices to protect the patient during a procedure or anesthesia	During a procedure or anesthesia.	Once the patient has recovered from anesthesia and devices are not removed
Side Rails	Used to keep the patient from **falling out of bed or with a specialty mattress**	Used to keep the patient from **getting out of bed.**
Mittens	N/A	Patient cannot flex fingers or does not have access to his / her body.
Arm Boards	To protect site of intravenous access.	If used to prevent the patient from having access to his or her body.
Adaptive Devices: Seat belts, waist belts, Geri chairs, etc.	The patient can remove the device (or remove themselves from the device) in the same manner in which it was applied (e.g. unlatching a seat belt, untying a knot, letting the side rail down)	The patient cannot easily remove the device.
Covered bed	Covered bassinet for infants or toddlers.	For adults to keep them from getting out of bed.
Protective interventions for infants, toddlers and pre- school children	Stroller safety belts; seat belts for high chairs; etc.	N/A
Holding the patient	Light touching during escort	Therapeutic hold. Generally used when holding a patient to give medication or treatment
Forensic Devices (handcuffs, shackles)	Used for patients in the direct custody of a law enforcement officer.	shall not be used as a device for restraint
Walking Restraints	NA	Device used to prevent the elopement of a patient on an involuntary legal hold during transport to an offsite facility. (Arlington Campus only)

Examples of Seclusion

Not Seclusion	Seclusion
Confinement on a locked unit or ward where the patient is with others.	Confinement in a locked room apart from other patients
Having the patient agree to confine their movements to a room with an open door.	Physically preventing a patient from leaving an unlocked room
A "time out" in a quiet (unlocked) location.	Preventing a patient from leaving an unlocked room through intimidation.

ATTACHMENT 4.2

Antipsychotic Medications Used to Manage Violent Behavior

Not Chemical Restraint	Chemical Restraint
Common use of medications, within the standard of care and practice, and well-documented by literature	Uncommon or outmoded use of medications for the management of behavior. Lack of documentation of the behaviors indicating the need for the medication. (Such use is generally prohibited.)
Order may be PRN	Orders may **not** be PRN
Order renewed as required in medication management policy.	Order renewed at least every 4 hours for adults, every 2 hours for adolescents, every 1 hours for children. (**One-time orders preferred**.)
Medication and dose are consistent with professional standards of practice.	
Used for the safety of patients or others and to help the patient more effectively interact with their environment.	
May NOT be used for staff convenience.	
Documentation describes the behavior supporting the use of the medication.	
Monitoring of vital signs appropriate for the potential sedating effects of the medication and dose.	

ATTACHMEN 4.3

Restraint and Seclusion Training Plan

The patient has the right to safe implementation of restraint or seclusion by a trained staff. Minimum training shall include:

1. The policy review and education for physicians and other licensed practitioners who order restraint or seclusion.
2. The instruction and competency requirements of hospital staff who assess and plan care for patients that require restraints or seclusion include:
    a. Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require the use of a restraint or seclusion.
    b. The use of nonphysical intervention skills.
    c. Choosing the least restrictive intervention based on an individualized assessment of the patient's medical, or behavioral status or condition.
    d. The safe application and use of all types of restraint or seclusion used by the staff member, including training on how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia);
    e. Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary.
    f. Monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, and vital signs.
    g. The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic re-certification.
    h. Documentation requirements, including but not limited to the plan of care, patient and family education, currently prescribed forms and computerized flowsheets.
3. The instructions and competency requirements for hospital staff that monitor patients in restraints or seclusion include:
    a. Recognition of signs of physical and psychological distress.
4. Training shall be completed as part of orientation and on a periodic basis.
5. The hospital shall document in the staff personnel records that training and demonstration of competency has been completed.

RIVERSIDE UNIVERSITY HEALTH SYSTEM – MEDICAL CENTER

Housewide

	Document No: 668	Page 1 of 7
Title: Suicide Prevention	**Effective Date:** 12/6/2024	☐ **RUHS – Behavioral Health** ☐ **RUHS – Community Health Centers** ☐ **RUHS – Hospital Based Clinics** ☒ **RUHS – Medical Center** ☐ **RUHS – Public Health** ☐ **Departmental**
Approved By:  Jennifer Cruikshank CEO/Hospital Director		☐ **Policy** ☒ **Procedure** ☐ **Guideline**

1. SCOPE

1.1 The Suicide Prevention policy applies to all patients admitted and being treated at the Riverside University Health System (RUHS) – Medical Center, Moreno Valley campus, and excludes Arlington campus.

2. DEFINITIONS

2.1 5150 (72 hour hold): When a person, as result of a mental health disorder, is a danger to others, or to themselves, or gravely disabled, trained personnel may evaluate and place on a hold if criteria are met.

2.2 5250 (14 day hold): An additional 14 days of involuntary treatment beyond the 72-hour hold when psychiatric specialists conclude that a person is in need of additional treatment and the person has first been offered voluntary treatment for a mental health disorder and has refused it.

2.3 5585 (72-hour minor hold): Refers to a 72 hour hold for a minor and for purposes of this document is considered synonymous with the term 5150

2.4 Code BERT: Behavioral Emergency Response Team – a team of behavioral health staff trained in de-escalation techniques

2.5 Code Green: Security, law enforcement and BERT team response to incidents involving potentially physically violent patients or visitors.

2.6 Constant Observation: Refers to when the patient is assigned trained staff who keep the patient within continuous visual observation to ensure safety.

2.7 Contraband: Any illegal or prohibited possessions.

2.8 Danger to Others (DTO): Words or actions that indicate the person in question, as a result of mental illness, either intends to cause harm to a particular individual or intends to engage in dangerous acts with gross disregard for the safety of others.

2.9 Danger to Self (DTS): A deliberate intention to harm oneself (e.g. overdose) or a disregard for personal safety to the point where injury is imminent (e.g., wandering in heavy traffic). A patient who has made a serious threat of, or attempted, suicide with the use of a firearm or other deadly weapon. The danger must be present, immediate, substantial, physical and demonstrable. Gravely disabled is a subset of DTS.

2.10 Gravely Disabled: - A condition in which a person, as a result of a mental disorder, is unable to provide for their basic personal needs for food, clothing or shelter or unable to make rational use of resources made available for their own self care. Patients on legal hold soley for Grave Disability, who are NOT suicidal and are otherwise cooperative, may at the discretion of the Psychiatrist, be monitored/observed by means other than continuous observation.

2.11 Ligature resistant: Points where a cord, rope, bed sheet, or other fabric/material can be looped or tied to create a sustainable point of attachment that may result in self-harm or loss of life.

2.12 Non-suicidal behaviors: Not all self-injurious behavior is the result of suicidal ideation, planning or attempts. In the assessment of patients, an effort should be made to distinguish between suicidal and non-suicidal behaviors.

2.13 P4 Suicide Risk Screen: An evidenced based, clinically trialed tool for assessing potential suicide risk in patients. P4 is a mnemonic for the 4 screening questions: past suicide attempt, suicide plan, probability of completing suicide, and preventive factors. Any individual who responds "yes" to a question about thoughts of self-harm is asked 4 additional questions—the 4 P's on past history which include past attempts, plan, probability, and preventive factors. Patients are classified as minimal, lower, and higher risk based upon responses Patient Safety Attendant (PSA): A staff member who has received training and achieved competency to provide for the safety of a patient who is designated as suicidal.

2.14 PCLS Team (Psychiatric Consultation & Liaison Services): A team of qualified staff with specific training and education in the management and treatment of psychiatric patients.

2.15 Risk of Suicide Questionnaire (RSQ): A suicide screening tool for use with patients ages 8 to 21. A "yes" response to any of the four questions is considered to be a positive screen.

2.16 Suicide: The act or an instance of taking one's own life voluntarily and intentionally.

2.17 Suicidal behaviors: Attempts to cause self-harm with the intent to die as a result of that behavior.

2.18 Suicidal ideation: Thinking about, considering or planning suicide.

2.19 Suicide precautions: A method of observation implemented when a patient's potential for suicide is high and poses an imminent threat to the patient's well- being. Suicide precautions require continuous observation of the patient at ALL times with regular environmental rounds to spot potential hazards

3. POLICY

3.1 All patients who are 12 years of age and older will be screened for risk of suicidal ideation and behavior. The screen will be recorded in the Medical Record.

a. Adults are screened by Registered Nurses in the ED or Inpatient setting using the P4 Suicide Risk Screen

b. Children and adolescents eight (8) years and older are screened by Registered Nurses in the ED or inpatient setting using the Risk of Suicide Questionnaire (RSQ).

3.2 All patients identified to be at risk for suicide *(irrespective of classification)* should have Suicide Precautions implemented. Any patient making suicidal statements is considered at risk and immediately placed on suicide precautions.

3.3 A Registered Nurse may initiate suicide precautions when a physician is not immediately available.

3.4 When crisis intervention techniques are ineffective staff will ensure safety to the extent possible and call a “Code BERT” or a “Code Green”, depending on the severity of the situation.

3.5 When possible, patient care areas should be ligature resistant. When the environment cannot be adapted due to the medical nature of the facility, the ligature risk will be mitigated by the close observation of suicide risk patients by licensed staff or PSAs.

4. GUIDELINES

4.1 The Registered Nurse (RN) will complete the age appropriate Suicide Risk Screen upon arrival to ED or upon admission to inpatient units. When a patient is identified as a potential suicide risk:

a. Initiate suicide precautions with a constant observer per protocol. (Refer to Section 5. Suicide Precaution Guidelines)

b. Notify the attending physician.

i. A Suicide Precaution order must be written by the Physician.

ii. Assure orders for a psychiatry consult and notify Psychiatric Consultation and Liaison Services (PCLS) to complete a Suicide Assessment.

- An order for a psychiatry consult is placed through the electronic medical record. In the event of downtime, the order should be faxed to Psychiatric Consultation and Liaison Services (PCLS) at Ext. # 65949 and notify the PCLS team by phone at Ext. # 65948.
- If no answer, leave a message with patient's medical record number, date of birth, unit patient is on, the name of person calling and call back number.

c. The House Supervisor will be notified as soon as possible for staffing purposes.

d. When Suicide Precautions are implemented, the Plan of Care plan must be updated.

e. The Registered Nurse assesses the patient on admission for the presence of medication delivery devices (e.g. medication patches, ambulatory infusion pumps, etc.). If present, the RN notifies the physician to assess for continued need of the device.

4.2 The Attending Physician and Psychiatrist will assess and evaluate the patient as soon as reasonably possible and at least daily while on Suicide Precautions.

4.3 A daily suicide assessment will be completed and documented by the PCLS team or psychiatrist for any patient on suicide precautions.

4.4 The decision to discontinue suicide precautions shall be reflected in the assessment and plan by the Psychiatrist and may be actioned (ordered) by the primary team.

4.5 All suicidal patients must be evaluated and declared by the psychiatrist that they are no longer suicidal prior to discharge and/or transferred to another facility unless the transfer is for higher level of care / medical emergency and protective observation is continued during transport.

5. SUICIDE PRECAUTIONS. The following is to be followed once a patient is identified to have suicidal ideation or behaviors.

5.1 **Protective Observation**: A trained workforce member will provide continuous observation. This requires personnel to maintain direct line-of-site monitoring. Observation is continuous and attested to in the medical record prior to handoff. Protective observation is intended to provide support to clients who lack the capacity to prevent acting on suicidal ideation.

a. Monitor/assist with all aspects of the patient's activities of daily living, including during toileting and hygiene, bathroom, shower, and bathing.

b. Explain to the patient that it is for the patient's own safety to observe all activities of daily living

c. Staff assigned to continually observe a patient at risk for self-harm will immediately communicate any change in affect, behavior or compliance to the assigned registered nurse

d. In the context of transmission-based precaution, if observation occurs outside of the room, the 1:1 observer must be able to maintain full continuous view of the patient, with the door closed and be able to intervene without delay when necessary. The observer would have to maintain appropriate (clean) personal protective isolation to ensure entry into the room without delay if necessary.

5.2 **Environmental Safety:**

a. Thoroughly survey the room and remove potential items the patient may use to harm themselves. This is done at the beginning of each shift and after any visitors leave.

b. Patient’s personal belongings will be examined and recorded by a trained staff member and will be stored appropriately in designated areas. All clothing, shoes, and unsafe belongings are to be removed and locked away for the patient's safety. This is to decrease the possibility of patient elopement. Access to specific personal belongings will be approved by the physician.

c. For home medications, refer to policy HW 857, Patient's Personal Home Medication.

d. All objects that pose a risk for self-harm that can be removed without adversely affecting the ability to deliver medical care should be removed.

e. For any contraband items within the hospital, contact the in-hospital Security Officer if the patient is unwilling to comply. Contraband items to include, but not limited to: pocketknives, switchblades, razor blades, illegal drugs, guns, cigarette lighters.

f. Be aware of ligature risk and that the trained workforce member or licensed nurse mitigates the risks of non-removable items (*IV pump cords, call lights, etc.*) to the patient by constant observation.

g. Patients may have visitors at the discretion of the physician and/or nurse. Determination will be made based on the observed response of the patient to the visitor (i.e. the visitor has a calming effect on the patient versus the patient becomes overly anxious, angry, or agitated).

h. Visitors should be advised to limit personal belongings and any personal items (purses etc) which are subject to inspection by hospital personnel.

i. Identify that the patient is on suicide precautions when ordering dietary meals and snacks. Patients will then receive plastic utensils and paper cups. Check all meal trays to remove unsafe items before distributing meals to the patient.

5.3 **Establish a positive therapeutic alliance with the patient:** Consider the following evidence informed activities; engage with a calm, caring, supportive, accepting and nonjudgmental demeanor, use active listening skills, encourage the patient to talk about his/her feelings, help the patient identify, accept, and work through these emotions even if they are uncomfortable or painful, discuss protective factors.

6. DOCUMENTATION

6.1 Nursing will initiate and document the following:

a. The age-appropriate suicide screen (in ED or via Admission Assessment)

b. Suicidal risk care plan

c. Room safety interventions will be documented upon the initiation of suicide precautions and the start of each shift by both the RN and the PSA or licensed nurse assigned as the constant observer.

d. The PSA or licensed nurse assigned as the constant observer will document room safety interventions whenever visitors leave and when other staff have completed procedures or processes within the room. Example: Make sure EVS did not leave cleaning fluids, check for sharps after a procedure in room, etc.

e. The PSA or licensed nurse assigned as the constant observer will attest to observation and safety interventions in the medical record prior to handoff.

f. Patient behavior and intervention will be documented every 2 hours by the assigned licensed nurse in the medical record on designated forms or flowsheet.

g. Update Patient Suicide Risk Care Plan every shift and PRN

h. Education provided to the patient and family as appropriate.

i. PCLS team shall document the complete Suicide Risk Assessment Plan and any patient pertinent information.

7. DISCHARGE PLANNING

7.1 Discharge planning for the patient identified as being at risk for suicide shall follow normal discharge protocols. In addition, the following are to be completed:

a. The physician will perform a final assessment of the patient's suicide risk

b. At-risk patients shall be provided a referral list that includes both private and public communication agencies providing, or arranging for, the evaluation, counseling and care of persons at risk of suicidal ideation and behavior. The list must include, but not be limited to, hotlines and locally available mental health services.

8. TRAINING

8.1 All RN Staff will be educated and evaluated for competency on suicide risk assessment and mitigation upon hire and periodically as determined by policy change and quality/performance improvement measures.

8.2 Staff who could be assigned the care of a patient at risk for suicide will be educated and evaluated for competency in suicide risk mitigation upon hire/transition to another role and periodically as determined by policy change and quality/performance improvement measures.

9. REFERENCES

9.1 Ca. Health and Saf. Code § 1259.6

9.2 The Joint Commissions National Patient Safety Goal (NPSG) 15.01.01-15.01.06

9.3 National Action Alliance for Suicide Prevention: Transforming Health Systems Initiative Work Group. (2018). Recommended standard care for people with suicide risk: Making health care suicide safe. Washington, DC: Education Development Center, Inc.

9.4 Horowitz L, Wang PS, Koocher GP, et al. Detecting suicide risk in a pediatric emergency department: development of a brief screening tool. *Pediatrics.* 2001;107(5):1133–1137.

9.5 RUHS- MC Policy 258 Observation of Patients

9.6 Priyanka, Dube et al., The P4 Screener: Evaluation of a Brief Measure for Assessing Potential Suicide Risk in 2 Randomized Effectiveness Trails of Primary Care and Oncology Patients. Primary Care Companion Journal of Clinical Psychiatry. 2010; 12(6). [PMCID: PMC3067996]

9.7 Shindhe, Shireesh S, Nagarajaiah, Reddemma, K.; Suresh, B. M., Sindhe, Sateesh. PREVENTION OF INPATIENT SUICIDE: Saving Lives. Indian Journal of Psychiatric Nursing 5(1):p 53-55, January 2013. | DOI: 10.4103/2231-1505.261781

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Document Owner: Nursing Administration	**Replaces Policy:** NURS 271 Suicide Prevention 6/2007, 10/2015, 11/13/2017; 9/2021

Date Reviewed	Reviewed By:	Revisions Made Y/N	Revision Description
08/01/2024	Triennial Review Adhoc, Psychiatry, Nursing, Social Work, Regulatory	Y	Update references, update definition 2.8, 2.9, add definition 2.15, specify screening for age 12 and above, specify 3.4 use of BERT team, update PCLS workflow, 4.4 primary team can DC suicide precautions in consultation with psychiatry, 5.8 provision for emergency transfer, guidelines; protective observation activities, transmission based precaution provision, documentation by attestation, 5.2b procedures for belongings, update PSA to trained workforce member, visitor provisions, meal tray provision, addition of therapeutic alliance, discharge planning in accordance with AFL 23-02, add training plan.
10/17/2024	Nursing P&P	N	approved
11/5/2024	PAC	N	
11/14/2024	MEC	N	

RIVERSIDE UNIVERSITY HEALTH SYSTEM –

Medical Center and Hospital Based Clinics

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Title: High-Alert Medications	**Effective Date:** 11/22/2024	☐ **RUHS – Behavioral Health** ☐ **RUHS – Community Health Centers** ☒ **RUHS – Hospital Based Clinics** ☒ **RUHS – Medical Center** ☐ **RUHS – Public Health** ☐ **Departmental**
Approved By: Jennifer Cruikshank CEO/ Hospital Director		☒ **Policy** ☐ **Procedure** ☐ **Guideline**

1. SCOPE

This policy applies to all medications stored and utilized for adult and pediatric patients: RUHS – Medical Center Moreno Valley and Arlington campuses, and hospital-based clinics.

2. DEFINITIONS

2.1 Automated Dispensing Cabinets. Automated dispensing cabinets are computerized drug storage devices or cabinets that allow medications to be stored and dispensed near the point of care, while controlling and tracking drug distribution.[3,4]

2.2 Bar Code Medication Administration (BCMA). Bar Code Medication Administration is a technology designed to prevent medication errors in the healthcare setting and improve the quality and safety of medication administration. The overall goals of BCMA are to improve accuracy, prevent errors, and generate electronic records of medication administration.

2.3 Clinical Decision Support. Clinical decision support is technology that provides clinicians with knowledge and patient-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care. Examples of this include allergy and therapeutic duplication alerts.

2.4 Computerized physician order entry (CPOE). CPOE is the process of a medical professional entering medication orders or other physician instructions electronically instead of on paper charts. A primary benefit of CPOE is that it can help reduce errors related to poor handwriting or transcription of medication orders.

2.5 High-Alert Medications. The Joint Commission defines High-Alert Medications as Medications that bear a heightened risk of causing significant harm to individuals when they are used in error.

2.6 Independent Double Check (IDC). The Institute for Safe Medication Practices defines an Independent Double Check as a procedure in which two clinicians separately check (alone and apart from each other) each component of prescribing, dispensing, and verifying the high-alert medication before administering it to the patient.

2.7 Medication Use Process. Encompasses the following categories: Procuring, Storing, Prescribing, Transcribing, Preparing, Dispensing, Administering, Monitoring.

2.8 Smart Infusion Pump. Medication infusion pumps deliver parenteral medications at precise rates or in specific amounts. “Smart” infusion pumps have built in software that can alert users to potential errors. This software (sometimes referred to as Drug Error Reducing or “DER” software) maintains a drug library that provides medication dosing guidelines by establishing concentrations, dose limits, and clinical advisories.

3. POLICY

3.1 Standard medication safety measures at RUHS include the following:

a. PRESCRIBING AND TRANSCRIBING:

- Use of CPOE including standardized electronic order sets with clinical decision support technology.

b. PREPARING AND DISPENSING:

- Use of bar code medication technology both within the pharmacy and at the automated dispensing cabinets.
- Use of standardized formulas for compounding both extemporaneous and sterile preparations
- Independent double checks for target patient populations and/or medication classes, i.e. pediatric and neonatal orders/doses

c. ADMINISTERING:

- Use of BCMA technology
- Use of smart infusion pumps

In the event of an electronic downtime, either planned or unplanned, downtime procedures will be followed.

3.2 High-Alert Medications require heightened attention by those involved in the medication use process because of the risk of causing significant harm when used in error. In addition to standard safety measures detailed above, other safety measures utilized to mitigate the risk of High-Alert Medications include, but are not limited to, the following: special storage, use of specified auxiliary labels, Independent Double Check (IDC), and specific monitoring. Appendix A details these measures based on medication category.

3.3 If there is a risk to patient safety at any point along the medication use process, the organization supports staff in STOPPING the activity being performed and elevating the concern through the appropriate chain of command.

4. REFERENCES

4.1 The Joint Commission standards MM.01.01.03 and NPSG.03.05.01

4.2 CMS Conditions of Participation § 482.23(c)(1), § 482.23(c)(2), § 482.23(c)(4), § 482.25(a), and § 482.25(b)(6)

4.3 Adapted from the Institute for Safe Medication Practices “Proceedings From the ISMP Summit on the Use of Smart Infusion Pumps” 2009.

4.4 Adapted from the Institute for Safe Medication Practices “Guidance on the Interdisciplinary Safe Use of Automated Dispensing Cabinets” 2008.

5. ATTACHMENTS

5.1 Appendix A: High-Alert Medications Grid

Document History:

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Sponsored by: Pharmacy Department	**Replaces Policies:** Nursing PnP 700: Continuous Infusion of High Risk Nursing PnP 708: High Risk and High Alert Administration Pharmacy PnP F624: Handling of High-Risk (High Alert) Medications in Pharmacy Department

Date Reviewed	**Reviewed By:**	**Revisions Made?**	**Revision Description**
7/11/23	MSO/Pharmacy Review Committee.	Yes	*Annual Review *Add "Scope" *Add two new categories (Liposomal formulation & Vasopressors/inotropes).
8/7/23	P&T	N	
9/14/23	MEC	N	
11/30/2023	Policy Approval Committee	N	
5/2/2024	Pre-Nursing P&P	Y	Updates needed to Appendix A
6/11/2024	Pharmacy Review Committee	N	
6/20/2024	Nursing P&P	N	Approved
7/1/2024	P&T	N	
8/14/2024	PAC	N	
9/12/2024	MEC	N	

APPENDIX A: HIGH-ALERT MEDICATION GRID

HIGH-ALERT MEDICATION CATEGORY		PROCUREMENT & STORAGE	PRESCRIBING & TRANSCRIBING	PREPARING & DISPENSING	ADMINISTERING	MONITORING
ANTICOAGULANTS AND THROMBOLYTICS	**PARENTERAL ANTICOAGULANTS and THROMBOLYTICS** Examples include alteplase (ACTIVASE®), argatroban, bivalirudin (Angiomax), enoxaparin (LOVENOX®), fondaparinux (ARIXTRA®), heparin, tenecteplase (TNKASE®)	- Prefilled syringes of enoxaparin and fondaparinux procured - The number of heparin concentrations is minimized. - Premixed heparin infusion bags with standard 100 unit/mL concentration are procured. -Alteplase and tenecteplase are located in the ED and ICU Pyxis only.	- CPOE - Standardized order sets are used for alteplase, tenecteplase, bivalirudin, argatroban, and heparin infusions.	- Concentrations for intravenous infusions of alteplase, argatroban, bivalirudin, and heparin standardized. - Barcode technology used in the pharmacy during preparation of compounded items. - Barcode technology used during distribution and dispensing for vials, syringes, and premixed bags. - HIGH ALERT auxiliary label adhered to product for alteplase, argatroban, bivalirudin, and heparin infusions.	- For intravenous anticoagulant and thrombolytic infusions (**excludes** heparin flushes and alteplase for catheter occlusion), IDC done upon initial administration, each bag or rate change, and at handoff. - Smart infusion pumps utilized to administer intravenous anticoagulant or thrombolytic infusions. - Dedicated line required for alteplase administration. - Med administration guidelines in place for IV thrombolytics in stroke and pulmonary embolism - BCMA	-1:1 nursing ratio for the first 8 hours after administration of thrombolytic, when applicable. - Standardized labs for argatroban, LMWH and heparin monitoring. - Standardized neurological checks when thrombolytics are administered.
	ORAL ANTICOAGULANTS Examples include apixaban, rivaroxaban, warfarin	- Unit-dosed products procured if available.	- CPOE, BPA to be triggered if patient has received DOAC or LMWH within the past 24 hours. - Pharmacist protocols utilized for warfarin initiation and maintenance which includes documentation and assessment of the patient's baseline INR. 6- Order sets for DOAC to maintain dosing per indication. - Allow for continuation of home medication dosing	- Barcode technology used during distribution and dispensing.	- BCMA	- Pharmacist protocols utilized to monitor labs and adjust dosing for patients on warfarin therapy. - Warfarin education to patient/caregiver completed by a pharmacist to all patients initiated on warfarin therapy. - DOAC education to patient/caregiver completed by a pharmacist or nurse to all patients initiated on DOAC therapy.

LEGEND: CPOE = Computerized Physician Order Entry BCMA = Bar Code Medication Administration IDC = Independent Double Check

HIGH-ALERT MEDICATION CATEGORY		PROCUREMENT & STORAGE	PRESCRIBING & TRANSCRIBING	PREPARING & DISPENSING	ADMINISTERING	MONITORING
CHEMOTHERAPY / HAZARDOUS	**PARENTERAL CHEMOTHERAPY**	- Storage of tier 1 injectable hazardous drugs (chemotherapy) limited to the Infusion Center Pharmacy - Prepared parenteral chemotherapy is hand-delivered and stored in segregated bins located in the medication rooms of patient care units.	- CPOE, separate oncology prescribing module from EHR. - Chemotherapy must be ordered by attending physician. - No verbal orders for chemotherapy are allowed.	- Vinca alkaloids are standardly prepared in 50 mL of normal saline to prevent inadvertent intrathecal administration. - Barcode technology used in the pharmacy during preparation of compounded items. - Tier 1-3 hazardous drug warning level applied to final product per NIOSH. - CHEMOTHERAPY final prep is placed in a separate identifying bag. - Chemotherapy and HD parenteral therapy dispensed with tubing and lines primed. - Reminder for PPE pop-up at Pyxis upon removal of medication	- IDC - Chemotherapy Nurse administers parenteral chemotherapy. - Smart infusion pumps utilized to administer intravenous chemotherapy infusions (exception: peripherally administered small volume vesicant chemotherapy). - BCMA - Nursing chemotherapy and biotherapy med administration guidelines in place for best practices	- Oncology Pharmacist reviews labs, IV lines attached to prepared medication, vitals prior to initiation, and for all subsequent dose dispenses. - Hardstop reviews in separate oncology module.
ELECTROLYTES	**CONCENTRATED ELECTROLYTES** Examples include *concentrated* calcium chloride, calcium gluconate, magnesium sulfate, potassium chloride, potassium phosphate, sodium phosphate Hypertonic Saline (concentrations >0.9% aka) 3% and 23.4%,	- Concentrated electrolytes are stored only in the pharmacy in designated HIGH ALERT bins Exceptions: calcium chloride, calcium gluconate, magnesium sulfate, and 3% NaCl, which are also located in areas where emergency care may be needed (e.g., crash carts, Pyxis in critical care areas). - Procure 3% hypertonic saline from different manufacturer when possible and store separately from 23.4% HTS, or normal saline.	- CPOE - Guidelines for prescribing.	- Concentrated electrolytes are diluted to concentration safe for administration prior to dispensing. - Barcode technology used in the pharmacy during preparation of compounded items. - Barcode technology used during distribution and dispensing for premixed items. - CENTRAL LINE ONLY auxiliary label adhered when applicable to central line concentrations of electrolytes; - HIGH ALERT auxiliary label adhered to hypertonic saline, magnesium doses 20 gm or greater, and potassium 20meq and greater. - Pharmacist pre-check when compounding with concentrated electrolytes. - Hypertonic solutions distributed by Pharmacy, 3% HTS stored in ED Resus Pyxis	- IDC for hypertonic saline and intravenous magnesium doses 20 gm or higher. - Smart infusion pumps utilized to administer intravenous electrolytes. - BCMA - Guidelines for administration and use exist for electrolyte replacement, HTS, and parenteral nutrition	

LEGEND: CPOE = Computerized Physician Order Entry BCMA = Bar Code Medication Administration IDC = Independent Double Check

HIGH-ALERT MEDICATION CATEGORY		PROCUREMENT & STORAGE	PRESCRIBING & TRANSCRIBING	PREPARING & DISPENSING	ADMINISTERING	MONITORING
PARENTERAL NUTRITION	**PARENTERAL NUTRITION** Includes both total and peripheral parenteral nutrition	- Standard bulk preparations of amino acids, dextrose, and lipids are procured.	- CPOE - Pharmacist protocols utilized for dosing parenteral nutrition in adults and pediatrics and neonates. - Method of ordering of parenteral nutrition standardized.	- Special compounder with barcode and gravimetric technology used to prepare individualized bags for patients. - IDC done by two pharmacists comparing TPN order to compounder label. - Pharmacist pre-check prior to manual addition of additives. - HIGH ALERT auxiliary label adhered to prepared product.	- Smart infusion pumps utilized to administer parenteral nutrition. IDC – performed by nurses for NICU and Pediatric PN-BCMA	- Pharmacist protocols utilized to monitor labs and make adjustments to parenteral nutrition as needed.
STERILE WATER	**STERILE WATER**	- Sterile water for enteral use is stocked in nursing wards - Sterile water for irrigation BOTTLES is in limited stock on patient care units - When utilized for large volume irrigation, only sterile water 2 LITER bags are distributed by the materials management department to the patient care unit upon request only. - Sterile water bags used for compounding are sequestered in the pharmacy. -Sterile water vials stored in pyxis for medication reconstitution.		- Barcode technology used in the pharmacy during preparation of compounded items. - Barcode technology used during distribution and dispensing for sterile water VIALS.	- Med administration guidelines define the indicated use of Sterile water for enteral use, and indicate when sterile water for irrigation may be used	

LEGEND: CPOE = Computerized Physician Order Entry BCMA = Bar Code Medication Administration IDC = Independent Double Check

HIGH-ALERT MEDICATION CATEGORY		PROCUREMENT & STORAGE	PRESCRIBING & TRANSCRIBING	PREPARING & DISPENSING	ADMINISTERING	MONITORING
EPIDURALS	**EPIDURALS** Examples include bupivacaine and ropivacaine epidurals	- Premixed ropivacaine epidural with standard concentration procured. - Premixed ropivacaine epidurals segregated in the pharmacy from other similar sized bags.	- CPOE - Order set for PCEA, by anesthesia only - Order set for PCRA by both anesthesia providers and surgeons	- Barcode technology used in the pharmacy during preparation of compounded items. - Barcode technology used during distribution and dispensing for premixed items.	- New starts/1st bags initiated by the Anesthesia practitioner, or Surgeon based on protocol - Epidurals administered using smart infusion pumps specifically configured for epidural use only. - Regional analgesia administered via dedicated pumps and library - Pumps for epidural/regional use are programmed by Provider only - Dedicated smart infusion pump library for epidurals. - BCMA - IDC	- Monitoring and guideline per protocol by anesthesia/surgeon, and nursing

LEGEND: CPOE = Computerized Physician Order Entry BCMA = Bar Code Medication Administration IDC = Independent Double Check

HIGH-ALERT MEDICATION CATEGORY		PROCUREMENT & STORAGE	PRESCRIBING & TRANSCRIBING	PREPARING & DISPENSING	ADMINISTERING	MONITORING
INSULINS	**INSULINS** Examples include insulin lispro, regular insulin, isophane insulin, and insulin glargine	- Small (3 mL) vial size procured when commercially available for use and stored in Pyxis - Stored in designated HIGH ALERT bins in pharmacy areas. - Commercially available IV insulin bags procured for use only in the OR core	- CPOE - Standardized order sets used for continuous insulin infusions.	- Concentration for insulin infusion standardized. - Regular insulin compounded for use in the emergency department, ICU and operating room. - Barcode technology used in the pharmacy during preparation of compounded items. - Barcode technology used during distribution and dispensing for premixed items. - Pharmacist direct observation when compounding with insulin. - HIGH ALERT auxiliary label adhered to product. - IDC when preparing patient specific long-acting insulin. - Pharmacy prepares patient specific doses of long-acting insulin glargine.	- Smart infusion pumps utilized to administer intravenous insulin infusions. - Intravenous insulin infusions restricted to critical care units. - For insulin infusions, IDC done upon initial administration, each bag change, with each rate change, and at handoff. - IDC performed when IV insulin syringe is administered for hyperkalemia - For subcutaneous insulin, IDC prior to each dose administered. - BCMA	- Standardized frequencies of blood glucose checks. - Guidelines for response and management of hypoglycemia
NEUROMUSCULAR BLOCKERS	**NEUROMUSCULAR BLOCKERS** Examples include succinylcholine, rocuronium, and cisatracurium	- Stored in the pharmacy in designated lidded bins. -Stored in rapid sequence intubation kits in pyxis.	- CPOE - Standardized order sets utilized for neuromuscular blocker infusions.	- Barcode technology used in the pharmacy during preparation of compounded items. - Barcode technology used during distribution and dispensing for premixed items. - Pharmacist pre-post check when compounding. - PARALYZING AGENT auxiliary label adhered to compounded preparations as well as to vials and prefilled syringes.	- Neuromuscular blocker infusions restricted to critical care units. - Smart infusion pumps utilized to administer intravenous neuromuscular blocker infusions. - BCMA	- Train of four monitoring utilized during neuromuscular blocker infusions, when applicable. - Reversal agents readily available.

LEGEND: CPOE = Computerized Physician Order Entry BCMA = Bar Code Medication Administration IDC = Independent Double Check

HIGH-ALERT MEDICATION CATEGORY		PROCUREMENT & STORAGE	PRESCRIBING & TRANSCRIBING	PREPARING & DISPENSING	ADMINISTERING	MONITORING
OPIOIDS AND BENZODIAZEPINES	**CONTINUOUS INTRAVENOUS OPIOID and BENZODIAZEPINE INFUSIONS AND PATIENT-CONTROLLED ANALGESIA (PCA)** Examples include intravenous infusions of fentaNYL, morphine, HYDROmorphone (DILAUDID®), and midazolam (VERSED®) as well as morphine PCA and HYDROmorphone PCA	- All controlled substances are maintained under locked storage both in the pharmacy and at patient care units. - fentaNYL, midazolam, and morphine infusion bags with standard concentrations. - Premixed morphine PCA and HYDROmorphone PCA syringes with standard concentrations procured.	- CPOE - Standardized order sets utilized. - Automatic stops for opioids and benzodiazepines to promote review of therapy by providers. - Standard concentrations and volumes defined in med administration guidelines	- Barcode technology used in the pharmacy during preparation of compounded items. - Barcode technology used during distribution and dispensing for premixed items. - Pharmacist pre-post check when compounding.	- For continuous infusions, IDC done upon initial administration, each bag change, and at handoff. - For PCAs, IDC done upon initial administration, each syringe change, each dose/rate change, and at handoff. - Opioid and benzodiazepine infusions restricted per prescribing guidelines. - Smart infusion pumps utilized to administer infusions and PCA. - BCMA - Use of IV med lockboxes on IV poles during administration outside of ICU	- Patients on PCA have continuous end tidal CO2 monitoring as well as standardized frequencies of vital signs checked and documented. - For patients on continuous infusion of opioids and benzodiazepine, mechanical ventilation is required and have continuous pulse oximetry monitoring. - Monitoring tools for sedatives and opioids include RASS, CPOT scales.
	FENTANYL PATCH	- All controlled substances are maintained under locked storage both in the pharmacy and at patient care units.	- CPOE - Required prescriber documentation attesting to patient opioid-tolerant status for all fentanyl patch orders. - Pharmacist review completed on all fentanyl patch orders to ensure patient is opioid-tolerant prior to dispensing.	- Barcode technology used during distribution and dispensing.	- Patch removal is documented on medication administration record. - BCMA	- Adherence to fentanyl patch safe prescribing shared at PIPSC
SEDATIVE INFUSIONS (NON-NARCOTIC)	**SEDATIVE INFUSIONS (NON-NARCOTIC)** Examples include dexmedetomidine and propofol	- Propofol for the OR stored inside the OR room in designated location. - Propofol and dexmedetomidine are stored in ED and ICU pyxis.	- CPOE - Standardized order sets utilized.	- Barcode technology used during distribution and dispensing. - Standard concentration for infusions. - Pharmacist pre-post check when compounding.	- Infusions for this category of medications are restricted to critical care units. - Smart infusion pumps utilized to administer intravenous infusions. - BCMA	- Monitoring of propofol use in the ORs

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HIGH-ALERT MEDICATION CATEGORY		PROCUREMENT & STORAGE	PRESCRIBING & TRANSCRIBING	PREPARING & DISPENSING	ADMINISTERING	MONITORING
TARGETED PATIENT POPULATIONS	**PATIENT POPULATIONS WHERE MEDICATION ERRORS ARE HIGHLY LIKELY TO RESULT IN HARM** Examples include neonatal and pediatric populations Pregnant patients / women of childbearing age	- Medications used specifically in neonates are stored in a segregated area of the pharmacy in designated bins.	- CPOE - Standardized weight-based dosing utilized. - Dual Pharmacist verification of all neonatal orders. - Dual Pharmacist verification of targeted pediatric medications: aminoglycosides (gentamicin, tobramycin, and amikacin), vancomycin, and TPN orders Pregnancy test review for medication orders with potential or risk of harm in pregnancy for women of childbearing age	- Patient-specific, dose for medication prepared by pharmacy for scheduled (routine) pediatric and neonatal medications. - Barcode technology used in the pharmacy during preparation of compounded items. - Barcode technology used during distribution and dispensing. - For medications prepared on patient care units, IDC is done on medications where a partial amount of a vial, ampule, or cup is drawn up. This excludes medications used in an emergency situation.	- Smart infusion pumps utilized to administer intravenous infusions. - Separate infusion pumps used to administer continuous albuterol therapy. - BCMA Dedicated smart infusion pump (Sapphire) for administration of epidurals in the laboring patient	- Pharmacist specialists trained in neonatal and pediatric populations present
OXYTOCIN	**OXYTOCIN**	- Procure premixed bags - Stored separately from other infusion bags in L&D/OB area	- CPOE - Order sets for induction and post-partum - Standard concentrations used	- Barcode technology used in the pharmacy during preparation of compounded items. - Barcode technology used during distribution and dispensing. - OXYTOCIN label affixed to both sides of the bag	- Smart infusion pumps utilized to administer intravenous infusions. - Medication use guideline for the use of Oxytocin	- Response and use monitoring per protocol
LIPOSOMAL FORMULATIONS	**LIPOSOMAL FORMULATIONS** Examples include liposomal amphotericin B (AmBisome®)	- Stored in the pharmacy in designated bins.	- CPOE - Infectious diseases consultation and approval required for AmBisome®.	- Barcode technology used in the pharmacy during preparation of compounded items. - Barcode technology used during distribution and dispensing. - Pharmacist pre-post check when compounding.	- Smart infusion pumps utilized to administer intravenous infusions. - BCMA	

LEGEND: CPOE = Computerized Physician Order Entry BCMA = Bar Code Medication Administration IDC = Independent Double Check

HIGH-ALERT MEDICATION CATEGORY		PROCUREMENT & STORAGE	PRESCRIBING & TRANSCRIBING	PREPARING & DISPENSING	ADMINISTERING	MONITORING
VASOPRESSORS AND INOTROPES	**VASOPRESSORS and INOTROPES** Examples include norepinephrine, EPINEPHrine, phenylephrine, vasopressin, DOBUTamine, DOPamine	- Stored in the pharmacy in designated bins. - Norepinephrine, DOBUTamine, and DOPamine infusion bags with standard concentrations stored separately from other infusion bags in the ICU and ED Pyxis. - Norepinephrine, EPINEPHrine, phenylephrine, vasopressin prefilled syringes and/or vials and DOBUTamine premixed bags are also located in areas where emergency care may be needed (e.g., crash carts, code boxes, Pyxis in critical cares areas).	- CPOE	- Barcode technology used in the pharmacy during preparation of compounded items. - Barcode technology used during distribution and dispensing. - Pharmacist pre-post check when compounding. - CENTRAL LINE ONLY auxiliary label adhered to central line concentrations. - Placement of pre-filled syringes in OR pyxis when possible and cost-effective	- Infusions for this category of medications are restricted to critical care units. - Smart infusion pumps utilized to administer intravenous infusions. - BCMA -RUHS has Peripheral IV Vasopressor Medication Administration policy.	- Nurse to assess peripheral IV function every 2 hours if vasopressor is given peripherally. - Immediate notification to the medical team if peripheral IV extravasation is noted.

LEGEND: CPOE = Computerized Physician Order Entry BCMA = Bar Code Medication Administration IDC = Independent Double Check

RIVERSIDE UNIVERSITY HEALTH SYSTEM – MEDICAL CENTER

Housewide

	Document No: 811	Page 1 of 9

Title:	**Effective Date:**	☐ **RUHS – Behavioral Health** ☐ **RUHS – Community Health Centers** ☐ **RUHS – Hospital Based Clinics** ☒ **RUHS – Medical Center** ☐ **RUHS – Public Health** ☐ **Departmental**
Automated Dispensing System (Pyxis®)	11/22/2024	
Approved By:  Jennifer Cruikshank CEO/ Hospital Director		☒ **Policy** ☐ **Procedure** ☐ **Guideline**

1. PURPOSE

1.1 To define Automated Dispensing System user security policy, training requirements, ADS contents, downtime procedures, and quality assurance processes.

2. DEFINITIONS

2.1 Automated Dispensing System (ADS) – Computerized medication storage device that allows for secure medication storage and dispensing, such as Medstation® and Anesthesia Cart

2.2 Pyxis® - BD Carefusion Automated Dispensing System trade name.

2.3 MedStation® - Automated medication dispensing system supporting decentralized medication management.

2.4 CII Safe® - Stores, tracks and monitors the replenishment of controlled substance inventory.

2.5 Pyxis Profile® - Software that interfaces with the pharmacy computer order entry / approval system to Pyxis System software that requires pharmacist review / activation of all medication orders before medication access is granted at the ADS.

2.6 BioID - Fingerprint recognition technology used to verify the identity of the Pyxis user.

2.7 Blind Count - Pyxis functionality used during dispense process that requires the user to inventory the contents of the pocket and verify count without a machine prompt of how many doses should be in the pocket. This function is primarily used for controlled substances.

2.8 Console - Pyxis Server located in Pharmacy that links to all ADS and stores centralized databases including formulary, users, and transactions.

2.9 Override - A process that allows a user to remove medications from a patient's profile on the ADS prior to the entry of a medication order into the pharmacy computer system and subsequent pharmacist verification process. The list of overridable medications is approved by the Pharmacy and Therapeutics Committee and managed by Pharmacy. The process for selection of medications that are overridable is driven by:

a. Patient Safety: e.g. naloxone, diphenhydramine, furosemide

b. Patient Suffering / Pain: narcotics, anti-emetics

c. Patient Comfort: anxiolytics

d. Emergent situations as dictated by Director and Assistant Directors of Pharmacy

2.10 Override Groups – A preset list of medications that is available to users by override based upon nursing assignment areas and corresponding patient needs in those areas.

2.11 Critical Override – A function that allows nursing staff to override all medications in an ADS during periods of critical downtime when medication orders are unable to be verified and the interface between the pharmacy system and the ADS is not functioning. Functionality is managed by pharmacy.

2.12 Lead Time – The time period prior to the administration time of an order, in which the medication will be available to be accessed from Pyxis machine (i.e., if the administration time of famotidine 20 mg is 0900 and the lead time is set at 2 hours, then the order of famotidine will be available on the Pyxis Patient Profile at 0700).

2.13 Lag Time - The time period after an order is discontinued from the pharmacy computer system, but the medication can still be accessed from Pyxis machine (i.e., a one-time order for furosemide 20 mg at 0900 will not drop off the Pyxis Patient Profile until 1100, if the lag time is set for 2 hours).

2.14 Security User Template Assignments - All security user template assignments are performed by Pharmacy System Managers only.
a. Nursing (or other designated staff) are entered and maintained in the Pyxis ADS
b. Nursing (or other designated staff) that is assigned to a specific work area will only have Pyxis ADS access in their respective work area**.**
c. Nursing (or other designated staff) that is temporary assigned to a specific work area (e.g. floater or registry) user has access to temporarily assign area after activation by charge nurse for a single 14-hour period.

2.15 Privilege Templates – All privilege templates are assigned by Pharmacy System Managers only

a. Pyxis users will be assigned an appropriate privilege template in accordance with their respective security user template.

2.16 Electronic health record (EHR) – Electronic version of a patient's medical history that is managed by healthcare providers, which includes the following but not limited to patient's allergies, laboratory results, medications, and encounter notes.

3. POLICY

A. **Pyxis Security: User ID/ BioID; Authorized Access**

a. **User ID/ Password Assignment**

i. Acquiring Pyxis access should not be considered as a "STAT" request. The policies on access are to be followed and are designed to protect patient confidentiality and to maintain the security of medications stored in Pyxis ADS.

ii. Nurse Managers, Pharmacy Directors or designee, Education department directors, Anesthesia department designees, House Supervisors, and individuals designated by Nursing management are authorized to complete a Pyxis System Access Request (SAR) form to request access to the Pyxis system.

iii. Pharmacy maintains a list of users who may authorize Pyxis System Access.

iv. New users must complete the Pyxis tutorial training and EHR training before a user shall be granted Pyxis access.

v. The employee/user shall be required to present a certificate(s) of Pyxis tutorial Moodle training completion, SAR form, and two valid forms of US Government picture IDs, The 1st form must be the Riverside County employee badge and the 2nd can be any of the following: US passport, state ID or driver license, permanent resident card to the Education Department or Staffing Office. The Education Department, Staffing Office, or Pharmacy Compliance shall forward completed documents to Pharmacy Informatics.
vi. The user I.D. must be the same as the user's employee ID number.
vii. The initial password will be randomly assigned by authorized pharmacy personnel.
viii. First-time users shall be prompted to change their password the first time they sign onto the system.
ix. All access passwords are confidential and, if revealed, can lead to disciplinary action, up to and including termination.
x. Users shall be required to complete BioID registration the first time they log in. This one-time process enables each user to register their biometric information in ADS. After successfully registering in the system, users have BioID log in rights in each station where they have access privileges.
xi. A user who has problems with their BioID must report to their supervisor, who will submit an e-mail to Pharmacy Informatics. Pharmacy will then contact the user to verify and evaluate their fingerprint before they can be exempted.
xii. Only Pharmacy personnel with the proper level of security (Pharmacy Directors and designated staff) can add, revise, and terminate users in the Pyxis Console.
xiii. No user shall add temporary users to the Pyxis ADS. All Pyxis access shall be granted by Pharmacy Informatics.
xiv. Terminated users or those with no activity within 180 days will have their access removed within the Pyxis Console and CII Safe®.
xv. Human Resources will notify the Pharmacy Supervisor when employees are terminated so that their Pyxis access will be revoked accordingly. Additionally, Nurse Managers shall e-mail Pharmacy Administration as soon as an employee is terminated.
xvi. Periodically, and no less often than yearly, Pharmacy shall print a report of users for nursing departments to determine that individuals listed are still employed and that the employee's Pyxis privileges are appropriate.

B. **ADS Contents**
   a. All ADS units shall contain a managed formulary of orderable medications.
   b. Additional medications may be added to the ADS if space allows. If additional space is not available in the ADS, Pharmacy shall send the ordered medication to the nursing floors to be stored in a secure medication storage area outside of Pyxis (e.g., cassettes, patient specific medication bins, etc.).

C. **Pharmacist Review of Medication Orders in Profile Service Areas**
   a. Prior to removal of medications from an ADS, it is required that a registered pharmacist review the medication order and enter it into the pharmacy information system.
   b. Pharmacists shall enter all medication orders into the pharmacy information system and review them for appropriateness.
   c. Upon pharmacist verification of the medication order, Pyxis Profile shall release the corresponding medication in Pyxis for dispensing and administration under the corresponding patient.

d. Exceptions to this procedure shall be managed by the Pyxis Profile "Override" functionality and will be reviewed and approved by the Pharmacy and Therapeutics Committee. Exceptions shall include, but are not limited to the following:
    i. Considerations for areas where the physician directly controls the ordering, dispensing, administration and monitoring process components of medication use.
    ii. Code Blue events (pursuant to Emergency Standing Orders).
    iii. Situations that would compromise patient safety result in suffering / loss of comfort if the medication were not administered promptly or if the patient's condition warrants.
    iv. A STAT medication needed to treat an adverse medication event (medication reaction treatment/antidote).

D. **Medication Administration from ADS**
    a. See HW 852 on Medication Administration. All medications packaged with barcodes shall be scanned for accuracy using barcode recognition technology prior to confirming medication removal from Pyxis.

E. **Orderable medications not stored in ADS**
    a. First Doses
        i. If medication is not available in ADS, Pharmacy shall send the ordered medication to the nursing floor to be stored in a secure medication storage area outside of Pyxis (e.g., cassettes, etc.).
    b. Subsequent doses for medications not added to ADS:
        i. Pharmacy shall send a 24-hour supply of the ordered medication to the nursing floor to be stored in a secure medication storage area outside of ADS.
    c. Controlled Substances not routinely stocked in ADS shall be dispensed from the Inpatient Pharmacy.
    d. Oversized/ Bulk Medication Storage / Access
        i. Oversized or bulk medications shall be stored in a secure location in the nursing area.
    e. Patients' own medications are not to be stored in ADS.

F. **Override Function in Profile ADS**
    a. Override refers to a process where a nurse withdraws and administers a medication before a pharmacist has had an opportunity to review the order. The following criteria shall drive which medications nursing can access before a pharmacist has reviewed a medication order.
        i. Medications that may be overridden and that are included on the override list shall be driven by the patient condition and will be dictated by:
            1. Patient Safety
            2. Patient Suffering/Pain
            3. Patient Comfort
            4. Emergent situations as dictated by Director and Assistant Directors of Pharmacy
        ii. Any changes to privilege templates will be reviewed by Pharmacy Informatics, who will require the approval of the Director of Pharmacy or Assistant Directors of Pharmacy.
    b. The Pharmacy department shall routinely evaluate medications for addition or deletion from the override list and make recommendations to the Pharmacy and Therapeutics Committee.
    c. The Pharmacy and Therapeutics Committee shall determine which medications and under what conditions nursing shall be able to override the medication removal process prior to a pharmacist's review.
    d. Pharmacy shall routinely monitor the override report for compliance.

e. When overriding a medication that has not been reviewed by a pharmacist, the nurse is responsible for screening for allergies, appropriate dose, route, frequency, and all other relevant clinical criteria to ensure patient safety.
f. Override medications are intended for STAT and first-time doses that meet the override criteria. Nurses shall not override for medications that already appear on the patient's Pyxis Profile screen.
g. If the medication does not appear on the list of override medications and the nurse does not have access to the medication, they must contact Pharmacy for resolution.

G. **Override Orders**
   a. It is the responsibility of the Pyxis user, who is overriding the Pyxis Profile system to retrieve a medication, to obtain a physician order in compliance with regulatory requirements. All overridden medications shall be reconciled by linking to a verified EHR medication order.

H. **Override Groups for Profile ADS**
   a. Based upon the patient needs in their assigned area, nursing staff shall be linked to an override medication group.
   b. Override medications are entity specific and will be maintained by the Pharmacy System Managers with nursing and medical staff contribution.

I. **Overridden Controlled Substances Without Corresponding Order**
   a. Pharmacy shall review narcotic override reports within 24 hours or the first workday after holiday or weekend and shall refer any overridden medications without orders to the appropriate department for resolution.

J. **Critical Override**
   a. Pyxis failure: critical override shall be manually activated or shall automatically activate after 15 minutes of ADS failure. The pharmacy administrator-on-call must be notified.
   b. Others: the pharmacy administrator-on-call should be contacted for authorization. The pharmacy administrator-on-call should consider the workload, staffing issues, and other circumstances.
   c. Critical override is only turned on when necessary and should be turned off as soon as possible. The pharmacy administrator-on-call must ensure the Pyxis is taken off critical override when appropriate.

K. **Wasting of Partially Used Doses or Unusable Doses of Controlled and Non-Controlled Substances**
   a. All medications including controlled substances that have been removed from the ADS, opened, used, or have a compromised tamper-resistant system, shall be wasted in compliance with Federal and State regulations. Two authorized users, the user wasting and a witness, shall document wasted controlled substances in Pyxis.
   b. Pharmacy Staff shall review Pyxis Narcotics record with administration record.

L. **ADS Medication Load/Unload (Pocket Assignment)**
   a. Load/unload Privileges: All designated pharmacy staff shall have load/unload privileges, but Pharmacy Informatics will oversee load/unload activities. Pharmacy will load/unload medication data as necessary to optimize medication-related patient care.

M. **Stock Replenishment**
   a. Pharmacy will be responsible for maintaining adequate inventory levels of Pyxis formulary medications.
      i. A pharmacy technician shall pull the medications based on the fill list with all items at or below minimum periodic automatic replacement (PAR) level.
      ii. A pharmacist will check the stock before it leaves the Pharmacy.

iii. A pharmacy technician shall deliver and refill the medications in the Pyxis ADS.

N. **Console Settings**

a. Lead time shall be set at two (2) hours and lag time shall be set at four (4) hours.

b. Menu timeout shall be set at thirty (30) seconds. The Pyxis MedStation® will automatically log the user out if there is no activity within this time. For Pyxis Anesthesia Cart, the menu timeout shall be set at fifteen (15) minutes. However, it is the responsibility of the user to log out after each use to prevent diversion.

c. Discharge delay shall be set at two (2) hours. This time window will allow a user to return or waste a medication on a patient that was recently discharged.

O. **Downtime Procedures**

a. Documentation of Pyxis Hardware and Software Problems

i. All patient care areas will call the Inpatient Pharmacy for initial triage with Pyxis Problems at 951.486.4490.

ii. RUHS staff will call the Vendor Technical Support (BD Pyxis) at 1.800.727.6102 to report all equipment problems or failures. The Vendor Technical Support (BD Pyxis) will keep a log of Pyxis problems for tracking purposes.

b. **Downtime Procedures for Hardware / Electrical Power Outage or extended H.I.S Downtime**

i. In the event of an ADS failure, the following medication dispensing procedures shall be followed.

1. All medications that are stored within the failed ADS shall not be utilized.
2. The nursing staff shall coordinate with the inpatient pharmacy staff to have all requested medications be delivered from the inpatient pharmacy.

ii. The nursing staff shall reconcile the inventory count of controlled substances as soon as power is reestablished.

1. The following table describes the most common failure types:

Failure Type	Result	Remediation	Contact
Power Outage	Station down	Troubleshoot power source	a. RUHS Helpdesk b. Pharmacy c. Pyxis Technical Support
Hospital Information Systems Failure	No Admit, Discharge, Transfer (ADT)	Follow hospital downtime procedure; Admitting / nursing to notify Rx of ADT information	a. RUHS Helpdesk b. Pharmacy c. Pyxis Technical Support
Pharmacy Information Systems Failure	Verified orders not passing to profile, no ADT	Critical override occurs after 15 minutes	Pharmacy to notify RUHS Helpdesk
Pyxis Server Failure	Verified orders not passing to profile, no ADT, no refill function	Critical override occurs after 15 minutes, Pharmacy has to go to the ADS to print refill reports	a. Pyxis Technical Support b. RUHS Help desk
ADS Failure			
ADS Unresponsive	ADS does not respond to user input	Reboot	a. Pharmacy b. Pyxis Technical Support

			c. RUHS Helpdesk
Communication Failure	Verified orders not passing to profile, no ADT, no refill function	Reboot and check network cable for connection	a. Pharmacy b. RUHS communications c. Pyxis Technical Support
Drawer Failure	Cannot open drawer	Recover drawer	a. Pharmacy b. Pyxis Technical Support
Hardware Failure	Verified orders not passing to profile, no ADT, no refill function	Open the back of ADS w/ keys if necessary	a. Pharmacy b. Pyxis Technical Support
Interface Failure (network)	Verified orders not passing to profile, ADT, no refill function	Critical override occurs after 15 minutes	a. Pharmacy b. RUHS Helpdesk c. Pyxis Technical Support

c. **Resumption of Power and /or Pyxis Interface Downtime**
   i. The EHR shall populate Pyxis with patient demographic information when the patient is admitted.
   ii. The Contact Serial Number (CSN), NOT Medical Record number (i.e. hospital identification number), shall be manually entered to avoid billing compliance issues.
   iii. Upon resumption of electrical power and/or Pyxis, the pharmacy staff shall restock, inventory and correct the inventory in Pyxis.

P. **Data Archiving**
   a. Regular data archiving is automatically conducted daily onto the RUHS network drive. Retrieval of archived data is readily accessible through a Web-based archiving software.

Q. **Adding Patients to Pyxis**
   a. Patient names shall be automatically entered into Pyxis via the ADT/Pyxis interface.
   b. If the patient info is not automatically populated in Pyxis correctly and it is the responsibility of the nurse to inform Pharmacy to aid in the resolution of the missing patient profile
      i. See downtime protocols in Section O

R. **Operating Room/Surgical Suite ADS**
   a. **Machine Access:** The following personnel shall be granted user access to the ADS:
      i. Anesthesia Provider
      ii. RN, LVN
      iii. Pharmacy Technician
      iv. Pharmacist
      v. OR Technician (for stock supply drawers only)
   b. **Machine Refilling**
      i. Pharmacy shall refill Pyxis periodically throughout the day as indicated.
   c. **Controlled Substance Waste**
      i. Controlled substances waste shall not be returned to stock and shall be wasted to return bin with receipt in the presence of a licensed

witness who is an
authorized user. The witness shall document the waste electronically in the Pyxis System.

ii. Pharmacy Staff shall review Pyxis Narcotics record with Anesthesia administration record.

d. **Emergency Backup**
   i. The Pyxis keys shall be stored in the Pharmacy narcotics vault.
e. **Formulary Adjustments to Anesthesia Pyxis**
   i. Requests to adjust the formulary of the Anesthesia system shall be a formal process between the Chair of Anesthesia and Pharmacy Administration.
   ii. Medications stored in the Anesthesia system will require the review and approval for inclusion by the Pharmacy and Therapeutics Committee.

S. **Quality Assurance for Pyxis**
   a. **Controlled Substance Inventory**
      i. A complete controlled substances count of each ADS shall be performed by nursing every shift. In non-24-hour setting, inventory is performed daily, usually at the end of the day.
      ii. A complete controlled substances count on each Anesthesia Cart shall be performed by Residents and SRNAs/CRNAs on the last case of the day.
   b. **Blind count** functionality shall be used for medications including, but not limited to controlled substances and designated medications.
   c. **Quality checks**
      i. Medication outdates:
         1. The outdate tracking function shall be used to track outdates of Pyxis medications.
         2. Personnel filling Pyxis medications are responsible for updating the medication expiration date within the system.
         3. The removal of outdates shall occur no less frequently than every thirty (30) days by personnel designated to perform this function.
      ii. Pocket access frequency and PAR levels shall be evaluated periodically to assess appropriateness of ADS contents.
   d. **Accuracy of Medication Fill by Pharmacy**
      i. All Pyxis medications intended for Pyxis stock replenishment will be checked by a licensed pharmacist prior to leaving the Pharmacy.
      ii. Bar code medication administration (BCMA) is enabled for all Pyxis devices to ensure the accuracy of stocked medication.
      iii. Narcotics refill accuracy: Pharmacy supervisor or designee shall review the Pyxis CII Safe comparison report daily to ensure refill accuracy between pharmacy dispensing and Pyxis ADS refill.
      iv. Nursing and pharmacy staff shall report all ADS fill errors to pharmacy management via the incident report process.
   e. For more information about Quality Assurance, refer to Policy PHARM B209

T. **Returning medications**
   a. Any medication removed from the Pyxis ADS that is not administered to a patient and remains in its original, sealed, and untampered packaging shall be placed in the return bin.
   b. Medications should not be returned to Pyxis if adulterated or removed from patient care areas for any reasons except for direct patient care. If medication is unable to be returned to the ADS, call the inpatient pharmacy for guidance. (Refer to Policy PHARM F600 for details)

Document History:

Release Dates: New as housewide	**Retire Date:** N/A
Sponsored by: Pharmacy	**Replaces Policy:** PHARM B218 Automated Dispensing System 4/03, 09/08, 2/09, 5/10, 1/12, 6/12, 7/12, 11/12, 6/16

Date Reviewed	**Reviewed By:**	**Revisions Made?**	**Revision Description**
6/27/23	Justin Chang	Yes	Updated wording, definitions, migrated to new template, and removed redundant sections already covered in other policies.
8/8/23	Pharmacy Review Committee	Yes	Added scope of policy section and revised header to state “Housewide”
9/11/23	P&T	Yes	Add for Anesthesia Providers
10/1/2023	PAC		
9/12/2024	MEC	No	

RIVERSIDE UNIVERSITY HEALTH SYSTEM – MEDICAL CENTER
Housewide

	Document No: 820	Page 1 of 10
Title: Inpatient Penicillin and Cephalosporin Direct Oral or Graded Oral Challenge Protocol	**Effective Date:** 11/22/2024	☐ **RUHS – Behavioral Health** ☐ **RUHS – Care Clinics** ☒ **RUHS – Medical Center** ☐ **RUHS – Public Health** ☐ **RUHS – Hospital Clinics** ☐ **Departmental**
Approved By:  Jennifer Cruikshank CEO/ Hospital Director		☐ **Policy** ☐ **Procedure** ☒ **Guideline**

1. SCOPE

1.1 Penicillin and / or cephalosporin graded challenge, and direct oral challenge will be limited to the adult patient population and upon formal recommendations from the Infectious Diseases Consult Service.

1.2 Penicillin and / or cephalosporin graded challenge, and direct oral challenge should be considered for patient population with low-risk penicillin allergy history

2. DEFINITIONS

2.1 Graded Oral Challenge: A method of cautiously administering a drug, for the purposes of this protocol in three successive increasing doses, when the risk of allergic reaction is low. Graded challenge differs from desensitization because the immune response to an antibiotic is not modified. Patients who are unlikely to be allergic to an antibiotic are candidates for graded challenge.

2.2 Desensitization: A process of giving a medication in a controlled and gradual manner (e.g. 12 or more successive dose increases), which allows a patient with a true medication allergy to temporarily tolerate the medication without an allergic reaction.

2.3 Direct Oral Challenge: Administering a full treatment dose of a drug when the risk of allergic reaction is very low. Similar to a graded challenge, there is no modification to the immune response to an antibiotic. Patients who are unlikely to be allergic to an antibiotic are candidates for graded challenge.

3. BACKGROUND

3.1 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 while 10% are reported to have a true penicillin allergy.

3.2 Randomized controlled study has shown that when used with risk assessment tool, direct oral penicillin challenge in patients with a low-risk penicillin allergy was noninferior compared with standard-of-care skin testing followed by oral challenge.

3.3 The rate of cross-reactivity (IgE-mediated reactions) to cephalosporins in penicillin allergic patients is ≤ 2%. Rates of carbapenem cross reactivity are <1% (0.6%) (Refer to **Appendix C**).

3.4 Monobactams (Aztreonam) does not have cross-reactivity to penicillin although it is less efficacious and more expensive than beta-lactams.

3.5 Patients labeled with a penicillin allergy often require alternatives that are broader spectrum with more adverse effects leading to more healthcare resource utilization

and higher risk of adverse reactions,
antimicrobial resistance, and *Clostridioides Difficile* infections.

4. GUIDELINE

4.1 Evaluating a patient with a penicillin allergy

a. Conduct detailed interview on penicillin allergy history to determine risk of severe hypersensitivity (refer to Table 2).

b. Risk assessment tool such as PEN-FAST can be used to determine patient's risk of IgE-mediated reactions to penicillin and/ or cephalosporin (Refer to Table 3).

c. The best available allergy history should be obtained from the patient and/or family and caregivers.

d. Patient's electronic medical records and outside records (if available) should be reviewed for any past receipt of beta-lactam antibiotics.

4.2 Documentation

a. Details of the patient's beta-lactam allergy history should be documented in patient's electronic medical records.

b. Whenever possible, documentation should include risk categories based on guidance from **Table 2,3** & **Appendix A-C.**

5. PENICILLIN/ CEPHALOSPORIN ALLERGY GRADED / DIRECT CHALLENGE

5.1 Nursing instruction for protocol administration. Monitor patients for symptoms of allergic reactions during the protocol administration.

a. Vitals (blood pressure, heart rate, respiratory rate, SpO2) should be obtained at baseline prior to first dose and prior to each dose increase (in the setting of graded challenge).

b. Monitor vitals as appropriate based on visual observation and/ or patient report of symptoms (including but not limited to flashing, urticaria, angioedema, nausea/ vomiting, dizziness, wheezing, chest tightness etc.)

c. Ensure rescue medications are at bedside for graded / direct challenge – Epinephrine 0.3mg/3mL, diphenhydramine 50 mg/mL, and methylprednisolone 40 mg/mL.

d. Administer medications in the setting of an allergic reaction. Inform primary provider(s) immediately if reactions develop.

5.2 Graded oral challenge

a. Beta blockers must be held 24 hours and antihistamines 48 hours before the protocol is initiated.

b. Give 80mg Amoxicillin PO x 1 and observe for 30 minutes.

c. If no reaction is observed, proceed to Amoxicillin 500mg PO x 1 observe for 60 minutes. If no reaction is observed, proceed with treatment dose.

d. Cephalosporin graded challenge may be performed in similar manner where 10% dose of the specified cephalosporin is given followed by close monitor for 30 minutes.

e. If no reaction is observed,
proceed to 50% dose of the specified cephalosporin is given followed by close monitor for 60 minutes. If no reaction is observed, proceed with treatment dose.

f. Result of patient's graded challenge with penicillin and/ or cephalosporin, whether positive or negative, should be documented in patients electronic medical record including the allergy warning label (left hand panel).

5.3 Direct oral challenge

a. Beta blockers must be held 24 hours and antihistamines 48 hours before the protocol is initiated.

b. Give full oral dose of penicillin or cephalosporin (agent selection dependent on patient's allergy history per Appendix A-B).

c. Observe for 60 minutes.Result of patient's direct challenge with penicillin and / or cephalosporin, whether positive or negative, should be documented in patients electronic medical record including the allergy warning label (left hand panel).

6. REFERENCES

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6.2 2015 Sexually transmitted diseases guidelines. Centers for Disease Control and Prevention (CDC). Management of patient with a penicillin allergy section. Accessed 11/1/2018 at https://www.cdc.gov/std/tg2015/pen-allergy.htm

6.3 Solensky R, Earl H, Gruchalla RS. Clinical approach to penicillin-allergic patients: a survey. Ann Allergy Asthma Immunol 2000;84:329-33.

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7. ATTACHMENTS

7.1 **Table 1:** Types of drug hypersensitivity reactions (Gell and Coomb's classification)

7.2 **Table 2:** Interview Questions on Assessing Penicillin/ Cephalosporine Allergy

7.3 **Table 3:** PEN-FAST Score

7.4 **Appendix A:** Penicillin Allergy Skin Testing or Challenge Process

7.5 **Appendix B:** Cephalosporin Allergy Skin Testing or Challenge Process

7.6 **Appendix C:** Penicillin and Cephalosporin Cross-Reactivity Table

Document History:

Release Dates: 7/18/2023	**Retire Date:** N/A
Sponsored by: Pharmacy	**Replaces Policy:** HW 820 Penicillin Allergy Protocol Desensitization

Date Reviewed	**Reviewed By:**	**Revisions Made Y/N**	**Revision Description**
1/17/24	Infectious Disease Review	Yes	Removed Penicillin skin testing section. Updated reference Updated to include PEN-FAST tool Further delineated section 5
2/13/24	PRC	Yes	Rewording 3.1 and 5.2c, removal 5.2a
4/4/24	Pre-Nursing P&P	Yes	Addition of definition desensitization, removal of brand name products, rewording 5.1.a and 5.1.b, tables moved
4/18/2024	P&P		
8/6/2024	P&T		
7/2/2024	PAC	No	
8/8/2024	MEC	No	

Table 1. Types of drug hypersensitivity reactions (Gell and Coomb's classification)

Gell & Coomb's Class	Onset	Clinical Presentation
IgE-mediated (Type I)	Immediate, minutes to an hour	Urticaria (hives): raised, pruritic, fades without scarring Angioedema, laryngeal edema, bronchospasm, anaphylaxis
Cytotoxic (Type II)	Delayed, 5-15 days	Hemolysis, thrombocytopenia, neutropenia, interstitial nephritis
Immune complex mediated (Type III)	Delayed, 7-21 days	Serum sickness, small cell vasculitis, interstitial nephritis
Delayed Hypersensitivity (Type IV)	Delayed, 7-21 days	Dermatitis
Drug reaction with eosinophilia and systemic symptoms (DRESS, Type IVb)	Delayed, 2-6 weeks	Fever and morbilliform rash, lymph node enlargement and organ involvement
Severe Cutaneous Allergic Reactions (Type IVc)	Delayed, 4-28 days	Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN)

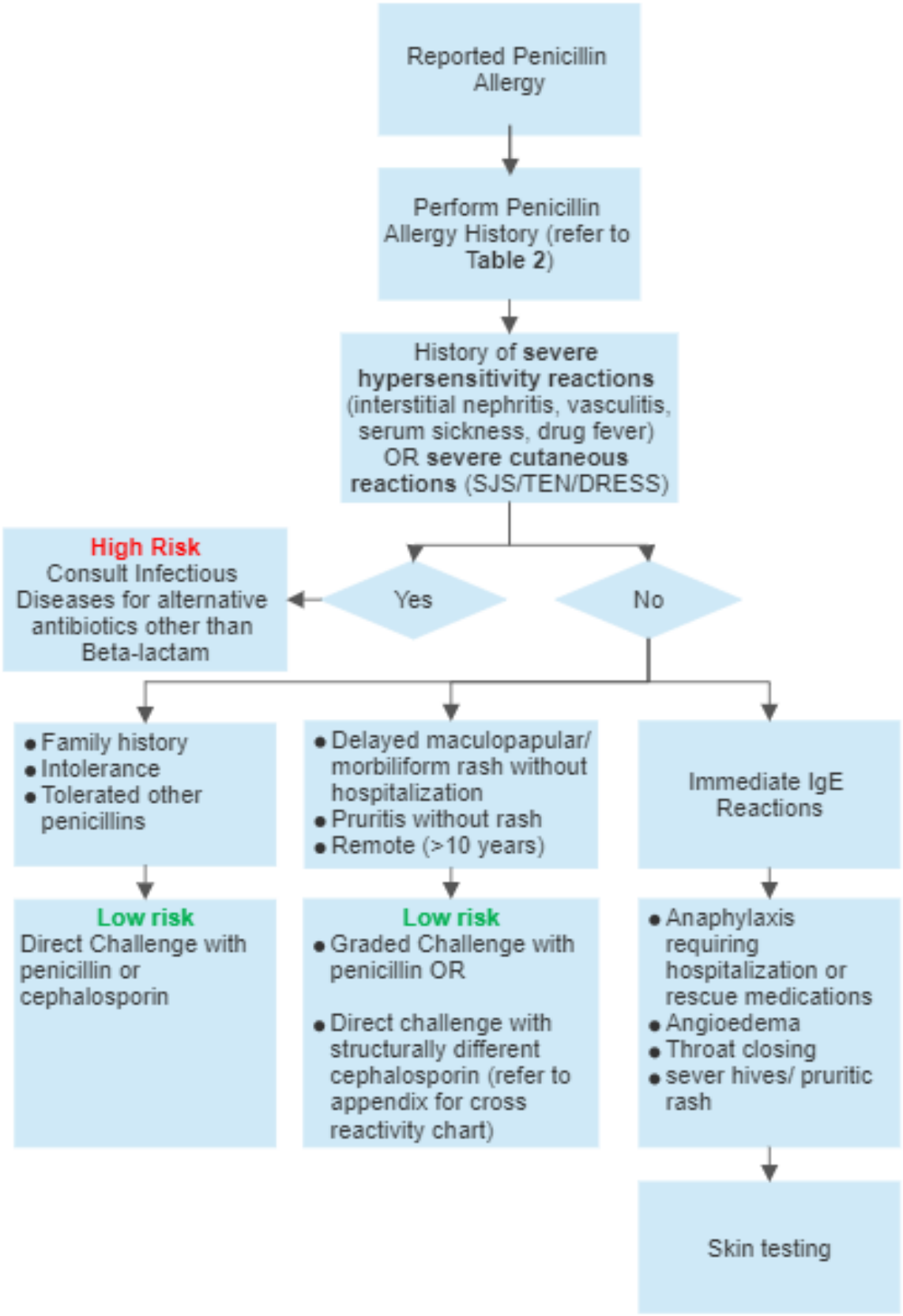
Table 2. Interview Questions on Assessing Penicillin/ Cephalosporine Allergy

Source of the report	• Patient self-report the allergy • Report by a family member • Report by a healthcare professional
What antibiotic	• Which beta-lactam caused the reaction • Dose and route of administration (if available) • Any co-current new medication given at the same time with the antibiotic
Timing	• How long after receiving the medication did the reaction occur (minutes, hours, several days)? • What was the patient's age when the reaction happened?
Recurrence	• Did similar reactions occur with re-exposure of same or other beta-lactams?
What type of reactions	**Low risk:** • Intolerance (gastrointestinal symptom, itch without rash, headache etc.) • Lab abnormality related to antibiotic side effects (QTc prolongation, hyperkalemia, liver enzyme elevations etc.) • Delayed maculopapular rash that is self-limiting and not requiring hospitalization **Medium-high risk:** • Delayed maculopapular rash that requires hospitalization • Anaphylaxis, angioedema, airway compromise • Severe cutaneous reactions consist of blisters, skin peeling, and/or involvement of mucous membrane (SJS/TEN)
Medical care	• Did the reaction require medical care and/or rescue medications such as steroid, diphenhydramine, or epinephrine? • Did the reaction led to need for hospitalization?
Past beta-lactam exposure	Has the patient tolerated other penicillin or cephalosporin since the reaction (ask both generic/trade names)? Consider using medication / pill images as appropriate. *Indicates brand names in Mexico • **Amoxicillin** (Amoxil, Larotid, Acimox*) • **Amoxicillin / Clavulonic acid** (Augmentin, Clavipen*) • **Cephalexin** (Keflex, Acacin*, Cefalver*, Keftab) • Cefadroxil (Duricef*) • Cefoxitin (Mefoxin*, Renoxitin) • Cefotetan (Apatef, Cefotan) • **Cefdinir** (Omnicef) • Cefixime (Suprax, Denvar*) IV cephalosporins: Cefazolin, Cefuroxime, Ceftriaxone, Ceftazidime, Cefepime

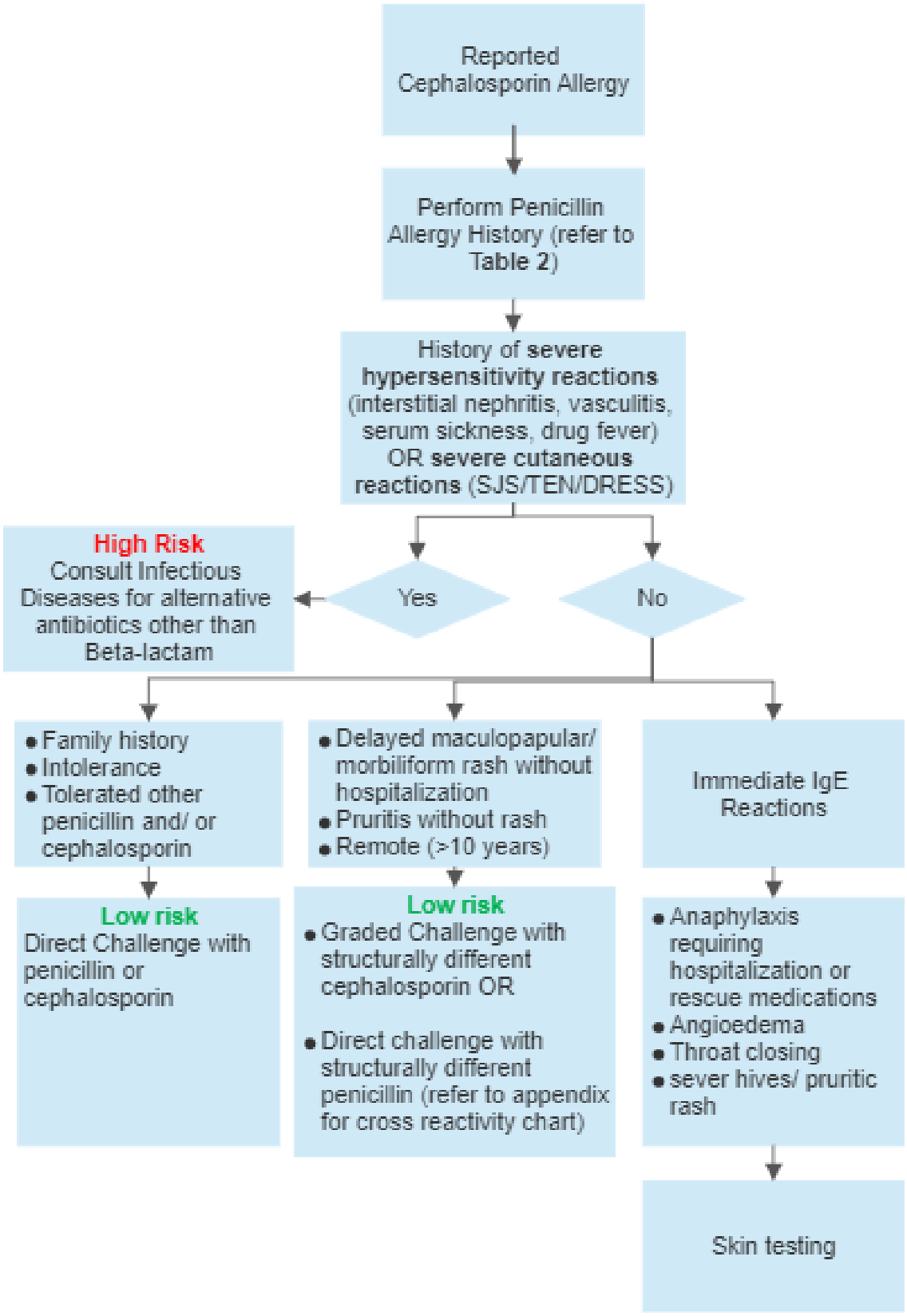
Table 3. PEN-FAST Score

Reaction	Answer	Points
5 years or less since reaction	No	0
	Yes	2
Anaphylaxis, angioedema or severe cutaneous adverse reaction (TEN, SJS, DRESS)	No	0
	Yes	2
Treatment required after reaction	No	0
	Yes	1
Total Points	0-2	Low risk, **proceed with oral challenge**
	3	Moderate risk, **consider penicillin skin testing**
	>4	High risk, **do not proceed with oral challenge**

Appendix A: Penicillin Allergy Skin Testing or Challenge Process



Appendix B: Cephalosporin Allergy Skin Testing or Challenge Process



Appendix C: Penicillin and Cephalosporin Cross-Reactivity Table

Beta-lactams	AMOXICILLIN*	AMPICILLIN	CLOXACILLIN	PENICILLIN	PIPERACILLIN*	CEFADROXIL	CEFAZOLIN	CEPHALEXIN	CEFOXITIN	CEFPROZIL	CEFUROXIME	CEFIXIME	CEFOTAXIME	CEFTAZIDIME	CEFTRIAXONE	CEFEPIME	ERTAPENEM	IMIPENEM	MEROPENEM
AMOXICILLIN*		X[1]	X[5]	X[4]	X[3]	X[1]	✓	X[1]	✓	X[2]	✓	✓	✓	✓	✓	✓	✓	✓	✓
AMPICILLIN	X[1]		X[5]	X[4]	X[3]	X[2]	✓	X[2]	✓	X[2]	✓	✓	✓	✓	✓	✓	✓	✓	✓
CLOXACILLIN	X[5]	X[5]		X[5]	X[5]	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
PENICILLIN	X[4]	X[4]	X[5]		X[5]	✓	✓	✓	X[3]	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
PIPERACILLIN*	X[3]	X[3]	X[5]	X[5]		X[3]	✓	X[3]	✓	X[3]	✓	✓	✓	✓	✓	✓	✓	✓	✓
CEFADROXIL	X[1]	X[2]	✓	✓	X[3]		✓	X[1]	✓	X[2]	✓	✓	✓	✓	✓	✓	✓	✓	✓
CEFAZOLIN	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
CEPHALEXIN	X[1]	X[2]	✓	✓	X[3]	X[1]	✓		✓	X[2]	✓	✓	✓	✓	✓	✓	✓	✓	✓
CEFOXITIN	✓	✓	✓	X[3]	✓	✓	✓	✓		✓	X[2]	✓	✓	✓	✓	✓	✓	✓	✓
CEFPROZIL	X[2]	X[2]	✓	✓	X[3]	X[2]	✓	X[2]	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓
CEFUROXIME	✓	✓	✓	✓	✓	✓	✓	✓	X[2]	✓		X[3]	X[1]	X[3]	X[1]	X[2]	✓	✓	✓
CEFIXIME	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X[3]		X[3]	X[3]	X[3]	X[3]	✓	✓	✓
CEFOTAXIME	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X[1]	X[3]		X[3]	X[1]	X[1]	✓	✓	✓
CEFTAZIDIME	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X[3]	X[3]	X[3]		X[3]	X[3]	✓	✓	✓
CEFTRIAXONE	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X[1]	X[3]	X[1]	X[3]		X[1]	✓	✓	✓
CEFEPIME	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X[2]	X[3]	X[1]	X[3]	X[1]		✓	✓	✓
ERTAPENEM	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		X[5]	X[5]
IMIPENEM	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X[5]		X[5]
MEROPENEM	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X[5]	X[5]	

* Also applies to beta-lactamase inhibitor combinations (amoxicillin-clavulanate and piperacillin-tazobactam)

LEGEND:	
Penicillins	
1st Generation Cephalosporins	
2nd Generation Cephalosporins	
3rd Generation Cephalosporins	
4th Generation Cephalosporins	
Carbapenems	
✓	Different structure. CONSIDERED SAFE TO PRESCRIBE

Reaction likely based on side chain:	
X[1]	Same side chain - clinical evidence of cross reaction. DO NOT PRESCRIBE
X[2]	Same side chain - Theoretical risk of cross reaction, no clinical studies. DO NOT PRESCRIBE
X[3]	Similar side chain - Potential for cross reaction. DO NOT PRESCRIBE
Reaction likely based on Beta-lactam ring	
X[4]	Clinical evidence of cross reaction. DO NOT PRESCRIBE
X[5]	Theoretical risk of cross reaction, no clinical studies. DO NOT PRESCRIBE

RIVERSIDE UNIVERSITY HEALTH SYSTEM – MEDICAL CENTER
Housewide

	Document No: 828	Page 1 of 5
Title: Smart Infusion Pump System	**Effective Date:** 11/22/2024	☐ **RUHS – Behavioral Health** ☐ **RUHS – Community Health Centers** ☐ **RUHS – Hospital Based 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 RUHS Medical Center and Infusion Center, encompassing guidance for use of the various smart infusion pump systems.

2. DEFINITIONSsss

2.1 Smart Infusion Pump: A programmable infusion device used to control the administration of drugs, fluids or blood products by establishing standard concentrations, dose limits, and clin`ical advisories to reduce medication administration errors.

2.2 Drug Library: a drug data set to define a list of drugs and concentrations appropriate for each profile. Programming via the drug data set automates programming steps, including the drug name, drug amount and diluent volume, and represents established best practice.

2.3 Epidural Anesthesia: a type of anesthesia block in which a local anesthetic with or without analgesic drugs are injected into the epidural space surrounding the spinal cord. The pump module used for epidural drug delivery must be clearly differentiated from those used for other routes of administration.

2.4 Guardrails: Drug Error Reducing Software for the ALARIS™ Infusion System.

2.5 Guardrails Hard Limit: Does not allow the operator of the infusion system to adjust the rate of drug delivery outside of the parameters currently set within the dataset.

2.6 Guardrails Soft Limit: Allows the operator of the infusion system to adjust the rate of drug delivery above the maximum dose or below the minimum dose. When a soft limit is reached, the operator will be asked to review and approve the infusion rate to assure that an error has not been made before overriding and Guardrails limit. A visual and auditory prompt will occur indicating that the infusion is being delivered above or below the Guardrails limit when a soft limit is overridden. The visual alert will stay visible during the infusion.

2.7 PCA Module: The ALARIS™ PCA module integrates a syringe-based patient-controlled analgesia (PCA) device with a large volume pump, syringe and EtCO2 modules on a single hardware platform. The PCA module is indicated for use on adults, pediatrics and neonates for continuous or intermittent delivery through

clinically acceptable routes of administration: such as intravenous (IV), subcutaneous or epidural.

2.8 Profile: Represents a specific drug library for a corresponding patient care area within the ALARIS™ Infusion System. Each profile contains drug configurations that are appropriate for that patient population or mode of delivery (Epidural, Critical Care, Medical/Surgical, Oncology, Pediatrics, and Nursery).

2.9 Programming (Point-of-Care) Module: The PC unit (also known as Pump Brain) of the ALARIS™ Infusion System provides a common interface for programming infusions and monitoring. Each programming module has the ability to control various pumping modules (PCA, Syringe, and Pump).

2.10 Pump Module: The ALARIS™ module (commonly known as a channel) that is attached to the programming module for the delivery of intravenous fluids or medications.

2.11 Syringe Module: The ALARIS™ module that is attached to the programming module for the delivery of intermittent medications via syringe. This attaches to the ALARIS™ Point of Care unit for the delivery of concentrated drugs through advance pressure monitoring and rate flow accuracy.

3. GUIDELINE

3.1 Intravenous medications, solutions, and blood products for infusion shall be administered via a smart infusion pump.

a. Exception: perioperative area may utilize manual flow regulator for maintenance fluid only.

3.2 All staff that utilize the smart infusion system shall complete an education program and a hands-on demonstration prior to utilization of the pump. The Chief Nursing Officer is responsible for training of nursing users, the Director of Pharmacy is responsible for training of pharmacy users, and other respective managers are responsible for training their staff.

3.3 Drug Library

a. The library will be routinely maintained and updated by pharmacy in collaboration with other disciplines, at least annually, or more often as necessary.

b. The Chair of Pharmacy & Therapeutics (P&T) Committee, a pharmacy director, or a pharmacy director's designee will review and approve each infusion pump drug library update. Once approved, the new infusion pump drug library will be uploaded to the server and activated. In addition, the infusion pump drug library will be reported at the subsequent P&T Committee meeting.

3.4 When a patient transfers from one unit to another, the receiving unit is responsible to check and/or change the ALARIS™ profile to meet the level of care provided on that unit.

3.5 Excluding the L&D Epidural Pumps, all pumps and modules are returned to Central Processing Department after their use for proper cleaning and disinfection.

a. The L&D epidural pumps will be cleaned on the unit

3.6 DO NOT USE Smart Infusion System pumps less than the maximum close distance from the magnetic resonance imaging (MRI) suite. The exception to this is the MRidium® MRI-Safe smart infusion pump.

3.7 Infusion pumps used for enteral feeding **shall NOT be used to administer medications.**

4. ALARIS™ INFUSION SYSTEM

4.1 Assemble all needed equipment, open tubing and solution packages, prime tubing, invert all y-ports to purge air. When priming is complete use roller clamp to stop flow.

4.2 Ensure that secondary tubing is unclamped before infusion.

4.3 Medications and solutions delivered by the ALARIS™ Infusion System shall be administered using the appropriate clinical profile entry from the GUARDRAILS DRUGS or GUARDRAILS IV FLUIDS library.

4.4 BASIC INFUSION and DRUG CALCULATION modes shall only be used when there is no option for the medication or concentration in the drug library. In these instances, the user will notify the pharmacist so that the medication can be added to the drug library in the future.

4.5 When initiating intravenous therapy, select YES when the programming module asks “Is this a new patient?” This will definitively clear the settings from the prior patient.

4.6 Select the appropriate profile for the area in which the infusion will run.

4.7 Verify medication administration information that appears on the Alaris™ pump screen matches providers’ orders and relevant pharmacy labels, e.g. dose, rate, and volume.

4.8 Any alerts must be reviewed and addressed prior to starting medication infusion.

4.9 Refer to the ALARIS™ Quick Reference Guide for further instructions.

5. NEONATAL TRANSPORT PUMP

5.1 During neonatal transport, a smart infusion pump (Perfusor® Space Syringe Pump) will be used if medication administration is required.

a. Prior to overriding the dose in Perfusor® Space Infusion Pump, the nurse shall:

- Complete a two practitioners, RN, and RN designee, verification of the Dose Mode entry screen with the original physician order. The RN designee must be a licensed individual competent in medication administration to the neonatal patient.
- If an original order is outside the pre-programmed limits, the nurse will notify the physician to verify the infusion order.
- The nurse will document the verification in the progress notes and nursing flow sheet.

6. EPIDURAL INFUSION/PERIPHERAL NERVE BLOCK

6.1 Infusion delivered via the neuroaxial route will be administered by a dedicated smart infusion pump.

6.2 **For patient safety, the smart infusion pump being used for epidural/peripheral nerve block shall not be used for medications for routes other than epidural or peripheral nerve block**

a. The drug library will only contain the epidural and peripheral nerve block infusions

b. **L&D stores and maintains its own dedicated smart infusion pumps for epidural infusion.**

6.3 A patient will have intravenous (IV) access at all times when epidural infusions are being administered.

6.4 **A different smart infusion pump that is visually distinctive from the epidural pump needs to be used for IV infusions**

6.5 **Epidural/Peripheral nerve block infusions shall use epidural/peripheral nerve block-dedicated tubing without a "Y" connector injection port**

6.6 Epidural anesthesia is initiated and programmed by an Anesthesia Care Provider.

6.7 Orders for medications infused via the neuroaxial routes are written per policy.

6.8 Anesthesia Care Providers will label the epidural tubing at both ends of the tubing.

6.9 A resuscitation bag and mask must be readily available in the patient care area where epidural medication is administered.

7. MRidium® MRI IV Infusion System

7.1 MRidium® MRI IV Infusion System is the only MRI-Safe smart infusion system that can be used in an MRI Room.

a. Transition of continuous medications to the MRidium® Infusion System will occur in the MRI holding area prior to MRI procedure.

- In critical care areas, transition may occur at the bedside for high risk patients

7.2 This system is not intended for long term patient care outside of an MRI environment.

8. Safety and Malfunction Concerns

8.1 Suspected infusion pump malfunction:

a. 2nd qualified staff member to verify the provider's order and smart infusion pump programming to see if the error/malfunction still happens despite correct programming.

b. If the smart infusion pump is found to be malfunctioning:

- Remove the smart infusion pump including disposables (i.e. tubing) and medications involved in the incident from patient care area.
- Notify nurse manager/director or chain of command.
- Follow institution policy for reporting broken or malfunctioning equipment(i.e. Incident report and HEMS).

9. REFERENCES

9.1 ALARIS™ Infusion System, version 9.33, September 2017

9.2 ALARIS™ Infusion System User Manual Addendum, January 2018

9.3 Alaris™ System User Manual, Version 9.33, July 2019

9.4 ASHP. (2018, October). ASHP Guidelines on Preventing Medication Errors in Hospitals. American Journal of Health-System Pharmacy, 75(19), 267-289.

9.5 Centers for Medicare & Medicaid Services Conditions of Participation §482.23(c)(4)

9.6 IRadimed Corporation 3860+ MRidium Infusion System Operator's Manual September 2018.

9.7 ISMP. Proceedings from the ISMP Summit on the Use of Smart Infusion Pumps: GUIDELINES FOR SAFE IMPLEMENTATION AND USE. 2009

9.8 ISMP. Acute Care ISMP Medication Safety Alert. Epidural – IV Route Mix-ups: Reducing the Risk of Deadly Errors. July 3, 2008.

9.9 HW Policy 555: Reporting Broken and Malfunctioning Equipment

9.10 HW Policy 603.6: Regional Epidural Anesthesia Pain Management

9.11 HW Policy 603.7 Regional Analgesia via Catheter

Document History:

Prior Release Dates: 6/15/2018, 3/4/19, 12/10/2020, 2/1/2024	**Retire Date:** N/A
Document Owner: Pharmacy Department	**Replaces Policy:** Pharmacy Dept PnP C315 ALARIS™ Infusion Pump Nursing Dept PnP 718 Infusion Pump: ALARIS™ Infusion System Pharmacy Dept PnP377 Neonatal Transport: SPACE Infusion Pump System HW 845 Smart Infusion Pumps for Epidural Infusion

Date Reviewed	Reviewed By:	Revisions Made Y/N	Revision Description
5/14/2024	Pharmacy Review Committee	Yes	Changed PC Unit to drug library
6/3/2024	Pre-Nursing P&P	Yes	Add a referencing Policy and corrections to some language
6/20/2024	Nursing P&P	Yes	Update a referenced policy
7/1/2024	P&T	No	
8/14/2024	PAC	N	
9/12/2024	MEC	N	

RIVERSIDE UNIVERSITY HEALTH SYSTEM - MEDICAL CENTER

Housewide

	Document No: 836	Page 1 of 3
Title: Look-Alike/Sound-Alike Medication Error Prevention	**Effective Date:** 11/22/2024	☐ **RUHS – Behavioral Health** ☐ **RUHS – Community Health Centers** ☒ **RUHS – Hospital Based Clinics** ☒ **RUHS – Medical Center** ☐ **RUHS – Public Health** ☐ **Departmental**
Approved By: Jennifer Cruikshank CEO/ Hospital Director		☐ **Policy** ☐ **Procedure** ☒ **Guideline**

1. **SCOPE.** This policy applies to all medications stored and utilized for adult and pediatric patients: RUHS – Medical Center Moreno Valley and Arlington campuses, and hospital-based clinics.

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; also consider procuring medications from different manufacturers when high risk products may *look similar* and create confusion when storing and dispensing.

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 January 1, 2021

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 2019

4.4 Institute for Safe Medication Practices: Look-Alike Drug Names with Recommended Tall Man Letters - Published 2023

5. ATTACHMENTS

5.1 APPENDIX A

Document History:

Prior Release Dates: 12/28/2015, 12/2018, 9/7/2021, 2/10/2023, 11/18/2023	**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**
	MSO	yes	melatonin and memantine are added as the result of IR# SI-41194
5/2/2024	Pre-Nursing P&P	N	
5/16/2024	Nursing P&P	N	Consent Agenda Item
7/1/2024	P&T	N	
8/14/2024	PAC	N	
9/12/2024	MEC	N77	

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

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 liposomal amphotericin B 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®	
buPROPion	busPIRone	buPROPion is used to treat depression or as an aid to smoking cessation. busPIRone is used to manage anxiety disorders.
busPIRone	buPROPion	
BUPivacaine	ROPivacaine	BUPivacaine and ROPivacaine are two different local anesthetics used for similar indications.
carBAMazepine	OXcarbazepine	carBAMazepine and OXcarbazepine are two different antiseizure agents used for the management of epilepsy and neuropathic pain.
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	
chlordiazePOXIDE	chlorproMAZINE	chlordiazePOXIDE is used for the management of acute alcohol withdrawal symptoms and anxiety disorders. chlorproMAZINE is used for the treatment of bipolar disorder, schizophrenia, and nausea/vomiting.
chlorproMAZINE	chlordiazePOXIDE	
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.
dexAMETHasone	dexmedeTOMIDine	dexAMETHasone is a systemic corticosteroid used to treat inflammatory disorders, including adrenal insufficiency. dexAMETHasone is available as both parenteral and oral formulations. dexmedeTOMIDine (Precedex®) is an alpha-adrenergic agonist used for sedation. dexmedeTOMIDine (Precedex®) is available only as a parenteral formulation.
dexmedeTOMIDine	dexAMETHasone	
diazePAM	dilTIAZem	diazePAM is a benzodiazepine used for the management of alcohol withdrawal syndrome, anxiety, and seizures. dilTIAZem is a calcium channel blocker used for the management of hypertension, angina, and atrial fibrillation.
dilTIAZem	diazePAM	
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	
droNABinol	droPERidol	droNABinol is a cannabinoid used as an antiemetic and appetite stimulant. droPERidol is a first-generation antipsychotic used for the management of acute agitation and postoperative nausea/vomiting. droNABinol is only available orally, whereas droPERidol is only available parenterally.
droPERidol	droNABinol	
DULoxetine	FLUoxetine	Both DULoxetine and FLUoxetine are antidepressants. DULoxetine is a serotonin/norepinephrine reuptake inhibitor (SNRI). FLUoxetine is a selective serotonin reuptake inhibitor (SSRI).
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	
FLUoxetine	DULoxetine	Both DULoxetine and FLUoxetine are antidepressants. DULoxetine is a serotonin/norepinephrine reuptake inhibitor (SNRI). FLUoxetine is a selective serotonin reuptake inhibitor (SSRI).
fluPHENAZine	fluvoxaMINE	fluPHENAZine is a first-generation antipsychotic used for the management of psychotic disorders. fluvoxaMINE is an antidepressant used for the management of depression and anxiety disorders. fluPHENAZine is available in oral and parenteral formulations, whereas fluvoxaMINE is only available orally.
fluvoxaMINE	fluPHENAZine	
glipiZIDE	glyBURIDE	glipiZIDE and glyBURIDE are two different medications in the same drug class (sulfonylureas) used for treatment of diabetes mellitus.
glyBURIDE	glipiZIDE	
guaiFENesin	guanFACINE	guaiFENesin is an expectorant used for the management of acute or chronic cough. guanFACINE is an alpha-adrenergic agonist used for the management of hypertension.
guanFACINE	guaiFENesin	
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)	

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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 for 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	
levETIRAcetam	levoFLOXacin	levETIRAcetam is used for the treatment of seizures. levoFLOXacin is a fluoroquinolone antibiotic used for the treatment of certain infections.
levoFLOXacin	levETIRAcetam	
LORazepam	ALPRAZolam	ALPRAZolam and LORazepam are two different medications in the same drug class (benzodiazepines) used for similar indications.
medroxyPROGESTERone	methylPREDNISolone	medroxyPROGESTERone is a progestin contraceptive available to be administered as orally, IM, and SQ. methylPREDNISolone is a systemic corticosteroid used to treat inflammatory disorders available to be administered orally, IV, IM and intra-articular.
methylPREDNISolone	medroxyPROGESTERone	
melatonin	memantine	The FDA does not regulate supplements. Consequently, melatonin is not officially FDA-approved for any indication. However, melatonin receptor agonists such as ramelteon and tasimelteon are FDA-approved for the treatment of insomnia. Non-FDA-approved Indications for melatonin include insomnia.
memantine	melatonin	Memantine (NAMENDA) is an N-methyl-D-aspartate (NMDA) receptor antagonist indicated for the treatment of moderate to severe dementia of the Alzheimer's type.
methIMAzole	metOLazone	methIMAzole is an antithyroid agent used for the management hyperthyroidism and thyrotoxicosis. metOLazone is a thiazide diuretic used for the management of edema or volume overload.
metOLazone	methIMAzole	
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	
midazolam- Versed®	verapamil	Midazolam is a benzodiazepine and anticonvulsant, while verapamil is a calcium channel blocker.
morphine	HYDROmorphone	HYDROmorphone (commonly referred to by its brand name Dilaudid®) and morphine are both opioids used to control pain but are dosed differently.
niCARdipine	NIFEdipine	niCARdipine (Cardene®) and NIFEdipine (Procardia XL®) are both calcium channel blockers used to treat hypertension. niCARdipine (Cardene®) is available orally and parenterally. NIFEdipine (Procardia XL®) is only available orally. NIFEdipine IR is not recommended for use due to safety concerns, including hypotension, MI, arrythmias, and stroke.
NIFEdipine	niCARdipine	
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.
OLANZapine	QUEtiapine	Both OLANZapine (ZyPREXA®) and QUEtiapine (SEROquel®) are second-generation antipsychotics used for similar indications. OLANZapine (ZyPREXA®) is available orally and parenterally, whereas QUEtiapine (SEROquel®) is only available orally.
OXcarbazepine	carBAMazepine	carBAMazepine and OXcarbazepine are two different antiseizure agents used for the management of epilepsy and neuropathic pain.
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	
prednisoLONE	predniSONE	prednisoLONE and predniSONE are both systemic corticosteroids used to treat inflammatory disorders. predniSONE is the prodrug of prednisoLONE. Dose equivalency is 1:1.
predniSONE	prednisoLONE	
QUEtiapine	OLANZapine	Both OLANZapine (ZyPREXA®) and QUEtiapine (SEROquel®) are second-generation antipsychotics used for similar indications. OLANZapine (ZyPREXA®) is available orally and parenterally, whereas QUEtiapine (SEROquel®) is only available orally.
rifabutin	rifAMPin	

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rifAMPin	rifabutin	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	rifAXIMin	rifAMPin and rifAXIMin are two different medications in the same drug class (rifamycins) but have different indications and are dosed differently. rifAMPin is available in both parenteral and oral formulations, whereas rifAXIMin is only available orally.
rifAXIMin	rifAMPin	

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®)	
ROPivacaine	BUPivacaine	BUPivacaine and ROPivacaine are two different local anesthetics used for similar indications.
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	
traMADol	traZODone	traMADol is a C-IV opioid analgesic used for the management of pain. traZODone is serotonin reuptake inhibitor used for the management of depression and is often used off-label for sleep.
traZODone	traMADol	
valACYclovir	valGANciclovir	Both valACYclovir and valGANciclovir are antivirals. valACYclovir is used for the treatment of herpes and varicella. valGANciclovir is used for the treatment of cytomegalovirus (CMV).
valGANciclovir	valACYclovir	
VECuronium	VERsed	Vecuronium is a nondepolarizing neuromuscular blocking agent used to relax muscles or as an adjunct in general anesthesia during surgical procedures. VERsed (midazolam) is a benzodiazepine and anticonvulsant.
VERsed	VECuronium	

RIVERSIDE UNIVERSITY HEALTH SYSTEM – MEDICAL CENTER

Housewide

	Document No: 874	Page 1 of 5
Title: Hand Hygiene and Garbing for Sterile Compounding	**Effective Date:** 11/22/2024	☐ **RUHS – Behavioral Health** ☐ **RUHS – Community Health Centers** ☐ **RUHS – Hospital Based Clinics** ☒ **RUHS – Medical Center** ☐ **RUHS – Public Health** ☐ **Departmental**
Approved By: Jennifer Cruikshank CEO/ Hospital Director		☒ **Policy** ☒ **Procedure** ☐ **Guideline**

1. SCOPE

1.1 Applies to all staff that have been trained and completed designated competencies related to sterile compounding located in the Riverside University Medical Center Moreno Valley Campus Inpatient Pharmacy and Infusion Center.

1.2 Standardizes the process of hand hygiene and garbing for all authorized personnel working in controlled environments of the ante-area and buffer/clean rooms, to reduce sources of viable and nonviable contamination.

2. DEFINITIONS

2.1 Garbing: The act of donning personal protective equipment.

2.2 Line of Demarcation: A visible line on the floor of the Ante room distinguishing the clean and dirty side of the room.

2.3 Ante-area: An area where personnel hand hygiene and garbing procedures, staging of components and other high particulate generating activities are performed, that is adjacent to the area designated for sterile compounding.

2.4 Buffer/clean room: An area where the primary engineering control (PEC) is physically located.

2.5 Primary Engineering Control (PEC): a device that provides an ISO Class 5 or better environment through the use of non-turbulent, unidirectional HEPA-filtered first air for compounding sterile preparations.

2.6 IPA. Isopropyl Alcohol 70%.

2.7 HD(s). Hazardous drugs include those used for cancer che-motherapy, antiviral drugs, hormones, some bioen-gineered drugs, and other miscellaneous drugs. Drugs considered hazard-ous 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

3. POLICY

3.1 All compounding and/or maintenance personnel (persons other than trained compounding personnel), who perform facility cleaning must receive training on hand hygiene and garbing as well as successfully complete the Competency Assessment: Hand Hygiene and Garbing prior to entering the buffer area/cleanroom environment.

3.2 Individuals not trained on this procedure can enter controlled areas only if accompanied by a trained and qualified person.

3.3 Individuals experiencing rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections or other communicable disease, or those wearing cosmetics, artificial eye lashes, nail polish, or artificial nails shall be excluded from the ISO Class 5 and compounding areas until their conditions are remedied.

3.4 Compounding personnel shall not wear any wrist, hand, finger, or other visible jewelry, piercing, headphones, ear-buds, or personal electronic devices.

3.5 Until the hand hygiene and garbing activities described in this procedure are completed, no personnel may enter the clean area of the ante-area or enter the buffer area for any reason.

3.6 Personal protective equipment consisting of a low-lint gown, head cover, face mask, facial hair covers (if applicable), and shoe covers must be worn inside the designated area at all times.

3.7 Sterile gloves must be used for compounding.

3.8 Gloves are to be routinely disinfected with sterile IPA before entering or re-entering the PEC and after contact with non-sterile objects. Gloves shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected.

3.9 Eye-shields are not required unless the staff member is performing an activity that has a relatively higher likelihood of splashing of cleaning materials such as performing cleaning of controlled area ceilings.

3.10 Personal protective equipment must be donned and removed in an ante-area or immediately outside the segregated compounding area.

3.11 Personnel shall don personal protective equipment in an order that proceeds from those activities considered the dirtiest to those considered the cleanest. Compounding personnel scrubs must be clean and not soiled. Scrubs must be free of human and animal hair/fur.

3.12 Legs must be completely covered below the hem of the gown:

a. Shorts or skirts worn without stockings are not acceptable.

b. Closed toe shoes must be worn at all times.

c. Nylon stockings are acceptable.

3.13 For HDs compounding:

a. Second pair of shoe covers must be donned before entering the clean room and doffed when exiting. Shoe covers worn in HD handling areas must not be worn in

other areas to avoid spreading HD contamination and exposing other healthcare workers.

b. Two pairs of sterile gloves that meet the ASTM D-6978 standard must be worn when compounding.

c. The outer gloves are removed inside the ISO 5 area after compounding and used to transfer the decontaminated final compounded sterile product (CSP) out of the PEC

d. Personnel must use a coated chemotherapy compounding gown that close in the back, seamless or have sealed seams to prevent accidental contamination

4. PROCEDURES

4.1 Hand Hygiene and Garbing activity proceeds in an order from dirtiest to cleanest and generally occurs in this order:

a. Don low-lint head cover, low-lint face mask and low-lint facial hair cover (if applicable) in any order, must cover all of hair.

b. Use low-lint towel to wipe corrective eyeglasses with sterile IPA or other appropriate disinfectant (if applicable)

c. Don low-lint shoe covers.

d. Remove debris from underneath fingernails using a nail cleaner (nail pick) under running water followed by vigorous hand washing.

e. Perform 30 seconds hand and forearm up to elbows wash with soap.

f. Dry hands and forearms thoroughly with low-lint towel.

g. Don low-lint gown with full closure.

h. Apply alcohol-based surgical rub with persistent activity to all surfaces of hand and fingers and allow hands to dry.

i. Don sterile powder-free gloves in the anteroom or buffer area.

j. Sanitize all surfaces of gloved hands with sterile IPA

4.2 Gloving

a. Antiseptic hand cleansing must be performed using an alcohol-based surgical hand scrub with persistent activity.

b. Allow hands to dry completely.

c. Sterile gloves shall be the last item donned before compounding begins

d. Don the first glove with an ungloved hand by grabbing an inner surface, sliding the hand into it and pulling it on.

e. Don the second glove by slipping the gloved hand into the cuff of the second and placing the ungloved hand into the free glove.

f. Inspect both gloves for damage and replace if any defects (tears, holes and rips) are noted.

g. Gloves may become punctured or torn. If tearing or a puncture occurs, the compounder must perform hand hygiene again and re-glove.

h. Gloved hands will be sprayed with sterile IPA at the following times:

i. Prior to entering the ISO 5 space (for instance to put materials into the hood);

ii. At the start of each batch prior to compounding;

iii. Any time the compounder's hand re-enter the ISO Class 5 area;

iv. Periodically during prolonged periods of compounding within the Class 5 area.

i. Spraying gloved hands with sterile IPA must occur away from the hood in order to prevent damage to the HEPA filter.

j. Spray gloved hands with sterile IPA and rub hands together to completely coat surfaces of gloves with IPA.

k. Allow sterile IPA to dry completely.

4.3 Exiting the Buffer Area/Clean Room

a. Temporary exit from the buffer area:

i. Remove gloves.

ii. Remove the gown which may be saved for subsequent use during the same compounding day/shift provided it is not visibly soiled. If retained, it must be hung on a hook on the clean side of the anteroom and operator initials should be written inside.

iii. Wash hands

iv. Remove the face mask, facial hair cover, head cover, gloves and shoes cover on "dirty side" of the ante-area.

b. Exiting at the end of the shift or day:

i. The disposable gown must be discarded at the end of the compounding shift or day.

4.4 For HD compounding:

i. The outer gloves are removed inside the ISO 5 area after compounding and used to transfer the decontaminated final compounded sterile product (CSP) out of the PEC.

ii. Remove the outer pair of shoe covers in buffer room

iii. Remove the HD gown by pulling it at the waist/hips until it pulls away from the shoulders. Slowly remove the gown, turning it inside out and discard in trace waste

iv. Remove the inner gloves.

v. Wash hands and wrists with soap and water to remove any HD residue

vi. Walk to dirty side of the ante room and remove the remainder of the garb (bouffant cap, mask, and inner shoe covers)

5. REFERENCES

5.1 USP <797> Pharmaceutical Compounding-Sterile Preparations 2023.

5.2 USP <800> Hazardous Drugs – Handling in Healthcare Settings 2023

5.3 California Code of Regulations Title 16 Section 1751.5 Sterile Compounding Attire.

Document History:

Prior Release Dates: 05/2013, 5/2/18	**Retire Date:** N/A
Document Owner: Pharmacy	**Replaces Policy:** Pharmacy A103

Date Reviewed	**Reviewed By:**	**Revisions Made Y/N**	**Revision Description**
08/13/2024	Pharmacy Review Committee	Y	Replaced term 'shedding free' to 'low-lint' to follow updated 2023 USP standard minor term modifications. Added HDS definition.
09/09/2024	P&T	N	
10/24/2024	PAC	N	

RIVERSIDE UNIVERSITY HEALTH SYSTEM – MEDICAL CENTER

Housewide

	Document No: 877	Page 1 of 3
Title: Immediate – Use Compounded Sterile Preparation (CSP)	**Effective Date:** 11/22/2024	☐ **RUHS – Behavioral Health** ☐ **RUHS – Community Health Centers** ☐ **RUHS – Hospital Based 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, with 3 or fewer sterile products, and a maximum beyond use date (BUD) of 4 hours starting from the initiation of compounding.

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 Aseptic technique: methods used to prevent contamination with microorganisms. Includes hand hygiene, disinfecting work surfaces, and personal protective equipment.

2.2 CSP: Compounded sterile preparation

2.3 ISO: International Organization for Standardization. Standards designed to ensure the quality, safety and efficiency of products, services and systems. Designs standards for clean rooms to prevent bacterial and other organismal contaminants.

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

2.5 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.

2.6 Designated person(s): One or more individuals assigned to be responsible and accountable for the performance and operation of the compounding facility and personnel in the preparation of CSPs.

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

a. Carcinogenicity

b. Teratogenicity or developmental toxicity

c. Reproductive toxicity in humans

d. Organ toxicity at low doses in humans or animals

e. Genotoxicity

f. New drugs that mimic existing hazardous drugs in structure or toxicity

3. POLICY

3.1 Immediate Use CSPs are compounded in less than ISO Class 5 conditions (e.g., bedside, countertop, operating room), with 3 or fewer sterile products, and a maximum beyond use date (BUD) of 4 hours starting from the initiation of compounding.

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 4 hours following the start of the preparation of the CSP.

3.5 For single patient use only.

3.6 If administration has not begun within 4 hours following the start of preparing theCSP, the CSP shall be promptly, properly, and safely discarded.

3.7 Training and Competency Assessments

a. Personnel compounding immediate use CSPs are provided education, training, and competency assessment consistent with their job descriptions.

b. Competency is assessed and documented prior to compounding independently and every 12 months.

4. PROCEDURE

4.1 Select and prepare a work surface that is free of clutter and is sanitized prior to starting the compounding process with: 70% isopropyl alcohol, or sodium hypochlorite (bleach).

4.2 Stage medications and supplies in such a way as to reduce the risk of introduction of particulate matter or biological fluids, or mix-up with other conventionally manufactured products or CSPs before, during, and after preparation of the CSP.

4.3 Perform hand hygiene and always don medical grade gloves. Change gloves if they become torn, punctured or contaminated.

a. Additional PPE may be required, or recommended when handling hazardous medications. Refer to policy.

4.4 Sanitize critical sites (e.g., vial stoppers, ampule neck, injection port of an IV bag) with 70% isopropyl alcohol wipes prior to puncture or entry.

4.5 Prepare CSPs in accordance with evidence-based information for physical and chemical stability including, but not limited to, approved labeling mixing and storage requirements, stability and compatibility studies and data.

4.6 Use proper aseptic technique during CSP compounding manipulations.

4.7 Assign the most conservative BUD to the CSP possible that does not exceed 4 hours from the start of compounding. If administration does not occur within the assigned BUD (less than (<) 4 hours), promptly and appropriately discard the CSP.

4.8 Ensure single dose starting components are only used for one patient and dispose of unused drug or components drawn from a single-dose container appropriately.

4.9 If the CSP(s) cannot remain in the direct line of site of the preparer from the time of compounding until administration, label the CSP with the following:

a. Patient identification information

b. Names and amounts of all active ingredients

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

d. Date and time from start of CSP preparation

e. Exact 4-hour time period within which the administration of the CSP must occur.

4.10 Prior to dispensing, perform a final visual verification of the CSP(s) and reject the preparation if visual contamination in found.

4.11 Ensure administration of the CSP begins within 4 hours of the start of compounding. Promptly and safely discard of the CSP if administration does not occur within the 4-hour timeframe.

5. REFERENCES

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

5.2 Elsevier Performance Manager-Clinical Skills

5.3 HW 852 Medication Administration

5.4 HW 851 Handling of Hazardous Medications

5.5 United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding-Sterile Preparations. 2022 version.

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10/02/2023	Pharmacy Review Committee	Y	Update with new USP 797 standards
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RIVERSIDE UNIVERSITY HEALTH SYSTEM – MEDICAL CENTER
Housewide

	Document No: 894	Page 1 of 7
Title: Pharmacotherapeutic Management of Patients with Alcohol Withdrawal Syndrome AWS	**Effective Date:** 11/22/2024	☐ **RUHS – Behavioral Health** ☐ **RUHS – Community Health Centers** ☐ **RUHS – Hospital Based Clinics** ☒ **RUHS – Medical Center** ☐ **RUHS – Public Health** ☐ **Departmental**
Approved By:  Jennifer Cruikshank CEO/ Hospital Director		☐ **Policy** ☐ **Procedure** ☒ **Guideline**

1. SCOPE

1.1 This guideline will provide interdisciplinary guidance for pharmacotherapeutic symptomatic management of non-pregnant adults in the Emergency Department and inpatient units presenting with suspected alcohol withdrawal syndrome.

1.2 This guideline is not intended to provide comprehensive clinical advice concerning all aspects of management of alcohol withdrawal patients.

2. DEFINITIONS

2.1 AWS: Alcohol withdrawal syndrome.

2.2 CIWA-Ar: Clinical Institute Withdrawal Assessment for Alcohol, revised. The CIWA-Ar consists of 10 criteria related to typical alcohol withdrawal symptoms and yields a maximum of 67 points. See attachment 6.1 for scoring components.

2.3 GABA (gamma-aminobutyric acid): Primary inhibitory neurotransmitter

2.4 NMDA (*N*-methyl-D-aspartate): Receptor that is acted on by glutamate, the primary excitatory neurotransmitter

2.5 Lorazepam equivalents:

a. 1 mg lorazepam equivalent = 5 mg diazepam = 10 mg chlordiazepoxide

3. GUIDELINE

3.1 Pathophysiology:

a. Alcohol withdrawal symptoms occur due to abrupt cessation or reduction in alcohol intake in individuals with a history of chronic and heavy use.

i. In healthy individuals without chronic alcohol use, GABA activity is counterbalanced by the activity of glutamate, the primary excitatory neurotransmitter, on the NMDA receptors.

ii. With acute alcohol use, ethanol acts on GABAA ligand-gated receptors to increase the body's net neuroinhibitory response.

iii. With chronic use, conformational changes of the GABAA and NMDA receptors occur in order to balance the additional depressive effect of ethanol

and result in downregulation
of the GABAergic pathway and upregulation of the glutamatergic pathway.

iv. Upon alcohol cessation, the upregulated excitatory glutamate-NMDA pathway overwhelms the GABAergic pathway, leading to the typical withdrawal symptoms observed.

3.2 Symptom timeline:

a. Withdrawal symptoms may appear as early as 8 hours after alcohol cessation and typically peak at 72 hours.

b. Risk for seizures is greatest within the first 48 hours with delirium tremens typically beginning three days after the appearance of symptoms but may begin as early as one day after.

c. Symptoms generally resolve within 7 days.

3.3 Treatment strategies

a. There are three main dosing regimens used for AWS management:

i. Fixed-dose taper (scheduled) regimen

ii. Symptom-triggered regimen

iii. Loading-dose regimen

b. The standard of care in the hospital setting uses a benzodiazepine symptom-triggered regimen based on the patient's CIWA-Ar score. Utilizing a symptom-triggered regimen has been shown to reduce total benzodiazepine consumption and treatment duration in patients at low risk for developing severe AWS when compared with a fixed-dose regimen.

3.4 Treatment agents:

a. Refer to Attachment 6.2 Alcohol Withdrawal Flowchart for treatment and dosing recommendations.

b. Benzodiazepines are currently the cornerstone for treatment of AWS due to their proven efficacy in reducing symptoms.

i. They facilitate the binding of GABA to GABAA receptors and increase the frequency of channel opening, therefore their action is dependent on the presence of endogenous GABA.

ii. Limitations with benzodiazepine use include benzodiazepine-induced delirium, high nursing burden due to frequent monitoring requirements, benzodiazepine-refractory cases of severe AWS, among others. For these reasons, other agents such as antiepileptics, dexmedetomidine, ketamine, and propofol have been studied as alternative or adjunctive therapy.

iii. Lorazepam, diazepam, and chlordiazepoxide are commonly used; however, no benzodiazepine is currently recommended over the others. Longer-acting agents may be preferred.

c. Lorazepam

i. Lorazepam is frequently used as a short-acting agent due to its shorter half-life and metabolism to an inactive metabolite. Its onset of action is 15-30 min.

ii. Lorazepam is preferred in the elderly population and those with hepatic dysfunction.

d. Diazepam

i. Benefits of using diazepam include its rapid onset (5 min when given IV) and long half-life, allowing it to act as both a fast-acting agent and long-acting agent (with accumulation). It is hepatically metabolized to an active metabolite and is renally eliminated.

ii. In patients with moderate or severe AWS, use of a diazepam loading-dose regimen has shown similar safety and efficacy outcomes as a symptom-triggered method, with possible reduction in total benzodiazepine use, decreased delirium tremens duration, and more rapid improvement in initial symptoms. Concern for over-sedation with diazepam loading due to the prolonged half-life of the drug and its active metabolites can be avoided when dosing is symptom-based, continued until clinical improvement is seen, and held when sedation or symptom-based goals are met. This is possible because of the quick onset of diazepam with peak sedation occurring within a few minutes of dose administration.

iii. Diazepam should be used with caution in the elderly population or patients with significant hepatic dysfunction.

e. Chlordiazepoxide

i. Chlordiazepoxide is primarily used as a long-acting agent and is hepatically metabolized to an active metabolite and is renally eliminated.

f. Phenobarbital:

i. Phenobarbital is an older antiepileptic agent that has action on both the GABA and glutamate pathways, as compared with benzodiazepines, which act solely on the GABA pathway. It acts on the GABAA receptor by prolonging the duration of the ligand-gated channel opening and has additional therapeutic action independent of endogenous GABA levels.

ii. When combined with benzodiazepines, it produces synergistic action on the GABAA receptor due to their different binding sites and mechanisms. It is not recommended to mix phenobarbital with benzodiazepines due to risk of over-sedation and respiratory depression.

iii. It has a quick onset (5 min if given IV) and a long half-life (3-4 days) that offers self-tapering capability.

iv. A study comparing high dose phenobarbital (10mg/kg) to benzodiazepine treatment found a reduction in ICU admission rate with similar rate of adverse effects. Other studies investigated administration of lower phenobarbital doses and found similar outcomes as standard benzodiazepine therapy.

v. Use with caution in patients with significant hepatic dysfunction/cirrhosis; on direct oral anticoagulants (DOACs), HIV medications, or tacrolimus; on home phenobarbital; or if underlying neurological injury/trauma.

vi. A maximum dose for alcohol withdrawal has not been established. Caution and more frequent monitoring recommended if doses greater 20mg/kg/day are administered.

g. Adjunctive or alternative agents include dexmedetomidine, propofol, ketamine, clonidine, and some anticonvulsants.

i. Dexmedetomidine is an alpha-2 agonist that reduces sympathetic activation. It is recommended as an adjunct to benzodiazepines, phenobarbital, or propofol for symptom management in refractory cases and should not be used as monotherapy as it does not address the underlying mechanism of alcohol withdrawal.

ii. Propofol is a GABA agonist and NMDA antagonist with evidence for use in refractory alcohol withdrawal requiring mechanical ventilation, including refractory delirium tremens.

iii. Ketamine is an NMDA antagonist with some evidence for use in refractory withdrawal as an adjunctive agent to reduce benzodiazepine requirements.

iv. Clonidine is a centrally acting alpha-2 agonist that may be used as an adjunctive agent to reduce autonomic hyperactivity and alleviate symptoms of anxiety.

v. Some anticonvulsants, including gabapentin, carbamazepine, and valproic acid, may be used as adjunctive agents as well.

h. Supportive care with thiamine, folic acid, and multivitamin is a critical component of AWS management.

i. Thiamine is essential for carbohydrate metabolism, and deficiency may lead to Wernicke encephalopathy due to decreased glucose utilization. Clinical manifestations include neurological symptoms such as altered mentation, nystagmus, and ataxia.

ii. Thiamine 100 mg daily for 3-5 days should be administered to prevent Wernicke encephalopathy. If there is concern for existing Wernicke encephalopathy, thiamine 500 mg IV every 8 hours for 3 days should be administered.

iii. Folic acid deficiency may lead to megaloblastic anemia.

iv. Vitamins are frequently deficient in patients due to malnutrition/malabsorption.

i. Refer to HW 830 Adult Guidelines for the Administration of Parenteral Medications for permitted locations of specific medication administration.

4. GUIDELINE

4.1 Alcohol withdrawal syndrome should be suspected in all patients presenting with acute symptoms and a history consistent with alcohol withdrawal. Patients with suspected AWS should have their CIWA-Ar score assessed upon admission.

4.2 Refer to Attachment 6.2 Alcohol Withdrawal Treatment Flowchart for treatment recommendations.

4.3 Adjunctive medications such as dexmedetomidine, propofol, ketamine, clonidine, and anticonvulsants may be ordered as clinically appropriate.

4.4 Supportive care should be ordered as clinically appropriate.

5. REFERENCES

5.1 Daeppen JB, et al. Symptom-triggered vs fixed-schedule doses of benzodiazepine for alcohol withdrawal: a randomized treatment trial. Arch Intern Med. 2002 May 27;162(10):1117-21.

5.2 The ASAM Clinical Practice Guideline on Alcohol Withdrawal Management. J Addict Med. 2020 May/Jun;14(3S Suppl 1):1-72.

5.3 Rosenson J, Clements C, Simon B, Vieaux J, Graffman S, Vahidnia F, et al. Phenobarbital for acute alcohol withdrawal: a prospective randomized double-blind placebo-controlled study. J Emerg Med. 2013 Mar;44(3):592-598.e2.

5.4 Sullivan JT, Sykora K, Schneiderman J, Naranjo CA, Sellers EM. Assessment of alcohol withdrawal: the revised clinical institute withdrawal assessment for alcohol scale (CIWA-Ar). Br J Addict. 1989 Nov;84(11):1353-7.

6. ATTACHMENTS

6.1 Clinical Institute Withdrawal Assessment for Alcohol, revised (CIWA-Ar)[35]

6.2 Alcohol Withdrawal Treatment Flowchart

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5/09/2023	Pharmacy Review Committee	Y	Add dexmedetomidine to chart 6.2, add CIWA-Ar scale to 6.1
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9/12/2024	MEC	N	

ATTACHMENT 6.1 Clinical Institute Withdrawal Assessment for Alcohol, revised

Appendix: Addiction Research Foundation Clinical Institute Withdrawal Assessment for Alcohol (CIWA-Ar)

Patient_____ **Date** |_|_|_|_| y m d **Time**____:____ **(24 hour clock, midnight=00:00)**

Pulse or heart rate, taken for one minute: _____ **Blood pressure:** _____/_____

NAUSEA AND VOMITING—As "Do you feel sick to your stomach? Have you vomited?" Observation.
0 no nausea and no vomiting
1 mild nausea with no vomiting
2
3
4 intermittent nausea with dry heaves
5
6
7 constant nausea, frequent dry heaves and vomiting

TREMOR—Arms extended and fingers spread apart. Observation.
0 no tremor
1 not visible, but can be felt fingertip to fingertip
2
3
4 moderate, with patient's arms extended
5
6
7 severe, even with arms not extended

PAROXYSMAL SWEATS—Observation.
0 no sweat visible
1 barely perceptible sweating, palms moist
2
3
4 beads of sweat obvious on forehead
5
6
7 drenching sweats

ANXIETY—Ask "Do you feel nervous?" Observation.
0 no anxiety, at ease
1 mildly anxious
2
3
4 moderately anxious, or guarded, so anxiety is inferred
5
6
7 equivalent to acute panic states as seen in severe delirium or acute schizophrenic reactions

AGITATION—Observation.
0 normal activity
1 somewhat more than normal activity
2
3
4 moderately fidgety and restless
5
6
7 paces back and forth during most of the interview, or constantly thrashes about

TACTILE DISTURBANCES—Ask "Have you any itching, pins and needles sensations, any burning, any numbness or do you feel bugs crawling on or under your skin?" Observation.
0 none
1 very mild itching, pins and needles, burning or numbness
2 mild itching, pins and needles, burning or numbness
3 moderate itching, pins and needles, burning or numbness
4 moderately severe hallucinations
5 severe hallucinations
6 extremely severe hallucinations
7 continuous hallucinations

AUDITORY DISTURBANCES—Ask "Are you more aware of sounds around you? Are they harsh? Do they frighten you? Are you hearing anything that is disturbing to you? Are you hearing things you know are not there?" Observation.
0 not present
1 very mild harshness or ability to frighten
2 mild harshness or ability to frighten
3 moderate harshness or ability to frighten
4 moderately severe hallucinations
5 severe hallucinations
6 extremely severe hallucinations
7 continuous hallucinations

VISUAL DISTURBANCES—Ask "Does the light appear to be too bright? Is its colour different? Does it hurt your eyes? Are you seeing anything that is disturbing to you? Are you seeing things you know are not there?" Observation.
0 not present
1 very mild sensitivity
2 mild sensitivity
3 moderate sensitivity
4 moderately severe hallucinations
5 severe hallucinations
6 extremely severe hallucinations
7 continuous hallucinations

HEADACHE, FULLNESS IN HEAD—Ask "Does your head feel different? Does it feel like there is a band around your head?" Do not rate for dizziness or lightheadedness. Otherwise, rate severity.
0 not present
1 very mild
2 mild
3 moderate
4 moderately severe
5 severe
6 very severe
7 extremely severe

ORIENTATION AND CLOUDING OF SENSORIUM—Ask "What day is this? Where are you? Who am I?"
0 oriented and can do serial additions
1 cannot do serial additions or is uncertain about date
2 disoriented for date by no more than 2 calendar days
3 disoriented for date by more than 2 calendar days
4 disoriented for place and/or person

Total CIWA-A Score_____
Rater's Initials_____
Maximum Possible Score 67

ATTACHMENT 6.2 Alcohol Withdrawal Treatment Flowchart