SVHCD QUALITY COMMITTEE

AGENDA

WEDNESDAY, February 28, 2024

5:00 p.m. Regular Session

Held in Person:

SVH Administrative Conference Room

To Participate Via Zoom Videoconferencing
use the link below:
https://sonomavalleyhospital-org.zoom.us/j/97100197319?pwd=ei84eXArRi9hY2c2bmd1UUdacVZEUT09&from=addon

Meeting ID: 971 0019 7319
Passcode: 369019

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AGENDA ITEM	RECOMMENDATION	
In compliance with the Americans with Disabilities Act, if you require special accommodations to attend a District meeting, please contact the Board Clerk, Whitney Reese, at wreese@sonomavalleyhospital.org at least 48 hours prior to the meeting.		
MISSION STATEMENT *The mission of the SVHCD is to maintain, improve, and restore the health of everyone in our community.*		
1. CALL TO ORDER/ANNOUNCEMENTS	*Kornblatt Idell*	
2. PUBLIC COMMENT SECTION *At this time, members of the public may comment on any item not appearing on the agenda. It is recommended that you keep your comments to three minutes or less. Under State Law, matters presented under this item cannot be discussed or acted upon by the Committee at this time. For items appearing on the agenda, the public will be invited to make comments at the time the item comes up for Committee consideration.*	*Kornblatt Idell*	
3. CONSENT CALENDAR • Minutes 01.24.24	*Kornblatt Idell*	Action
4. SURGICAL SERVICES QA/PI	*Cornell*	Inform
5. QUALITY COMMITTEE CHARTER	*Kornblatt Idell*	Action
6. QUALITY INDICATOR PERFORMANCE & PLAN	*Cooper*	Inform
7. POLICIES AND PROCEDURES	*Cooper*	Inform
8. CLOSED SESSION: a. Calif. Health & Safety Code §32155: Medical Staff Credentialing & Peer Review Report	*Kornblatt Idell*	Action
9. ADJOURN	*Kornblatt Idell*	

SONOMA VALLEY HEALTH CARE DISTRICT
QUALITY COMMITTEE
January 24, 2024, 5:00 PM
MINUTES
Via Zoom Teleconference

Members Present – In Person	Members Present cont.	Excused	Public/Staff – Via Zoom
Susan Kornblatt Idell Carl Speizer, MD Howard Eisenstark, MD Ingrid Sheets, EdD, MS, RN Michael Mainardi, MD Kathy Beebe, RN PhD Carol Snyder		Judith Bjorndal, MD Sujatha Sankaran, MD CMO Denise Kalos	Jessica Winkler, DNP, RN, NEA-BC, CCRN-K, CNO Kylie Cooper, RN, BSN, CPHQ, MBA, Quality and Risk Mgmt. Dawn Kuwahara RN BSN, Chief Ancillary Officer Lynn McKissock, Chief of HR John Hennelly, CEO Stacey Finn, Medical Staff Manager

AGENDA ITEM	DISCUSSION	ACTION
1. CALL TO ORDER/ANNOUNCEMENTS	*Kornblatt Idell*	
	Meeting called to order at 5:00 pm.	
2. PUBLIC COMMENT	*Kornblatt Idell*	
	None	

3. CONSENT CALENDAR	*Kornblatt Idell*	ACTION
• QC Minutes 12.06.23		**MOTION:** by Mainardi to approve, 2nd by Eisenstark. All in favor.
4. ED QA/PI	*Winkler*	INFORM
	Ms. Winkler presented the 2023 overview of the Emergency Department QA/PI. The presentation included ED volumes, transfers, left without being seen, and leaving against medical advice. Ms. Winkler spoke about the acuity levels that were seen in the ED, the most common diagnoses and patient demographics. Blood culture contamination quality metrics were reviewed. The targets combined met the goals. When looking individually at the metrics, they met or were very close to the goal. Documentation of observation of high-risk patients went over the volumes and ages high risk patients. Out of the CIHQ survey findings it was recommended that the ED add MD orders, finding and utilizing a specific flow sheet and documenting every hour or more. While the numbers improved since the May implantation there was a dip in December. Process improvement on left without being seen was reviewed. Another process improvement plan being worked on defines the role of the Triage. This includes changing the workflow and culture of the Triage and resource RN, and implementing nurse-initiated orders.	
5. PATIENT CARE SERVICE DASHBOARD Q4	*Winkler*	INFORM
	Ms. Winkler reviewed the patient care services dashboard. This included quality metrics on Medication Scanning rates (all depts met that metrics), QAPI the metrics were met with the exception of the continuous observation of high-risk patients, Case Management, Nursing Turnovers	

	(some turnover on all units), Pt Experience (Q Reviews) scores reviewed, and nursing staffing effectiveness (transfers/staffing and beds) One transfer out.	
6. WORKPLACE VIOLENCE PROGRAM	*McKissock*	INFORM
	Ms. McKissock presented the current workplace violence program. The program includes incident response, post-incident response & investigation, identification of the types of incidents and the corresponding reporting requirement to the staff and support to be provided to victims. The training for employees begins on the first day of employment; it includes an online initial training, an annual online course, conflict resolution/de-escalation workshops and management of aggressive behavior provided to key staff.	
7. QUALITY INDICATORS PERFORMANCE & PLAN	Cooper	INORM
	Mortality – No deaths in November. Eight deaths in December. All deaths were expected due to acuity and diagnosis. Patient Safety Indicators- No events. Adverse Event Reporting – No events including Pre-Op/Post Op discrepancies, adverse events from Anesthesia or operative adverse. Blood Products – In November there was one patient that fell out due to follow up labs not ordered. Medication Errors and Adverse Drug Reactions – No events reported. Patient Falls – One fall in December due to confusion. No injuries noted. Readmissions – 9% in Nov. and dropped to 5% in December. Blood Culture Contamination – The RN contamination rate has shown great improvement due to the ongoing education in the Emergency Department. Stroke Certification Measures- The overall numbers were low so the few fallouts significantly impacts meeting the	

	targets. The biggest concern was the time for Neuro consult. This issue has been addressed directly with UCSF. There was also a fall out with reading of images. This was due to an IT issue that has since been resolved. Utilization Management – case mix index was 1.45 which was high severity of illness. No one day stays. Because of the low numbers of one day stays that metric may be removed. Core Measures • Colonoscopies – Have remained at 100%. • ED arrival to departure times – In November it was at 112 minutes (goal of 130) In December it was 168 minutes, which is still under the national average. • ED LWBS – 0.2 and improvement from November to December. • CT/MRI results w/in 45 min of arrival • Sepsis – one fall out with blood draw, two with a no redraw of lactate, and one pt who missed the severe sepsis bundle. Infection Prevention- No HAI, hand hygiene met the goals CIHQ Corrective Action Plan compliance – Fall outs with temperature logs in the ED and OR. Currently in the process of trialing an automatic reporting thermometer. Safe transport of surgical supplies had one tray fall out. Antibiotic Stewardship training remains an opportunity for improvement. Family notification of hospitalization has opportunity for improvement at 89% patients being asked. Hand hygiene will remain on the report. Patient identification had one fall out. Medical staff restraint policy review is at 90%. Patient Satisfaction – No report - HCAHPS reported quarterly Rate My Hospital for November and December – all scores were over 4.5	
7. POLICIES AND PROCEDURES	*Cooper*	INFORM

	The following policies were presented for recommendation for approval by the Board of Directors: Admission and Discharge Criteria by Unit Antimicrobial Stewardship Body Fluid Exposure Prophylaxis Kit Preparation Cancellation No Show Controlled Substance Management CT Abdomen & Pelvis, Oral Preparation CT Scanner Quality Control Discrepancy, Emergency Department and Radiologist Dosimetry Gastrograffin Oral Prep for Adult ED patients Infection Control Water management Inspection of Nursing Units and Medication Storage Areas Preparation of Methotrexate IM Doses Using ChemoClave System Procedure Rehabilitation Services with Patients in Contract Isolation RETIRE: Adult Hypoglycemia Protocol Scope of Service- Pharmacy Department Surgical Hand Scrub-Antisepsis Universal Protocol	
8. CLOSED SESSION/REPORT ON CLOSED SESSION	*Kornblatt Idell*	ACTION
a. Calif. Health & Safety Code §32155: Medical Staff Credentialing & Peer Review Report	Ms. Finn presented the Medical Staff Credentialing for review and approval.	**MOTION:** by Speizer to approve, 2nd by Mainardi. All in favor.
9. ADJOURN.	*Kornblatt Idell*	
	Meeting adjourned at 6:16p.m.	

Perioperative Services Report

Current YTD Review
2/28/2024

Director of Perioperative Services
Kelli Cornell, RN

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Perioperative Department

Consists of:

- Pre-op
- Post-op
- Outpatient infusion
- Operating Room
- Sterile Processing
- Scheduling

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Scope of Services

- **Surgical Services**
  - Orthopedics
  - General
  - Gastroenterology
  - Ophthalmology
  - Urology
  - Gynecology
  - Cardiology
  - Pain

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Accomplishments 2023

Addition of needed staff including:

- **Perioperative Services Director**
- **Full time Nurse Navigator**
- **Fully staffed Sterile Processing Department**

Busy infusion service has grown from 40 in January to 76 in December

Successful conversion and adaptation to EPIC

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Challenges

- Managing a growing infusion service in the same space as pre-op and recovery patients

- Dr. Brown leaving creating uncertainty within the department.

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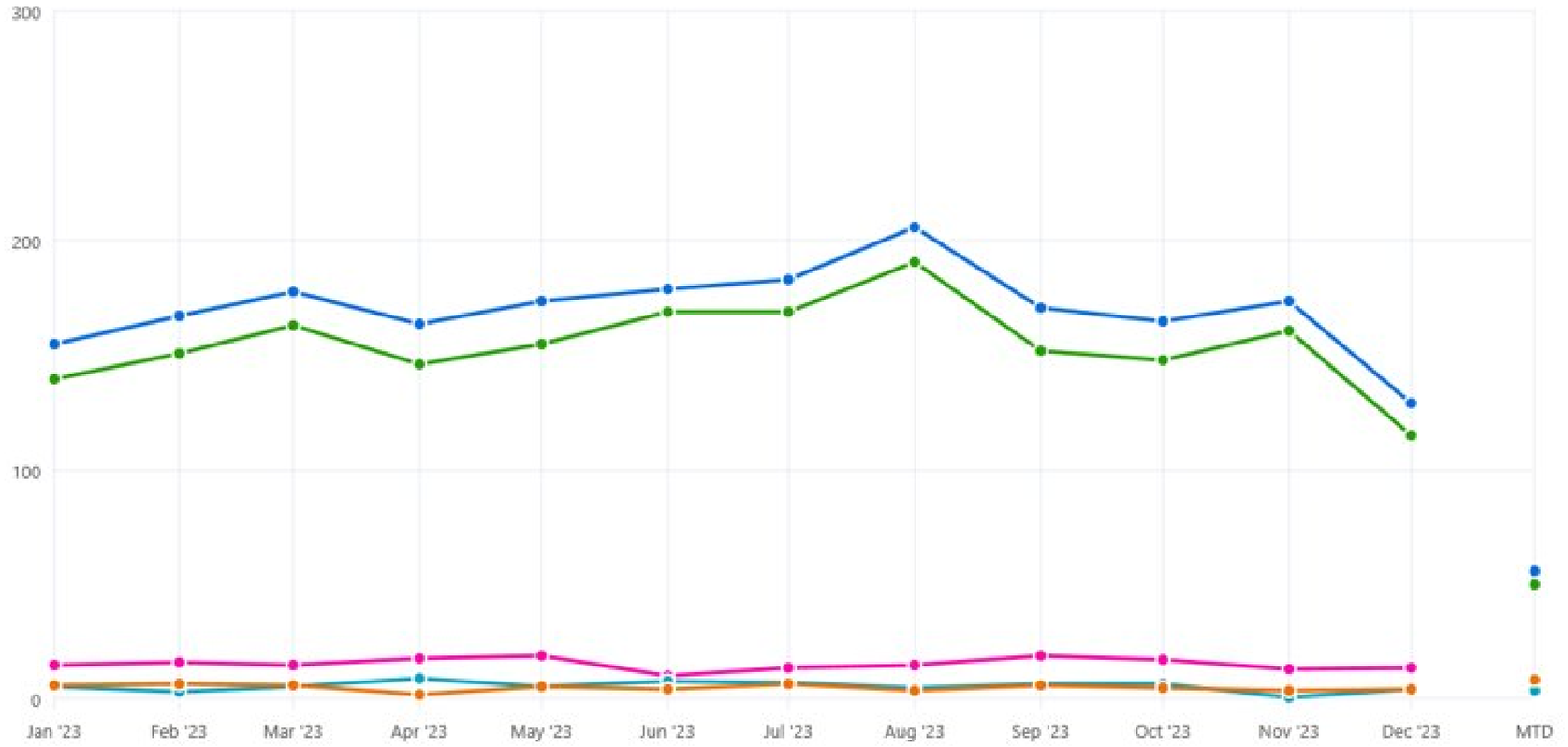
Volumes 2023

Case Volume

	Jan 23	Feb 23	Mar 23	Apr 23	May 23	Jun 23	Jul 23	Aug 23	Sep 23	Oct 23	Nov 23	Dec 23	QTD	MTD
Surgical Volume - Cases	155	167	178	164	174	179	183	206	171	165	174	129	56	56
Surgical Volume - IP Cases	15	16	15	18	19	10	14	15	19	17	13	14	6	6
Surgical Volume - OP Cases	140	151	163	146	155	169	169	191	152	148	161	115	50	50
Surgical Volume - Minutes	9,486	10,214	11,029	10,769	10,302	9,224	11,028	11,225	10,407	10,390	10,275	8,366	3,294	3,294
Add-on Percent	6 %	3 %	6 %	9 %	6 %	8 %	7 %	5 %	7 %	7 %	1 %	5 %	4 %	4 %
Day of Surgery Cancellations	6 %	7 %	6 %	2 %	6 %	5 %	7 %	4 %	6 %	5 %	4 %	5 %	8 %	8 %



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Quality Metrics

- Date of Service Cancelations
  - (12/2023) 6 out of 129 cases performed
  - (01/2024) 7 out of 182 cases performed

- Average Turnover times
  - (12/2023) 12 mins
  - (01/2024) 15 mins

- First Case on time starts
  - (12/2023) 28%
  - (01/2024) 18%

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Goals for 2024

- Growth of total joint program
- Reduce Date of Service Cancelations
- Increase first case on time starts
- Maintain turnover times
- Active participation in age-friendly initiative across the spectrum of care

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SUBJECT: Charter	POLICY: QA8610-108
	PAGE 1
DEPARTMENT: ORGANIZATIONAL	EFFECTIVE: 09.03.20
REVISED: 07.24.20	

NEW POLICY

OWNER:
Chief Quality Officer

AUTHORS/REVIEWERS:
Danielle Jones, MSN, BSN, RN, HACP, Chief Quality Officer

APPROVALS:
Policy & Procedure Team:
Board Quality Committee:
The Board of Directors:

SUBJECT: Charter	POLICY: QA8610-108
	PAGE 2
DEPARTMENT: ORGANIZATIONAL	EFFECTIVE: 09.03.20
REVISED: 07.24.20	

PURPOSE:

The Board Quality Committee is responsible for guiding and assisting the Executive Leaders, Medical Staff, and the Governing Board in fulfilling their responsibility to oversee safety, quality, and effectiveness of care at Sonoma Valley Hospital; and to meet or exceed standards and regulations that govern health care organizations.

RESPONSIBILITIES:

The Committee has three broad sets of responsibilities.

1. To directly oversee that quality assurance and improvement processes are in place and operating in the hospital.
2. To enhance quality across and throughout the patient care, technical, and operations of the Sonoma Valley Hospital. This encompasses all aspects of the interface and experience between patients, families, and the community. This also includes coordination and alignment within the organization.
3. To assure continual learning and skills development for risk surveillance, prevention, and continual improvement.

The committee examines all activities against the Institute of Medicine's Six Aims for Improvement: safe, effective, patient/family-centered, efficient, timely, and equitable. These aims are the drivers to the Triple Healthcare Aim: Better Care for patients and positive staff engagement, Better Population Health, Lower Per Capita Cost.

POLICY:

Oversight

As the governing body, the Governance Board is charged by law and by accrediting and regulatory organizations (e.g., Center for Improvement in Healthcare Quality CIHQ) with ensuring the quality of care rendered by hospital through its various divisions and departments. The Committee has the delegated authority to establish accountability in medical staff and management to assure improvement is occurring and targeted outcomes are achieved. To help meet this responsibility, the Board Quality Committee exists to:

- Develop the quality goals and blueprint (priorities and strategies) for Sonoma Valley Hospital, using an inclusive and data driven-process.

- Review and monitor patient safety, risk mitigation, quality assurance, and improvement plans and progress.

- Have the authority to initiate inquiries, studies, and investigations within the purview of duties assigned to the Committee.

- Perform, on behalf of the Governance Board and Medical Staff Leadership, such other activities as are required by the CIHQ, Centers for Medicaid and Medicare Services (CMS), and other external accrediting and regulatory bodies.

- Render reports and recommendations to the Executive Leadership Committee of Sonoma Valley Hospital, and Medical Board on its activities.

- Review all new and updated hospital organizational and department policies for adherence to quality and safety priorities.

- Review all Medical Staff credentialing.

Quality Integration

1. The Committee monitors the quality assurance and improvement activities of Sonoma Valley Hospital's entities to enhance the quality of care provided throughout the hospital or medical center system and encourage a consistent standard of care. Monitored activities include but are not limited to:
    a. Quality Performance Indicator Set
        i. Mortality
        ii. Preventable Harm Events
        iii. Healthcare Acquired Infections
        iv. Medication Events
        v. Never Events
        vi. Core Measures
        vii. Readmissions
        viii. Utilization Review
    b. Patient Experience
    c. Accreditation & Regulatory Standards
    d. Quality Assurance Performance Improvement
    e. Culture of Safety
    f. Risk Event Reports
    g. Policies & Procedures
    h. Patient Care Contracts

- The Committee ensures the coordination and alignment of quality initiatives throughout Sonoma Valley Hospital.

- The Committee may initiate inquiries and make suggestions for improvement.

- The Committee conducts annual reviews of the following key areas:
    - Improvement goal achievement
    - Clinical outcomes (priorities and improvement)
    - Patient Safety/Event Analysis/Risk Trending
    - Culture of Patient Safety
    - Accreditation and Regulatory Reviews
    - Environment of Care and Disaster Management plans

- The Committee monitors the progress of quality assurance and improvement processes and serves as champion of issues concerning quality to other committees.

- The Committee identifies barriers to improvement for resolution and systematically addresses and eliminates barriers and excuses.

PROCEDURE:

All Committee meetings will have a Standard Agenda, which will include:

- Quality Performance Indicator Set
- Clinical Priorities (clinical outcomes/process improvement), including:
    - Quality Assurance Performance Improvement
    - Patient harm
    - Patient safety (adverse event reduction, healthcare acquired infection reduction, risk mitigation)
    - Performance to accreditation and regulatory standards and requirements
    - Patient Experience
    - Culture of Safety
    - Policies and Procedures
    - Environmental safety and disaster management
    - Medical Staff Credentialing

SUBJECT: Charter	POLICY: QA8610-108
	PAGE 5
DEPARTMENT: ORGANIZATIONAL	EFFECTIVE: 09.03.20
REVISED: 07.24.20	

Rules

Authority to Act	In compliance with the Charter and as directed by Executive Leadership and the District Board
Meeting Schedule	At least ten meetings per year
Voting Members:	The Board Quality Committee shall have at least seven and no more than nine voting members. • Two Board members ○ One of whom shall be the QC chair, the other the vice-chair. • One designated position from the Medical Staff leadership (the Chief or Vice Chief). • At least four and no more than six members of the public selected by the Governing Board.
Quorum Requirement:	Half plus one member present.
Chair	One of the appointed Board Members
Composition	Voting Committee Members, Presenters, CEO, Chief Medical Officer (CMO) and Chief Nursing Officer (CNO), Chief Quality Officer (CQO)

REFERENCES:
www.hginstitute.org

Quality Indicator Performance & Plan

Board Quality Presentation February 2024

Data For January 2024

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Mortality

Mortality

Indicator	Performance	Most Recent	Trend	Period	⊙	🔔		✕
Acute Care Mortality Rate (M)	Target Met	4.5% (3/67)	Improved	Jan 2024	15.3%	n/a	n/a	3.4%
COPD Mortality Rate |M|	Target Met	0.0% (0/1)	No Change	Jan 2024	8.5%	n/a	n/a	0.0%
Congestive Heart Failure Mortality Rate |M|	Target Met	0.0% (0/6)	No Change	Jan 2024	11.5%	n/a	n/a	0.0%
Pneumonia Mortality Rate |M|	Target Met	0.0% (0/12)	Improved	Jan 2024	15.6%	n/a	n/a	3.6%
Ischemic Stroke Mortality Rate |M|	Target Met	0.0% (0/3)	No Change	Jan 2024	13.8%	n/a	n/a	0.0%
Hemorrhagic Stroke - Mortality Rate (M)	Target Met	0.0% (0/1)	No Change	Jun 2023	0.0%	1.0%	n/a	14.3%

Indicator	Performance	Most Recent	Trend	Period	⊙	🔔		✕
Sepsis, Severe - Mortality Rate (M)	Target Met	0.0% (0/3)	Improved	Jan 2024	25.0%	n/a	n/a	12.8%
Septic Shock - Mortality Rate (M)	Breaches Alarm	66.7% (2/3)	Deteriorated	Jan 2024	25.0%	n/a	n/a	27.6%

AHRQ Patient Safety Indicators

Quality > Patient Safety > AHRQ Patient Safety Indicators_PSI

Indicator	Performance	Most Recent	Trend	Period				
PSI 90 (v2023-1) Midas Patient Safety Indicators Composite, ACA (M)								
91% 9% History	Target Met	0.00 0/0.009	— No Change	Jan 2024	0.00	n/a	n/a	1.45
PSI 90 (v2023-1) Patient Safety Indicators Composite, ACA - Numerator Volume (M)								
91% 9% History	Target Met	0	— No Change	Jan 2024	0	n/a	n/a	0

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Adverse Events Reporting

Indicator	Performance	Most Recent	Trend	Period				
Adverse Event | SE (M) volume								
100%	Target Met	0	No Change	Jan 2024	0	1	n/a	0
History								

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Blood Products

Lab | Transfusion Effectiveness (M) 	Target Met	100.0% 6/6	No Change	Jan 2024	100.0%	99.0%	n/a	94.3%
Lab | Transfusion Reaction (M) 	Target Met	0.0% 0/41	No Change	Jan 2024	0.0%	1.0%	n/a	0.9%

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Significant Medication Errors and Adverse Drug Reactions

Indicator	Performance	Most Recent	Trend	Period				
Rx-ADEs-High Risk Med Errors Per 10,000 Doses (M)								
100% History	Target Met	0.13 1/75429	Deteriorated	Jan 2024	1.13	2.00	n/a	0.11
Rx-Administration Errors Per 10,000 Doses Dispensed								
91% 9% History	Target Met	0.13 1/75429	Improved	Jan 2024	1.00	3.00	n/a	0.36

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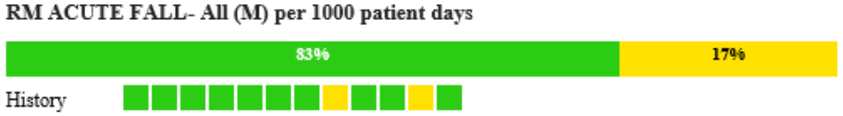
Patient Falls

Quality > Patient Safety > Falls

Indicator	Performance	Most Recent	Trend	Period				
RM ACUTE FALL- All (M) per 1000 patient days								
History 	Target Met	0.00 0/300	Improved	Jan 2024	3.75	4.00	n/a	0.94
RM ACUTE FALL- WITH INJURY (M) per 1000 patient days								
History 	Target Met	0.00 0/300	No Change	Jan 2024	3.75	4.00	n/a	0.00

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Readmissions

Readmissions

Indicator	Performance	Most Recent	Trend	Period	⊙	🔔		✕
30-DV Inpatients - % Readmit to Acute Care within 30 Days (M)								
100% / History	Target Met	2.86% 2/70	Improved	Jan 2024	15.30%	15.50%	n/a	4.64%
COPD, CMS Readm - % Readmit within 30 Days, ACA (M)								
66% / 17% / 17% / History	Target Met	0.0% 0/1	No Change	Jan 2024	19.5%	20.0%	n/a	9.1%
HF, CMS Readm Rdctn - % Readmit within 30 Days, ACA (M)								
91% / 9% / History	Target Met	0.0% 0/5	No Change	Jan 2024	21.6%	22.0%	n/a	2.7%
Hip/Knee, CMS Readm Rdctn - % Readmit within 30 Days, ACA (M)								
66% / 9% / 25% / History	Target Met	0.0% 0/3	No Change	Jan 2024	4.0%	5.0%	n/a	7.7%
PNA, CMS Readm Rdctn - % Readmit within 30 Days, ACA (M)								
91% / 9% / History	Target Met	0.0% 0/12	No Change	Jan 2024	16.6%	17.0%	n/a	1.8%
Sepsis, Severe - % Readmit within 30 Days (M)								
100% / History	Target Met	0.3% 1/3	Deteriorated	Jan 2024	12.0%	13.0%	n/a	0.0%
Septic Shock - % Readmit within 30 Days (M)								
100% / History	Target Met	0.0% 0/1	No Change	Jan 2024	13.3%	14.0%	n/a	0.2%

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Blood Culture Contamination

Indicator	Performance	Most Recent	Trend	Period	⊙	🔔
Blood Cultures -Contamination Rate |LAB| (M)						
100% / History	Target Met	1.7% 2/121	Deteriorated	Jan 2024	3.0%	4.0%
Blood Cultures -Total Contamination Rate (M)						
75% 16% 9% / History	Target Met	1.4% 3/214	Improved	Jan 2024	3.0%	4.0%
Blood Cultures -Contamination Rate |RN| (M)						
66% 9% 25% / History	Target Met	1.1% 1/93	Improved	Jan 2024	3.0%	3.1%

Month	RN-Contaminated Culture Reports (num)	Blood Cultures Drawn by RN (den)	Percent
Jan 2024	1	93	1.1%
Dec 2023	3	112	2.7%
Nov 2023	2	134	1.5%
Oct 2023	3	122	2.5%
Sep 2023	1	97	1.0%
Aug 2023	5	94	5.3%
Jul 2023	2	89	2.2%
Jun 2023	3	98	3.1%
May 2023	1	111	0.9%
Apr 2023	7	104	6.7%
Mar 2023	6	103	5.8%
Feb 2023	2	95	2.1%

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CIHQ Stroke Certification Measures

Stroke > Code Stroke Elapsed Time

Indicator	Performance	Most Recent	Trend	Period				
CDSTK-03|Median- Code Stroke Called |M| elapsed time (mins)								
91% / 9% — History	Target Met	2	Improved	Jan 2024	10	11	n/a	4
CDSTK-04|Median- Door to Phys Eval |M| minutes								
100% — History	Target Met	2	Deteriorated	Jan 2024	10	11	n/a	2
CDSTK-05|Median- Door to CT Scanner |M|elapsed time (minutes)								
91% / 9% — History	Target Met	4	Improved	Jan 2024	25	26	n/a	8
CDSTK-06|Median- Neuro Consult Contacted |M| minutes								
83% / 17% — History	Target Met	28	Improved	Jan 2024	30	31	n/a	22
CDSTK-07|Median- CT Read by Radiology |M| minutes								
91% / 9% — History	Target Met	28	Improved	Jan 2024	45	46	n/a	28
CDSTK-08|Median- Lab Results Posted |M| minutes								
91% / 9% — History	Target Met	28	Improved	Jan 2024	45	46	n/a	23
CDSTK-10|Median- Door to EKG Complete |M| minutes								
100% — History	Target Met	29	Improved	Jan 2024	60	61	n/a	36
CDSTK-11|Median-Door to tPA Decision |M| minutes								
83% / 17% — History	Target Met	39	Improved	Jan 2024	60	61	n/a	38
CDSTK-12|Median-Door to tPA |M| minutes								
25% / 17% / 58% — History	Target Met	58		Jan 2024	60	61	n/a	59

Utilization Management

Utilization Management

Indicator	Performance	Most Recent	Trend	Period	⊙	🔔		✕
MS-DRG Case Mix Index (CMI) |M|	Bet. Target & Alarm	1.51	Improved	Jan 2024	1.55	1.40	n/a	1.41
MS-DRG Case Mix Index (CMI) MEDICARE |M|	Target Met	1.59	Improved	Jan 2024	1.55	1.40	n/a	1.47
1 Day Stay Rate Medi-Cal |M|	Target Met	0.00% 0/7	No Change	Jan 2024	2.61%	5.00%	n/a	0.00%
1 Day Stay Rate-Medicare |M|	Target Met	0.00% 0/55	No Change	Jan 2024	8.10%	10.00%	n/a	0.00%
Medicare Risk-adjusted Average Length of Stay, O/E Ratio |M|	Target Met	0.78 169/216.31	Deteriorated	Jan 2024	0.99	1.00	n/a	0.87
Acute Care - Geometric Mean Length of Stay |M|	Breaches Alarm	4.52 45.2166/10	Deteriorated	Jan 2024	2.75	3.23	n/a	3.31

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Core Measures

Indicator	Performance	Most Recent	Trend	Period	⊙	🔔		✕
Core OP29/ASC9 - Colonoscopy:F/U for Avg Risk Pts (M)								
100% History	Target Met	100.0% 12/12	— No Change	Jan 2024	88.0%	50.0%	n/a	100.0%
Indicator	**Performance**	**Most Recent**	**Trend**	**Period**	⊙	🔔		✕
Core OP 18b Median Time ED Arrival to ED Departure - Reporting Measure (M)								
25% 8% 67% History	Bet. Target & Alarm	134.00	Improved	Jan 2024	132.00	140.00	n/a	148.75
Indicator	**Performance**	**Most Recent**	**Trend**	**Period**	⊙	🔔		✕
Core OP 22 ED LWBS Emergency Dept Left Without Being Seen (M)								
100% History	Target Met	0.4% 3/798	Deteriorated	Jan 2024	2.0%	2.5%	n/a	0.5%
Indicator	**Performance**	**Most Recent**	**Trend**	**Period**	⊙	🔔		✕
Core OP-23 - Head CT/MRI Results for STK Pts w/in 45 Min of Arrival (M)								
41% 25% 34% History	Target Met	100.0% 2/2		Jan 2024	72.0%	70.0%	n/a	73.3%

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Core Measures Sepsis

Indicator	Performance	Most Recent	Trend	Period	⊙	🔔		✕
SEP-1 Early Management Bundle, Severe Sepsis/Septic Shock (M)								
	Target Met	100.0% 6/6	Improved	Jan 2024	81.0%	80.0%	n/a	65.7%
SEPa - Severe Sepsis 3 Hour Bundle (M)								
	Target Met	100.0% 6/6	No Change	Jan 2024	94.0%	90.0%	n/a	83.6%
SEPb - Severe Sepsis 6 Hour Bundle (M)								
	Target Met	100.0% 4/4	Improved	Jan 2024	100.0%	90.0%	n/a	89.6%

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Infection Prevention

Infection Prevention

Indicator	Performance	Most Recent	Trend	Period	⊙	🔔		✕
IC-Surveillance| HAI-C.DIFF Inpatient infections per 10k pt days |M|								
90% 10% History	Target Met	0	— No Change	Jan 2024	1	1	n/a	0
IC-Surveillance| HAI-CAUTI Inpatient infections per 10k patient days |M|								
93% 7% History	Target Met	0	— No Change	Jan 2024	1	1	n/a	0
IC-Surveillance| HAI-CLABSI Inpatient infections per 10k patient days |M|								
96% 4% History	Target Met	0	— No Change	Jan 2024	1	1	n/a	0
IC-Surveillance| HAI-MRSA Inpatient infections per 10k patient days |M|								
100% History	Target Met	0	— No Change	Jan 2024	1	1	n/a	0
IC-Surveillance| HAI-SSI infections per 10k pt days |M|								
91% 9% History	Target Met	0	— No Change	Jan 2024	1	1	n/a	0
QA-02 | Hand Hygiene Practices Monitored |M|								
33% 16% 25% 26% History	Target Met	94% 47/50	Deteriorated	Jan 2024	90%	85%	n/a	85%

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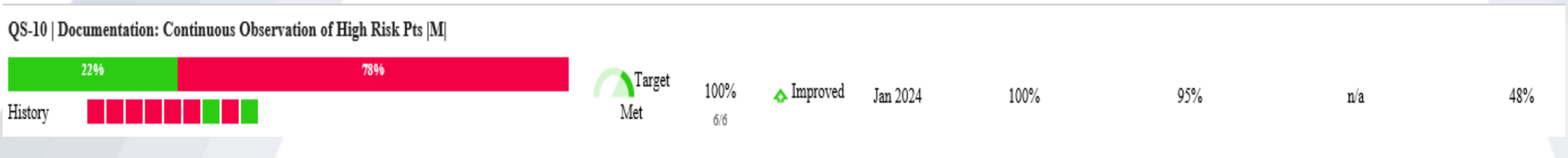
CIHQ Corrective Action Plan Monthly Compliance Condition Level Finidings



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Patient Satisfaction

4th Quarter Inpatient

Inpatient

Questions	Top Box	n	STATE CA Score	All PG Database Score
*Rate hospital 0-10	75.00	64	71.65	70.02
*Recommend the hospital	70.77	65	72.87	69.15
***Comm w/ Nurses Domain Performance**	82.13	66	77.40	78.83
*Nurses treat with courtesy/respect	89.39	66	83.50	85.43
*Nurses listen carefully to you	81.25	64	74.78	76.26
*Nurses expl in way you understand	75.76	66	73.91	74.78
***Response of Hosp Staff Domain Performance**	72.93	61	62.24	63.09
*Call button help soon as wanted it	70.18	57	60.92	61.30
*Help toileting soon as you wanted	75.68	37	63.92	64.31
***Comm w/ Doctors Domain Performance**	77.80	65	78.88	79.38
*Doctors treat with courtesy/respect	86.15	65	84.25	85.49
*Doctors listen carefully to you	75.38	65	77.86	77.98
*Doctors expl in way you understand	71.88	64	74.64	74.73
***Hospital Environment Domain Performance**	68.59	66	62.88	65.42
*Cleanliness of hospital environment	83.33	66	73.11	72.02
*Quietness of hospital environment	53.85	65	52.51	58.77
***Comm About Medicines Domain Performance**	61.52	38	61.98	60.43
*Tell you what new medicine was for	75.68	37	74.55	74.08
*Staff describe medicine side effect	47.37	38	49.34	46.78
***Discharge Information Domain Performance**	90.99	62	87.16	86.31
*Staff talk about help when you left	90.32	62	85.14	84.57
*Info re symptoms/prob to look for	91.67	60	89.17	88.03
***Care Transitions Domain Performance**	49.78	65	54.05	52.33
*Hosp staff took pref into account	53.13	64	48.37	46.75
*Good understanding managing health	50.77	65	53.58	51.60
*Understood purpose of taking meds	45.45	55	60.45	58.68

*CAHPS

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SONOMA VALLEY HEALTH CARE DISTRICT
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Patient Satisfaction

- 4th Quarter Outpatient Surgery

Ambulatory Surgery

Questions	Top Box	n	All PG Database Score	State of California Score
*Facility rating 0-10	88.89	72	87.86	86.26
*Recommend the facility	87.14	70	85.05	84.53
***Communication Domain Performance**	91.27	72	92.25	90.73
*Provided needed info re procedure	91.67	72	92.48	91.39
*Instructions good re preparation	92.86	70	94.27	93.51
*Procedure info easy to understand	93.06	72	93.81	92.57
*Anesthesia info easy to understand	92.42	66	94.50	92.82
*Anes side effect easy to understand	86.36	66	86.16	83.42
***Facility/Personal Trtment Domain Performance**	96.73	72	97.05	96.35
*Check-in run smoothly	91.67	72	95.44	94.39
*Facility clean	98.61	72	97.94	97.59
*Clerks and receptionists helpful	97.14	70	96.27	95.36
*Clerks and reception courteous	97.18	71	97.65	96.93
*Staff treat w/ courtesy, respect	98.61	72	98.08	97.60
*Staff ensure you were comfortable	97.14	70	96.91	96.19
***Discharge Domain Performance**	95.59	72	96.73	95.99
*Written discharge instructions	95.83	72	97.43	97.21
*Instructions regarding recovery	81.43	70	87.57	85.33
*Information re subsequent pain	100.00	67	98.42	97.82
*Information re subsequent nausea	98.04	51	98.52	97.98
*Information re subsequent bleeding	100.00	62	98.94	98.37
*Info on response to infection	98.21	56	99.54	99.35
Nurses Overall	89.10	72	89.02	87.34
Nurses concern for comfort	88.89	72	89.58	87.85
Info nurses gave to prep for proc	90.00	70	88.39	86.45
Nurses response concerns/questions	88.41	69	89.11	87.80
Care Provider Overall	85.50	67	84.13	80.57
CP explanation about proc	86.57	67	84.80	81.46
Info CP shared re how proc went	87.69	65	83.05	78.08
CP response to concerns/questions	84.85	66	86.69	83.88
CP expln why proc important	82.81	64	81.96	78.85
Staff worked together care for you	87.50	72	90.10	88.41

*CAHPS

Rate My Hospital
Scale 1-5
January Data

	Question Responses	Average Score
Sonoma Valley Hospital / Emergency Department	103	4.609 95% CI: 4.548—4.671
Sonoma Valley Hospital / Inpatient Care	15	4.810 95% CI: Not enough samples

	Question Responses	Average Score
Sonoma Valley Hospital / Outpatient Surgery	44	4.888 95% CI: 4.846—4.929

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Rate My Hospital
Scale 1-5
January Data

	Question Responses	Average Score
Sonoma Valley Hospital / Medical Imaging	220	4.903 95% CI: 4.883—4.923

	Question Responses	Average Score
Sonoma Valley Hospital / Hand and Physical Therapy	151	4.939 95% CI: 4.918—4.959

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SONOMA VALLEY HEALTH CARE DISTRICT
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Document Tasks By Committee

Listing of currently pending and/or upcoming document tasks grouped by committee.

Sonoma Valley Hospital

Run by: Finn, Stacey (sfinn)
Run date: 02/22/2024 1:04 PM

Report Parameters

Filtered by: Document Set: - All Available Document Sets -
Committee: 07 BOD-Quality (P&P Review)
Include Current Tasks: Yes
Include Upcoming Tasks: No

Grouped by: Committee

Sorted by: Document Title

Report Statistics

Total Documents: 13

Committee: **07 BOD-Quality (P&P Review)**

Committee Members: **Finn, Stacey (sfinn), Newman, Cindi (cnewman), Reese, Whitney (wreese)**

Current Approval Tasks (due now)

Document	Task/Status	Pending Since	Days Pending
Compounding Policies, Annual Review *Medication Management Policies (MM)*	**Pending Approval**	2/15/2024	7

Summary Of Changes: **Revised policy to separate table (Attachment A) from the body of the document.**

Moderators: **Kutza, Chris (ckutza), Newman, Cindi (cnewman)**

Lead Authors: **Kutza, Chris (ckutza)**

Approvers: **01 P&P Committee -> 04 MS-Performance Improvement/Pharmacy & Therapeutics Committee - (Committee) -> 05 MS-Medical Executive - (Committee) -> 07 BOD-Quality (P&P Review) - (Committee) -> 09 BOD-Board of Directors - (Committee)**

NEW:: Compounding Nonsterile Drug Products *Medication Management Policies (MM)*	**Pending Approval**	2/15/2024	7

Summary Of Changes: **NEW Policy**
policy to match newly updated revision to USP 795. Includes defining nonsterile compounding, defining scope of policy, added requirement for designated person overseeing process, addresses training of personnel, addresses requirements for facilities used for nonsterile compounding, addresses garbing, updates requirements for master formulation record, compounding records, and beyond use dates, defines need for QA program, includes need for self assessment documentation per state regulations.

Moderators: **Kutza, Chris (ckutza), Newman, Cindi (cnewman)**

Lead Authors: **Kutza, Chris (ckutza)**

Approvers: **01 P&P Committee -> 04 MS-Performance Improvement/Pharmacy & Therapeutics Committee - (Committee) -> 05 MS-Medical Executive - (Committee) -> 07 BOD-Quality (P&P Review) - (Committee) -> 09 BOD-Board of Directors - (Committee)**

NEW:: IV Compounding (Non-Pharmacy Location) *Medication Management Policies (MM)*	**Pending Approval**	2/15/2024	7

Summary Of Changes: **NEW policy. Major changes to current policy. This replaces MM8610-118 IV Compounding Outside the Pharmacy.**
Per USP 797
To define the process in which sterile injectable pharmaceuticals are mixed outside of the pharmacy in such a way as to ensure safe and timely provision of drug therapy to hospital patients and when it is appropriate to do so.
adresses need for training and competency assessments, defines medication prep area, clarifies when after hours compounding outside of the pharmacy is appropriate. Added attachments for SOP and Nursing competency.

Added attachments:

Compounding Sterile Preparations on Patient Care Units SOP (Standard Operating Procedure)
IV Compounding (Non-Pharmacy Location) Competency

Moderators: **Kutza, Chris (ckutza), Newman, Cindi (cnewman)**
Lead Authors: **Kutza, Chris (ckutza)**
Approvers: **01 P&P Committee -> 04 MS-Performance Improvement/Pharmacy & Therapeutics Committee - (Committee) -> 05 MS-Medical Executive - (Committee) -> 07 BOD-Quality (P&P Review) - (Committee) -> 09 BOD-Board of Directors - (Committee)**

NEW:: QAPI Procedures for Sterile Compounding Quality Assurance program. NEW — **Pending Approval** — 2/15/2024 — 7
Pharmacy Dept

Summary Of Changes: **This replaces legacy policy similar name numbered 8390-102 NEW POLICY Significant reorganization and content updates to ensure policy meets requirements from updated USP 797 standards.**
Defines requirement standards for Staff training and competency, Cleaning and Disinfecting compounding area, Environmental Controls & Microbiological Environmental Monitoring, End Product Sterility, Endotoxin, and Quantitative Testing, Adverse events and complaints related to sterile compounding. Added attachments that support the policy.

Moderators: **Newman, Cindi (cnewman)**
Lead Authors: **Kutza, Chris (ckutza)**
Approvers: **01 P&P Committee -> 04 MS-Performance Improvement/Pharmacy & Therapeutics Committee - (Committee) -> 05 MS-Medical Executive - (Committee) -> 07 BOD-Quality (P&P Review) - (Committee) -> 09 BOD-Board of Directors - (Committee)**

NEW:: Transfusion Transmitted Infectious Disease Notification — **Pending Approval** — 2/15/2024 — 7
Laboratory Services Policies (LB)

Summary Of Changes: **New to the portal. Policy was found in the department policies and is required for survey and CLIA. Approved by Medical Director in 2020. New: Clarification needed by Board Quality, changed verbiage from virus or parasite to infectious agent and added transfusion transmissible disease marker as well as disposition process of quarantined blood. Did not list all infectious diseases instead included most common.**

10-30-23 Updated policy to reflect Board Quality's comments for clarity.

Moderators: **Newman, Cindi (cnewman)**
Lead Authors: **Kuwahara, Dawn (dkuwahara), Ramos, Karen (kramos)**
ExpertReviewers: **Medical Director-Lab**
Approvers: **Kuwahara, Dawn (dkuwahara) -> 01 P&P Committee - (Committee) -> 02 MS-Medicine Department - (Committee) -> 03 MS-Surgery Department - (Committee) -> 04 MS-Performance Improvement/Pharmacy & Therapeutics Committee - (Committee) -> 05 MS-Medical Executive - (Committee) -> 07 BOD-Quality (P&P Review) - (Committee) -> 09 BOD-Board of Directors - (Committee)**

NEW:; Sterile Compounding (USP 797) — **Pending Approval** — 2/15/2024 — 7
Medication Management Policies (MM)

Summary Of Changes: **NEW POLICY replacing legacy Sterile Compounding (MM8610-117) policy due to substantial updates to the USP 797 Standards.**

Policy provides written guidelines for compounding sterile preparations including procurement, storage, ordering, preparation, facilities and equipment, staff education and training, labeling, and quality assurance/quality assurance records.

Moderators: **Kutza, Chris (ckutza), Newman, Cindi (cnewman)**
Lead Authors: **Kutza, Chris (ckutza)**
Approvers: **01 P&P Committee -> 04 MS-Performance Improvement/Pharmacy & Therapeutics Committee - (Committee) -> 05 MS-Medical Executive - (Committee) -> 07 BOD-Quality (P&P Review) - (Committee) -> 09 BOD-Board of Directors - (Committee)**

Patient Controlled Analgesia (PCA) — **Pending Approval** — 2/15/2024 — 7
Medication Management Policies (MM)

Summary Of Changes: **Updated nursing duties to include Q shift review of the settings, dual RN checks, clearing the pump of doses every 12 hours,**

and documentation of these activites in the medical record. Removed appendix from the body of the policy to make it a separate attachment.

Moderators: **Kutza, Chris (ckutza), Newman, Cindi (cnewman)**
Lead Authors: **Kutza, Chris (ckutza)**
ExpertReviewers: **Taylor, Jane (jtaylor)**
Approvers: **01 P&P Committee -> 04 MS-Performance Improvement/Pharmacy & Therapeutics Committee - (Committee) -> 05 MS-Medical Executive - (Committee) -> 07 BOD-Quality (P&P Review) - (Committee) -> 09 BOD-Board of Directors - (Committee)**

Pharmacy Staff Competency Assessment | **Pending Approval** | 2/15/2024 | 7
Pharmacy Dept

Summary Of Changes: **Reviewed, no changes**
Moderators: **Newman, Cindi (cnewman)**
Lead Authors: **Kutza, Chris (ckutza)**
ExpertReviewers: **McKissock, Lynn (lmckissock)**
Approvers: **01 P&P Committee -> 04 MS-Performance Improvement/Pharmacy & Therapeutics Committee - (Committee) -> 05 MS-Medical Executive - (Committee) -> 07 BOD-Quality (P&P Review) - (Committee) -> 09 BOD-Board of Directors - (Committee)**

RETIRE: Bloodborne Pathogen Exposure Control Policy | **Pending Approval** | 2/15/2024 | 7
Infection Prevention & Control Policies (IC)

Summary Of Changes: **RETIRE: Redundant (covered in plan)**
Moderators: **Newman, Cindi (cnewman)**
Lead Authors: **Montecino, Stephanie (smontecino)**
ExpertReviewers: **Kutza, Chris (ckutza), Kuwahara, Dawn (dkuwahara), Sankaran, Sujatha (ssankaran)**
Approvers: **Cooper, Kylie (kcooper) -> 01 P&P Committee - (Committee) -> 04 MS-Performance Improvement/Pharmacy & Therapeutics Committee - (Committee) -> 05 MS-Medical Executive - (Committee) -> 07 BOD-Quality (P&P Review) - (Committee) -> 09 BOD-Board of Directors - (Committee)**

RETIRE: Compounding Drug Products | **Pending Approval** | 2/15/2024 | 7
Medication Management Policies (MM)

Summary Of Changes: **RETIRE: Now obsolete due to industry updates (USP 797)**

Replaced by NEW Policy :Compounding Nonsterile Drug Products MM8610-237

Moderators: **Kutza, Chris (ckutza), Newman, Cindi (cnewman)**
Lead Authors: **Kutza, Chris (ckutza)**
Approvers: **01 P&P Committee -> 04 MS-Performance Improvement/Pharmacy & Therapeutics Committee - (Committee) -> 05 MS-Medical Executive - (Committee) -> 07 BOD-Quality (P&P Review) - (Committee) -> 09 BOD-Board of Directors - (Committee)**

RETIRE:: IV Compounding Outside of the Pharmacy | **Pending Approval** | 2/15/2024 | 7
Medication Management Policies (MM)

Summary Of Changes: **RETIRE due to major changes . USP 797**
New Policy MM6810-218 IV Compounding (Non-Pharmacy Location) will replace and in approval process

Moderators: **Kutza, Chris (ckutza), Newman, Cindi (cnewman)**
Lead Authors: **Kutza, Chris (ckutza)**
Approvers: **01 P&P Committee -> 04 MS-Performance Improvement/Pharmacy & Therapeutics Committee - (Committee) -> 05 MS-Medical Executive - (Committee) -> 07 BOD-Quality (P&P Review) - (Committee) -> 09 BOD-Board of Directors - (Committee)**

RETIRE:: QAPI Procedures Sampling Plan-IV Room | **Pending Approval** | 2/15/2024 | 7
Pharmacy Dept

Summary Of Changes:	**Retire as obsolete--new policy to replace with updated requirements and processes> NEW POLICY is named: QAPI Procedures for Sterile Compounding Quality Assurance program. Sampling Plan-IV Room**
Moderators:	**Newman, Cindi (cnewman)**
Lead Authors:	**Kutza, Chris (ckutza)**
Approvers:	**01 P&P Committee -> 04 MS-Performance Improvement/Pharmacy & Therapeutics Committee - (Committee) -> 05 MS-Medical Executive - (Committee) -> 07 BOD-Quality (P&P Review) - (Committee) -> 09 BOD-Board of Directors - (Committee)**

RETIRE:: Sterile Compounding **Pending Approval** 2/15/2024 7

Medication Management Policies (MM)

Summary Of Changes:	**Retire as obsolete. Replacing with new policy: Sterile Compounding (USP 797)**
Moderators:	**Kutza, Chris (ckutza), Newman, Cindi (cnewman)**
Lead Authors:	**Kutza, Chris (ckutza)**
Approvers:	**01 P&P Committee -> 04 MS-Performance Improvement/Pharmacy & Therapeutics Committee - (Committee) -> 05 MS-Medical Executive - (Committee) -> 07 BOD-Quality (P&P Review) - (Committee) -> 09 BOD-Board of Directors - (Committee)**

SUBJECT: Compounding Nonsterile Drug Products	POLICY #MM8610-237
	PAGE 1 OF 12
DEPARTMENT: Organizational	EFFECTIVE:
REVIEWED/REVISED:	

NEW POLICY

Policy to match newly updated revision to USP 795. Replaces Policy ***8610-137 Compounding Drug Products***

WHY:

Includes defining nonsterile compounding, defining scope of policy, added requirement for designated person overseeing process, addresses training of personnel, addresses requirements for facilities used for nonsterile compounding, addresses garbing, updates requirements for master formulation record, compounding records, and beyond use dates, defines need for QA program, includes need for self assessment documentation per state regulations.

OWNER:
Director of Pharmacy

AUTHORS/REVIEWERS:
Director of Pharmacy
Board Quality Committee

APPROVALS:
Policy & Procedure Team
PI/Pharmacy & Therapeutics Committee
Medical Executive Committee
The Board of Directors

SUBJECT: Compounding Nonsterile Drug Products	POLICY #MM8610-237
	PAGE 2 OF 12
DEPARTMENT: Organizational	EFFECTIVE:
REVIEWED/REVISED:	

PURPOSE:
To provide written guidelines for compounding nonsterile drug products including procurement, storage, preparation methodologies, facilities and equipment, staff education and training, labeling and quality assurance records.

DEFINITIONS:
Compounded nonsterile preparation (CNSP): A preparation not intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance[1].

SCOPE:

- Compounded nonsterile preparations include but are not limited to solid oral preparations, liquid oral preparations, rectal preparations, vaginal preparations, topical preparations (i.e., creams, gels, ointments), nasal and sinus preparations for local application, and otic preparations unless used in the setting of perforated eardrum.
- Breaking or cutting tablets, repackaging of conventionally manufacturer drug products, or reconstitution of a conventionally manufacturer nonsterile product in accordance with manufacturer approved labeling is *not* considered compounding and is *not* within the scope of this policy.
- Preparation of a single dose for a single patient when the medication is administered within 4 hours is *not* considered compounding and is out of scope of this policy. This includes crushing tablets or opening capsules to mix with food or liquid to facilitate dose administration.

POLICY:

- Compounded products are prepared pursuant to a patient-specific medical order/prescription.
- Compounded products are prepared as patient-specific compounds in the amount required to meet the patient's need.
  Exception: CNSPs may be prepared and stored in a limited quantity in advance of receipt of a patient-specific prescription or order, as necessary to ensure continuity of care for an identified patient population based on documented history of use.
- Compounded products prepared in the facility are *not* sold, transferred, or delivered to another facility or licensee unless the compounded preparation is patient-specific, a

[1] 2023 USP General Chapter <795> Pharmaceutical Compounding-Nonsterile Preparations

prescription/order has been obtained, and the pharmacy/facility is appropriately licensed and allowed by State regulations.

- Previously marketed drugs found to be unsafe, ineffective and/or removed from the commercial market may not be compounded.
- Drug products listed in the FDA's regulations as difficult to compound may not be compounded.
- USP General Chapter <795> compounding requirements are used to guide nonsterile compounding activities.
- A qualified designated person, or persons, oversees the nonsterile compounding program.
- Compounding activities are performed by trained personnel in a designated area of the pharmacy department in accordance with applicable state and federal laws, rules, and regulations, including professional practice standards.
- Standard Operating Procedures (SOPs) for the compounding processes and support activities are developed and maintained.
- A Quality Assurance (QA)/Quality Control (QC) program is maintained to monitor, evaluate, correct, and improve activities and processes. The program is reviewed at least every 12 months by the designated person(s). The review and any corrective actions are documented.
- Nonsterile compounding records are retained on file for 3 years, or as defined by the State and/or hospital policy.

PROCEDURE

Ordering / Prescribing

- Orders for compounded drug products that are not commercially available are allowed for use as defined in this policy:
  - Compounded drug products may be prescribed when medical necessity outweighs potential risk and no other therapeutic alternative is available.
  - Compounded drug products may be prescribed when commercially available products do not meet the needs of the patient. *Example* situations include:
    - The drug required is not manufactured in the needed strength.
    - The prescriber requests a different form of the drug to improve patient compliance with prescribed drug therapy.

- The prescribed drug needs to be combined in forms not available from the manufacturer to improve patient response and/or compliance to prescribed drug therapy.
- The patient is allergic to inactive ingredients (dye, lactose, etc.) in the manufactured form of the drug.
- The prescribed therapy requires tailoring to the individual patient (intravenous feeding solutions, etc.).

Nonsterile Compounding Oversight and Responsibility

Designated Person(s)
The designated person(s) is/are responsible and accountable for the performance and operation of the compounding processes and personnel. The individual(s) identified as designated person(s) is documented. See attachment: USP <795> Designated Person for Nonsterile Compounding

Compounding Personnel
Compounding personnel are responsible for understanding the fundamental practices and precautions for safe nonsterile compounding, following nonsterile compounding standard operating procedures (SOP), and recognizing and reporting to the designated person(s) any potential problems, deviations, failures, or errors that could affect the quality of the CNSP.

Pharmacist
The pharmacist performing or supervising the compounding process is responsible for:

- The integrity, potency, quality, and labeled strengths of the CNSP.
- The proper preparation, labeling, storage, and delivery of the CNSP.
- Final preparation verification and documentation.

Personnel Training and Evaluation

- A written training program describes the required training, frequency of training, and the process for evaluating the performance of individuals involved in the preparation of CNSPs. See attachment: Compounding Nonsterile Products Training Program.
- The training program includes demonstrating knowledge in core nonsterile compounding principles and demonstrating competency in performing nonsterile compounding-related activities based on assigned tasks.
- Personnel who perform or oversee compounding or support activities are trained in the SOPs relevant to their job duties.

- Personnel who perform nonsterile compounding receive training and demonstrate proficiency in compounding skills *before* independently compounding.
- Documentation of training and competency assessment is maintained.

Personal Hygiene and Garbing

- Personnel entering a compounding area maintain appropriate personal hygiene and report personal conditions with potential to contaminate the environment and CNSPs (e.g., rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infection) to the designated person(s). The designated person(s) evaluates whether these individuals may work in compounding areas.
- Personnel entering the compounding area to compound remove personal items that are not easily cleanable or may interfere with garbing, perform hand hygiene with soap and water, and don gloves. Additional garb is worn as needed for personnel protection and prevention of CNSP contamination. See attachment: Compounded Nonsterile Products-Hand Hygiene and Garbing SOP
- Garb is removed when exiting the compounding area. Gowns (except those worn in hazardous drug areas) may be reused during the same shift if not damaged or soiled and remain in the compounding area.

Facilities

- The designated nonsterile compounding area is the area immediately before the line of demarcation that indicates the pharmacy's Segregated Compounding Area (SCA) used for sterile compounding.
- The designated nonsterile compounding area is designed and maintained according to USP 795 guidelines. See summary below in Table 1: Nonsterile Compounding Area Requirements.

Table 1: Nonsterile Compounding Area Requirements

Topic	Requirement
General	• Space must be specifically designated for nonsterile compounding. • The method of designation (e.g., visible perimeter for non-hazardous) must be described in the facility's SOP. • Other activities must not occur in the space at the same time as compounding.
Physical Design	• The compounding area must be well lit, clean, and orderly. • Carpet should not be in the compounding space. • Surfaces should be resistant to damage by cleaning and sanitizing agents. • Hot and cold water and an easily accessible sink must be available.
Temperature	• Component storage areas must be monitored and *documented* at least daily on days that the facility is open. • The results of the temperature readings (temperature log or continuous temperature recording device) must be retrievable. • All temperature monitoring equipment must be calibrated or verified for accuracy as recommended by the manufacturer or every 12 months if not specified by the manufacturer. • Temperature parameters are based on storage requirements of components.

Cleaning and Sanitizing

- The process of cleaning of the nonsterile compounding environment is defined below in Table 2: Nonsterile Compounding Area Cleaning Requirements and meets or exceeds these requirements.
- Cleaning and sanitizing activities are performed by trained and appropriately garbed personnel using facility approved agents and procedures.
- Cleaning activities are documented.

Table 2: Nonsterile Compounding Area Cleaning Requirements

Site	Cleaning Frequency
Work Surfaces	• At the beginning and end of each shift on days when compounding occurs • After spills • When surface contamination is known or suspected • Between compounding CNSPs with different components
Floors	• Daily on days when compounding occurs • After spills • When surface contamination (e.g., from splashes) is known or suspected
Walls/Ceiling	• When visibly soiled • After spills • When surface contamination (e.g., from splashes) is known or suspected
Storage Shelves	• Every ***3 months*** • After spills • When surface contamination (e.g., from splashes) is known or suspected
Sink	• If visibly soiled, before using to clean any equipment used in nonsterile compounding.
Equipment/Utensils	• Before each use according to manufacturer recommendations • Between compounding CNSPs with different components • Rinse with *USP Purified Water*, distilled water, or reverse osmosis water

Beyond-Use Dates

- Each CNSP is assigned/labeled with a beyond-use date (BUD) which is the date beyond which the CNSP cannot be used and must be discarded. See attachment: Beyond Use Dating-Compounded Nonsterile Preparations
- The beyond-use date (BUD) for CNSPs takes into consideration:
  - Chemical and physical properties of components
  - Compatibility and degradation of container closure systems
  - Potential for microbial proliferation in the CNSP is based on the water activity (a_w) of aqueous and nonaqueous dose forms.
    - Compounders do *not* measure water activity. Data in USP <795> and USP <1112> are used for similar preparations.
    - When antimicrobial preservatives are not present, the CSNP is stored under refrigeration unless the physical and chemical properties are adversely impacted.

Master Formulation Record

- A Master Formulation Record (MFR) is a detailed step-by-step procedure describing how a CNSP is prepared.
- A MFR is created and maintained for each unique formulation of a CNSP.
- CNSPs are not compounded until a written MFR is developed and approved.
- MFRs contain:
  - Name, strength or activity, and dosage form of the CNSP
  - Identity and amount of each component
  - Container closure system(s)
  - Complete preparation instructions including equipment, supplies and description of compounding steps
  - Beyond-use date (BUD) and storage requirements
  - Reference source supporting the assigned BUD
  - Calculations to determine and verify quantities and/or concentrations, *if applicable*
  - Labeling requirements (e.g., shake well, protect from light, refrigerate)
- Changes to the MFR are approved by the designated person(s) or assigned designee and documented.

Compounding Record

- A Compounding Record (CR) is required to document the compounding process for *each* CNSP.
- Each compounding record is reviewed for completeness and is signed, initialed, or authenticated and dated by the individual performing the review.
- The compounding record is retained to allow for traceability of all components in the event of a recall or known quality issue.
- The compounding record includes:
  - Name, strength or activity, and dosage form of the CNSP
  - Date, or date and time of preparation
  - Assigned internal identification number (e.g., prescription or lot number)
  - Identification of the individual(s) involved in compounding and verification of the final CNSP
  - Name, vendor or manufacturer, lot number and expiration date of each component
  - Weight or measurement of each component
  - Total quantity prepared
  - Assigned beyond-use date and storage requirements
  - Calculations when applicable

Release Inspection and Testing

- Required release inspections are documented on each MFR.
- The pharmacist performing the release inspection visually inspects for:
  - Physical appearance is as expected (e.g., color, texture, physical uniformity)
  - Visual characteristics (e.g., phase separation of emulsions)
  - Labeling and CNSP is consistent with the compounding record and prescription or order
  - Container enclosure integrity (e.g., leak, cracks, improper seal)
- The pharmacist documents the results of the inspection on the CR.
- When a CNSP fails release inspection or testing it is clearly labeled as rejected and segregated from active stock to prevent use before appropriate disposal.

- When a CNSP will not be released or dispensed on the day of preparation, a visual inspection is performed immediately before dispensing to validate that no defects are present.

Re-Dispensing CNSPs

- Pharmacy Services has the sole authority for determining whether a CNSP not administered as originally intended can be used for an alternate patient or under alternate conditions.
- CNSPs that are not used must be returned to the pharmacy for appropriate disposition.
- Partially used CNSPs are *not* reused or re-dispensed.
- CNSPs may be re-dispensed only if there is adequate assurance that quality and packaging integrity were continuously maintained between the time the CNSP left the pharmacy and the time the CNSP returned to the pharmacy.
  - The CNSP was maintained under continuous refrigeration and protected from light, if required.
  - There is no evidence of tampering or readying for use.
  - The originally assigned beyond-use time and date is sufficient to support re-dispensing.
- CNSPs are *not* re-dispensed if there is not adequate assurance of all of the above.

Quality Assurance and Quality Control

- The Nonsterile Compounding Quality Assurance/Quality Control Program defines the procedures, activities, sampling, testing, and documentation of results to ensure the nonsterile compounding process consistently meets quality standards. See attachment: Nonsterile Compounding Quality Assurance-Quality Control Program
- The QA/QC program is reviewed at least every 12 months by the designated person(s).
- Aggregated data is reviewed and analyzed to identify opportunities for improvement. Corrective action is documented. A report summary of the overall QA/QC is reported to the facility QAPI program.

Recalls

Recalls of CNSPs are handled according to the facility policies for drug recalls.

Adverse Event Reporting and Complaint Handling

Adverse events and complaints are reported and handled according to the facility policies for adverse event reporting and complaint handling.

Handling, Storage, Packaging and Transport

- CNSPs are handled, stored, packaged, shipped, and transported in a manner that maintains the CNSPs quality and packaging integrity.
- CNSPs, components, equipment, and containers are stored off the floor.
- Packaging materials maintain the physical and chemical integrity and stability of CNSPs, and protect CNSPs from damage, leakage, contamination, degradation, and protect personnel from exposure.

Documentation

- The facility maintains written or electronic documentation records to include but not limited to the following:
  - Personnel training, competency assessments, and qualification records
  - Equipment records (e.g., calibration, verification, and maintenance reports)
  - COAs and documentation required for components not conventionally manufactured
  - SOPs, Master Formulation Records, and Compounding Records
  - Information related to complaints and adverse events
  - Results of investigations and corrective actions
  - Cleaning and sanitizing records
  - Temperature logs
- Compounding records (e.g., Master Formulation Record, Compounding Record, and release testing results if applicable) are maintained for at least 3 years, or longer as required by state laws and regulations.

Other Compounding Considerations

- Compounded drug products are prepared by the Pharmacy based on published literature and/or where there exists a formula for the preparation of these products whenever feasible.
  - Pharmacy and Therapeutics Committee review and approval is required for compounding drug products when supporting documentation in the literature is not available. In such cases, the prescribing physician is required to supply a formula for review and approval prior to compounding by the Pharmacy or a formula is researched based on available literature.
- FDA approved drug products (products with an NDC number) used in compounding do not require certificates of purity or analysis. Chemicals, bulk drug products, and components used to compound drug products will be obtained from reliable and appropriately licensed suppliers. Any available certificates of purity or analysis for chemicals, bulk drug substances,

or components used in compounding will be acquired and retained by the Pharmacy. Certificates of purity should be filed and retained for 3 years.

- Chemical(s) and drug substances are acceptable for use as the active ingredient(s) of the compounded product when the chemical or drug substance is:
  - An FDA-approved drug.
  - Listed in a book of widely used drug substances published by the United States Pharmacopeial Convention (authoritative body).
  - Listed in an FDA rule as acceptable for pharmacy compounding.
- Chemicals, bulk drug products, and components used for drug compounding will be stored and used in a way as to maintain their integrity, potency, quality, and labeled strength.

Self- Assessment Requirements
The primary purpose of the self-assessment is to promote compliance through self-examination and education.

- Prior to allowing any drug product to be compounded in the Pharmacy, the pharmacist in charge (PIC) must complete a self-assessment form (California State Board of Pharmacy form 17M-39). The self-assessment is to be completed:
  - Every two years before July 1st of odd-numbered years
  - Within 30 days of the start of a new PIC
  - Within 30 days of the issuance of a new pharmacy license

ATTACHMENTS:
USP <795> Designated Person for Nonsterile Compounding
Compounding Nonsterile Products Training Program
Compounded Nonsterile Products-Hand Hygiene and Garbing SOP
Beyond Use Dating-Compounded Nonsterile Preparations
Nonsterile Compounding Quality Assurance-Quality Control Program

REFERENCES:
CMS Conditions of Participation §482.25(a)
USP Chapters <795> 2023
USP Chapters <661> 2019
USP Chapters <1146> 2012
USP Chapters <1163> 2012
California Code of Regulations, Title 16 CCR, Article 4.5 Compounding § 1735 to 1735.8
US FDA Sec. 480.200 (CPG 7132b.11)

SUBJECT: Compounding Nonsterile Drug Products	POLICY #MM8610-237
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DEPARTMENT: Organizational	EFFECTIVE:
REVIEWED/REVISED:	

OWNER:
Director of Pharmacy

AUTHORS/REVIEWERS:
Director of Pharmacy
Board Quality Committee

APPROVALS:
Policy & Procedure Team:
PI/Pharmacy & Therapeutics Committee:
Medical Executive Committee:
The Board of Directors:

SUBJECT**:** IV Compounding (Non-Pharmacy Location)	POLICY #MM8610-218
	PAGE 1 OF 5
DEPARTMENT: Organizational	EFFECTIVE:
REVIEW/REVISED:	

NEW POLICY

To define the process in which sterile injectable pharmaceuticals are mixed outside of the pharmacy in such a way as to ensure safe and timely provision of drug therapy to hospital patients and when it is appropriate to do so.

Addresses need for training and competency assessments, defines medication prep area, clarifies when after-hours compounding outside of the pharmacy is appropriate.

Added attachments:

Compounding Sterile Preparations on Patient Care Units SOP (Standard Operating Procedure)

IV Compounding (Non-Pharmacy Location) Competency

WHY:

Major changes to current policy. This replaces MM8610-118 IV Compounding Outside the Pharmacy.

Per USP 797

OWNER:
Director of Pharmacy

AUTHORS/REVIEWERS:
Director of Pharmacy
Board Quality Committee

APPROVALS:
Policy & Procedure Team:
Performance Improvement/
Pharmacy & Therapeutics Committee:
Medical Executive Committee:
The Board of Directors:

SUBJECT**:** IV Compounding (Non-Pharmacy Location)	POLICY #MM8610-218
	PAGE 2 OF 5
DEPARTMENT: Organizational	EFFECTIVE:
REVIEW/REVISED:	

PURPOSE:

To define the process in which sterile injectable pharmaceuticals are mixed outside of the pharmacy in such a way as to ensure safe and timely provision of drug therapy to hospital patients and when it is appropriate to do so.

DEFINITIONS:

- **Compounded Sterile Preparation (CSP):** A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance.
- **Aseptic Technique:** A set of methods used to keep objects and areas free of microorganisms and thereby minimize infection risk to the patient. It is accomplished through practices that maintain the microbe count at an irreducible minimum.
- **Classified Area:** An area that maintains an air quality classification based on the ISO standards required in USP Chapter <797>.
- **Immediate-Use CSP:** A CSP meeting certain conditions that may be prepared outside of a classified area (e.g., patient care unit) for immediate (within four hours) administration.
- **Beyond -Use-Date (BUD) and Time:** The date, or the hour and date, after which a CSP must not be used. The date is determined from the date and time the preparation is compounded. BUD applies up to the time of administration. BUD does *not* apply to the duration of the administration and does *not* limit the infusion time. Once the infusion is started, the medication is considered 'used.'

BACKGROUND

There are times when preparation of a CSP outside of a classified area (i.e., outside of the pharmacy sterile compounding area) is necessary. Patient care personnel performing this task must employ strategies to minimize the likelihood of microbial contamination when preparing CSPs for immediate use.

POLICY:

- Preparation of sterile IV admixtures will be performed within the pharmacy IV room using sterile aseptic technique in accordance with standards required by USP Chapter 797.
- In the presence of an urgent situation when a delay could compromise patient safety, there is no ready to use product available, and/or during hours when the pharmacy is closed, it

may be necessary for nurses or other practitioners to prepare large volume parenteral IVs (LVPs) and/or small volume IV piggyback (IVPB) admixtures.

- For this to occur as safely as possible, the process will meet the requirements of an immediate use compounded sterile product as defined in policy MM8610-117 Sterile Compounding and USP 797.
- IV Push medications that are in unit of use containers (such as powder vials) and are aseptically reconstituted according to manufacturer instructions, drawn into a syringe, and immediately administered to the patient outside of the IV room AND doses in which a vial is directly connected to a bag via a device per manufacturer instructions (i.e. AddEase vial adapters) are not considered to be compounding.

PROCEDURE:

Training and Competency Assessment

See attachment: Nursing IV Compounding Competency 2023

- Nurses/clinical staff preparing CSPs receive training and have documented competency assessment to demonstrate their ability to safely perform the task.

Compounding Sterile Preparations on Patient Care Units

See attachment: Compounding Sterile Preparations on Patient Care Units SOP

- Compounded sterile preparations (CSPs) prepared on a patient care unit outside of a classified area are for immediate use.
- Staff use aseptic techniques and maintain a clean, uncluttered, and designated workspace (separate from other functions) for medication preparation.
- Preparation follows approved labeling and evidence-based information for physical and chemical compatibility.
- Preparation is limited to CSPs containing no more than three (3) different sterile products.
- Single-dose containers are *not* used for more than one (1) patient. Any unused portion of a single-dose container is discarded.
- Administration begins within four hours following the start of the preparation. If administration is *not* started within four hours, the CSP is discarded.

Medication Preparation Area

- To minimize the potential for contamination during preparation, CSP preparation is performed using aseptic technique in a clean, uncluttered functionally separate area designated for medication preparation.

Aseptic Technique

Aseptic technique is used when preparing and administering sterile medications. Aseptic technique includes but is not limited to:

- Hand hygiene *before* and *after* preparation and administration
- Disinfecting stoppers on vials and the neck of ampules
- Disinfecting additive ports and connectors

Other considerations

- For select IV medications that are generally deemed to be urgent or emergent in nature, the pharmacy will create kits that contain the appropriate medication vial(s) or ampule(s), the appropriate diluents into which the medication is injected, appropriate expiration dating, and labeling with instructions for mixing.
  - ✓ The kits are made for specific medications that are typically emergent in nature (i.e. vasopressors, antiarrhythmics, etc) that are not available in a ready to use form.
  - ✓ The kits are checked and sealed by a pharmacist before dispensing to nursing unit floor stock/automated dispensing cabinet.
- When a medication is needed urgently or emergently and no kit exists, the medication may be compounded by nursing personnel using aseptic sterile technique and is administered to the patient within 1 hour from the beginning of preparation.
  - ✓ Nursing personnel who compound medication in this situation will be trained and competent to do so.
- When the pharmacy is closed, a medication is scheduled to be administered to a patient, the medication is not available as a ready to use item, and it is determined that a medication is NOT urgent or emergent, the nursing supervisor will notify the on-call pharmacist.
  - o The on-call pharmacist will work with the nursing supervisor to develop a plan of action which may include but is not limited to:
    - ✓ The pharmacist coming into the hospital to prepare the dose in the pharmacy IV room.
    - ✓ Contacting the prescriber to change the order to an appropriate and readily available medication.
    - ✓ Holding the dose until the pharmacy is open when clinically appropriate to do so.

ATTACHMENTS:

- Nursing IV Compounding Competency 2023
- Compounding Sterile Preparations on Patient Care Units SOP

SUBJECT**:** IV Compounding (Non-Pharmacy Location)	POLICY #MM8610-218
	PAGE 5 OF 5
DEPARTMENT: Organizational	EFFECTIVE:
REVIEW/REVISED:	

REFERENCES:

- 2023 USP General Chapter <797> Pharmaceutical Compounding—Sterile Preparations
- Policy: MM8610-117 Sterile Compounding
- CMS Conditions of Participation § 482.25(b)(1), 482.23(c)
- CCR 1751.4

OWNER:
Director of Pharmacy

AUTHORS/REVIEWERS:
Director of Pharmacy
Board Quality Committee

APPROVALS:
Policy & Procedure Team:
Performance Improvement/
Pharmacy & Therapeutics Committee:
Medical Executive Committee:
The Board of Directors:

PROCEDURE: QAPI Procedures for Sterile Compounding Quality Assurance program. (Sampling Plan-IV Room)	POLICY #: 8390-2302
	PAGE 1 OF 4
DEPARTMENT: Pharmacy	EFFECTIVE:
REVISED/REVEIWED:	

NEW POLICY
QAPI Procedures for Sterile Compounding Quality Assurance program.
Sampling Plan-IV Room

WHY:

Significant reorganization and content updates to ensure policy meets requirements from updated USP 797 standards.
Defines requirement standards for Staff training and competency, Cleaning and Disinfecting compounding area, Environmental Controls & Microbiological Environmental Monitoring, End Product Sterility, Endotoxin, and Quantitative Testing, Adverse events and complaints related to sterile compounding. Added attachments that support the policy.

OWNER:
Director of Pharmacy

AUTHORS/REVIEWERS:
Director of Pharmacy
Board Quality Committee

APPROVALS:
Policy & Procedure Team:
Performance Improvement/
Pharmacy & Therapeutics Committee:
Medical Executive Committee:
The Board of Directors:

PROCEDURE: QAPI Procedures for Sterile Compounding Quality Assurance program. (Sampling Plan-IV Room)	POLICY #: 8390-2302
	PAGE 2 OF 4
DEPARTMENT: Pharmacy	EFFECTIVE:
REVISED/REVEIWED:	

PURPOSE:
To define and establish a procedure for the Sterile Compounding Quality Assurance/Process Improvement (QAPI) program. The program is designed to ensure that sterile compounding consistently meets applicable quality standards and sterile preparations meet specifications prior to their release for use.

IDENTIFICATION OF PERFORMANCE STANDARDS

Performance standards include:

- Staff training and competency
- Cleaning and disinfecting compounding area
- Environmental Controls & Microbiological Environmental Monitoring
- End Product Sterility, Endotoxin, and Quantitative Testing
- Adverse events and complaints related to sterile compounding

When results fall outside of the acceptable range or an action level is exceeded, a corrective action plan is implemented.

PROCEDURE:
Staff training and competency

- Collect data on completion of Aseptic Manipulation (Media-fill, Gloved Fingertip Testing (GFT), Surface Sampling), Hand Hygiene and Garbing with GFT, and knowledge-based core competencies.
- Training and competency components, assessments, and frequency of evaluation are defined in the document, “Sterile Compounding Training Program SOP”.
- Staff training data is collected from the completed documents:
  - Competency--Sterile Compounding Aseptic Manipulation
  - Competency--Sterile Compounding INITIAL Hand Hygiene and Garbing for Compounders (with GFT)
  - Competency--Sterile Compounding ONGOING Hand Hygiene and Garbing for Compounders (with GFT)

Cleaning and Disinfecting

- Collect data on completion of *daily* and *monthly* cleaning activities.
- Cleaning and disinfecting procedures being monitored are defined in the document, “Sterile Compounding Procedures”.
- Data is collected from the completed documents:
  - IV Room Cleaning Log
  - IV Hood Cleaning & Filter Change Record

Environmental Controls & Microbiological Environmental Monitoring

- Review records for completion of sterile compounding area certification/recertification requirements and microbiological surface testing.
- Requirements for certification are defined in the document "Environmental Control and Microbiological Air and Surface Monitoring Plan for Sterile Compounding".
- Requirements for Microbiological Environmental Monitoring are defined in the document "Environmental Control and Microbiological Air and Surface Monitoring Plan for Sterile Compounding".
- Data is collected from Vendor certification reports for all PECs (hoods) & results of viable surface testing logs.

End Product Sterility, Endotoxin, and Quantitative Testing

- Review results of annual sterility, endotoxin, and quantitative testing for sample sterile compounded products (two products selected annually).
- Collection and submission of samples are performed per instructions of the chosen vendor Dynalabs (https://dynalabs.us/)
- Data is collected from the testing result report provided by the vendor.

- *Adverse events and complaints related to sterile compounding*
- Collect data on complaints and events/variances related to sterile compounding.
- Data is collected from the hospital event reporting database.

ANALYSIS OF QUALITY ASSURANCE ASSESSMENT

Evaluating Performance

Aggregated data is reviewed and analyzed to identify opportunities for improvement. Performance that did *not* meet the defined performance threshold requires corrective action. Summaries of corrective actions taken are documented. Action plans may be requested to correct any deficient items as measured in the Quality Assurance Program.

REFERENCES:
Policy MM8610-117 Sterile Compounding
Procedure 8390-03 Sterile Compounding Procedures
CCR 1735.1; CCR 1735.8; CCR 1751.7
2023 USP General Chapter <797> Pharmaceutical Compounding—Sterile Preparations

ATTACHMENTS:
- Sterile Compounding Training Program SOP

PROCEDURE: QAPI Procedures for Sterile Compounding Quality Assurance program. (Sampling Plan-IV Room)	POLICY #: 8390-2302
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DEPARTMENT: Pharmacy	EFFECTIVE:
REVISED/REVEIWED:	

- Competency--Sterile Compounding Aseptic Manipulation
- Competency--Sterile Compounding INITIAL Hand Hygiene and Garbing for Compounders (with GFT)
- Competency--Sterile Compounding ONGOING Hand Hygiene and Garbing for Compounders (with GFT)
- IV Room Cleaning Log
- IV Hood Cleaning & Filter Change Record
- Environmental Control and Microbiological Air and Surface Monitoring Plan for Sterile Compounding

OWNER:
Director of Pharmacy

AUTHORS/REVIEWERS:
Director of Pharmacy
Board Quality Committee

APPROVALS:
Policy & Procedure Team:
Performance Improvement/
Pharmacy & Therapeutics Committee:
Medical Executive Committee:
The Board of Directors:

SUBJECT: Sterile Compounding (USP 797)	POLICY #MM8610-2317
	PAGE 1 OF 15
DEPARTMENT: Pharmacy	EFFECTIVE:
REVISED:	

NEW POLICY

WHY:

Significant changes to content and organization of original policy due to large revision of USP 797 standards. Updated most of policy to match newly updated standards.

Attachments to support policy

OWNER:

Director of Pharmacy

AUTHORS/REVIEWERS:

Director of Pharmacy

Board Quality Committee

APPROVALS:

Policy & Procedure Team:

Performance Improvement/

Pharmacy & Therapeutics Committee:

Medical Executive Committee:

The Board of Directors:

SUBJECT: Sterile Compounding (USP 797)	POLICY #MM8610-2317
	PAGE 2 OF 15
DEPARTMENT: Pharmacy	EFFECTIVE:
REVISED:	

PURPOSE

To provide written guidelines for compounding sterile preparations including procurement, storage, ordering, preparation, facilities and equipment, staff education and training, labeling, and quality assurance/quality assurance records.

DEFINITION

Compounded sterile preparation (CSP): A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug or bulk drug substance.[1]

SCOPE

- Compounded preparations that must be sterile include but are not limited to:
  - Injections, including infusions.
  - Irrigations for internal body cavities (i.e., any space that does not normally communicate with the environment outside of the body, such as the bladder or peritoneal cavity) Irrigations for the mouth, rectal cavity, or sinus cavity are not required to be sterile.
  - Ophthalmic dosage forms
  - Aqueous preparations for pulmonary inhalation. Nasal dosage forms for local application are not required to be sterile.
  - Baths and soaks for live organs and tissues
  - Implants
- Repackaging of a sterile product or preparation from its original container into another container is sterile compounding and subject to the requirements of this policy.
- Docking and activation of proprietary bag and vial systems for immediate administration is *not* considered compounding.
- Medication administration is *out of the scope* of this policy.

POLICY

- Sterile compounding services meet state and federal requirements and professional practice standards. USP General Chapter <797> (USP 797) is used to guide sterile compounding activities.

---

[1] 2023 USP General Chapter <797> Pharmaceutical Compounding-Sterile Preparations

- Compounded products are prepared pursuant to a patient-specific medical order/prescription in the amount required to meet the patient's need.

  Exception: CSPs may be prepared and stored in a limited quantity in advance of receipt of a patient-specific prescription or order, as necessary to ensure continuity of care for an identified patient population based on documented history of use.

- Compounded products prepared in the facility are *not* sold, transferred, or delivered to another facility or licensee unless the compounded preparation is patient-specific, a prescription/order has been obtained, and the pharmacy/facility is appropriately licensed and allowed by State regulations.
- Previously marketed drugs found to be unsafe, ineffective and/or removed from the commercial market may not be compounded.
- Drug products listed in the FDA's regulations as difficult to compound may not be compounded
- A qualified designated person, or persons, oversees the sterile compounding program.
- Trained pharmacy staff prepare compounded sterile preparations (CSPs) in a controlled sterile compounding environment in accordance with applicable state and federal laws, rules, and regulations, including professional practice standards.
- CSPs may be prepared on patient care units in urgent situations when a delay could harm the patient or when the CSP stability is short. (See Policy: IV Compounding Outside of the Pharmacy MM8610-118)
- Standard Operating Procedures (SOPs) for the compounding processes and support activities are developed, maintained, and reviewed at least every 12 months by the designated person(s) to ensure they reflect current practice. The review is documented.
- The pharmacy at Sonoma Valley Hospital does not prepare hazardous medications (i.e. Chemotherapy) as part of routine practice.
    - The exception to the above statement is the compounding of low volume hazardous medication needed for urgent patient care (such as methotrexate IM for treatment of ectopic pregnancy, see Procedure 8390-05: Preparation of Methotrexate IM Doses Using ChemoClave System).
- A Quality Assurance (QA)/Quality Control (QC) program is maintained to monitor, evaluate, correct, and improve activities and processes. The overall program is reviewed at least every 12 months by the designated person(s). The review and any corrective actions are documented.
- Sterile compounding records are retained on file for 3 years.

SUBJECT: Sterile Compounding (USP 797)	POLICY #MM8610-2317
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REVISED:	

PROCEDURE

Sterile Compounding Oversight and Responsibility

Designated Person(s)

The designated person(s) is/are responsible and accountable for the performance and operation of the compounding facility and compounding personnel. The individual(s) identified as designated person(s) is documented. See attachment**:** USP 797 Designated Person for Sterile Compounding

Compounding Personnel

Compounding personnel are responsible for understanding the fundamental practices and precautions of safe sterile compounding, following sterile compounding standard operation procedures (SOPs), and recognizing and reporting to the designated person(s) any potential problems, deviations, failures, or errors that could affect the quality of the CSP.

Pharmacist

The pharmacist performing or supervising the compounding process is responsible for:

- The integrity, potency, quality, and labeled strengths of the CSP.
- The proper preparation, labeling, storage, and delivery of the CSP.
- Final preparation verification and documentation.

Personnel Training and Evaluation

- A written training program describes the required training, the frequency of training, and the process for evaluating the performance of individuals involved in preparing CSPs (See attachment**:** Sterile Compounding Training Program).
- The training program includes demonstrating knowledge in core skills related to sterile compounding principles and demonstrating competency in performing sterile compounding-related activities based on assigned tasks and relevant to their job duties.
- Sterile compounding personnel receive training and demonstrate proficiency in compounding skills *before* independently compounding.
- Documentation of training and competency assessment is maintained.

Personal Hygiene and Garbing

- Personnel entering a compounding area maintain appropriate personal hygiene, perform hand hygiene and garb per facility SOP, and report personal conditions with potential to contaminate the environment and CSPs (e.g., rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infection) to the designated person(s). The designated person(s) evaluates whether these individuals may work in compounding areas.

- Garb is removed when exiting the compounding area per facility SOP. Gowns (except those worn in hazardous drug areas) may be reused during the same shift if not damaged or soiled and remain in the compounding area.

Facilities and Engineering Controls

The sterile compounding area is designed and maintained to minimize the risk of contamination of CSPs. Air quality is achieved and maintained by primary engineering controls (PEC) and secondary engineering controls (SECs).

Primary Engineering Control (PEC)

The PECs are located in a segregated compounding area (SCA) as described below under "Secondary Engineering Control (SEC)".

- The PEC operates continuously except for filter changes and other required maintenance. If PECs are turned off, they must operate for at least 30 minutes prior to initiating cleaning and compounding procedures.
- Pre-filters of the PEC are changed quarterly to ensure optimum life of the PEC's HEPA filter. This maintenance is documented.

Secondary Engineering Control (SEC)

The Segregated Compounding Area (SCA) is a designated space, area, or room that is not required to be classified and is defined with a visible perimeter. The SCA must contain a PEC and is suitable for preparation of Category 1 CSPs only (see section below "Beyond-Use-Dating (BUD) and CSP Categories"). Design requirements of an SCA are summarized below in Table 1: Segregated Compounding Area (SCA) Requirements.

Table 1: Segregated Compounding Area (SCA) Requirements

Topic	Requirement
CSP Category	Only Category 1 CSPs may be prepared
Beyond Use Dating (BUD)	Storage conditions and BUD for stable products • Controlled room temperature: Less than or equal to 12 hours • Refrigerated: Less than or equal to 24 hours
Physical Design	• Designated, separate area(s) dedicated to compounding with a visual perimeter (e.g., demarcation such as a door, walls, or visible marking on the floor) to establish the boundaries • No unsealed windows, or doors opening to the outside within the perimeter of the SCA • Located away from restrooms, warehouse areas and food preparation areas • Sink must be at least 1 meter from the PEC and may be

	located either inside or in close proximity to the SCA • Area within one meter of the PEC should be dedicated only for sterile compounding (e.g., not storage, hand hygiene, donning and doffing garb) • All surfaces must be clean, uncluttered, and dedicated to compounding • Floors, walls, ceilings should be smooth, impervious, free from cracks and crevices, non-shedding and easily cleanable • Surfaces should be resistant to damage by cleaning agents and disinfectants • Dust-collecting overhangs should be avoided or minimized, and must be easily cleanable • No free-standing humidifiers/ dehumidifiers or air conditioners are allowed within the of the SCA
ISO Classification	Area is unclassified; no ISO classification requirement
Air Changes Per Hour (ACPH)	No ACPH requirement
Temperature and Humidity	Maintain at a temperature of 20°C (68°F) or cooler. Humidity monitoring is not required in an SCA.
Pressure Differential	No pressure differential required
Equipment / Shelving	• Furniture, equipment, and other materials necessary for compounding are kept to aminimum, are low-shedding, and easily cleanable/disinfected. • No shipping cartons or other corrugated or uncoated cardboard

Certification and Recertification

- ISO classified compounding areas (PECs and SECs) are certified initially and recertified at least every 6 months by an independent vendor.
- Certification test requirements include the following:
  - Airflow Testing - air velocity, volume, air changes per hour (ACPH), and room pressure differential (PD).
  - HEPA Filter Integrity Testing
  - Total Particle Count Testing/ISO Classification *(document the number of people in the room during testing)*
  - Dynamic Airflow Smoke Pattern Testing *(simulated compounding occurs and document the number of people simulating compounding during testing)*

- The Environmental Control and Microbiological Monitoring Plan for Sterile Compounding defines procedures, frequency, actions, and documentation requirements for maintaining the physical plant environmental controls and non-viable airborne particle testing (see attachment: Environmental Control and Microbiological Air and Surface Monitoring Plan for Sterile Compounding)
- Classified areas are recertified if there are changes to the area such as redesign, construction, replacement or relocation of the PEC or alteration in the configuration of the room that could affect airflow or air quality.
- Certification and recertification reports are reviewed by the designated person(s).
- A corrective action plan is implemented and documented in response to out-of-range results. Data collected in response to corrective actions is reviewed to confirm that the actions taken have been effective.

Microbiological Air and Surface Monitoring

- The Environmental Control and Microbiological Monitoring Plan for Sterile Compounding defines the procedures, frequency, actions, and documentation requirements for the following:
  - Viable airborne sampling (microbial testing)
  - Viable surface sampling (microbial testing)
- When results fall outside of the acceptable range or action level is exceeded, a corrective action plan is implemented and documented.

Cleaning, Disinfecting and Applying a Sporicidal Agent in Compounding Area

- The Sterile Compounding Procedures define the cleaning requirements for different sterile compounding environments.
- Cleaning and disinfecting activities are performed by trained and appropriately garbed personnel using facility approved agents and procedures.
- The frequency, cleaning method(s), and the cleaning, disinfecting, and sporicidal agents are defined in Sterile Compounding Procedures. The manufacturer's directions or published data for the minimum contact time, or dwell time, for the agent(s) to be effective is/are defined.
- Cleaning activities are documented.

Components, Equipment and Supplies

- No shipping carton(s) or other corrugated or uncoated cardboard are allowed in a classified area or segregated compounding area (SCA).
- Equipment and supplies are not placed within 3 feet of a sink unless a splash guard is in place.
- Furniture, equipment, and supplies in the compounding area are limited to what is necessary to perform compounding activities. Furniture, carts, and other equipment are nonporous, or low shedding, and easy to clean and disinfect.
- Carts used to transport components or equipment to classified areas are *not* moved from the dirty side to the clean side of the anteroom.
- Equipment brought into a classified area is wiped with a sporicidal agent, EPA-registered disinfectant, or sterile 70% IPA using low-lint wipers.
- Monitoring equipment including temperature monitoring devices are calibrated or verified for accuracy as recommended by the manufacturer or every 12 months if not specified by the manufacturer.

Beyond-Use-Dating (BUD) and CSP Categories

- Each CSP is assigned/labeled with a beyond-use-date (BUD) which is the date, or the hour and date, beyond which the CSP *cannot* be used and must be discarded.
- The BUD is determined from the date and time that preparation of a CSP is initiated.
- BUD does *not* limit the duration of time a CSP may be administered (e.g., infused).
- BUD is based on the risk of microbial contamination. Only Category 1 CPSs can be made in an SCA as summarized below in Table 2: Maximum BUD for Category 1 CSPs.

Table 2: Maximum BUD for Category 1 CSPs

ISO 5 PEC placed in a non-ISO classified segregated compounding area (SCA)

Storage Conditions	
Controlled Room Temperature (20-25ºC)	Refrigerator (2-8ºC)
Less than or equal to 12 hours	**Less than or equal to 24 hours**

- BUDs are not additive. A CSP cannot be stored in the refrigerator for 24 hours, then 12 hours at room temperature. Once a CSP is moved from the refrigerator to room temperature, the CSP must be used within the timeframe for the new storage condition or its original storage BUD, whichever is shorter.

Conventionally Manufactured Single-Dose, Multi-Dose Containers, and Pharmacy Bulk Packages

- Single-dose vials when needle-punctured in an environment with ISO Class 5 or better air quality, must be used within six (6) hours. The container (e.g. vial) must remain within the ISO Class 5 or better air quality to be used for the full six hours, unless otherwise specified by the manufacturer.
- Opened single-dose ampules are *not* stored for future use.
- Open multiple-dose containers are assigned and labeled with a BUD of up to 28 days unless otherwise specified by the manufacturer.
- A pharmacy bulk package (PBP) is a sterile product for parenteral use that contains many single doses. PBPs are only entered or punctured in a PEC and are assigned and labeled with a BUD according to the manufacturer's labeling (e.g., 4 hours).

Single-Dose CSPs and CSP Stock Solutions

- When a single-dose CSP or CSP stock solution (a sterile mixture of components that is used to compound additional CSPs) is used as a component to compound additional CSPs, the original compounded single-dose CSP or CSP stock solution must be entered or punctured in a PEC and be stored under the conditions upon which its BUD is based (e.g., refrigerator, controlled room temperature).
- The component CSP may be used and labeled with a BUD of up to 12 hours or its assigned BUD, whichever is shorter. Any remainder must be discarded.
- BUDs assigned to CSPs prepared from a single-dose CSP or CSP stock solution may follow Beyond-Use-Dating (BUD) Category 1 or the remaining original BUD of the single-dose CSP or CSP stock solution used as a component, whichever is shorter.

Immediate-Use Compounding

When all the following conditions are met, compounding of CSPs for direct and immediate administration is not subject to the requirements for Category 1:

1. Aseptic techniques, processes, and procedures are followed, and written SOPs are in place to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs.
2. Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs.
3. The preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs (e.g., approved labeling, stability, and compatibility studies).
4. The preparation involves not more than 3 different sterile products.
5. Any unused starting component from a single-dose container must be discarded after preparation is complete. Single-dose containers must not be used for more than one patient.

6. Administration begins within 1 hour following the start of preparation. If administration has not begun within 1 hour following the start of preparation, it must be promptly, appropriately, and safely discarded.
7. Unless directly administered by the person who prepared it or administration is witnessed by the preparer, the CSP must be labeled with the names and amounts of all active ingredients, the name or initials of the person who prepared the preparation, and the 1-hour time period within which administration must begin.
8. If any sterile compounded drug preparation is compounded by the pharmacy outside of an ISO class 5 environment it must be labeled "for immediate use only" and administration shall begin no later than one hour following the start of the compounding process.
   a. Immediate use preparations as defined above shall be compounded only in those limited situations where there is a need for immediate administration of a sterile preparation compounded outside of an ISO class 5 environment and where failure to administer could result in loss of life or intense suffering.
   b. Any such compounding shall be only in such quantity as is necessary to meet the immediate need and the circumstance causing the immediate need will be documented in the applicable sterile compounding log for that product.

Proprietary Bag and Vial Systems

Proprietary bag and vial systems (e.g., addEASE, ADD-Vantage, Mini Bag Plus) docked for *future* activation and administration are docked in an ISO 5 PEC and are assigned a BUD based on the device manufacturer's labeling.

Protective Outer Wrappers

Commercially available intravenous products removed from protective outer wrappers are assigned BUD based on the manufacturers' recommendations.

Changes in Storage Environment (Refrigerators, Freezers, Warmers)

When commercially available products such as pre-mixed IVs or irrigation solutions are moved in or out of a refrigerator, freezer, or warmer, a BUD based on the manufacturer's recommendations is assigned.

Master Formulation Record (MFR)

- A Master Formulation Record (MFR) is a detailed step-by-step procedure that describes how a CSP is prepared.
- MFRs include:
  - Name, strength or activity, and dosage form of the CSP
  - All ingredients and amounts

- Type and size of container–closure system(s)
- Instructions for preparing the CSP, equipment, supplies, a description of the compounding steps, and any special precautions
- Description of the final CSP
- BUD and storage requirements
- Stability reference(s)
- Quality control (QC) procedures, if applicable
- Other information needed to describe the compounding process and ensure repeatability.

- Changes or alterations to MFRs are approved by the designated person(s) or assigned designee and documented.

Compounding Record (CR)

- A Compounding Record (CR) is required to document the compounding or repackaging process for *each* CSP.
- CRs may be stored electronically but must be readily retrievable.
- CRs include:
  - Name, strength or activity, and dosage form of the CSP
  - Date and time prepared
  - Internal identification number (e.g., prescription, order, or lot number)
  - The individuals involved in the compounding process and verifying the final CSP
  - Name of each component
  - Weight or volume, and strength or activity of each component
  - Total quantity compounded
  - BUD and storage requirements
  - If applicable, calculation and results of QC procedures

Labeling

Labeling procedures are defined to prevent labeling errors and CSP mix-ups.

Final Inspection and Release Check

- Before release and dispensing, CSPs are visually inspected by a pharmacist.
  - For accuracy of ingredients, correct size, strength, and quantity
  - Particulate matter, discoloration/clarity, and container-closure integrity

  - The CSP and its label match the prescription or medication order.
- The pharmacist documents the inspection on the CR.
- CSPs with observed defects are discarded.

Re-Dispensing CSPs

- Pharmacy Services has the sole authority for determining whether a CSP not administered as originally intended can be used for an alternate patient or under alternate conditions.
- CSPs that are not used must be returned to the pharmacy for appropriate disposition.
- CSPs may be re-dispensed only if there is adequate assurance that quality and packaging integrity were continuously maintained between the time the CSP left the pharmacy and the time the CSP returned to the pharmacy.
  - The CSP was maintained under continuous refrigeration and protected from light, if required.
  - There is no evidence of tampering or readying for use.
  - The originally assigned beyond-use time and date is sufficient to support re-dispensing.
- CSPs are *not* re-dispensed if there is not adequate assurance of all of the above.

Quality Assurance and Quality Control

- The Sterile Compounding Quality Assurance/Quality Control Program defines the procedures, activities, sampling, testing, and documentation of results to ensure the sterile compounding process consistently meets quality standards.
- The QA/QC program describes the methodologies used to monitor performance in the following categories.
  - Staff training and competency
  - Microbiological environmental monitoring
  - Cleaning and disinfection compounding area(s)
  - Environmental control and equipment monitoring
  - Adverse medication events related to sterile compounding
  - Standards for annual qualitative and quantitative integrity, potency, quality, and labeled strength analysis of the compounded drug products.
- The QA/QC program is reviewed at least every 12 months by the designated person(s).

- Aggregated data is reviewed and analyzed to identify opportunities for improvement. Corrective action is documented. A report summary of the overall QA/QC is reported to the facility QAPI program.

Recalls

Recalls of CSPs are handled according to the facility policies for drug recalls.

Adverse Event Reporting and Complaint Handling

Adverse events and complaints are reported and handled according to the facility policies for adverse event reporting and complaint handling.

Handling, Storage, Packaging and Transport

- CSPs are handled, stored, packaged, shipped, and transported in a manner that maintains the CSPs quality and packaging integrity.
- CSPs, components, equipment, and containers are stored off the floor.
- Packaging materials maintain the physical and chemical integrity and stability of CSPs, and protect CSPs from damage, leakage, contamination, degradation, and protect personnel from exposure.

Documentation

- The facility maintains written or electronic documentation records to include but not limited to the following:
  - Personnel training, competency assessments, qualification records, and corrective actions for failures
  - Certification reports
  - Environmental air and surface monitoring procedures and results
  - Facility and engineering control monitoring records
  - Cleaning records
  - Equipment records (e.g., calibration, verification, and maintenance reports)
  - Receipt of components
  - SOPs, Master Formulation Records (when used), and Compounding Records
  - Information related to complaints and adverse events
  - Investigations and corrective actions in response to failures or out-of-range results
- Compounding records (e.g., Master Formulation Record, Compounding Record, and release testing results if applicable) are maintained for at least 3 years.

Self- Assessment Requirements

The primary purpose of the self-assessment is to promote compliance through self-examination and education.

- Prior to allowing any drug product to be compounded in the Pharmacy, the pharmacist in charge (PIC) must complete a self-assessment form (California State Board of Pharmacy form 17M-39). The self-assessment is to be completed:
  - Every two years before July 1st of odd-numbered years
  - Within 30 days of the start of a new PIC
  - Within 30 days of the issuance of a new pharmacy license

POLICY ATTACHMENTS:

- USP 797 Designated Person for Sterile Compounding
- Sterile Compounding Training Program SOP

REFERENCES

- CMS Conditions of Participation § 482.25(b)(1), 482.23(c)
- FDA Final Guidance: Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act Accessed August 2023
- 2023 USP General Chapter <797> Pharmaceutical Compounding—Sterile Preparations
- CCR 1751.4
- Policy: IV Compounding Outside of the Pharmacy MM8610-118
- Procedure: Preparation of Methotrexate IM Doses Using ChemoClave System 8390-05
- Procedure: Sterile Compounding Procedures 8930-03

OWNER:

Director of Pharmacy

AUTHORS/REVIEWERS:

Director of Pharmacy

SUBJECT: Sterile Compounding (USP 797)	POLICY #MM8610-2317
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DEPARTMENT: Pharmacy	EFFECTIVE:
REVISED:	

Board Quality Committee

APPROVALS:

Policy & Procedure Team:

Performance Improvement/

Pharmacy & Therapeutics Committee:

Medical Executive Committee:

The Board of Directors:

SUBJECT: Transfusion Transmitted Infectious Disease Notification	POLICY: LB#8610-138 Page 1 of 5
DEPARTMENT: Organizational	EFFECTIVE: 03/2020
REVISED~~: 02/2023~~:	

NEW POLICY
policy was filed under the Laboratory's department policies and is not in the policy portal. It should be an organizational policy.

WHY:

Policy is required for accreditation and CLIA

OWNER:
Chief Ancillary Officer

AUTHORS/REVIEWERS:
Laboratory Manager
Laboratory Medical Director

SUBJECT: Transfusion Transmitted Infectious Disease Notification	POLICY: LB#8610-138 Page 2 of 5
DEPARTMENT: Organizational	EFFECTIVE: 03/2020
REVISED~~: 02/2023~~:	

PURPOSE:

This policy describes the process for investigating transfusion transmitted infectious disease when information is received after the time of donation that may affect the safety to any donor blood or recipient. Transmission-transmitted infections are predominantly acquired by the transfusion ~~of a virus or parasite~~of an infectious agent, in which a delay generally occurs between transfusion and manifestation of symptoms and signs of infection.

POLICY:

All transfusion transmitted infectious disease agents~~s~~ will be investigated and notification is made to recipients who may have been exposed to a transfusion transmissible disease agent from a blood transfusion.

PROCEDURE:

Blood Productions may be quarantined, returned, or destroyed upon notification by the blood supplier for a variety of reasons. A biological recall indicates the product was incorrectly collected or processed. A market withdrawal is associated with a product that has been delivered to the consignee but now additional information on the donor makes the product unsuitable for transfusion. A traceback is initiated when the supplier finds a donor to have a transfusion transmissible disease agent and contacts the consignees to determine the disposition of past donations from this donor, possibly going back years. Once the process is initiated the response is similar in all cases.

Traceback/Lookback involves:

- Tracking and identification of the location and disposition of blood component products that were manufactured from donations by a particular donor.
- The steps taken to track and quarantine unsuitable blood or blood components.
- The notification of consignees when a previous donor subsequently tests positive for ~~the~~ an ~~most~~ infectious disease marker~~s~~.

Recipient Traceback Notifications

Investigation is conducted to notify recipients who may have been exposed to a transfusion transmissible disease marker from a blood transfusion. Most commonly, confirmatory test is positive for one of the following:

1. Anti-Human Immunodeficiency Virus (HIV)-1
2. Anti-HIV 2
3. HIV Nucleic Testing (NAT)
4. Anti-Hepatitis C Virus (HCV)
5. HCV NAT

HIV TRACEBACK ("LOOKBACK")

When the supplemental (additional, more specific) test for HIV is positive or when the screening test is reactive and there is no available supplemental test that is approved for such use by FDA, the blood bank must notify transfusion recipients of previous collections of blood and blood components at increased risk of transmitting HIV infection, or the recipient's physician of record, of the need for recipient HIV testing and counseling. The blood bank must also notify the recipient's physician of record, or a legal representative or relative if the recipient is a minor, deceased, judged incompetent by a State Court, or if the recipient is competent but State Law permits a legal representative or relative to receive information on behalf of the recipient. Reasonable attempts must be made to perform the notification within 12 weeks after receiving the supplemental test evidence of HIV infection from VITALANT BLOOD SERVICES. (Blood Bank Service).

HCV Traceback ("Lookback")

Requirements are similar for notification for HCV with the exception that notification is not required for patients who are deceased.

A. Recipient Traceback ("Lookback") Notification is received from VITALANT BLOOD SERVICES when:
    - Subsequent to market withdrawal for one of the markers specified above now with a confirmatory test of positive.
    - Donor of a distributed product has an infection requiring traceback.
B. The Blood Bank Clinical Lab Scientist assigned at the time will look up the following and log in Transfusion Transmitted Infectious Disease Investigation Log:
    - Date
    - Donor Identification Number and Component
    - Patient Name
    - Patient Medical Record Number
    - Physician taking care of the patient
C. Quarantine in date blood and blood components as directed on bottom shelf in refrigerator if available. The Blood Bank Service will notify the Lab regarding the disposition of the quarantined blood whether it be destroyed or returned.

D. If confirmatory results are pending, the letter is filed under pending confirmation. If all testing is complete, go to step F.
E. If test is negative, no further action is required. If test is positive, continue to step F.
F. File screen and confirmation together under "Confirmed"
G. Send HIV/HCV Lookback Notification Form to the ordering physician requesting they notify the recipient and return a copy of the notification form to the lab within 12 weeks.~~ Reasonable attempts will be made to contact the recipient with 12 weeks. Document date/time for all attempts made to contact appropriate party~~.
H. When form is returned, note date responded on log.
I. Make a copy for our records and send original Lookback Notification form to Medical Records for patient's chart.
J. File form in "Returned Forms" area of binder.
K. Complete Traceback Recipient Status form with as much information as possible. This form needs to be returned within 60 days. Make a copy for our files, send original to Donor and Client Support Center. If VITALANT BLOOD SERVICES does not receive~~d~~ the form back within 60 days, they will send a second (and FINAL) notice for which a response is required in 30 days.

NOTE:

In the event the provider is unable to notify the patient, the lab will do so documenting their attempts on the lookback form ~~refuses or otherwise fails to notify recipient or is no longer at the facility, the lab will notify the patient. For non-HIV and non-HCV notification letters from VITALANT BLOOD SERVICES, refer the letter to the pathologist who will determine if notification is necessary~~.

REFERENCES:

Standards for Blood Banks and Transfusion Services 33rd Edition. April 2022
Code of Federal Regulations (CFR) Requirements for HIV/HCV Lookback Requirements

OWNER:
Chief Ancillary Officer

AUTHORS/REVIEWERS:

SUBJECT: Transfusion Transmitted Infectious Disease Notification	POLICY: LB#8610-138 Page 5 of 5
DEPARTMENT: Organizational	EFFECTIVE: 03/2020
REVISED~~: 02/2023~~:	

Laboratory Manager
Board Quality Committee

APPROVALS:
Policy & Procedure Team:
Medicine Committee:
Surgery Committee:
Performance Improvement/
Pharmacy & Therapeutics Committee
Medical Executive Committee:
The Board of Directors: