SONOMA VALLEY HOSPITAL
SONOMA VALLEY HEALTH CARE DISTRICT
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SVHCD QUALITY COMMITTEE MEETING
AGENDA
WEDNESDAY, January 27, 2016
5:00 p.m. Regular Session
(Closed Session will be held upon adjournment of the Regular Session

Location: Schantz Conference Room
Sonoma Valley Hospital – 347 Andrieux Street, Sonoma CA 95476

AGENDA ITEM	RECOMMENDATION	
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	*Hirsch*	
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.	*Hirsch*	
3. CONSENT CALENDAR • QC Minutes, 11.18.15 • No December 2015 Minutes	*Hirsch*	Action
4. PATIENT CARE SERVICES Q4 DASHBOARD	*Kobe*	Inform
5. POLICY & PROCEDURES • CNO Multiple October 2015 • HIM Multiple August 2015 • QS8610-106 Code Blue Management • PC8610-306 De-clotting Central Venous Devices • LAB Multiple October 2015 • SNF Multiple December 2015 • PHARMACY ❖ MM8610-102 Controlled Substance ❖ MM8610-156 Electrolyte Replacement ❖ MM8610-157 Drug Supply Chain	*Lovejoy*	Action
6. QUALITY REPORT JANUARY 2016	*Lovejoy*	Inform/ Action
7. REVIEW 2015 WORK PLAN AND PROPOSED 2016 WORK PLAN	*Lovejoy*	
8. CLOSING COMMENTS/ANNOUNCEMENTS	*Hirsch*	
9. ADJOURN	*Hirsch*	
10. UPON ADJOURNMENT OF REGULAR OPEN SESSION	*Hirsch*	
11. CLOSED SESSION:	*Dr. Sebastian*	Action

• Calif. Health & Safety Code § 32155 Medical Staff Credentialing & Peer Review Report • Board Quality Dashboard		
12. REPORT OF CLOSED SESSION	*Hirsch*	Inform/ Action
13. ADJOURN	*Hirsch*	

3.

CONSENT

+

SONOMA VALLEY HEALTH CARE DISTRICT
QUALITY COMMITTEE
REGULAR MEETING MINUTES
Wednesday, November 18, 2015
Schantz Conference Room

Committee Members Present	Committee Members Present cont.	Members Not Present	Admin Staff /Other
Jane Hirsch Carol Snyder Michael Mainardi Cathy Webber Ingrid Sheets Susan Idell H. Eisenstark Kelsey Woodward Brian Sebastian, M.D. Keith Chamberlin, MD, MBA		Joshua Rymer	Leslie Lovejoy Robbie Cohen, M.D. Michelle Donaldson Scott Perryman, M.D. Gigi Betta

AGENDA ITEM	DISCUSSION	ACTION
1. CALL TO ORDER/ANNOUNCEMENTS	*Hirsch*	
The meeting was called to order at 5:00pm		
2. PUBLIC COMMENT	*Hirsch*	
No public comment.	None	
3. CONSENT CALENDAR	*Hirsch*	Action
QC Minutes, 10.28.15		**MOTION** to approve Consent by Idell and 2nd by Mainardi. All in favor.
4. BARIATRIC SERVICE AT SONOMA VALLEY HOSPITAL	*Dr. Scott Perryman*	Inform
Dr. Scott Perryman gave an engaging presentation on Bariatric services available at SVH. Topics included the rise of obesity in America, the three Bariatric surgery procedures offered and the benefits of the Destination Care Model.		
5. POLICY & PROCEDURE There are no Policies or Procedures for this meeting.	*Lovejoy*	Action
6. QUALITY REPORT NOVEMBER 2015	*Lovejoy*	Inform/Action
Ms. Lovejoy reported on the Leapfrog Survey Report results and		

AGENDA ITEM	DISCUSSION	ACTION
gave a detailed report on areas of opportunity for improvement 2015-16. In the interest of time, Ms. Lovejoy gave an abbreviated Quality Report.		
7. CLOSING COMMENTS	*Hirsch*	
8. ADJOURN	*Hirsch*	
9. UPON ADJOURNMENT OF REGULAR OPEN SESSION	*Hirsch*	
10. CLOSED SESSION	*Sebastian*	Action
Calif. Health & Safety Code § 32155 Medical Staff Credentialing & Peer Review Report		
11. REPORT OF CLOSED SESSION	*Hirsch*	Inform/Action
There was no credentialing report.		
12. ADJOURN Meeting adjourned at 6:00pm	*Hirsch*	

4.

PATIENT CARE SERVICES DASHBOARD

Patient Care Services Dashboard 2015

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Medication Scanning Rate	2015				
	Q1	Q2	Q3	Q4	Goal
SNF	N/A	80.0%	76.7%	80.6%	90%
Acute	80.0%	81.0%	88.8%	83.1%	90%
ED	80.0%	87.0%	85.4%	82.4%	90%

Falls (Per 1000 days)	2015				
	Q1	Q2	Q3	Q4	50th %tile
SNF	0.0	1.1	2.2	1.6	
Acute	0.0	1.0	0.0	3.3	
TOTAL	0.0	1.1	1.0	2.5	2.32%

Hospital Acquired Pressure Ulcer Incidents (Per 1000 admissions)	2015				
	Q1	Q2	Q3	Q4	National
SNF	0.0	2.4	1.6	0.5	3.17
Acute	0.0	2.0	1.3	0.0	3.68

Nursing Turnover	2015 RNs/Quarter				
	Q1	Q2	Q3	Q4	Goal
SNF (n=15)	0	1	1	1	≤1
Acute (n=92)	0	0	0	2	≤3
Healing at Home (n=18)	N/A	N/A	1	2	≤1
Total Nursing Turnover	N/A	N/A	2	5	≤5

Professional RN Certification	2015				
	Certification		Higher Education		
*2015 Accomplishments	SVH	Goal	Undergrad (Bachelors)	Graduate (Masters)	PostGrad (PhD)
Emergency (CEN) (n=24)	0	1	14%		
ICU (CCRN) (n=17)	2	3	31%	6%	
The Birthplace (n=17)	1	2	62%	19%	
Med Surg (MSRN) (n=19)	1	1	42%	6%	
Surgery (AORN, ASPAN) (n=15)	3	4	66%		
SNF (Gerontology, Palliative care, Long-term care, Resident Assessment Coordinator) (n=15)	10	10	57%	7%	7%
Case Management (n=8)	2	3	63%		12%
Healing at Home (n=18)	2	3	50%	11%	

*2015: Received $25K from grateful patient; funded wound care certification for SNF RN; Funded attendance at Risk Conference; purchased Continuing Education modules for SVH Certified Nursing Assistants. Surgery RN received BSN

5.

POLICY AND PROCEDURE

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POLICY AND PROCEDURE
Approvals Signature Page

Review and Approval Requirements

The SVH departmental/organizational policies and/or procedures on the attached list have been reviewed and approved by the following organizational leaders for meeting all of the following criteria. All of these policies and procedures are:

- Consistent with the Mission, Vision and Values of the Sonoma Valley Health Care District
- Consistent with all Board Policy, Hospital Policy and Hospital Procedures
- Meet all applicable law, regulation, and related accreditation standards
- Consistent with prevailing standards of care
- Consistent with evidence-based practice

We recommend their acceptance by the Quality Committee and that the Quality Committee forward them to the Sonoma Valley Health Care District Board with a recommendation to approve.

Organizational: Multiple Policies October 2015 List	
APPROVED BY:	DATE: **10-30-15**
Director's/Manager's Signature	Printed Name **Mark Kobe, RN MPA**

Douglas S Campbell, MD
Chair Medicine Committee

Date

Michael Brown, MD
Chair Surgery Committee

Date

Keith J. Chamberlin, MD MBA
President of Medical Staff

Date

Kelly Mather
Chief Executive Officer

Date

Sharon Nevins
Chair, Board of Directors

Date

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Policy Submission Summary Sheet

Title of Document: **Organizational Policies**

New Document or Revision written by: **Multiple Policies**

Date of Document: **10-28-15**

Type:	**Regulatory:**
X Revision **X New Policy**	**X CIHQ** ❑ **CDPH** **X CMS** ❑ **Other:**
Organizational: **X Clinical** **X Non-Clinical**	❑ **Departmental** ❑ **Interdepartmental** (list departments effected)

Please briefly state changes to existing document/form or overview of new document/form here:
(include reason for change(s) or new document/form)

All of the policy Chapter headings and numbers below have reviewed and/or revised to comply with the CIHQ Standards of Care.

LB8610-112 Adverse Tissue Reactions-Revised to become Surgical Services Department policy LB7420-112

LB8610-209 Chromosome Studies- Reviewed, no changes

MR8610-160 Clinical Documentation in the Patient Medical Record- Revised; telephone order to be signed within 30 days revised from 48 hours; added Reference

QS8610-204 Critical Value Reporting Policy- Reviewed; no changes

OI8610-215 Humidity & Temperature Monitoring in Surgery/Birthplace Suites- revised; to Organizational policies from Engineering Department, humidity range 30%-60% per CIHQ guidelines.

LB8610-220 Line Draws- **NEW** policy to outline procedure for line draws by nursing staff

LB8610-205 Nitrazine Testing for Amniotic Fluid- Reviewed, no changes

LB8610-211 Nurse Blood Administration Part 1 Patient Identification for Collection- Reviewed, no changes

LB8610-212 Nurse Blood Administration Part 2 Transfusion Patient Preparation- Revised; added patient given educational pamphlets regarding blood transfusions

LB8610-214 Nurse Blood Administration Part 4 Administration Guidelines- Revised; added a note regarding a transfusion must be started within 30 minutes of the unit leaving the Blood Bank

LB8610-215 Nurse Blood Administration Part 5 Post Transfusion- Reviewed, no changes

LB8610-216 Nurse Blood Administration Part 6 Massive Transfusion- Reviewed, no changes

LB8610-207 Pathology Specimen Handling- Reviewed, no changes

LB8610-208 Placenta Disposition- Reviewed, no changes

LB8610-109 Point of Care Testing (POCT)- Reviewed; added employee training/competencies kept in HR files

LB8610-113 Record Thermometer Documentation, Failure & Backup- Reviewed, no changes

PC8610-350 Urinary Catheter Insertion, Maintenance & Removal- Revised; replaces the Infection Control document IC8610-139. It now is a nursing and Infection Control document that provides clear guidance on criteria for insertion, removal and need for daily necessity assessment and documentation. The EMR was updated to correspond to the new policy and procedure.

QS8610-206 Verbal and Telephone Order Policy- Revised; electronic verbal and telephone orders must be authenticated by the provider within 30 days, revised from 48 hours; added Reference

Reviewed by:	Date	Approved (Y/N)	Comment
Policy & Procedure Team	10/20/2015	Yes	
Surgery Committee	11/04/2015	cancelled	
Surgery Committee	11/11/2015	Yes	
Medicine Committee	11/12/2015	Yes	
P.I. or P. T. Committee	n/a		
Medical Executive Committee	11/19/2015	Yes	
Board Quality	1/27/2016		
Board of Directors	2/04/2016		

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Multi-Oct

SUBJECT: Line Draws-**New Policy**	POLICY # LB8610-220
	PAGE 1 OF 2
DEPARTMENT: Organizational	EFFECTIVE: 10/15
APPROVED BY: CNO	REVIEW/REVISED:

Policy:
All line draws are performed by nursing staff.

Procedure:
Outpatient:
- The patient must have a valid physician order.
- The laboratory staff will notify the appropriate nursing floor.
- The patient will be transported to the appropriate nursing floor.
- An RN will perform the line draw.
- Identification of the patient & labeling of tubes at the bedside must be done according to lab policy.
- The nursing floor will send the tubes of blood to the laboratory for processing.

Inpatient or Emergency Department**:**
- RN will draw from the line.
- RN or laboratory staff will transfer to appropriate tubes.
- Tubes must be labeled according to lab policy.

Withdrawal of Specimen
Procedure:
- Follow standard nursing procedures for accessing the line
- Lippincott can be used as a resource if necessary. Use the following link. http://procedures.lww.com/lnp/procedureselect.do
- Discard 6 ml waste before withdrawing the specimen for testing.
- Label the specimen tubes using lab policy.

Order of Draw of Fill
The Order of Draw is important in order to avoid contamination of a specimen with an additive from another tube. Following is the Order of Draw used at Sonoma Valley Hospital Lab:
- Blood Cultures
- Lt Yellow ACD or SPS tubes (sterile)
- Red
- Gold
- Blue
- Lt Green
- Dk Green
- Lavender
- Pink
- Grey

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SUBJECT: Line Draws-**New Policy**	POLICY # LB8610-220
	PAGE 2 OF 2
DEPARTMENT: Organizational	EFFECTIVE: 10/15
APPROVED BY: CNO	REVIEW/REVISED:

References:

Advanced Medical Assistant Custom Web Design, Phlebotomy Order of Draw, www.phlebotomypages.com/new_draw.htm, 2013.

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POLICY AND PROCEDURE
Approvals Signature Page

Review and Approval Requirements

The SVH departmental/organizational policies and/or procedures on the attached list have been reviewed and approved by the following organizational leaders for meeting all of the following criteria. All of these policies and procedures are:

- Consistent with the Mission, Vision and Values of the Sonoma Valley Health Care District
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- Consistent with evidence-based practice

We recommend their acceptance by the Quality Committee and that the Quality Committee forward them to the Sonoma Valley Health Care District Board with a recommendation to approve.

Department: Health Information Management	
APPROVED BY:	DATE: **8-20-15**
Director's/Manager's Signature *Rosemary Pryszmant*	Printed Name **Rosemary Pryszmant, RHIA CCS**

Kenneth Jensen
Chief Financial Officer

Date

Brian Sebastian, MD
Chair, P.I. & P.T. Committee

Date

Keith J. Chamberlin, MD MBA
President of Medical Staff

Date

Kelly Mather
Chief Executive Officer

Date

Sharon Nevins
Chair, Board of Directors

Date

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Policy Submission Summary Sheet

Title of Document: **Health Information Management Department**

New Document or Revision written by: **Rosemary Pryszmant, RHIA, CCS**

Date of Document: **08-20-2015**

Type:	**Regulatory:**
X Revision ❑ New Policy	X CIHQ X CDPH X CMS ❑ Other:
Organizational:	❑ **Departmental** ❑ **Interdepartmental** (list departments effected)
❑ Clinical X Non-Clinical	

Please briefly state changes to existing document/form or overview of new document/form here:
(include reason for change(s) or new document/form)

8700-102	**HIM Scope of Services-** Reviewed; no changes
8700-101	**Medical Record Department Code of Ethics-**Reviewed; no changes
8700-135	**Medical Record Department-Goals and Objectives-** Reviewed; no changes
8700-103	**Abstracting-** Reviewed; no changes
8700-104	**Access to Medical Records (Health Information), Patient's-** Reviewed; no changes
8700-105	**Accounting of Disclosures –**reviewed; updated references
8700-106	**Adding a Medical Record Number for an Advance Directive-** Reviewed; updated depart titles
8700-107	**Advance Directive-**reviewed; updated from paper system to scanning/electronic process
8700-108	**Amendment of Medical Record Information-** Reviewed; no changes
8700-109	**Analysis of Special Procedures -** Reviewed; no changes
8700-110	**Assign a New Physician Number to Paragon-** Reviewed; no changes
8700-111	**Assisting Physicians with Record Completion-**Reviewed; updated
8700-112	**Birth Certificate Worksheet-** Reviewed; updated
8700-113	**Chart Thinning-** Reviewed; no changes
8700-114	**Coding Code of Ethics-** Reviewed; updated ICD-10
8700-115	**Coding Emergency Department Records-** Reviewed; updated ICD-10
8700-116	**Coding Guidelines-** Reviewed; updated ICD-10
8700-117	**Coder Telecommuting-** Reviewed; no changes
8700-118	**Committee/Review Charts-** Reviewed; no changes
8700-119	**Complications and Infections-** Reviewed; no changes
8700-120	**Computer Downtime -** Reviewed; no changes
8700-121	**Confidentiality of Patient Information-** Reviewed; no changes
8700-122	**Contracted Services-** Reviewed; updated transcription company name Mediscribes
8700-123	**Correcting Duplicate Numbers-** Reviewed; no changes
8700-124	**Creating a Duplicate Medical Record-** Reviewed; no changes
8700-125	**Customer Courtesy and Support-** Reviewed; updated
8700-126	**Discharge Data Reporting-** Reviewed; no changes
8700-127	**Discharge Reconciliation-** Reviewed; no changes
8700-128	**Disclosure of HIV Test Results-** Reviewed; no changes
8700-129	**Disclosure of Health Information Relating to Alcohol and Drug Abuse-** Reviewed; no changes
8700-130	**Disclosure of Medical Information Pertaining to patients with Mental Disorders or Developmental Disabilities-** Reviewed; no changes
8700-132	**Emergency Room Record Processing-retire;** no paper process
8700-133	**Facsimile Transmission of Patient Information-**Reviewed; updated equipment used
8700-134	**Forms Committee-**Reviewed; no changes
8700-136	**Handling Medical Record Completion By Mail-** Reviewed; no changes
8700-137	**History and Physical Monitoring for Timeliness-**Reviewed; updated to CIHQ standard
8700-138	**HIV Test Result Filing-** Reviewed; no changes

8700-139	**Hospital Closure of Ownership Change-** Reviewed; no changes
8700-140	**Incomplete Medical Records-**Reviewed; update reports manager deficiency system
8700-141	**Long Term Physician Illness-** Reviewed; no changes
8700-142	**Maintenance of Fetal Monitoring Tracings-** Reviewed; no changes
8700-143	**Medical Record Availability-**Reviewed; updated to CIHQ standard
8700-144	**Medical Record Content-** Reviewed; no changes
8700-146	**Medical Records Department Storage Area-**Reviewed; updated "basement" as location
8700-147	**Medical Record Indices-**Reviewed; updated reports
8700-148	**Medical Record Photocopy Fee-**Reviewed; updated fees
8700-149	**Medical Record Retrieval-** Reviewed; no changes
8700-150	**Missing Medical Records-** Reviewed; no changes
8700-151	**Moving Records to Off Site Storage & Purging Medical Records (Fort Docs)-**Reviewed; contact updated
8700-152	**New Medical Staff Members, Orientation for-**Reviewed; updated to CIHQ standard
8700-153	**Paragon HIS Chart Locator-**Reviewed; updated paper records reference
8700-154	**Physician Documentation Refusal-**Reviewed; updated to CIHQ standard
8700-155	**Purging Medical Records-** Reviewed; updated remove old tracking process
8700-156	**Quality Improvement Plan, HIM Department-**Reviewed; update credentials, remove old reference dates
8700-157	**Records Retention-** Reviewed; no changes
8700-158	**Re-disclosure of Health Information-** Reviewed; no changes
8700-159	**Release of Information: Adoption-** Reviewed; no changes
8700-160	**Release of Information: Lab/Pathology-** Reviewed; no changes
8700-161	**Release of Information: Patient Requests-** Reviewed; updated hours, fees; added PDH custodianship
8700-162	**Release of Information: Pursuant of Subpoena-**Reviewed; updated Bactes copying services
8700-163	**Release of Information: Telephone Requests-** Reviewed; no changes
8700-165	**Release of Patient Health Information-** Reviewed; no changes
8700-166	**Release of Information to Health Care Providers-**Reviewed; removed old tracking process
8700-167	**Release of Information for Minors (not Emancipated)-** Reviewed; no changes
8700-168	**Reporting Delinquent Records and Physician Suspension Days-** Reviewed; no changes
8700-169	**Reprinting a Registration Record (Facesheet)-** Reviewed; no changes
8700-170	**Request by Patient for Radiology Reports/Films, Burning CD/DVDs-**Reviewed; updated dept hours
8700-171	**Retirement of Medical Records-** Reviewed; no changes
8700-172	**Security of Employees Medical Records-** Reviewed; no changes
8700-173	**Security of Health and Hospital Information-**Reviewed; updated personnel to maintain keys & location
8700-174	**Security of Medical Records in Litigation-**Reviewed; updated to current standard
8700-175	**Shredding of Patient Health Information-**Reviewed; updated location
8700-176	**Social Networks-** Reviewed; no changes
8700-178	**Subpoena Request, Processing of-**Reviewed; updated
8700-180	**Timely Completion, Medical Record Review-**Reviewed; updated CIHQ standard
8700-181	**Unidentifiable Patient Health Information-** Reviewed; no changes
8700-182	**Unit Medical Record-** Reviewed; no changes
8700-183	**Unit Medical Record and Storage Locations-** Reviewed; updated
8700-184	**Work Flow for Request of Medical Records-**Reviewed; updated old tracking system

Reviewed by:	Date	Approved (Y/N)	Comment
Policy & Procedure Team	n/a		
Surgery Committee	n/a		
Medicine Committee	n/a		
P.I. Committee	**08/27/2015**	No	No Quorum
P.I. Committee	**10/22/2015**	Yes	
Medical Executive Committee	**11/19/2015**	Yes	
Board Quality	**1/27/2016**		
Board of Directors	**2/04/2016**		

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SONOMA VALLEY HEALTH CARE DISTRICT
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POLICY AND PROCEDURE
Approvals Signature Page

Review and Approval Requirements

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We recommend their acceptance by the Quality Committee and that the Quality Committee forward them to the Sonoma Valley Health Care District Board with a recommendation to approve.

Organizational: QS8610-106 Code Blue: Code Management for Patient Emergency	
APPROVED BY:	DATE: **11-11-15**
Director's/Manager's Signature	Printed Name **Mark Kobe, RN MPA**

Mark Kobe, RN MPA
Chief Nursing Officer

11-11-15
Date

Douglas S Campbell, MD
Chair Medicine Committee

11/12/15
Date

Keith J. Chamberlin, MD MBA
President of Medical Staff

Date

Kelly Mather
Chief Executive Officer

Date

Sharon Nevins
Chair, Board of Directors

Date

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Policy Submission Summary Sheet

Title of Document: **Organizational Policies**

New Document or Revision written by: **Mark Kobe, RN MPA**

Date of Document: **11-11-15**

Type:	**Regulatory:**
X **Revision** ❑ **New Policy**	X **CIHQ** X **CDPH** X **CMS** ❑ **Other:**
Organizational:	❑ **Departmental** ❑ **Interdepartmental** (list departments effected)
X **Clinical** ❑ **Non-Clinical**	

Please briefly state changes to existing document/form or overview of new document/form here:
(include reason for change(s) or new document/form)

QS8610-106 Code Blue: Code Management for Patient Emergency- Revised; Policy was amended/revised to reflect upgrade in 3rd Floor Nurse Call System. See Procedures, Section E. This reflects addition of Stat RT Code button which summons Respiratory Therapy personnel only versus entire Code Blue Team

Reviewed by:	Date	Approved (Y/N)	Comment
Policy & Procedure Team	n/a		
Surgery Committee	n/a		
Medicine Committee	**11/12/2015**	Yes	Mark Kobe to present
P.I. or P. T. Committee	n/a		
Medical Executive Committee	**11/19/2015**	Yes	Mark Kobe to present
Board Quality	**1/27/2016**		
Board of Directors	**2/04/2016**		

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POLICY AND PROCEDURE
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Review and Approval Requirements

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We recommend their acceptance by the Quality Committee and that the Quality Committee forward them to the Sonoma Valley Health Care District Board with a recommendation to approve.

Organizational: PC8610-306 De-Clotting Central Venous Devices with Thrombolytic-New policy	
APPROVED BY:	DATE: **11-04-15**
Director's/Manager's Signature	Printed Name **Mark Kobe, RN MPA**

Mark Kobe, RN MPA
Chief Nursing Officer — 11-5-15 Date

Douglas S Campbell, MD
Chair Medicine Committee — Date

Keith J. Chamberlin, MD MBA
President of Medical Staff — Date

Kelly Mather
Chief Executive Officer — Date

Sharon Nevins
Chair, Board of Directors — Date

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Policy Submission Summary Sheet

Title of Document: **Organizational Policies**

New Document or Revision written by: **Multiple Policies**

Date of Document: **10-28-15**

Type:	**Regulatory:**
❑ **Revision** X **New Policy**	X **CIHQ** X **CDPH** X **CMS** ❑ **Other:**
Organizational:	❑ **Departmental** ❑ **Interdepartmental** (list departments effected)
X **Clinical** ❑ **Non-Clinical**	

Please briefly state changes to existing document/form or overview of new document/form here:
(include reason for change(s) or new document/form)

PC8610-306 De-Clotting Central Venous Access Devices (CVAD) with Thrombolytic- New policy;
The utilization of percutaneously inserted central lines (PICC) by specially trained nurses is a common occurrence. Occasionally, these lines due 'clot off' and need to be 'de-clotted' so that the patient doesn't have to experience placement of a new PICC line. De-clotting of PICC lines and any Central Venous Access Devices (CVAD) is within the scope of practice for bedside RNs. This policy describes the process and steps for de-clotting of CVADs.

Reviewed by:	Date	Approved (Y/N)	Comment
Policy & Procedure Team	n/a		
Surgery Committee	n/a		
Medicine Committee	**11/12/2015**	Yes	Mark Kobe to present
P.I. or P. T. Committee	n/a		
Medical Executive Committee	**11/19/2015**	Yes	Mark Kobe to present
Board Quality	**1/27/2016**		
Board of Directors	**2/04/2016**		

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De Clott

SUBJECT: De-Clotting Central Venous Access Devices (CVAD) with Thrombolytic-NEW	POLICY #PC8610-306 PAGE 1 OF 1
DEPARTMENT: Organizational	EFFECTIVE: 11/15
APPROVED BY: CNO	REVIEW/REVISED:

Purpose:
To define the process in which appropriate thrombolytic is reconstituted, dosed and administered to de-clot CVADs. Thrombolytics are indicated for the restoration of function to CVADs as assessed by the ability to withdraw blood.

Policy:
A physicians order is required to administer a thrombolytic in a clotted CVAD. SVH pharmacy may reconstitute an appropriate concentration and dosage of thrombolytic for the nurse declotting the CVAD or Cathflo is available from SVH formulary in a single-use, 2mg vial. Certain causes of catheter dysfunction should be considered before treatment with thrombolytic (i.e., catheter malposition, mechanical failure, constriction by a suture, etc.).

Procedure:
NOTE: If the SVH pharmacy is reconstituting an appropriate concentration and dosing of thrombolytic for the RN, then you may skip steps 1-4.

1. After washing hands using aseptic technique, reconstitute Cathflo to a final concentrations of 2 mg/mL
2. Aseptically withdraw 2.2 mL of Sterile Water for injection. DO NOT USE Bacteriostatic Water for Injection.
3. **Inject** the 2.2 mL of Sterile Water for injection into the Cathflo vial, directing the diluents stream into the powder. Slight foaming is not unusual; let the vial stand undisturbed to allow large bubbles to dissipate
4. **Mix** by gently swirling until the contents are completely dissolved. Complete dissolution should occur within 3 minutes. DO NOT SHAKE.
5. **Inspect** the product prior to administration for foreign matter and discoloration.
6. **Withdraw** 2 mL of reconstituted solution from the vial
7. **Scrub** the hub of the CVAD for 14 to 30 seconds.
8. **Instill** the dose of thrombolytic or Cathflo into the occluded catheter using an appropriately sized syringe
9. After **30 minutes** of **dwell time**, assess the catheter function by attempting to aspirate blood. If the catheter is functional, go to step11; if not functional, go to step 10.
10. **Assess** catheter function after a total of **120 minutes** of dwell time by attempting to aspirate blood. If catheter if functional, go to step 11. If catheter is still occluded, a second dose of equal amount may be instilled. Repeat steps 1-9.
11. If catheter function has been restored, **aspirate** 3 mL to 5 mL of blood to remove thrombolytic and residual clot. Then gently irrigate the catheter with 0.9% Sodium Chloride. Any unused solution should be discarded.

Reference:
2015 Genentech USA, Inc. www.cathflo.com/dosing/index.jsp

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POLICY AND PROCEDURE
Approvals Signature Page

Review and Approval Requirements

The SVH departmental/organizational policies and/or procedures on the attached list have been reviewed and approved by the following organizational leaders for meeting all of the following criteria. All of these policies and procedures are:

- Consistent with the Mission, Vision and Values of the Sonoma Valley Health Care District
- Consistent with all Board Policy, Hospital Policy and Hospital Procedures
- Meet all applicable law, regulation, and related accreditation standards
- Consistent with prevailing standards of care
- Consistent with evidence-based practice

We recommend their acceptance by the Quality Committee and that the Quality Committee forward them to the Sonoma Valley Health Care District Board with a recommendation to approve.

Department: Laboratory Department	
APPROVED BY: **Laboratory Manager**	DATE: **10-19-15**
Director's/Manager's Signature	Printed Name **Lois Valenzuela**

Brian Sebastian, MD
Chair, P.I. & P.T. Committees — Date

Leslie Lovejoy, RN PhD
Chief Quality Officer, CQO — Date

Keith J. Chamberlin, MD MBA
President of Medical Staff — Date

Kelly Mather
Chief Executive Officer — Date

Sharon Nevins
Chair, Board of Directors — Date

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Policy Submission Summary Sheet

Title of Document: **Laboratory Department Policies**

New Document or Revision written by: **Lois Valenzuela**

Date of Document: **10-19-15**

Type:	**Regulatory:**
X Revision **❑ New Policy**	**X CIHQ** **X CDPH** **X CMS** **❑ Other:**
Organizational: **X Clinical** **X Non-Clinical**	**X Departmental** **❑ Interdepartmental** (list departments effected)

Please briefly state changes to existing document/form or overview of new document/form here:
(include reason for change(s) or new document/form)

7500-02	**Amended Reports-** Reviewed; no changes
7500-04	**Approved Panel List-** Reviewed; no changes
7500-06	**Approved Reference Labs-** Reviewed; no changes
7500-08	**Competency Assessment -** Reviewed; no changes
7500-10	**Computer Downtime -** Reviewed; no changes
7500-16	**Discontinue Orders -** Reviewed; no changes
7500-17	**Emergency Release of Blood Products-** Reviewed; no changes
7500-18	**Fainting Patient-** Reviewed; no changes
7500-20	**Fax Log Retrieval-** Reviewed; no changes
7500-22	**House Call-** Reviewed; no changes
7500-24	**Infant Heel Stick-** Reviewed; no changes
7500-26	**Laboratory Fax Policy -** Reviewed; no changes
7500-28	**Laboratory Specific Disaster Plan -** Reviewed; no changes
7500-30	**Manual Entry Review -** Reviewed; no changes
7500-32	**Method Validation of Analytical Procedures -** Reviewed; no changes
7500-34	**Newborn Screening 14 Day Review-** Reviewed; no changes
7500-38	**Out Patient and Pre-Op Urine Collection -** Reviewed; no changes
7500-40	**Outpatient Service-** Reviewed; no changes
7500-42	**Personnel Responsibility and Accountability -** Reviewed; no changes
7500-46	**Policy or Procedure Changes-** Reviewed; no changes
7500-48	**Pre-Operative Testing-** Reviewed; no changes
7500-50	**Priority Lab Work-** Reviewed; no changes
7500-52	**Proficiency Testing -** Reviewed; no changes
7500-54	**PTO/Time Off Requests -** Reviewed; no changes
7500-56	**Reagent and Supply Handling—Dating and Visual Inspection -** Reviewed; no changes
7500-58	**Reflex Testing-**Revised; updated Rapid Strep A billed to insurance
7500-60	**Release of Information-** Reviewed; no changes
7500-62	**Requests for Laboratory Tests-** Reviewed; no changes
7500-64	**Results Reporting-** Reviewed; no changes
7500-66	**Retention of Clinical Laboratory Records -** Reviewed; no changes
7500-68	**Retention of Clinical Laboratory Specimens -** Reviewed; no changes
7500-70	**Retention of Pathology Records -** Reviewed; no changes
7500-72	**Retention of Records—Cease of Operation -** Reviewed; no changes
7500-74	**Review of Patient Results and Quality Control-** Reviewed; no changes
7500-82	**Specimen Collection 24 Hour Urine -** Reviewed; no changes
7500-84	**Specimen Collection and Processing-** Reviewed; no changes

7500-86	**Specimen Rejection-** Reviewed; no changes
7500-88	**Specimens Collected at Outside Sites-** Reviewed; no changes
7500-90	**Staffing and Service Availability -** Reviewed; no changes
7500-91	**Synovial Fluid Exam-** Reviewed; no changes
7500-94	**Temperature Control in the Laboratory -** Reviewed; no changes
7500-96	**Temperature Daily Checks -** Reviewed; no changes
7500-98	**Venipuncture-** Reviewed; no changes

Reviewed by:	Date	Approved (Y/N)	Comment
Policy & Procedure Team	n/a		
Surgery Committee	n/a		
Medicine Committee	n/a		
P.I. or P. T. Committee	**10/22/2015**	Yes	
Medical Executive Committee	**11/19/2015**	Yes	
Board Quality	**1/27/2016**		
Board of Directors	**2/04/2016**		

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POLICY AND PROCEDURE
Approvals Signature Page

Review and Approval Requirements

The SVH departmental/organizational policies and/or procedures on the attached list have been reviewed and approved by the following organizational leaders for meeting all of the following criteria. All of these policies and procedures are:

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- Consistent with prevailing standards of care
- Consistent with evidence-based practice

We recommend their acceptance by the Quality Committee and that the Quality Committee forward them to the Sonoma Valley Health Care District Board with a recommendation to approve.

Departmental: Skilled Nursing Facility Department Policies	
APPROVED BY: **Director of Nursing SNF**	DATE: **12-28-15**
Director's/Manager's Signature ME Evans	Printed Name **Melissa Evans, RN**

Mark Kobe, RN MPA
SNF Administrator

Date

Rolf Olness, MD
Medical Director SNF

Date

Douglas S Campbell, MD
Chair Medicine Committee

Date

Keith J. Chamberlin, MD MBA
President of Medical Staff

Date

Kelly Mather
Chief Executive Officer

Date

Sharon Nevins
Chair, Board of Directors

Date

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Policy Submission Summary Sheet

Title of Document: **SNF Department Policies**

New Document or Revision written by: **Melissa Evans, RN**

Date of Document: **12-28-15**

Type:	**Regulatory:**
X Revision X New Policy	X CIHQ X CDPH X CMS ❑ Other:
Organizational:	X **Departmental**
X Clinical ❑ Non-Clinical	❑ **Interdepartmental** (list departments effected)

Please briefly state changes to existing document/form or overview of new document/form here:

All Department policies below were reviewed and to current standard with CMS, OBRA. Title 22, CFR, or CIHQ Standard of Care. SNF specific policies included to satisfy Survey recommendations and to meet regulatory requirements.

6580-102	Activity Evaluation-OBRA 485.15
6580-104	Administering Medication through an Enteral Tube, CMS F332, F333, F 425
6580-106	Antipsychotic Medication Use OBRA
6580-108	Behavioral Assessment, Intervention and Monitoring OBRA 483.13, 483.20. 483.25
6580-110	Bladder Training and Toilet Plans for Urinary Incontinence MDS (CAAs) Section H
6580-112	Care Planning-Interdisciplinary Team OBRA 483.20
6580-114	Charting and Documentation OBRA 483.10, 483.60, 483.75
6580-116	Contact Isolation Precautions of Rehab Patient in SNF
6580-118	Delirium - Clinical Protocol MDS (CA As) Section C
6580-120	Dementia – Clinical Protocol MDS (CA As) Section I
6580-122	Dental Services OBRA 483.20
6580-124	Falls Management in SNF CIHQ, FEMA
6580-126	Hospice Care Room (HCR) Criteria for Case Managers at SVH
6580-128	MDS Completion and Submission Timeframes OBRA 483.20
6580-130	MDS Electronic Transmission OBRA 483.20
6580-132	MDS Error Correction OBRA 483.20
6580-134	Medical Prevention and Screening - Clinical Protocol MDS CAAs Section B
6580-136	Pantry - Food Brought in by Family/Visitors OBRA 483.35
6580-138	Resident Assessment Instrument OBRA 483.20
6580-140	Resident Meals, Assisting with "In-Room" OBRA 483.20
6580-142	Resident Nutrition Services OBRA 483.20
6580-144	Transfer or Discharge Notice OBRA 483.12
6580-146	Urinary Continence and Incontinence – Assessment and Management
6580-148	Wandering Unsafe Resident OBRA Regulatory
6580-150	Weighing and Measuring the Resident OBRA Regulatory

Reviewed by:	Date	Approved (Y/N)	Comment
Surgery Committee	n/a		
Medicine Committee	01/14/2016	yes	
P.I. or P. T. Committee	n/a		
Medical Executive Committee	01/21/2016	Yes	
Board Quality	01/27/2016		
Board of Directors	02/04/2016		

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POLICY AND PROCEDURE
Approvals Signature Page

Review and Approval Requirements

The SVH departmental/organizational policies and/or procedures on the attached list have been reviewed and approved by the following organizational leaders for meeting all of the following criteria. All of these policies and procedures are:

- Consistent with the Mission, Vision and Values of the Sonoma Valley Health Care District
- Consistent with all Board Policy, Hospital Policy and Hospital Procedures
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- Consistent with prevailing standards of care
- Consistent with evidence-based practice

We recommend their acceptance by the Quality Committee and that the Quality Committee forward them to the Sonoma Valley Health Care District Board with a recommendation to approve.

Organizational: Medical Management Policies MM8610-102 Controlled Substance Management MM8610-156 Electrolyte Replacement Protocol, MM8610-157 Drug Supply Chain Security- NEW	
APPROVED BY: **Director of Pharmacy**	DATE: **12-01-15**
Director's/Manager's Signature	Printed Name **Chris Kutza**

Brian Sebastian, MD
Chair, P.I. & P.T. Committees

Date

Leslie Lovejoy, RN PhD
Chief Quality Officer, CQO

Date

Keith J. Chamberlin, MD MBA
President of Medical Staff

Date

Kelly Mather
Chief Executive Officer

Date

Sharon Nevins
Chair, Board of Directors

Date

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Policy Submission Summary Sheet

Title of Document: **Organizational Policy**

New Document or Revision written by: Chris Kutza

Date of Document: **12-01-15**

Type:	**Regulatory:**
X **Revision** ❑ **New Policy**	X **CIHQ** X **CDPH** X **CMS** ❑ **Other:**
Organizational:	❑ **Departmental** ❑ **Interdepartmental** (list departments effected)
X **Clinical** ❑ **Non-Clinical**	

Please briefly state changes to existing document/form or overview of new document/form here:
(include reason for change(s) or new document/form)

MM8610-102 Controlled Substance Management- Revised; added specifics regarding how to waste controlled substances in order to make it irretrievable and/or unusable.

MM8610-156 Electrolyte Replacement Protocol-Revised; reduced the frequency of lab draws

MM8610-157 Drug Supply Chain Security- New Policy; required to describe processes to comply with FDA regulation about drug supply chain security to minimize the risk of counterfeit drugs being distributed.

Reviewed by:	Date	Approved (Y/N)	Comment
Policy & Procedure Team	n/a		
Surgery Committee	n/a		
Medicine Committee	n/a		
P.I. or P. T. Committee	12/03/2015	Yes	
Medical Executive Committee	1/21/2016	YES	
Board Quality	1/27/2016		
Board of Directors	2/04/2016		

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SUBJECT: Drug Supply Chain Security	POLICY #MM8610-157
	PAGE 1 OF 9
DEPARTMENT: Organizational	EFFECTIVE: 10/2015
APPROVED BY: Director of Pharmacy	REIVEW/REVISED:

Purpose:
To establish procedures in compliance with federal regulations defined in Title II of the Drug Quality and Security Act (DQSA), Drug Supply Chain Security that protect consumers by improving detection and removal of potentially dangerous, adulterated and/or counterfeit products from the pharmaceutical distribution supply chain.

Background:
The Drug Quality and Security Act (DQSA) was signed into law in November 2013. *Title II of the act, The Drug Supply Chain Security Act* (DSCSA) established new definitions and requirements related to product tracing and outlines steps to building an electronic system that 10 years after enactment will identify and trace prescription drugs distribution in the United States. Many milestones will be implemented until DSCSA completion in 2023. Initial milestones are implemented for enforcement in 2015. This policy reflects the first phase.
The DSCSA replaces pedigree requirements of the *Prescription Drug Marketing Act* (PDMA) and preempts state requirements unless state requirements are more stringent.
The DSCSA requirements apply to transactions or changes in ownership of finished dosage forms performed by authorized trading partners including dispensers (pharmacies).

Definitions:

- **Trading partner**: A manufacturer, repackager, wholesale distributor, dispenser or third-party logistics provider.
- **Dispenser**: A retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor.
- **Third-party logistics provider**: An entity that provides or coordinates warehousing or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product.
- **Product:** A prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution); does not include blood or blood components intended for transfusion, radioactive drugs or radioactive biological products, imaging drugs, intravenous products, medical gas, homeopathic drugs, or a drugs compounded in compliance with section 503A or 503B.
- **Transaction:** The transfer of product between persons in which a change of ownership occurs. *Exemptions*: The term transaction does not include the distribution of; sample medications, blood and blood component products, IV fluids, dialysis solutions, medical gases, etc. See Attachment A: Exceptions to the DSCSA Tracing Requirements

- **Transaction History (TH)**: A statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.
- **Transaction Information (TI)**: TI includes the:
  - Proprietary or established name or names of the product
  - Strength and dosage form
  - National Drug Code number
  - Container size and the number of containers
  - Lot number
  - Date of the transaction
  - Date of the shipment, if more than 24 hours after the date of the transaction
  - Business name and address of the person from whom ownership is being transferred
  - Business name and address of the person to whom ownership is being transferred.
- **Transaction Statement(TS):** A statement or attestation, in paper or electronic form, that the entity transferring ownership:
  - Is authorized as required under the Drug Supply Chain Security Act;
  - Received the product from a person that is authorized;
  - Received transaction information and a transaction statement from the prior owner of the product;
  - Did not knowingly ship a suspect or illegitimate product
- **Suspect product:** A product for which there is reason to believe that such product is:
  - Potentially counterfeit, diverted, or stolen;
  - Potentially intentionally adulterated
  - Potentially the subject of a fraudulent transaction; or
  - Appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

Policy:
It is the policy of Sonoma Valley Hospital to maintain awareness about suspicious activity or potential threats to the drug supply chain, and to devote attention and effort to detect suspect product.

- Obtain pharmaceuticals only from authorized trading partners as defined by the Food Drug and Cosmetic Act
- Trace, quarantine, investigate, retain samples, clear, notify others and dispose of suspect or illegitimate products
- Accept ownership of product only if the prior owner provides the transaction history (TH), transaction information (TI), and transaction statement (TS)

- Provide subsequent owners with the TH/TI/TS unless the transaction is exempt or the sale is from dispenser to dispenser to fill a specific patient need
- Retain records of TH/TI/TS for no less than **6 years** after the transaction
- Respond to request for TH/TI/TS due to a recall or investigation of suspect or illegitimate product from the Secretary of Health and Human Services or other appropriate Federal or State official within **2 business days**
- Return a product to the trading partner where the product was obtained without providing tracing information

Procedure:
CONFIRM AUTHORIZED TRADING PARTNERS

- Pharmaceuticals are only obtained from authorized trading partners.
- Trading partners (manufacturers, repackagers, wholesale distributors, dispensers, and third-party logistics providers) are confirmed to be authorized as defined by the Food Drug and Cosmetic Act.
    - Manufacturer's and repackagers are confirmed as authorized trading partners using the FDA's drug establishment registration database
    - Wholesale distributors, third-party logistic providers and dispensers, are validated with the state authority to confirm licensure.

IDENTIFICATION OF SUSPECT PRODUCT
Characteristics that might increase the likelihood that a product is a suspect or illegitimate product are listed in Attachment B: Characteristics of Suspect or Illegitimate

Strategies employed to identify suspect product include, but are not limited to:

- Avoid unsolicited offers and offers for product for sale at a very low price or one that is "too good to be true."
- Examine the package and the transport container (case or tote) for signs that it has been compromised (e.g., opened, broken seal, damaged, repaired, or altered).
    - Identify any unexplained changes since it was last received.
    - Identify if product inserts are missing or do not correspond to the product.
    - Verify shipping addresses, postmarks, or other materials to validate that the product did not come from an unexpected foreign entity or source.
- Examine the label on the package, or the label on the individual retail unit, for;

- Missing information, such as the lot number or other lot identification, NDC, or strength of the drug
- Altered product information, such as smudged print or print that is very difficult to read
- Misspelled words
- Bubbling in the surface of a label
- Lack of an Rx symbol
- Foreign language with little or no English provided
- Foreign language that is used to describe the lot number
- A product name that differs from the name of the FDA-approved drug
- A product name that is the product name for a foreign version of the drug
- Lot numbers and expiration dates on product that do not match the lot numbers and expiration dates of its outer container.

QUARANTINE

- Identified suspect products are quarantined to prevent distribution or transfer until they are cleared for distribution or dispensing; or are determined to be illegitimate.
- Suspect products are quarantined in a physically separate area that is clearly identified.

NOTIFICATIONS

Upon determination that a product is suspect or illegitimate, immediate trading partners and the FDA are notified within **24 hours** of the determination.

FDA Notification

FDA Form 3911 accessed at the FDA website
http://www.accessdata.fda.gov/scripts/cder/email/drugnotification.cfm

Termination of Notification in Consultation with the FDA

To terminate notification in consultation with the FDA when the notification is believed to be no longer necessary access the FDA website
http://www.accessdata.fda.gov/scripts/cder/email/drugnotification.cfm

INVESTIGATION

Upon identification of a suspect product, an investigation is promptly conducted in coordination with trading partners (wholesale distributor, manufacturer) to determine if the product is illegitimate.

- Validate transaction history and transaction information and otherwise investigate to determine if the product is illegitimate.
- If investigation determines that the product is not illegitimate and the product is cleared, the FDA is notified and the product may be distributed or dispensed.
- If investigation determines that the product is an illegitimate product
  - The product is removed from the pharmaceutical distribution supply chain, which may include disposal or return of the product for disposal.
  - A sample of the product is retained for further physical examination or laboratory analysis of the product by the manufacturer or other appropriate Federal or State official upon request.
- Records of the investigation are retained for at least **6 years** after the conclusion of the investigation.

OBTAINING, RETAINING AND RETREIVING TRANSACTION RECORDS TH/TI/TS
Transaction records (TH/TI/TS) are obtained from authorized trading partners for all applicable products. The records are maintained and retained in a readily retrievable manner for at least **6 years** from date of the transaction.

RECORD RETENTION REQUIREMENTS
Transaction records (TH/TI/TS), suspect product investigations and notifications must be retained for **6 years**.

Reference:

- Title II of the Drug Quality and Security Act-Drug Supply Chain Security (DSCSA) (http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm376829.htm Accessed April 2015
- *Draft Guidance:* Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification Accessed April 2015
- *Draft Guidance*: DSCSA Standards for the Interoperable Exchange of Information for Tracing of Human, Finished Prescription Drugs: How to exchange product tracing information Accessed April 2015
- FDA Drug Supply Chain Security Act Implementation Plan: http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm382022.htm

Attachments:

ATTACHMENT A: EXCEPTIONS TO THE DSCSA TRACING REQUIREMENTS

- Intracompany distribution of any product between members of an affiliate or within a manufacturer
- Distribution of product between hospitals or healthcare entities under common control
- Distribution of product for emergency medical reasons, which includes a public health emergency, and excludes a drug shortage unless caused by such a public health emergency
- Distribution of product samples by a manufacturer or a licensed wholesale distributor
- Distribution of blood or blood components intended for infusion
- Distribution of minimal quantities of product by a licensed retail pharmacy to a licensed practitioner for office use
- Products transferred to or from a facility that is licensed by the Nuclear Regulatory Commission or by a State pursuant to an agreement with the Commission
- Product comprised of a device and one or more other regulated components (such as a drug/device, biologic/device, or drug/device/biologic) that are physically, chemically, or otherwise combined or mixed and produced as a single entity
- Distribution of intravenous product intended for fluid and electrolyte replenishment (e.g., sodium, chloride, potassium) or calories (e.g., dextrose and amino acids)
- Distribution of intravenous product used to maintain equilibrium of water and minerals in body (e.g., dialysis solution)
- Product intended for irrigation or sterile water
- Distribution of medical gas
- Drugs compounded in compliance with section 503A or 503B.

ATTACHMENT B: CHARACTERISTICS OF SUSPECT PRODUCTS

Characteristics that might increase the likelihood that a product is a suspect or illegitimate product:

Trading Partners and Product Sourcing

- Purchasing from a new source that is not confirmed as an authorized trading partner
- Receiving an unsolicited sales offer from an unknown source
- Purchasing on the Internet from an unknown source
- Purchasing from a source that a trading partner knows or has reason to believe has transacted business involving suspect products

Supply, Demand, History, and Value of the Product

- Product that is in high demand, volume or price
- Product that is in higher demand because of its potential or perceived relationship to a public health or other emergency (e.g., antiviral drugs)
- Product that has been previously or is currently being counterfeited or diverted (e.g., HIV, antipsychotic, or cancer drugs).
- Product that has been previously or is currently the subject of a drug shortage

Appearance of the Product

- Appearance of a package or a container used for transport (e.g., case or tote) that seems suspicious (e.g., it has a label that contains misspellings or appears different from the standard label for that product in color, font, images, or otherwise)
- Package that uses foreign terms, such as a different drug identification number rather than the National Drug Code (NDC)
- Package that is missing information, such as the lot number or other lot identification, or the expiration date
- Package that is missing anti-counterfeiting technologies normally featured on the FDA-approved product that are easily visible to the eye, such as holograms, color shifting inks, or watermarks.
- Finished dosage form that seems suspicious (e.g., a different shape or color from the FDA-approved product, a different or unusual imprint, an unusual odor, or signs of poor quality like chips or cracks in tablet coatings or smeared or unclear ink imprints)

ATTACHMENT C: DRUG TRANSFER/SALE FORM (PAGE 1)

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DRUG TRANSFER/SALE FORM

TRANSACTION INFORMATION (TI)

FROM:
Name _____
Address _____
City, State, ZIP _____
DEA # _____
Required for CII-CV

TO:
Name _____
Address _____
City, State, ZIP _____
DEA # _____
Required for CII-CV (DEA Form 222 required for CII transactions)

Order Date: _____ Ship Date _____

Product Name, Strength and Dosage Form: _____

NDC Number: _____ Container Size: _____ Number of Containers: _____

Lot Number: _____ Expiration Date: _____

TRANSACTION HISTORY (TH) (or attach previous T3s)

Previous Seller Name	Previous Seller Address	# of Containers*	Previous Transaction Date*	Previous Ship Date*

Above named seller/supplier received the product from:

Previous Seller Name	Previous Seller Address	# of Containers*	Previous Transaction Date*	Previous Ship Date*

Above named seller/supplier received the product from:

Previous Seller Name	Previous Seller Address	# of Containers*	Previous Transaction Date*	Previous Ship Date*

**Information not required if wholesaler received the product directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager that purchased the product directly from the manufacturer.*

TRANSACTION STATEMENT (TS)

I attest as the party transferring ownership; to be authorized and registered, received product from authorized (registered party), received Transaction Information and a Transaction Statement from the prior owner, did not knowingly ship suspect or illegitimate product, had systems and processes in place to comply with verification requirements, did not knowingly provide false transaction info and did not knowingly alter the transaction history.

ORDER PREPARED BY: _____ **DATE:** _____

ORDER RECEIVED BY: _____ **DATE:** _____

Note: Maintain records for six (6) years. Current verifications of DEA registration and State license are on file.

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SUBJECT: Drug Supply Chain Security	POLICY #MM8610-157
	PAGE 9 OF 9
DEPARTMENT: Organizational	EFFECTIVE: 10/2015
APPROVED BY: Director of Pharmacy	REIVEW/REVISED:

ATTACHMENT C: DRUG TRANSFER/SALE FORM (PAGE 2)

The following transactions are exempt:

- ☐ This product was obtained prior to July 1, 2015.
- ☐ Distribution between facilities under common ownership
- ☐ This product is being supplied to another dispenser for a *specific patient* need and will not be kept as stock.
- ☐ Minimal quantities of product from a licensed retail pharmacy to a licensed practitioner for office use
- ☐ Emergency distribution
- ☐ Blood or blood components for transfusion
- ☐ Radioactive drugs or radioactive biological products
- ☐ Imaging drugs
- ☐ Medical gases
- ☐ Compounded drugs
- ☐ Dialysis solutions
- ☐ Irrigation solutions
- ☐ Sterile water (irrigation or injectable)
- ☐ Combination kits or trays that do not include a controlled substance, i.e., first aid kits, suture kits
- ☐ IV products intended for replenishment of fluids and electrolytes (sodium, chloride, potassium, etc.) or calories (dextrose, amino acids, lipids)
- ☐ Drug samples

6.

QUALITY COMMITTEE REPORT JANUARY 2016

To: Sonoma Valley Healthcare District Board Quality Committee
From: Leslie Lovejoy
Date: 01/27/16
Subject: Quality and Resource Management Report

December/January Priorities:

1. New Quality & Risk Initiatives
2. Leapfrog Action Plan development
3. Work plan evaluation and 2016's Plan development

1. ***New Quality and Risk Initiatives:***

A. ***California Hospital Patient Safety Organization Initiative (CHPSO):***

CMS has mandated that all hospitals participate in a Patient Safety Organization by the end of 2015. The hospital decided to join CHPSO and has had it first orientation sessions. As they use the Midas software engine, downloading the contents of our E-notification system along with all peer review related data and intense analyses will be seamless. Our data is aggregated and analyzed by the PSO and we will receive comparative reports in the future.

Created in 2008 by the California Hospital Association, CHPSO is a federally designated Patient Safety Organization (PSO) dedicated to the elimination of preventable patient harm and improving the quality of health care delivery. With over 350 member hospitals in the western United States, CHPSO is one of the largest PSOs in the nation and is a trusted leader in the analysis, dissemination and archiving of patient safety information. CHPSO collects incident reports and other reports of patient safety issues in a legally protected manner. As a result, CHPSO obtains a larger view of potential patient hazards and is able to identify emerging risks and understand the causes and corresponding solutions.

Benefits to SVH and member hospitals: CHPSO works together with member hospitals and other state and federal agencies on quality improvement and patient safety issues that are relevant to their communities, while maintaining patient and provider confidentiality and legal privilege. CHPSO provides leadership on national performance improvement programs, uses its leverage to work with vendors and manufacturers of medical equipment to improve safety and take unsafe products off the market, and provides educational resources such as webinars, safety alerts and education sessions.

B. ***California Hospital Engagement Network (CALHEN 2.0):***

The hospital has also elected to participate in this California based performance improvement network for 2016. While this is also patient safety focused, the clinical indicators are more process oriented and for the most part nursing based. We will begin reporting data in 2016 and will also benefit from shared aggregated reporting with other participating hospitals. The indicators that will be measured are:

1. Mandated for all hospitals: Sepsis Management; Reduction of HAI's

2. General Data Collection
    - Adverse Drug Events
    - Catheter-Associated Urinary Tract Infection (CAUTI)
    - Central Line-Associated Blood Stream Infection (CLABSI)
    - Early Elective Deliveries and Obstetrical (OB) Harm
    - Injuries from Falls and Immobility
    - Pressure Ulcers (PrU)
    - Surgical Site Infections (SSI)
    - Venous Thromboembolisms (VTE)
    - Ventilator Associated Events (VAE)
    - Readmissions within 30 days (all cause) (20% reduction)
3. There are two process measures that we are looking at as well:
    - Prevention of C. Difficile transmission
    - Iatrogenic Delirium in the ICU

The core team for this project are Mark Kobe, Chris Kutza (Pharmacy), the Nurse Leaders, Kathy Mathews, Chelsey Holdsworthy(Rehab) and Cindi Newman (Quality Data Analyst).

2. ***Leapfrog Action Plan Implementation:***

We have begun to actively work on the needed actions to bring us into alignment with the National Quality Forum recommendations for improving patient safety. Jane will be working with this committee and the Board to document current processes and to plan education this year for each member. Mark will be working to integrate a patient or family member into the patient Experience Team and we will continue to find ways for community members to come and share their stories with us at our meetings. The Senior Team will be making the monthly Safety Rounds with the Facilities Director. I have scheduled a report from the Director of Pharmacy to discuss medication error reporting and Adverse Events on the work plan. I will continue to keep you informed about all the activities during the course of this year.

3. ***Work Plan evaluation and development of the 2016 Work Plan:***

Attached you will find both work plans for the committee's discussion and plan development.

7.

QUALITY WORKPLANS 2015 AND 2016

2015 Quality Committee Work Plan

January	February 2/25/15	March 3/25/15	April 4/22/15
▪ AHRQ Culture of Safety Survey Report ▪ Proposed 2015 Plan	▪ Completed 2014 Quality Dashboard & proposed 2015 dashboard ▪ 2015 QA/PI Project prioritization ▪ SNF annual report (Melissa)	▪ Annual review of QA/PI Program ▪ Medical Staff QA/PI process (Dr. Cohen)	▪ Annual Home Care Report *(Barbara) ▪ Patient Care Services Report (Mark, Lisa)
May 5/27/15	**June 6/24/15**	**July 7/28/15**	**August 8/26/15**
▪ Annual Infection Control Report* (Kathy) ▪ Update on the Patient Experience (Mark)	▪ Wound Care Service Line Report (Dawn) ▪ Health Roundtable & SVCHC Relationship (Kelly)	▪ Annual Risk Management Report (Kathy/Leslie) ▪ Care Coordination Process (Dr. Cohen/Leslie)	● Surgical Services Transformation Project (Allan) ● Palliative Care Project (Dr Sebastian/Cohen/Leslie)
September 9/23/15	**October 10/28/15**	**November 11/18/15**	**December 12/16/15**
▪ Performance Improvement Reports – PI Fair ▪ Hospitalist Services (Dr. Cohen, Dr. Verducci)	▪ Bariatric Service Line (Michelle, Dr. Perryman) ▪ Update on OB (Mark, Cynthia & Dr. Amara)	▪ Annual Contract Evaluation Report* (Laura)	▪ Evaluation of the Quality Committee Work Plan

*Required

2016 Draft Quality Committee Work Plan

January	February	March	April
▪ 2015 Plan evaluation and development of 2016 Plan ▪ 3rd Quarter Quality Dashboard and Harm Score discussion	▪ AHRQ Culture of Safety Results ▪ 2015 Contract Evaluation Report*	▪ Annual review of QA/PI Program	▪ Annual Home Care Report *(Barbara) ▪ Skilled Nursing Report
May	**June**	**July**	**August**
▪ Annual Infection Control Report* (Kathy)	▪ Patient Care Services Report (Mark)	▪ Annual Risk Management Report (Kathy)	• Medication Safety Report *(Chris)
September	**October**	**November**	**December**
▪ Performance Improvement Reports – PI Fair		▪ Annual Contract Evaluation Report* (Laura)	▪ Evaluation of the Quality Committee Work Plan

*Required