Salinas Valley Memorial Healthcare System
A Public Healthcare District

February 17, 2023

TO: Legal Counsel

News Media
Salinas Californian
El Sol
Monterey County Herald
Monterey County Weekly
KION-TV
KSBW-TV/ABC Central Coast
KSMS/Entravision-TV

The next regular meeting of the **QUALITY AND EFFICIENT PRACTICES COMMITTEE - COMMITTEE OF THE WHOLE** of the Salinas Valley Memorial Healthcare System will be held **WEDNESDAY, FEBRUARY 22, 2023, AT 8:30 A.M., IN THE DOWNING RESOURCE CENTER, CEO CONFERENCE ROOM, ROOM 117,** at **SALINAS VALLEY MEMORIAL HOSPITAL, 450 E. ROMIE LANE, SALINAS, CALIFORNIA, or VIA TELECONFERENCE (Visit svmh.com/virtualboardmeeting for Access Information)**.

Pursuant to SVMHS Board Resolution No. 2023-01, Assembly Bill 361, and guidance from the Monterey County Health Department in response to concerns regarding COVID-19, Board Members of Salinas Valley Memorial Healthcare System, a local health care district, are permitted to participate in this duly noticed public meeting via teleconference and certain requirements of The Brown Act are suspended.

Pete Delgado
President/Chief Executive Officer

Committee Members: Catherine Carson, Chair; Rolando Cabrera, MD, Vice Chair; Pete Delgado, President/CEO; Allen Radner, MD, Chief Medical Officer; Clement Miller, Chief Operating Officer; Lisa Paulo, Chief Nursing Officer; Rakesh Singh, MD, Medical Staff Member; Michele Averill, Community Member

QUALITY AND EFFICIENT PRACTICES COMMITTEE
FEBRUARY 2023 - COMMITTEE OF THE WHOLE
SALINAS VALLEY MEMORIAL HEALTHCARE SYSTEM

WEDNESDAY, FEBRUARY 22, 2023, 8:30 A.M.
DOWNING RESOURCE CENTER, CEO CONFERENCE ROOM 117

Salinas Valley Memorial Hospital
450 E. Romie Lane, Salinas, California
or via Teleconference
(Visit svmh.com/virtualboardmeeting for Access Information)

Pursuant to SVMHS Board Resolution No. 2023-01, Assembly Bill 361, and guidance from the Monterey County Health Department in response to concerns regarding COVID-19, Board Members of Salinas Valley Memorial Healthcare System, a local health care district, are permitted to participate in this duly noticed public meeting via teleconference and certain requirements of The Brown Act are suspended.

AGENDA

1. Call to Order / Roll Call

2. Approve the Minutes of the Quality and Efficient Practices Committee Meeting of January 23, 2023. (DELGADO)
   - Motion/Second
   - Action by Committee/Roll Call Vote

3. Patient Care Services Update (PAULO)
   - Report from Night Shift Unit Practice Council

4. Public Input

   This opportunity is provided for members of the public to make a brief statement, not to exceed three (3) minutes, on issues or concerns within the jurisdiction of this District Board which are not otherwise covered under an item on this agenda.

5. Closed Session

6. Reconvene Open Session/Report on Closed Session

7. Reportable Adverse Events Procedures- discussion

8. Discussion of Quality/Patient Safety Dashboard Development

9. Adjournment

   The next Quality and Efficient Practices Committee Meeting is scheduled for **Monday, March 20, 2023 at 8:30 a.m.**

This Committee meeting may be attended by Board Members who do not sit on this Committee. In the event that a quorum of the entire Board is present, this Committee shall act as a Committee of the Whole. In either case, any item acted upon by the Committee or the Committee of the Whole will require consideration and action by the full Board of Directors as a prerequisite to its legal enactment.

The Committee packet is available at the Committee Meeting, at www.svmh.com, and in the Human Resources Department of the District. All items appearing on the agenda are subject to action by the Committee.

Requests for a disability related modification or accommodation, including auxiliary aids or services, in order to attend or participate in a meeting should be made to the Board Clerk during regular business hours at 831-755-0741. Notification received 48 hours before the meeting will enable the District to make reasonable accommodations.

QUALITY & EFFICIENT PRACTICES COMMITTEE
COMMITTEE OF THE WHOLE

AGENDA FOR CLOSED SESSION

Pursuant to California Government Code Section 54954.2 and 54954.5, the board agenda may describe closed session agenda items as provided below. No legislative body or elected official shall be in violation of Section 54954.2 or 54956 if the closed session items are described in substantial compliance with Section 54954.5 of the Government Code.

CLOSED SESSION AGENDA ITEMS

HEARINGS/REPORTS
(Government Code §37624.3 & Health and Safety Code §§1461, 32155)

Subject matter: (Specify whether testimony/deliberation will concern staff privileges, report of medical audit committee, hospital internal audit report, or report of quality assurance committee): _____

1. Report of the Medical Staff Quality and Safety Committee
    - Patient Safety Program priorities for 2023
    - Summary of Patient Safety and Risk Management Report
      Cath Lab Safety Incident Action Plans
    - Accreditation and Regulatory Report

    Consent Agenda:
    - Full reports of the Patient Safety and Risk Management Program
    - Environment of Care Committee reports
    - Stroke Program Report
    - National Patient Safety Goals
    - Transfusion Committee Report
    - Pharmacy and Therapeutic Committee Reports
    - Infection Prevention Program and Antibiotic Stewardship reports

ADJOURN TO OPEN SESSION

CALL TO ORDER
ROLL CALL

(Chair to call the meeting to order)

SALINAS VALLEY MEMORIAL HEALTHCARE SYSTEM
QUALITY AND EFFICIENT PRACTICES COMMITTEE MEETING
COMMITTEE OF THE WHOLE
MEETING MINUTES
JANUARY 23, 2023

SVMHS Board Resolution No. 2022-21, Assembly Bill 361, and guidance from the Monterey County Health Department in response to concerns regarding COVID-19, Board Members of Salinas Valley Memorial Healthcare System, a local health care district, are permitted to participate in this duly noticed public meeting via teleconference and certain requirements of The Brown Act are suspended.

The Quality and Efficient Practices Committee convened at 8:35 a.m. in the Downing Resource Center, CEO Conference Room 117.

Committee Members Present: Catherine Carson, Chair, Pete Delgado, Lisa Paulo, Allen Radner, MD, and Rakesh Singh, MD;
Via Teleconference: Rolando Cabrera, MD, Vice-Chair

Committee Members Absent:
Michele Averill and Clement Miller

Other Board Members Present Constituting Committee Of The Whole**:**
Joel Hernandez Laguna, Juan Cabrera, Victor Rey, Jr. *(all via teleconference)*

Guests:
Ann Buco Aninzo, PI Specialist, Brenda Bailey, Risk Manager, Aniko Kukla, Quality Services Manager, Troy Scott, Director Case Management, Marisol Soria, Chair, Perinatal Unit Practice Council, Julie Vasher, Director/Women's & Children's Services

Rakesh Singh, MD, joined the meeting at 8:36 a.m.

Victor Rey, Jr. joined the meeting at 8:38 a.m.

A quorum was present and Chair Carson called the meeting to order at 8:35 a.m.

APPROVAL OF MINUTES FROM THE QUALITY AND EFFICIENT PRACTICES COMMITTEE MEETING OF DECEMBER 12, 2022

Approve the minutes of the Quality and Efficient Practices Committee for the December 12, 2022 meeting, as presented. The information was included in the Committee packet.

No public input received:

MOTION:

Upon motion by Committee member Delgado, second by Dr. Radner, the Quality and Efficient Practices Committee minutes of December 12, 2022 were approved.

Ayes: Committee members: Carson, R. Cabrera, Delgado, Paulo, Radner, Singh; Noes: None; Abstentions: None; Absent: Committee member Averill and Miller. Motion Carried.

PATIENT CARE SERVICES UPDATE

Lisa Paulo MSN/MPA, RN, Chief Nursing Officer, review patient experience targets for ambulatory, inpatient and ED, all very close to target. "How Would You Rate" has dipped slightly while the Press Ganey mean is well below SVMH scores. FY15 through FY23 Year over Year Press Ganey scores were reviewed. Performance improvement strategies include executive/leader priority, evidence based practices, performance improvement specialist, Patient Experience Steering Committee, employee engagement, staffing management, vacancy/turnover reduction and ED throughput.

Ms. Paulo introduced Perinatal Unit Practice Council Marisol Soria, Chair, Perinatal Unit Practice Council and Julie Vasher, Director, Women's and Children's Services, who provided a report on the Perinatal UPC recent activities.

Accomplishments:

1. Robes are distributed to laboring patients admitted to Labor and Delivery
2. Patients wear the robes proudly and express being more comfortable when ambulated in the hallways during labor
3. Patients continue to wear robes through they stay

Current Focus: NTSV: Nulliparous Term Singleton Vertex Cesarean Section

1. Goal to reduce rate of C-Section for first time moms to be below 23.6%
2. Additional training provided to nurses for spinning babies and SWELLS 2.0
3. SVMH and peer trends

What Is Coming:

1. Team birth: June/2023
2. Infant-driven feeding in NICU: Summer/2023
3. Joey Bands, a newborn fall reduction strategy: TBD

Discussion: Are patient comments being analyzed? Yes, all comments are reviewed by leaders and staff. Nurse sensitive indicators are being reviewed by leaders and appropriate staff, e.g., night-shift nurses are working on Quiet at Night. How can we partner with physicians before the decision of Cesarean Section is made? There is an interdisciplinary meeting before C-Section. Are rates shared with physicians and are outliers addressed? Dr. Radner stated data is shared with physicians and there are no current data indicating chronic C-Sections at this time; inappropriate C-Section data by one or more physicians would be addressed. Do we offer TOLAC and VBAC? Yes, with an 82% success rate. Does the community know; patients may not be aware? Ms. Vasher reported work is being done on the Perinatal landing page on the hospital website. Mr. Delgado commented on what a great service we are providing with the Joey Bands.

PUBLIC INPUT

No public comment received.

CLOSED SESSION

Chair Carson announced that the item to be discussed in Closed Session is *Hearings/Reports – Report of the Medical Staff Quality and Safety Committee*. The meeting recessed into Closed Session under the Closed Session protocol at 8:58 a.m.

RECONVENE OPEN SESSION/REPORT ON CLOSED SESSION

The Committee reconvened Open Session at 9:35 a.m., Chair Carson reported that in Closed Session, the Committee discussed *Hearings/Reports – Report of the Medical Staff Quality and Safety Committee*.

No action taken in the Closed Session.

ADJOURNMENT

There being no other business, the meeting adjourned at 9:36 a.m. The next Quality and Efficient Practices Committee Meeting is scheduled for **Wednesday, February 22, 2023 at 8:30 a.m.**

ATTEST:

_____

Catherine Carson, Chair
Quality and Efficient Practices Committee

/KmH

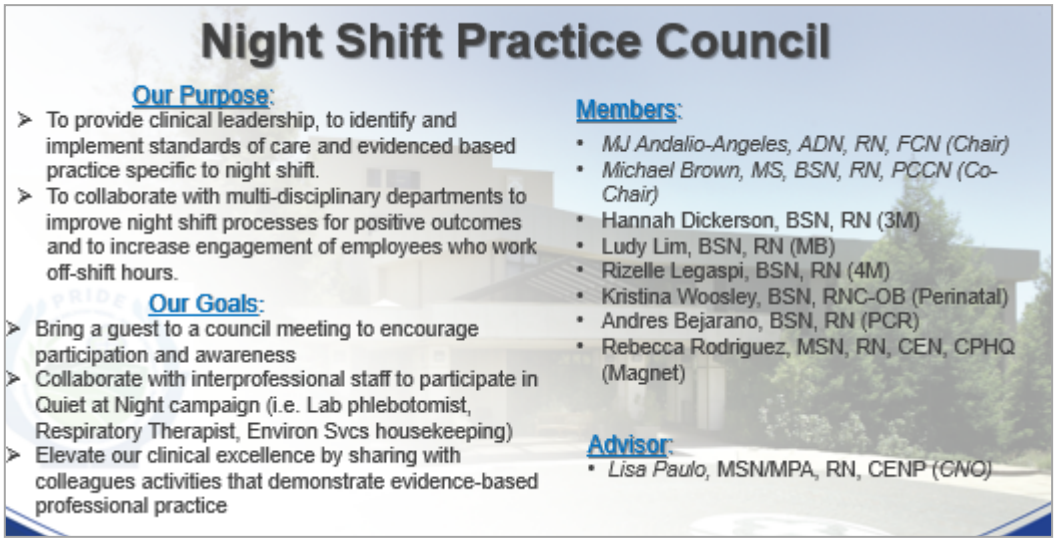
Board Paper: Quality & Efficient Practices Committee

Agenda: Patient Care Services Update
Executive Sponsor: Lisa Paulo, MSN/MPA, RN
Date: February 22, 2023

Pillar/Goal Alignment:

☐ Service ☐ People ☒ Quality ☐ Finance ☐ Growth ☐ Community

QUALITY:



What We Did Next:
Quiet At Night Initiative: Commitment Statement Posters

Purpose

- To invite all night shift staff to commit to adhere to improvement opportunities listed in the Quiet At Night initiative Commitment Statements

Background: Evidence-based Research

- "Improving Patient Satisfaction With Quietness" A scholarly project submitted to the Faculty of Liberty University, in partial fulfillment of the requirements for the degree of Doctor of Nursing Practice by Victoria Rondez Squier, RN Liberty University, Lynchburg VA, September 2019
- The WHO (World Health Organization) Noise Guidelines for Sleep Quality.

Go-Live Date

- Began educating staff at the Nov 1st Professional Development Fair
- Night Shift UPC members rounded on night shift staff throughout Nov/Dec to educate and encourage them to sign the posters

Salinas Valley Memorial Healthcare System

Silent Halls Help Healing
Our Commitments

SHHH... SILENT HALLS HELP HEALING

OUR COMMITMENTS:

Promote a Culture of Quiet with Staff
I will institute a "library voice" policy when working on the floor and speak up to encourage others to do the same.

Use Easy Solutions
When clinically possible, I will cluster care, quietly close the door of patients' rooms, and keep them closed throughout the night.

Harness Simple Technology
I will give applicable patients headphones, the Pocket Talker and a "Quiet Pack," and offer the viewing of our audio/video C.A.R.E. channel.

Take a Close Look at Monitors
(Telemetry Units)
I will proactively mitigate the number of monitor alarm events.

Involve Patients
I will keep my patients informed and engaged as to what to anticipate during their hospital stay.

Respond Swiftly
I will respond quickly to IV infusion pump alarms and patient call bells.

Reduce Environmental Noise
I will report/address disturbing noises on the unit such as squeaky cart wheels, slamming doors, etc.

Salinas Valley Memorial Healthcare System

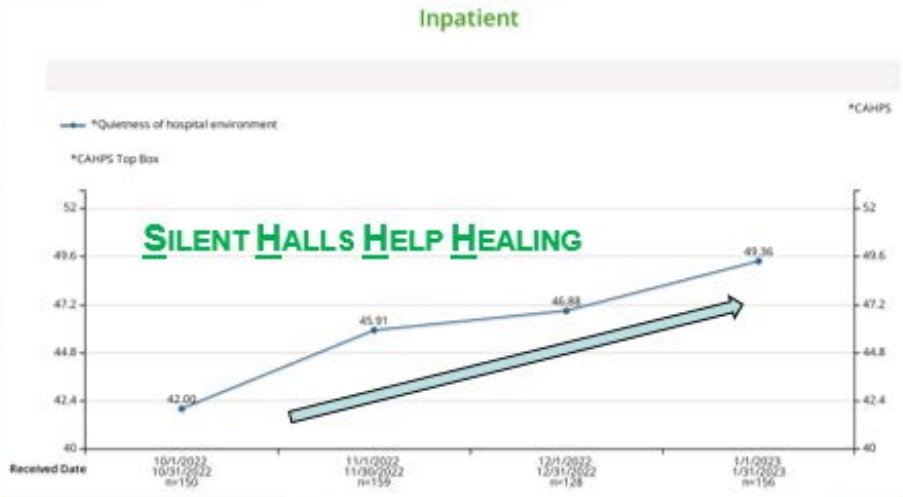
How do we show our COMMITMENT?

- All nursing units have been provided their own "Commitment Statement" poster
- Each Night Shift staff member was invited to sign the poster board as his/her pledge of commitment to the initiative
- Those staff members that provided their signatures received a personal nightlight (Lumify)
- Anticipate a culture change with every employee taking accountability to keep noise levels down for our in-patient clients

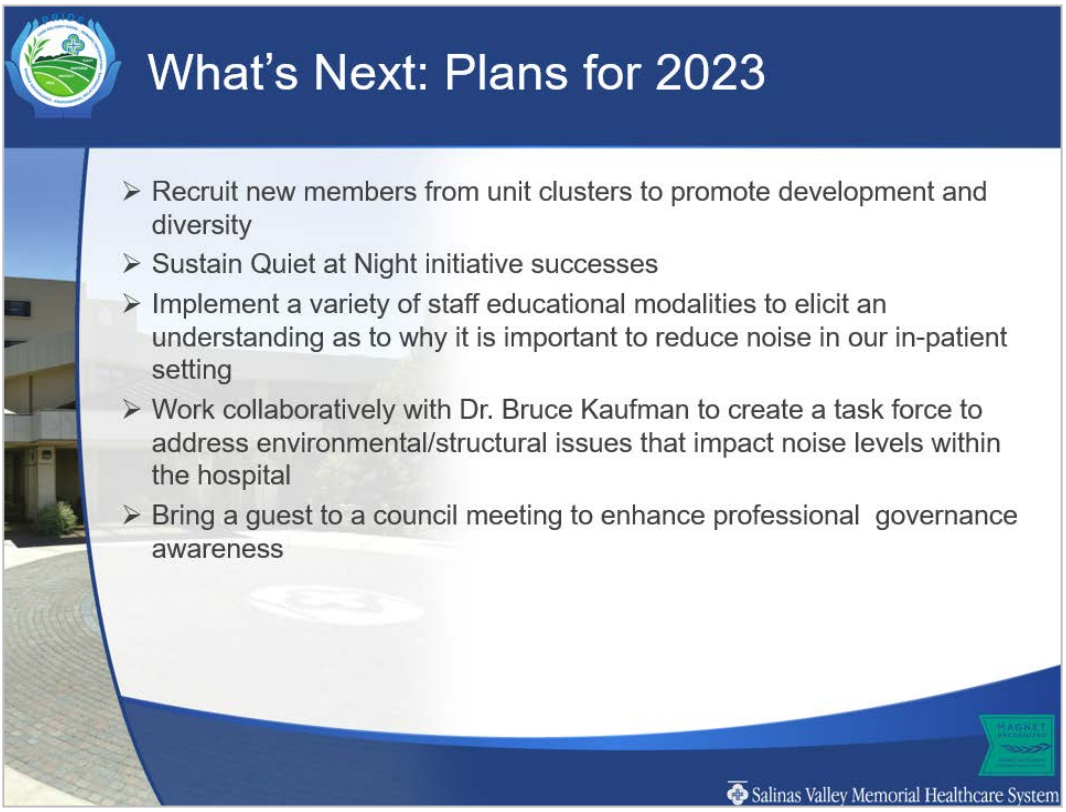
Salinas Valley Memorial Healthcare System

And the survey says…

Quietness at Night Initiative



Salinas Valley Memorial Healthcare System


What's Next: Plans for 2023
Recruit new members from unit clusters to promote development and diversity
Sustain Quiet at Night initiative successes
Implement a variety of staff educational modalities to elicit an understanding as to why it is important to reduce noise in our in-patient setting
Work collaboratively with Dr. Bruce Kaufman to create a task force to address environmental/structural issues that impact noise levels within the hospital
Bring a guest to a council meeting to enhance professional governance awareness
Salinas Valley Memorial Healthcare System

PUBLIC INPUT

CLOSED SESSION

(Report on Item to be Discussed in Closed Session)

RECONVENE OPEN SESSION/
REPORT ON CLOSED SESSION

DISCUSSION OF REPORTABLE ADVERSE EVENTS PROCEDURES

Status **Active** PolicyStat ID **12515002**

Last Approved	07/2020	Owner	Lea Woodrow: Director of Accreditation and Regulatory Complianc
Last Revised	07/2020		
Next Review	07/2023	Area	Administration

Reportable Adverse Events

I. POLICY STATEMENT:

A. Serious adverse events also known as an unexpected occurrence, sentinel event and adverse event which may or may not result in patient harm are reviewed to determine if the event meets the criteria for a sentinel event, serious adverse event, or reportable "never event" and the harm associated with the event.

B. The hospital will make all attempts to inform the patient or the party responsible for the patient of the adverse event by the time the report is made (to CDPH).

II. PURPOSE:

A. To guide staff with investigating and responding timely to sentinel events, serious adverse events.

B. Understand the factors that contribute to an event and to improve processes to reduce the probability of the event occurring in the future.

C. To comply with federal, state and regulatory agencies.

III. DEFINITIONS:

A. **Action Plan (AP)** is the product of the Comprehensive Systematic Analysis that identifies the strategies the organization intends to implement to reduce the risk of a similar patient safety event occurring in the future..

B. **Adverse Event** is an injury that was caused by medical management rather than the patients' underlying condition. Not all adverse events are the result of medical error.

C. **Adverse outcome** is a result that differs from the anticipated result of a treatment or procedure and results in harm to the patient

D. **Comprehensive Systematic Analysis** (CSA) previously known as Root Cause Analysis -RCA is

a comprehensive systematic analysis used to identify the factors that underlie a serious adverse event or sentinel event. A comprehensive systematic analysis focuses primarily on systems and processes, not on individual performance. The comprehensive systematic analysis will be completed within 45 calendar days of the serious adverse or sentinel event or of becoming aware of the event

E. **Disclosure** a process to provide open and honest communication with patients and families after adverse events or unexpected outcome by the physician or designee.

F. **HEART** – Beta Healthcare initiative, (Healing, Empathy, Accountability, Resolution, Trust)

G. **Near Miss** is an event that did not reach a patient.

H. **Never Events** is an adverse event that is reportable under CA Health and Safety Code, §1279.1(b) (1)-(7) ,

I. **PSAT** – Patient Safety Advisory Team – A multidisciplinary administrative team that determine if the event is reportable to CDPH (Never/Sentinel event definitions), requires a full Comprehensive Review or debrief, if the event meets the HEART criteria and the disclosure process.

J. **Sentinel Event** is an unexpected occurrences involving death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition.

    1. NOTE: The term sentinel event and medical error are not synonymous; not all sentinel events occur because of an error and not all errors result in sentinel events.

K. **Risk thereof** includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.

L. **Unexpected Adverse Outcome** is an adverse outcome that was not expected to be the result of the patient's treatment and there was harm suffered as a result.

IV. GENERAL INFORMATION:

A. All areas under the Salinas Valley Memorial Hospital are subject to the policy and procedure.

B. Under the direction of the Patient Safety Officer (PSO), the Patient Safety and/or Risk Management Divisions shall collaborate with the responsible unit leaders to conduct an initial investigation of the facts of the event and identify discipline(s) to participate in the review. Specific staff participants will be recommended based on the facts known.

C. Any records, data, and knowledge collected for or by individuals assigned to investigate and review adverse events as part of the Quality Improvement Process and are confidential subject to California SB 1157 and/or the Patient Safety Work product.

D. If an event meets the criteria as a sentinel event or reportable "never event", a Comprehensive Systems Analysis (RCA) may be completed.

E. If the event is determined not to be a sentinel event, it will be addressed in accordance with established occurrence reporting processes.

F. SVMHS supports disclosure to patients/families as soon after the event as possible. DISCLOSURE OF UNANTICIPATED OUTCOMES POLICY.

G. Patient confidentiality will be maintained at all times.

V. PROCEDURE:

A. Immediate Action following a serious adverse or sentinel event.

1. Responsibilities of Staff Involved in the event

    a. Stabilize the situation including but not limited to the following:

        1. Assess the patient and assure their safety.
        2. Notify attending physician to examine the patient.

    b. If the event involves a medical device, immediately notify Biomedical Engineering to sequester the devices that may have been involved in the event. Leave everything intact - i.e. leave pumps on but running into a receptacle, leave equipment in the room, leave all monitors/pumps on. Save syringes/vials/ IV bags/ tubing and/or any other equipment and supplies. Under no circumstances is the equipment or evidence to be worked on, repaired, cleaned or altered from the condition it was in at the time of the event. MEDICAL DEVICE INCIDENT REPORTING PROGRAM

    c. Immediately after the patient is stabilized and the area / secured, contact the Administrative Supervisor and unit leader.

    d. Document patient assessment and subsequent interventions and the facts surrounding the event in the electronic health record.

    e. Enter the event in the electronic WeCare occurrence reporting system. (Staff should not write or keep any additional notes of event).

2. Responsibilities of Unit Leader / Administrative Supervisor

    a. Assess the situation to assure staff and patient safety and identify immediate actions.

    b. Contact the Patient Safety Officer (PSO) / designee and ascertain the known facts surrounding the event.

    c. Determine the need to initiate the Care for the Caregiver process. Assure staff involved in the event are capable of continuing their care assignment. Staff may be removed from their assignment, if necessary, to assure continued safety of other patients. Offer support through trained counselors / EAP, or hospital Chaplain as needed or requested.

    d. Reinforce confidentiality and security.

    e. Inform staff that all media inquiries are to be referred to Media/Public Relations. Facilitate the immediate sequestering of equipment, ensure documentation in the medical record, and conduct further notifications, as needed.

    f. Consult with Patient Safety Officer / Risk Management designee to identify the appropriate contact person to initiate the initial communication with the patient / family in accordance with the DISCLOSURE OF UNANTICIPATED OUTCOMES POLICY

g. Review applicable patient care policies and procedures to assess the compliance or lack thereof by staff, in relationship to the event.

h. Conversations with the patient/family should be witnessed and documented in the medical record.

3. Responsibilities of the PSO / Designee

a. The PSO will notify the Manager, Regulatory and Accreditation prior to close of business day and a Patient Safety Advisory Team (PSAT) meeting will be scheduled within 24 hours, to include leaders of the involved areas, PSO, Chief Medical Officer / designee, Chief Nursing Officer (if a clinical event), Risk Manager and others as necessary.

b. Upon determination if event meets criteria as a sentinel / serious adverse event, the PSAT team will determine if a report to Board of Directors is indicated based on the results of the investigation.

c. If event meets criteria as reportable to the California Department of Public Health (CDPH), notification shall be made in accordance with the mandated reporting requirements.

d. In concert with the unit leader / Risk Manager will review the situation with the attending physician to determine who, when to fully disclose event to patient/family, determine the appropriate parties to be included in the disclosure meeting and other relevant information and processes. Disclosure may be withheld if there are legal, ethical, regulatory, or psychological reasons that could cause harm to the patient. The Bioethics Committee may be consulted as a resource if decision is made to withhold disclosure. DISCLOSURE OF UNANTICIPATED OUTCOMES POLICY

e. Notify Accounting for further handling related to accounting/billing and charges related to event. Bill will be placed on hold until reviewed in detail. RM will facilitate the ongoing process in collaboration with the Administrative Adjustment Committee.

4. Responsibilities of Risk Manager / Designee

a. Initiate investigation with the leader of the involved unit and begin evaluation of the event. Initiate investigation and chronology of event with the staff involved in the event.

b. Collaborate with unit director(s) and staff to address immediate communication issues, sequester equipment, etc. as previously described.

c. The Biomedical Department in collaboration with the Risk Manager/ designee will be responsible for receiving and storing the impounded evidence. Medical Device Incident Reporting Program

d. Notify hospital liability carrier of event and open precautionary file.

B. Comprehensive Systematic Analysis Process

1. Each sentinel / adverse event is to be documented in the form of a Comprehensive Systematic Analysis (CSA).

2. RM facilitates the completion of the (CSA). Investigate the event and determine why it happened with staff involved.
    a. Investigate the event and determine why it occurred such as:
        i. Internal factors – staffing, errors of omission, overdose/under dose of medication.
        ii. Process factors – process not completed per policy, investigation reveals a problem with the process.
        iii. Equipment factors – failure, malfunction, electrical shock.
        iv. Environmental factors – power failure, backup generator failure, hazardous spill.
    b. Work with the staff and unit leaders to develop corrective actions. The use of statistical tools/analysis used, i.e., flowchart, cause and effect diagram, scatter diagram, Pareto chart may be used if needed.
    c. Work with staff and unit leaders on mitigating strategies with corrective actions to help prevent reoccurrence. Assign responsibility for the action plan. Answer the questions: How will we ensure this never happens again? And who is responsible? Define when actions need to be completed by (i.e. 45 days from event).
    d. In collaboration with the unit leaders the Quality Department staff facilitates the measures of successes/compliance with reporting to the appropriate committees.
3. Responsibility of Unit Leader
    a. Attend and assure involved staff can participate in the meetings.
    b. Define and implement corrective action plans, as assigned.
    c. Monitor the implementation and effectiveness of action plans.
    d. Participate in reporting of action plans and effectiveness.
    e. Review and submit status of corrective actions & monitoring as indicated in the action plan.

VI. EDUCATION/TRAINING:

A. Education and/or training is provided as needed.

VII. REFERENCES:

A. The Joint Commission
B. CHA Consent Manual E. HSC 1279.1 (b)

Attachments

A: Serious Adverse Events

Approval Signatures

Step Description	Approver	Date

Standards

No standards are associated with this document

ATTACHMENT A

1. The following are examples of occurrences that would meet the definition of a sentinel event, serious adverse event, including never events, but are not necessarily limited to:

(1) Surgical events, including the following:

A. Surgery performed on a wrong body part that is inconsistent with the documented informed consent for that patient. A reportable event under this subparagraph does not include a situation requiring prompt action that occurs in the course of surgery or a situation that is so urgent as to preclude obtaining informed consent.

B. Surgery performed on the wrong patient.

C. The wrong surgical procedure performed on a patient, which is a surgical procedure performed on a patient that is inconsistent with the documented informed consent for that patient. A reportable event under this subparagraph does not include a situation requiring prompt action that occurs in the course of surgery, or a situation that is so urgent as to preclude the obtaining of informed consent.

D. Retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained.

E. Death during or up to 24 hours after induction of anesthesia after surgery of a normal, healthy patient who has no organic, physiologic, biochemical, or psychiatric disturbance and for whom the pathologic processes for which the operation is to be performed are localized and do not entail a systemic disturbance.

(2) Product or device events, including the following:

A. Patient death or serious disability associated with the use of a contaminated drug, device, or biologic provided by the health facility when the contamination is the result of generally detectable contaminants in the drug, device, or biologic, regardless of the source of the contamination or the product.

B. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. For purposes of this subparagraph, "device" includes, but is not limited to, a catheter, drain, or other specialized tube, infusion pump, or ventilator.

C. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a facility, excluding deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

D. Any magnetic resonance adverse events may also be reported to the FDA via the Medwatch program.

(3) Patient protection events, including the following:

A. An infant discharged to the wrong person.

B. Patient death or serious disability associated with patient disappearance for more than four hours, excluding events involving adults who have competency or decision making capacity. ***TJC has no time frame***

C. A patient suicide or attempted suicide resulting in serious disability while being cared for in a health facility due to patient actions after admission to the health facility, excluding deaths resulting from self-inflicted injuries that were the reason for admission to the health facility. ***TJC - or within 72 hours of discharge***

(4) Care management events, including the following:

A. A patient death or serious disability associated with a medication error, including, but not limited to, an error involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration, excluding reasonable differences in clinical judgment on drug selection and dose.

B. A patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.

C. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a facility, including events that occur within 42 days post-delivery and excluding deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy.

D. Patient death or serious disability directly related to hypoglycemia, the onset of which occurs while the patient is being cared for in a health facility.

E. Death or serious disability, including kernicterus, associated with failure to identify and treat hyperbilirubinemia in neonates during the first 28 days of life. For purposes of this subparagraph, "hyperbilirubinemia" means bilirubin levels greater than 30 milligrams per deciliter.

F. A Stage 3 or 4 ulcer (injury), acquired after admission to a health facility, excluding progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission.

G. A patient death or serious disability due to spinal manipulative therapy performed at the health facility.

(5) Environmental events, including the following:

A. A patient death or serious disability associated with an electric shock while being cared for in a health facility, excluding events involving planned treatments, such as electric counter shock.

B. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by a toxic substance.

C. A patient death or serious disability associated with a burn incurred from any source while being cared for in a health facility.

D. A patient death associated with a fall while being cared for in a health facility.

E. A patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health facility.

(6) Criminal events, including the following:

A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider.

B. The abduction of a patient of any age.

C. The sexual assault / death of a patient / staff, LIP, visitor or vendor within or on the grounds of a health facility.

D. The death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of a facility.

(7) An adverse event or series of adverse events that cause the death or serious disability of a patient, personnel, or visitor.

"Serious Disability" means a physical or mental impairment that substantially limits one or more of the major life activities of an individual, or the loss of bodily function, if the impairment lasts more than seven (7) days or is still present at the time of discharge from an inpatient health care facility, or the loss of a body part.

Additional TJC Sentinel Events:

(1) Prolonged fluoroscopy with a cumulative dose >1500 rads to a single field or any delivery of radiotherapy to the wrong body region or > 25% above the planned radiotherapy dose.
(2) Unanticipated death of a full term infant.
(3) Neonatal serum bilirubin >30 milligrams/deciliter

Additional CMS events (§ 482.13 Condition of Participation: Patient's Rights)

Additional CA SB 1237 Requirements:

1) A facility that uses CT X-ray systems shall notify the department, the affected patient, and the patient's treating physician immediately, in writing, of the occurrence of any of the following events:
   A. Irradiation of the wrong patient or irradiation of a body part other than that intended by the ordering physician and surgeon.
   B. A diagnostic dosage that exceeds by 50 percent or more the protocols established in subdivision (a).

2) Each facility that utilizes therapeutic X-ray systems operating at energies below one million electron volts (MeV) shall notify and report to the department, in accordance with department regulations, and shall also notify the affected patient and his or her treating physician within 10 days, in writing, of the occurrence of any of the following events:
   A. Irradiation of the wrong individual or wrong treatment site.
   B. Any treatment consisting of three or fewer fractions, with the calculated total administered dose differing from the total prescribed dose by more than 10 percent of the total prescribed dose.
   C. Any exposure resulting in a calculated total administered dose differing from the total prescribed dose by more than 10 percent of the total prescribed dose.

3) Each facility that utilizes therapeutic X-ray systems operating with energies at or above one MeV shall notify and report to the department, in accordance with department regulations, and shall notify the affected patient and his or her treating physician within 10 days, in writing, of the occurrence of any of the following events:

A. Any event involving irradiation of the wrong individual, administration of the wrong type of radiation or the wrong energy, or irradiation of the wrong treatment site.
B. Any treatment consisting of three or fewer fractions, with the calculated total administered dose differing from the total prescribed dose by more than 10 percent of the total prescribed dose.
C. Any exposure resulting in a calculated total administration dose differing from the total prescribed dose by more than 20percent of the total prescribed dose.

LICENSING AND CERTIFICATION

REPORTABLE ADVERSE EVENTS

Health and Safety Code, Section 1279.1 (b) (1) – (7) reflects the following:

1279.1.

(b) For purposes of this section, "adverse event" includes any of the following:
(1) Surgical events, including the following:
(A) Surgery performed on a wrong body part that is inconsistent with the documented informed consent for that patient. A reportable event under this subparagraph does not include a situation requiring prompt action that occurs in the course of surgery or a situation that is so urgent as to preclude obtaining informed consent.
(B) Surgery performed on the wrong patient.
(C) The wrong surgical procedure performed on a patient, which is a surgical procedure performed on a patient that is inconsistent with the documented informed consent for that patient. A reportable event under this subparagraph does not include a situation requiring prompt action that occurs in the course of surgery, or a situation that is so urgent as to preclude the obtaining of informed consent.
(D) Retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained.
(E) Death during or up to 24 hours after induction of anesthesia after surgery of a normal, healthy patient who has no organic, physiologic, biochemical, or psychiatric disturbance and for whom the pathologic processes for which the operation is to be performed are localized and do not entail a systemic disturbance.
(2) Product or device events, including the following:
(A) Patient death or serious disability associated with the use of a contaminated drug, device, or biologic provided by the health facility when the contamination is the result of generally detectable contaminants in the drug, device, or biologic, regardless of the source of the contamination or the product.
(B) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. For purposes of this subparagraph, "device" includes, but is not limited to, a catheter, drain, or other specialized tube, infusion pump, or ventilator.
(C) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a facility, excluding deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.
(3) Patient protection events, including the following:
(A) An infant discharged to the wrong person.

(B) Patient death or serious disability associated with patient disappearance for more than four hours, excluding events involving adults who have competency or decision making capacity.
(C) A patient suicide or attempted suicide resulting in serious disability while being cared for in a health facility due to patient actions after admission to the health facility, excluding deaths resulting from self-inflicted injuries that were the reason for admission to the health facility.
(4) Care management events, including the following:
(A) A patient death or serious disability associated with a medication error, including, but not limited to, an error involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration, excluding reasonable differences in clinical judgment on drug selection and dose.
(B) A patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.
(C) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a facility, including events that occur within 42 days postdelivery and excluding deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy.
(D) Patient death or serious disability directly related to hypoglycemia, the onset of which occurs while the patient is being cared for in a health facility.
(E) Death or serious disability, including kernicterus, associated with failure to identify and treat hyperbilirubinemia in neonates during the first 28 days of life. For purposes of this subparagraph, "hyperbilirubinemia" means bilirubin levels greater than 30 milligrams per deciliter.
(F) A Stage 3 or 4 ulcer, acquired after admission to a health facility, excluding progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission.
(G) A patient death or serious disability due to spinal manipulative therapy performed at the health facility.
(5) Environmental events, including the following:
(A) A patient death or serious disability associated with an electric shock while being cared for in a health facility, excluding events involving planned treatments, such as electric countershock.
(B) Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by a toxic substance.
(C) A patient death or serious disability associated with a burn incurred from any source while being cared for in a health facility.
(D) A patient death associated with a fall while being cared for in a health facility.
(E) A patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health facility.
(6) Criminal events, including the following:
(A) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider.
(B) The abduction of a patient of any age.
(C) The sexual assault on a patient within or on the grounds of a health facility.
(D) The death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of a facility.
(7) An adverse event or series of adverse events that cause the death or serious disability of a patient, personnel, or visitor.

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DISCUSSION OF QUALITY/PATIENT SAFETY DASHBOARD DEVELOPMENT

ADJOURNMENT