
MERP Program & Medication Safety

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Disclosure

I have no significant or relevant relationships or other affiliations to disclose

Learning Objectives

- Describe CDPH's Medication Error Reduction Plan (MERP) survey activities since start of the MERP program in 2009.
- State the MERP survey documents and information requested upon entrance.
- Identify common survey findings.

Medication Error Reduction Plan

- Condition of licensure General Acute Care Hospitals and Surgical Clinics adopt a formal plan to eliminate or substantially reduce medication-related errors
- Facility MERPs submitted to CDPH by January 1, 2002 – for review and approval.
- Must be implemented by 2005
- CDPH required to monitor implementation

Medication-Related Error (Procedures/Systems)

- Prescribing
- Prescription order communication
- Product labeling
- Packaging and nomenclature
- Compounding
- Dispensing
- Distribution
- Administration
- Education
- Monitoring
- Use

Health and Safety Code (HSC) 1339.63(d)

MERP Survey Process

- Surveys are triennial
- Managed by CDPH Pharmaceutical Consultant Unit
- Approximately 32 hospitals/quarter
- Outcome(s):
 - No deficiencies
 - Deficiencies noted under HSC and/or California Code of Regulations (CCR), Title 22.
 - State Immediate Jeopardy finding with or without a penalty.
 - Federal Complaint Validation survey with deficiencies noted under 42 Code of Federal Regulations with or without Condition Level deficiencies.
 - Federal Immediate Jeopardy finding
 - Failure to report an Adverse Event (mandatory)

Mandatory Reporting –Adverse Event

- Mandatory reporting of 28 types of Adverse Events (AEs) to CDPH
- The Department may assess a civil penalty of \$100 per day for each day for failure to report timely.
- Medication Related AEs: Patient death or serious disability
 - Associated with a medication error
 - Directly related to hypoglycemia
 - Associated with the use of a contaminated drug, device, or biologic provided by the health facility
 - Associated with use or function of a device in patient care in which the device is used or functions other than as intended.

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 or loss lasts more than seven days or is still present at the time of discharge from an inpatient health care facility, or the loss of a body part.”

[HSC 1279.1(d)]

Failure To Report Adverse Event Penalties Assessed

9

	Fiscal Year <u>2007/08</u>	Fiscal Year <u>2008/09</u>	Fiscal Year <u>2009/10*</u>
Penalties Issued	94	153	47
Amount Fined	\$283,900	\$673,000	\$269,600
Amount Collected	\$257,900	\$538,330	\$212,100

Updated as of 03/15/10

MERP Survey – Communication

- CDPH issued guidance – All Facilities Letters (AFL):
 - AFL 08-39: Guidance on MERP survey process
 - AFL 09-31: Establishes MERP email address to address questions about the survey process:
 - ✓ MERP@cdph.ca.gov
- CDPH AFLs
<http://www.cdph.ca.gov/certlic/facilities/Pages/LnCAFL.aspx>

MERP Survey Activities

- Off site: MERP file and License review
- On site
 - Entrance conference
 - Document request
 - MERP facility questionnaire
 - Clinical record review
 - Medication storage assessment
 - Medication pass observation
 - Review medication error reports
- Exit Conference

On Site - Entrance Conference

- Conducted with Administrator and representatives as deemed
- Document Request
- MERP Survey Facility Questionnaire
- MERP Survey Evaluation
 - Voluntary
 - Mailed to Chief
 - Can be anonymous
 - Provided upon entrance
 - *"Attachment C: MERP Survey Evaluation"*

Entrance Conference – Document Request

- P&Ps related to med errors, administration times, emergency med use
- List of patients in last three months
 - PCA delivered medications
 - Fentanyl transdermal
 - Droperidol
 - Insulin drip
 - Reversal agents (Narcan, D50W, glucagon, Vit K, protamine, flumazenil)
- Current MERP and evidence of annual reviews

Attachment A: MERP Entrance Conference Documents Request

Entrance Conference – Document Request

- Medication error reports for last 3 yrs
- Outcome data related to medication errors
- Committee minutes - oversight of MERP 3 yrs
- Adverse events since July 1, 2007
 - related to a contaminated drug, device, or biologic; use or function of a device other than is intended (where "device" refers to equipment associated with medication delivery); medication error or hypoglycemia

Attachment A: MERP Entrance Conference Documents Request

MERP Questionnaire

- Intent: provide structure to survey process and improve efficiency, effectiveness and consistency of MERP survey activities.
- Organized as a workbook to facilitate collection of data and information that will be requested during interview process
- Not mandatory
- Three questions related to compliance with HSC 1339.63(e)(1)(2)(3) – frequently cited

Attachment B: MERP Survey Facility Questionnaire

MERP Questionnaire – Question A

- Is there a method to address each of the “procedures and systems” so as to identify weakness or deficiencies? [HSC 1339.63(e)(1)]
 - Guidance:
 - ✓ What methodology is utilized for evaluating each procedures and systems (11) that can contribute to medication errors.
 - Method: procedure or process
 - Should be ongoing
 - ✓ Examples; evaluation of external alerts, medication pass observation, QAPI studies, analysis of medication error reports, FEMA studies, DUEs etc

Question A: MERP Survey Questionnaire

Procedure or System:	Methodology:	Evaluation frequency:	Date last completed:	Weaknesses or deficiencies identified:	Date identified:
Prescribing:			___/___/___	Use for question B	___/___/___
Prescription order communications:			___/___/___		___/___/___
Product labeling:			___/___/___		___/___/___
Packaging and nomenclature:			___/___/___		___/___/___
Compounding:			___/___/___		___/___/___
Dispensing:			___/___/___		___/___/___

MERP Questionnaire – Question B

- Has the plan been modified when weakness or deficiencies are noted to achieve the reduction of errors? [HSC 1339.63(e)(3)]
- Guidance
 - ✓ Were weakness or deficiencies identified?
 - ✓ If identified, was the plan modified?
 - ✓ Was there follow-up done to assess effectiveness of the plan modification?
 - ✓ Look back 36 months

Question B: MERP Survey Questionnaire

Procedure or system:	Date identified:	Weakness identified:	Plan modification:	Date initiated:	Follow-up assessment done:
Prescribing:	____/____/____	From Question A		____/____/____	
	____/____/____			____/____/____	
	____/____/____			____/____/____	
Prescription order communication:	____/____/____			____/____/____	
	____/____/____			____/____/____	
	____/____/____			____/____/____	



MERP Questionnaire –Question C

- Has an annual review been done to assess the effectiveness of the plan for each of the procedures and systems? [HSC 1339.63(e)(2)]
 - Guidance
 - ✓ Annual review should have started 2006
 - ✓ Approximately every 12 months thereafter
 - ✓ Must address all 11 procedures and systems
 - ✓ Methodology used to assess effectiveness should provide objective and relevant evidence that informs policy decision makers in the evaluation and development of corrective actions

Question C: MERP Survey Questionnaire

Procedure or system:	Annual review date (required):	Interval review date(s) (optional):	Does the annual review demonstrate assessment for effectiveness?	Comment:
Prescribing:	____/____/2006	____/____/2006 ____/____/2006	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
	____/____/2007	____/____/2007 ____/____/2007	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
	____/____/2008	____/____/2008 ____/____/2008	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
	____/____/2009	____/____/2009 ____/____/2009	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
	____/____/2010	____/____/2010 ____/____/2010	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	



CDPH INTERNET

“The Medication Error Reduction Plan (MERP) Program seeks to improve the safe use of medications in hospitals. This objective will be achieved by surveying for implementation of each hospital’s MERP in accordance with Health and Safety Code 1339.63 and California Code of Regulations, Title 22. CDPH desires to work collaboratively with hospitals, therefore, to foster the implementation of medication safety strategies which will decrease identified system vulnerabilities.”

Attachments A, B and C Available online:

<http://www.cdph.ca.gov/programs/LnC/Pages/MERP.aspx>

Survey Process - Technology

- Has the facility implemented the technology specified in their plan?
- If none of the technology identified in the plan was implemented determine if alternate form was implemented by 2005.
 - Must be based on independent expert scientific advice demonstrate that it has been effective in eliminating or reducing errors

HSC 1339.63(e)(4)

Survey Process – Identification of Medication Errors

- What is the facility's process to proactively identify medication errors?
- Does the process include concurrent and retrospective review of care?
- Is the process reactive rather than proactive?

HSC 1339.63(e)(5)

Survey Process – Analysis of Medication Errors

- Ascertain process for analyzing potential and actual medication errors.
- Is it multidisciplinary? (RPh, RN, MD and administration)
- How frequently does this occur? (“regularly analyze”).
- How are potential errors identified?
- Are all medication errors analyzed?
- How has medication error analysis been used to change current procedures and systems?

HSC 1339.63(e)(6)

Survey Process – External Alerts

- What external sources does the facility utilize for identification of potential/actual risk points related to medication errors?
- How has the facility utilized these external alerts to modify current process and systems?

HSC 1339.63(e)(7)

Survey Activities

- Medication pass observation
 - SNF process
 - ICU
 - Medical/Surgical Unit
- Inspections – ED, Surgery, ICU, Med/surgical
- Clinical record review
 - Sample from requested records
 - Open records – ED, ICU, Med/Surgical

Survey Activities

- Medication error reports
 - Sample from each of the past 3 years
- Emergency medication
 - Crash Carts
 - Malignant Hyperthermia
 - Locations
 - ✓ ED
 - ✓ Surgery (including PACU)
 - ✓ ICU
 - ✓ Medical/surgical

MERP Survey Summary

January 2009 – August 2010

- 381 – Hospitals to be surveyed
- 240 – Selected to be surveyed (63%)
 - ✓ January 1, 2009 – September 30, 2010
- 175 – Completed surveys (73%)
- 153 – Noted deficiencies (87%)
- 22 – In compliance (13%)

Data as of 9/15/2010

MERP Survey Summary

- On average three (3) different deficient practices are cited per non-compliant Statement of Deficiencies issued.
- Common deficiencies
 - CCR 70263(c)(1) – 40%
 - Health and Safety Code
 - ✓ 29% - 1339.63 (e)(2)
 - ✓ 23% - 1339.63 (e)(1)
 - ✓ 20% - 1339.63 (e)(6)

Regulation/Law

- CCR Title 22 – 70263(c)(1) Must develop policies and procedures for establishment of safe and effective systems for procurement, storage, distribution, dispensing and use of drugs.
- H&S Code 1339.63(e)(1)(2)(6)
 - Identify weakness or deficiencies that could contribute to errors -23%
 - Conduct an annual review to assess effectiveness of the implementation of MERP – 29%
 - Include a multidisciplinary process to regularly analyze all errors – 20%

Medication Safety System Vulnerabilities

- Management of High Risk Medications
 - Fentanyl Transdermal Patch
- Provision of Emergency Medications
- Safe Storage of Medications
 - Includes all areas listed on CDPH issued license (e.g. outpatient)

High Risk Medications

- Use of droperidol without pre-screening and cardiac monitoring
- Fentanyl Transdermal Patch
- Issued CDPH Medication Safety Alert – November 2007



MARK B HORTON, MD, MSPH
Director

State of California—Health and Human Services Agency
California Department of Public Health



ARNOLD SCHWARZENEGGER
Governor

November 5, 2007

AFL 07-33

TO: GENERAL ACUTE CARE HOSPITALS

SUBJECT: **MEDICATION SAFETY: USE OF MEDICATIONS WITH “BOXED WARNINGS”**

BACKGROUND: The Department of Public Health’s Center for Healthcare Quality Licensing and Certification Program is issuing this letter to address concerns pertaining to the safe use of medications whose labeling contains boxed warnings, also sometimes called black box warnings. The concerns identified have been noted throughout the state and have resulted in both licensing and federal noncompliance determinations, including Immediate Jeopardy declarations.

This letter is intended to provide guidance on the safe use of medications. The guidance is based on California Code of Regulations (CCR), Title 22, Section 70263(c) (1), 42 Code of Federal Regulations (CFR), Part 482.25 and 21 Code of Federal Regulations (CFR), Part 201.57. Use of medications must be in a manner that promotes patient safety in full consideration of the medication’s inherent risks. We ask that you consider

Survey Findings – Fentanyl Patch

- August 2008 – July 2010 – 22 hospitals
- 48 patients
- Not opioid tolerant – 46 (96%)
- Used to treat acute pain – 9 (19%)
- Lack of adequate indication – 6 (12.5%)
- Initial dose excessive – 9 (19%)
- Patient harm noted – 4 (8%)

Survey Findings

- Lack of a Policy and Procedure on BBW and/or use of Fentanyl – 13 (59%)
 - When present was not sufficient to support safe use
 - ✓ Vague – restated manufacturer warnings
 - ✓ Lack of guidance on how to resolve prescribing concerns noted upon RPh review
 - ✓ Competency evaluation on application of P&P including ability to determine opioid tolerance

Common System Vulnerabilities

- Lack of clear procedural steps to promote safe use of Fentanyl at all points of care.
- Knowledge deficit – MD, RN, RPh
- Use without RPh review
- Available in ADCs on override
- Competency evaluation

Emergency Medications

- Provision of emergency medications to ensure safe and effective use – pediatric, neonate and adult
- Supplies
 - Adequate
 - Accurate
 - Checked and sealed by a RPh
- Competency
- AFL 05-02

February 1, 2005

AFL 05-02

TO: General Acute Care Hospitals

SUBJECT: Storage and Use of Emergency Medications

BACKGROUND: The Department of Health Services, Licensing and Certification program is issuing this letter to address concerns pertaining to the provision of emergency medications. The concerns identified have been noted throughout the state and have resulted in both licensing noncompliance determinations and Federal Immediate Jeopardy declarations.

This letter is intended to provide guidance for the establishment, storage and use of emergency medications. The recommendations are based on California Code of Regulations, Title 22, Section 70263(f) (1-3) and standards of practice such as the Institute for Safe Medication Practice (ISMP) and American Society for Health-System Pharmacists (ASHP). The storage of emergency medications must be in a manner that provides for comprehensive and safe treatment of emergent clinical situations in an expeditious manner consistent with standards of clinical practice. We ask that you consider these recommendations to evaluate provision of emergency medications stored and utilized in clinical service areas.

Emergency Medications – Treatment of Malignant Hyperthermia (MH)

- Standard of Practice – Malignant Hyperthermia Association of United States - MHAUS.org
 - Provides list of necessary supplies and medications to treat MH – if triggering agent used
- Triggering agent used without access MH supplies/medications
- Lack of adequate supplies
 - Dantrolene – 36 vials immediately available where ever triggering agents are use.

MHAUS

- **Q: Must we stock 36 vials of dantrolene if our OR is very close to a fully equipped hospital and the patient could be transported there quickly?**
- **A:** Yes, a stock of 36 vials is recommended. The patient experiencing an MH episode must be stabilized before being transported... The full 36 vials of dantrolene is inexpensive insurance against patient injury or death and a malpractice claim, which the facility will lose. *The full 36 vials of dantrolene should be available within five minutes of the diagnosis of MH.*

MHAUS.org FAQ

Safe Storage

- Recalls
 - Board of Pharmacy - guidelines on Drug Distribution
 - http://www.pharmacy.ca.gov/licensing/best_practices_recalls.pdf
- Expired medications available
- High Risk meds available – hypertonic saline
- ADC over rides
- Refrigeration/warming
 - Lack of monitoring
 - Inaccurate temperature

CDPH ALERT — Check Your Medication Refrigerators

September 2009, Vol. 1 No. 7

CDPH has identified a number of situations in which the storage of refrigerated medications has not protected the health and safety of patients.

The situations have involved refrigerators located on clinical units (e.g. emergency department) and in the pharmacy where the noted refrigerator temperature was outside of the acceptable range.

Refrigerator temperature shall be between 2.2° Celsius (36° Fahrenheit) and 7.7° Celsius (46° Fahrenheit) in accordance with California Code of Regulations (CCR), Title 22, Section 70263 (q)(6).

In all cases the failure to maintain an appropriate temperature range was over an extended period of time (e.g. months) and involved both elevated temperatures (greater than 8° Celsius) and lower temperatures (below 2° Celsius).



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State of California—Health and Human Services Agency
California Department of Public Health



ARNOLD SCHWARZENEGG
Governor

December 10, 2009

AFL 09-56

TO: All Facilities

SUBJECT: Medication Safety: Storage of Medications Requiring Refrigeration

BACKGROUND: The Department of Public Health's Center for Health Care Quality Licensing and Certification Program is issuing this letter to address concerns pertaining to the safe use of medications that require refrigeration. The concerns identified have been noted throughout the state and have resulted in both licensing and federal noncompliance determinations, including Immediate Jeopardy declarations.

Failure to store medications at the appropriate temperature, as specified by the manufacturer, can have significant impact on patient care. Numerous medications have minimal tolerances for temperatures outside a relatively narrow range and once the manufacturer's established limits are breached, the product may be rendered less than optimally effective or ineffective. This is particularly true for the majority of vaccines

MERP and Beyond



- Medication Safety Committee
 - ED Order Review
 - High Risk/High Alert Medications
 - MERP

Best Practices?

“The department may work with the facility's health care community to present an annual symposium to recognize the best practices for each of the procedures and systems.”

[HSC 1339.63 (g)]

Are you willing to host a symposium?

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Thank you!