

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA040001344	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 06/17/2009
NAME OF PROVIDER OR SUPPLIER COMMUNITY MEDICAL CENTER FRESN		STREET ADDRESS, CITY, STATE, ZIP CODE 2823 FRESNO STREET FRESNO, CA 93715		
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A 000	Initial Comment Surveyor: 23014 The following reflects the findings of the California Department of Public Health during a licensure survey. This was a survey to determine compliance with the California Health and Safety Code 1339.63. Representing the California Department of Public Health: Michael Alexander, Pharmaceutical Consultant II and Debra Brown, Pharmaceutical Consultant II. The survey was limited to the hospital's compliance with California Health and Safety Code 1339.63 and does not represent the findings of a full inspection of the facility. Pharm - Pharmacist CDPH - California Department of Public Health RN - Registered Nurse IRIS - Incident Reporting Intranet System MERP - Medication Error Reduction Plan	A 000		
A 006	1339.63 (e)(1) Procedures and Systems Evaluate, assess, and include a method to address each of the procedures and systems listed under subdivision (d) to identify weaknesses or deficiencies that could contribute to errors in the administration of medication (including, but not limited to, prescribing, prescription order communications, product labeling, packaging and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use). This Statute is not met as evidenced by: Surveyor: 23014	A 006		

Licensing and Certification Division

TITLE

(X6) DATE

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

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A 006	<p>Continued From page 1</p> <p>Based on staff interview and administrative document review, the hospital's MERP failed to include a method identify weaknesses or deficiencies resulting in medication errors in each of the 11 areas listed in subdivision (d) of the California Health and Safety Code 1339.63. The 11 areas included prescribing, prescription order communications, product labeling, packaging and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use. Weaknesses or deficiencies in the 11 areas had the potential to expose patients to unnecessary adverse effects of medications administered in error.</p> <p>Findings:</p> <p>1. On 06/23/09, between 8:30 and 9:30 a.m., the hospital provided a group presentation by pharmacy and nursing management. The presentation summarized the facility's implementation of the 11elements of Health and Safety Code 1339.63. With regard to technology implementation, under medication administration, the hospital discussed the implementation of "smart pumps". Smart pumps were specialized pumps for the administration of intravenous medications. They were pre-programmed with a medication concentrations (strengths) and dose limitation safeguards for various medications such as vasopressors (to increase blood pressure) determined by the hospital to help prevent medication errors. The pumps were programmed in November 2008. During the hospital presentation, Pharm 1said he had noted a decrease in medication error reports related to incorrect pump settings since the purchase and use of smart pumps.</p> <p>The facility's written MERP (Plan to Eliminate Or</p>	A 006		

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A 006	<p>Continued From page 2</p> <p>Substantially Reduce Medication-Related Errors) which was revised 2/12/09, indicated that the smart pumps had been put in use hospital-wide in November 2008. The plan described a goal to measure the effectiveness of their new pump technology by evaluating smart pump data.</p> <p>During an interview on 6/24/09 at 9:25 a.m., RN 7, who was on the smart pump steering committee, said the smart pump over-ride data (from 5/09 and 6/09) was recently being examined. The hospital was in the process of learning what to do with over-ride data. Over-rides occurred when a nurse ignored the pre-programmed settings which provided safeguards for patients being administered intravenous medication. RN 7 said, "once the data was analyzed, it would allow the hospital to identify occurrences when the nurse had over-ridden the pre-determined pump settings." RN 7 further said the steering committee was currently unable to examine smart pump over-rides. As a result, the reasons for the over-rides and potential medication errors which may have resulted from over-rides had not been determined. At this time, Pharm 2 said the hospital needed to examine the download data but had not yet done so. Pharm 2 said that he had "not worked directly with the steering committee" to determine reasons for overrides but "would do so once the initial work was done."</p> <p>2. On 6/23/09 at 10:00 a.m., Pharm 1 reviewed the hospital's current medication error reduction plan. He said the hospital did not have medication error data to identify weakness or deficiencies in three of the 11 items under subdivision (d). The three items were nomenclature, compounding, and use.</p>	A 006			

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A 007	Continued From page 3	A 007		
A 007	<p>1339.63 (e) (2) Annual Review</p> <p>Include an annual review to assess the effectiveness of the implementation of each of the procedures and systems listed under subdivision (d). Subdivision (d) defines a "medication-related error" to mean " any preventable medication-related event that adversely affects a patient in a facility listed in subdivision (a), and that is related to professional practice, or health care products, procedures, and systems, including, but not limited to, prescribing, prescription order communications, product labeling, packaging and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.</p> <p>This Statute is not met as evidenced by: Surveyor: 23014 Based on staff interview and administrative document review, the hospital did not conduct annual reviews in 2006 and 2007 to assess the effectiveness of medication error reduction interventions for each of the procedures and systems listed under subdivision (d) of the California Health and Safety Code 1339.63. Lack of effectiveness of interventions to reduce medication errors had the potential to expose patients to unnecessary risks attributable to medication errors.</p> <p>Findings:</p> <p>Examination of documents provided by the hospital on 6/23/09 included the following subjects: California Department of Public Health License, Medication Error Reduction Plan, Multidisciplinary Team Members (MERP), Performance Improvement, and Reports. None</p>	A 007		

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A 007	Continued From page 4 of the documents provided listed assessments of the effectiveness of the implementation of each of the procedures and systems listed under subdivision (d). Procedures and systems listed under subdivision (d) included: prescribing, prescription order communications, product labeling, packaging and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use. On 6/23/09 at 2:40 p.m., Pharm 1 and Pharm 2 were interviewed. Pharm 1 said the hospital conducted an annual review in 2008 but did not conduct annual reviews in 2006 and 2007. Pharm 1 said the hospital did not address the systems and procedures listed in subdivision (d) in the 2008 annual review.	A 007			
A 008	1339.63 (e) (3) Annual Modifications Be modified as warranted when weaknesses or deficiencies are noted to achieve the reduction of medication errors. This Statute is not met as evidenced by: Surveyor: 23014 Based on staff interview and administrative document review, the hospital failed to modify their medication error reduction plan based on identified weaknesses or deficiencies. Weaknesses or deficiencies in their plan would have been demonstrated by the lack of success in reducing or eliminating medication errors. Failure to modify their plan as a result of identified deficiencies or weaknesses potentially exposed patients to adverse effects of drugs resulting from medication errors. Findings:	A 008			

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A 008	Continued From page 5 Review of documents provided by the hospital on 6/23/09 including "Medication Error Reduction Plan" and "Performance Improvement" did not show modification of their medication error reduction plan based on identified weaknesses or deficiencies. Pharm 1, at 2:40 p.m. on 6/23/09, said the hospital did not use medication error information to identify successes or failures of interventions to reduce medication errors. RN 6, at 2:45 p.m. on 6/23/09, said the hospital's reporting system made it difficult to determine weaknesses in their plan. Weaknesses would have been demonstrated by lack of success in reducing or eliminating medication errors.	A 008		
A 010	1339.63 (e)(5) Concurrent and Retrospective Review Include a system or process to proactively identify actual or potential medication-related errors. The system or process shall include concurrent and retrospective review of clinical care. This Statute is not met as evidenced by: Surveyor: 23014 Based on staff interviews and administrative document reviews, the hospital failed to maintain a medication error identification system which promoted the reporting of actual and potential errors. Identification of medication errors provided information which aided in the design of the hospital's MERP and in determining whether interventions in the MERP to decrease medication errors were successful. The absence of medication error information had the potential to increase patients' exposure to errors when:	A 010		

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A 010	<p>Continued From page 6</p> <ol style="list-style-type: none"> Physicians had not been reporting medication errors. Two of four registered nurses (RN 1, RN 2) who were interviewed did not mention that they should have reported medication errors in the hospital's medication error reporting systems. Four of four registered nurses (RN 1, RN 2, RN 3, RN 4) who were interviewed did not mention that they could have alternatively reported medication errors with the IRIS Quick Report Form, a one-page paper form. <p>Findings:</p> <ol style="list-style-type: none"> On 6/23/09 at 9:20 a.m., Pharm 1 said physicians did not report any medication errors during the last quarter of the year. He said he did not know why they were not reporting any medication errors. He said approximately 100 medication errors had been reported by other health care workers in previous quarters. On 6/23/09 at 2:55 p.m., RN 1 was interviewed in patient care area 5 West. She was asked about the process for reporting a medication error when one was observed. She said she notified the patient's physician, the patient, and her supervisor. She did not mention the need to report it in the IRIS computer system. <p>On 6/23/09 at 3:00 p.m., RN 2 was interviewed in patient care area 5 Central. She was asked about the process for reporting a medication error when one was observed. She said she notified the physician and her supervisor. She did not mention the need to report it in the IRIS computer system.</p> <p>On 6/23/09 at 3:10 p.m., RN 3 was interviewed in patient care area 7 West. At 3:20 p.m. RN 4 was</p>	A 010		

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A 010	Continued From page 7 interviewed in the Emergency Department. Both nurses were asked about the process for reporting medication errors. Both nurses said they reported medication errors in the IRIS computer system. 3. On 6/24/09, RN 5 said health care workers could report medication errors in the IRIS computer system or they could use the "IRIS Quick Report Form". She provided a copy of the form titled, the Iris Quick Report Form which was a one page paper form. This form required health care workers to fill in coments in order to report medication errors. It indicated that it was to be forwarded to risk management. None of the interviewed nurses (RN 1, RN 2, RN 3, and RN 4) mentioned the Iris Quick Report Form as an option for reporting medication errors. Hospital policy number 12138 titled, Incident Reporting Intranet System (IRIS), indicated the purposes were: "A. To provide a mechanism for reporting and tracking unusual incidents related to the care of patients; B. To improve responsiveness by assuring that incident review, appropriate investigation, and intervention are accomplished in a timely manner; C. To accumulate information for developing protocols and other measures to prevent subsequent recurrences." The policy did not address the option of using the IRIS Quick Report Form.	A 010		
A 011	1339.63 (e)(6) Multidisciplinary Process Include a multidisciplinary process, including health care professionals responsible for pharmaceuticals, nursing, medical, and administration, to regularly analyze all identified actual or potential medication-related errors and describe how the analysis will be utilized to	A 011		

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A 011	<p>Continued From page 8</p> <p>change current procedures and systems to reduce medication-related errors.</p> <p>This Statute is not met as evidenced by: Surveyor: 23014 Based on staff interview, the hospital failed to include a multidisciplinary process of health care professionals responsible for pharmaceutical, nursing, medical, and administration services to regularly analyze all identified actual or potential medication-related errors. Failure to use a multidisciplinary process to analyze all actual and potential medication errors potentially placed patients at greater risk to become recipients of medication errors.</p> <p>Findings:</p> <p>On 6/23/09 at 9:20 a.m., Pharm 1, who was the "Medication Safety Specialist" for the hospital, said he screened all medication errors before deciding which ones to send to the multidisciplinary Medication Management Committee. He said the Medication Management Committee had representatives from nursing, pharmacy, administration, and medical services. He said he sent only the ones he felt were significant to this Committee. Pharm 1 said he did not send all of them to the Medication Management Committee. He said he reported all of them in aggregate or "roll-up" form and specific examples to the Medication Management Committee. He indicated that aggregate or "roll-up" form did not allow each medication error to be analyzed by the Medication Management Committee. Pharm 2 and RN 8 acknowledged that the description of the process by Pharm 1 was correct.</p>	A 011		

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A 011	Continued From page 9 On 6/23/09 at 9:45a.m., Admin 1, who was the "Corporate Safety Officer", said the medication error data which went to the Medication Management Committee was based on reviews by Pharm 1.	A 011		