California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CA930000063	A. BUILDING _____ B. WING _____	04/22/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HENRY MAYO NEWHALL MEMORIAL HOSPITAL	23845 W MCBEAN PKWY VALENCIA, CA 91355

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E 000	Initial Comments The following reflects the findings of the California Department of Public Health, Licensing and Certification Program during a Medication Error Reduction Plan (Health and Safety Code Section 1339.63) survey. The survey was conducted April 6-8, 12-14, and 20-22, 2010. Representing the Department of Public Health: Surveyor ID #27873, Pharmaceutical Consultant II 1280.1 (c) Health and Safety Code Section For purpose of this section, "Immediate Jeopardy means a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or likely to cause, serious injury or death to the patient.	E 000	**E 000** **SUMMARY** The corrective actions taken are summarized below. For more information on each action, please see response to Tag E485, below. • Adjusted Hospital computer system ("Meditech") setting dose range alert to "All". The "All" setting includes all toxic drugs in the computer data base including Colistimethate and alerts the pharmacist if the dose ordered is outside of the clinically appropriate range. • Meditech renal notification parameters for Colistimethate were adjusted to notify the user during order entry of the patient's renal status. The ordering physician is then contacted as necessary. • Colistimethate was added to the Pharmacy's Daily Clinical Reminder report. This report alerts the pharmacist that review is needed. • Colistimethate was added to the Daily Renal Monitoring report. This report alerts the pharmacist of changes in values that may need dose adjustments. • Colistimethate has been included on the Daily Communication Log, indicating to the pharmacist when patients are receiving the drug. • A Multidisciplinary Medication Safety Team ("Team") was formed. Under the direction of a physician and the Director of Pharmacy, the Team analyzes all medication incidents for unusual occurrences and trends.	1/19/10 1/19/10 1/20/10 1/20/10 1/20/10 6/30/10
E 485	T22 DIV5 CH1 ART3-70263(g)(2) Pharmaceutical Service General Requirements (g) No drugs shall be administered except by licensed personnel authorized to administer drugs and upon the order of a person lawfully authorized to prescribe or furnish. This shall not preclude the administration of aerosol drugs by respiratory therapists. The order shall include the name of the drug, the dosage and the frequency of administration, the route of administration, if other than oral, and the date, time and signature of the prescriber or furnisher. Orders for drugs should be written or transmitted by the prescriber or furnisher. Verbal orders for drugs shall be given only by a person lawfully authorized to prescribe or furnish and shall be recorded promptly in the patient's medical record, noting	E 485		

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E 485	Continued From page 1 the name of the person giving the verbal order and the signature of the individual receiving the order. The prescriber or furnisher shall countersign the order within 48 hours. (2) Medications and treatments shall be administered as ordered. This Statute is not met as evidenced by: Based on review of Patient 1's medical record, review of facility documents, and interviews with the facility staff, the hospital failed to ensure that Patient 1 received the correct medication dosage as ordered by the physician. Patient 1 was prescribed Colistin (Colistimethate) Methanesulfonate, (an antibiotic used to treat infections), 5 milligrams (mg) per kilogram (kg), in "divided doses," intravenously (IV), every 8 hours. Based on the patient's weight, 70.3 kg, the physician's order for Colistin required the patient to receive 5 mg per kg, every 8 hours, in divided doses, which would have been 117 mg every 8 hours (a total dose of 350 mg per day). However, six (6) doses of 350 mg (three times more than the prescribed amount per dose) of Colistin were administered to Patient 1. The facility's failure resulted in Patient 1 developing acute renal failure (a sudden loss of kidney function characterized by decreased urine production and elevated blood urea nitrogen (BUN) and creatinine . As a result of the facility's failure, Patient 1 required hemodialysis treatments (a procedure which directs the patient's blood flow externally through a special	E 485	• The Chair of the Department of Medicine reviews all Medication Incident Reports on an ongoing basis for timely action and to follow up. The Chair forwards any recommendations to the Director of Quality, Director of Pharmacy and to the Team. • The policy "Medication – Orders" No. MM.414 has been revised to clarify when pharmacists must contact a physician for clarification. **E 485** In response to the findings of non-compliance discovered during the MERP survey the following comprehensive corrective action plans have been instituted: **1. HOSPITAL/PHARMACY ALERTS, NOTIFICATIONS AND REPORTS** **Action: Meditech Alert Settings Adjusted** The Hospital uses Meditech software as its electronic medical record and information management system, and First Data Bank ("FDB") as its Formulary Service Provider. The Meditech Dose Range Checking default identified in the Hospital's Meditech Customer Defined Parameters were revised to "ALL". The "ALL" setting will ensure dose range checking for all ranges provided by FDB and any ranges entered manually by Hospital staff. This setting includes the drug Colistimethate and all other drugs in the computer data base.	10/1/10 6/20/11 1/19/10

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E 485	Continued From page 2 machine which helps the body remove wastes before returning the blood to the patient). Findings: On April 7, 2010, during the Medication Error Reduction Plan (MERP) survey, a review of the facility's medication error reports revealed that an overdose of Colistin Methanesulfonate was given to Patient 1. Colistin (Colistimethate) is an antibiotic medication used to treat infections. The side effects of this drug include tingling or numbness in the extremities and mouth, weakness of the lower limb, increase BUN and creatinine levels, nephrotoxicity (poisonous effects of toxic chemicals and medications on the kidneys), dizziness, headache, slurred speech, respiratory arrest, rash, and itching. The dose for adults is based on the patient's ideal body weight. The dosing for intravenous was 2.5 milligram (mg)/kilogram (kg)/per day in 2 - 4 divided doses. According to the facility's policy and procedure on Medication Administration, Preparation, Control, Distribution, and Documentation dated January 27, 2009, medications would be administered safely to the patients as prescribed by the physician. The primary goal in medication administration included administering the correct dose of the drug. On April 7, 2010, a review of Patient 1's medical record was conducted. The History and Physical report dated [redacted] 2010, indicated Patient 1 was admitted to the facility with diagnoses that included pneumonia, chest pain and abdominal pain.	E 485	**Education:** All Clinical Pharmacists were educated regarding the new alert settings in late January 2010. **Responsible Person:** Director of Pharmacy. **Monitoring:** The Director of Pharmacy reviews updates to the Meditech Information system on at least a monthly basis. This review ensures that the most up to date information in regards to Dose Range Checking is available within Meditech and for review by the Hospital's Clinical Pharmacists. No incidents of incorrect medication doses for Colistimethate have been reported through the monitoring process since the Meditech Customer Defined parameters were set to "ALL". **Action: Adjust Renal Notification Parameters for Colistimethate** Within the Meditech drug dictionary set up for Colstimethate, a specific alert was set up to notify the user during order entry of the patient's renal status. If a patient has an alert for altered renal status during Colistimethate order entry, the pharmacist will contact the physician to request any adjustments to the ordered dose, as necessary, and will note this in the intervention log in Meditech. **Education:** The Pharmacy Staff was educated in person in January 2010. **Responsible Person:** Pharmacy Clinical Coordinator.	1/19/10

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E 485	Continued From page 3 According to the Infectious Disease Consultation Report dated [redacted] 2010, at 2:25 p.m., the physician's assessment included severe chronic obstructive pulmonary disease exacerbation with multi-drug resistant organisms as well as bronchitis/pneumonia. The physician's recommendations included to administer Colistin medication intravenously to Patient 1. A review of the Physician Progress Notes & Orders dated [redacted], 2010 at 2:15 p.m., indicated an order, "Colistin 5 mg/kg IV q8h (every 8 hours) in divided doses." A review of the Medication Administration Record (MAR) dated [redacted] 2010, indicated a handwritten Colistimethate Sodium 350 mg in 100 ml sodium chloride at 100 ml per hour every 8 hours IV. The MAR indicated the patient's weight was 70.3 kg and the physician's order for Colistin required the patient to receive 5 mg per kg every 8 hours in divided doses, which would have been 117 mg every 8 hours (a total dose of 350 mg per day). Further review of the MAR disclosed that the licensed nurses administered Colismethate 350 mg IV to Patient 1 on the following days and times: [redacted] 2010, at 8 p.m., [redacted] 2010, at 4 a.m., at 12 p.m., and at 8 p.m., and [redacted], 2010, at 4 a.m. and at 12 p.m., The MAR revealed the overdose was administered to Patient 1 every 8 hours for six (6) doses before being discovered and stopped at 1:30 p.m. on [redacted], 2010. The Progress notes (Intervention and Evaluation) dated [redacted], 2010, at 7:30 a.m., and at 10:55 a.m., disclosed the patient complained of numbness in his face, dry mouth, and saying,	E 485	**Monitoring:** The Pharmacy Clinical Coordinator will monitor the Meditech intervention log weekly for 90 days starting July 1, 2011 for appropriate contact with ordering physician as needed. Additional monitoring will be performed as needed based on the results of the 90 day review. **Action: Daily Clinical Reminder Report** Colistimethate was added to the Pharmacy's Daily Clinical Reminder Report. This report is generated on a daily basis and lists drugs identified as needing Clinical Pharmacist review. After review, the Clinical Pharmacist communicates any concerns to the physician requesting dosage adjustments or discontinuation of drug. **Education:** The Pharmacy Staff was educated in person in January 2010. **Responsible person:** Pharmacy Clinical Coordinator **Monitoring:** Clinical Pharmacists monitor the Daily Clinical Reminder Report on a daily basis to ensure that patients who are on the identified drugs, including Colistimethate, have their medical records reviewed to ensure that the drugs are being used safely and effectively. The Hospital notes that the effectiveness of the Daily Clinical Reminder Report is evident, in that no error in dosage of Colistimethate has been reported since this drug was added to the Daily Clinical Reminder report on 01/20/2010.	1/20/10

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E 485	Continued From page 4 "the antibiotics are killing me." At 11 a.m., the physician was notified. At 12:15 p.m., Patient 1 stated again, "the antibiotics are killing me," had severe dry mouth and complaining of "loss of motor ability." The Physician Progress Notes & Orders dated [redacted] 2010 at 1:30 p.m., indicated to hold Colistin until further orders. The Physician Progress Notes & Orders dated [redacted] 2010 at 5:30 p.m., revealed the patient developed acute renal failure secondary to (caused by) Colistin. The Renal Consultation Note dated [redacted], 2010, indicated the nephrologist's (Nephrologist A) initial impression was the acute renal failure was caused by hypersensitivity to radiocontrast material (medication used to highlight body organ functions during a special x-ray procedure). The CT (computed tomography) Scan report dated [redacted] 2010, indicated the patient received radiocontrast medium at 4 p.m. In an interview with Nephrologist A on April 8, 2010, at 12 p.m., he stated that the consultation was based upon the information he had at the time of the incident. Nephrologist A stated he misdiagnosed the situation as he thought the patient received only one (1) dose of Colistin. Nephrologist A stated the acute renal failure was caused by the overdose of Colistin. The Physician Progress Notes & Orders dated [redacted], 2010, disclosed the patient was suffering "from acute renal failure likely due to Colistin and IV contrast." The progress notes documented the pharmacy "mis-dosed" Colistin and the patient was given 5 mg/kg IV, every 8 hours, which was not in divided doses as ordered.	E 485	**Action: Daily Renal Monitoring Report** Colistimethate was added to the Pharmacy's Daily Renal Monitoring Report. This report is generated on a daily basis and lists drugs that may need adjustment based on renal function. If a patient's serum creatinine is 1.3 or above, a creatinine clearance is calculated. The pharmacist will indicate that the report has been reviewed by signing the daily log. **Education:** On 01/20/2010 Clinical Pharmacists were educated in person by the Director of Pharmacy regarding the addition of Colistimethate to the Daily Renal Monitoring Report. **Responsible Person**: Pharmacy Clinical Coordinator. **Monitoring:** Clinical Pharmacists review the report on a daily basis to ensure that drugs requiring possible dosing adjustments based on current renal function are identified and that the ordering physician is notified if necessary. The pharmacist reviewing the report will indicate that the report has been reviewed by signing the log. The Pharmacy Clinical Coordinator will monitor for completeness of review for 90 days beginning 07/01/2011. Additional monitoring will be performed as needed based on the results of the 90 day review.	1/20/10

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E 485	Continued From page 5 According to the facility's Medication Errors form dated [redacted], 2010 at 1:45 p.m., on [redacted], 2010 at 4:15 p.m., the physician prescribed an unclear order. The order was written for "Colistin 5 mg/kg IV every 8 hours in divided doses". Order entered as 350 mg IV every 8 hours, should have been 117 mg every 8 hours. Serum creatinine increased from 0.8 on [redacted] to 8.4 on [redacted] Patient received 6 doses before the order was discontinued. There was no evidence that the pharmacy and/or the licensed nurse called the physician to clarify the prescribed unclear order. A review of the facility's laboratory report dated [redacted] 2010, disclosed the patient's BUN level elevated to 32 milligram/deciliter (reference interval 6-19 mg/dl) and creatinine level increase to 4.9 mg/dL (reference interval 0.7-1.3 mg/dL). Urea is a byproduct secreted by the liver and removed from the blood by the kidneys. Creatinine is a byproduct of creatinine found in a person's bloodstream that is removed by the kidneys. If kidney function is abnormal, the BUN and Creatinine will increase in the blood. According to the Discharge Summary dated [redacted], 2010, Patient 1's BUN level was 5 mg/dL and creatinine level was 1 mg/dL on [redacted] 2010. However, the BUN level increased to 18 mg/dL and creatinine level rose to 3.3 mg/dL on [redacted] 2010, and continued to increase on [redacted], 2010 with a BUN level at 71 mg/dL and the creatinine level was 9.5 mg/dL. On [redacted], 2010, Patient 1's serum creatinine rose to 12.3 mg/dL. The Physician Progress Notes & Orders dated [redacted], 2010, revealed the treatment plan for	E 485	**Action: Daily "Off Service" Notes** Pharmacists assigned to clinical shift(s) utilize an electronic log to communicate important issues between off-going and on-coming staff. The on-coming pharmacist will follow up on any concerns identified by the off-going pharmacist. Patients receiving Colistimethate are specifically noted in the Daily "Off Service" Notes. **Education:** A memorandum was sent to pharmacy staff on 01/20/10 reminding pharmacists to include Colistimethate in the off-going/on-coming communication log located in pharmacy folder on the network shared drive. **Responsible Person:** Pharmacy Clinical Coordinator. **Monitoring:** The pharmacist assigned to the clinical shift will review the Daily "Off Service" Notes on a daily basis and perform follow up monitoring. Monitoring to date has revealed that all pharmacy staff are aware of the Daily "Off Service" Notes and utilize them appropriately. The reviewing pharmacist will sign the log indicating it has been reviewed. The Pharmacy Clinical Coordinator will monitor the log for signature for 90 days starting 07/01/11. Additional monitoring will be performed as needed based on the results of the 90 day review.	1/20/10

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E 485	Continued From page 6 acute renal failure was acute hemodialysis after a dialysis catheter placement. The Physician Progress Notes & Orders dated [redacted], 2010, revealed the catheter placement was completed for hemodialysis treatment. The Physician Progress Notes & Orders dated [redacted] 2010, disclosed the patient was to receive hemodialysis on that day. On [redacted], 2010, with the patient still requiring hemodialysis, Patient 1 was transferred to Hospital #2. The Discharge Summary dated [redacted], 2010, disclosed that due to elevated BUN and creatinine levels, the patient underwent hemodialysis. The patient's final discharge diagnoses included acute renal failure. A review of the History and Physical Examination Record dated [redacted], 2010, from Hospital #2 disclosed Patient 1 was transferred to Hospital #2 with diagnoses that included renal failure, likely chronic, and in need outpatient hemodialysis treatment. The Discharge Summary dated [redacted] 2010, from Hospital #2, disclosed the patient received hemodialysis treatments and his last treatment was on [redacted] 2010. The plan was to discharge the patient to home and to arrange with a dialysis center for continued hemodialysis treatments. A review of the Physician's Orders dated [redacted] 2010, from the dialysis center, indicated hemodialysis treatment every Monday and Friday for three weeks. The Progress Record dated [redacted] 2010, disclosed that the patient had received 4 hemodialysis as of that date. On [redacted], 2010, the hemodialysis	E 485	**2. FORMATION OF MULTIDISCIPLINARY MEDICATION SAFETY TEAM** **Action: Formation of Multidisciplinary Medication Safety Team** A Multidisciplinary Medication Safety Team ("Team") was formed in June 2010 to promptly review all medication errors. The Team is chaired by the Chair of the Pharmacy and Therapeutics Committee and the membership is made up by representatives from nursing, pharmacy, respiratory therapy, imaging and quality management. The first meeting took place on June 30, 2010. The Team categorizes medication errors by severity, reviews unusual occurrences, harm to patients, trends by unit or practitioner and type of errors. The Team also formulates corrective action plans to avoid similar errors and evaluates the effectiveness of the actions taken. **Education:** The Pharmacy and Therapeutics Committee was educated on the formation of the Multidisciplinary Medication Safety Team in August 2010. **Responsible Person:** Director of Pharmacy. **Monitoring:** Starting July 1, 2011, the Director of Pharmacy will undertake a review of the effectiveness of the actions taken by the Team over a period of 90 days. Additional monitoring will be performed as needed based on the results of the 90 day review. Monitoring will be conducted via a review of the errors identified and the breakdown of the error severity and patient impact.	6/30/10

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E 485	Continued From page 7 was discontinued when the patient's creatinine level had improved to 2.0 mg/dL. The facility's failure to ensure that a patient received the correct doses of medication as ordered by the physician, which resulted in the patient receiving an overdose of an antibiotic with side effects that included renal toxicity, developing acute renal failure, and undergoing hemodialysis treatment, is a deficiency that has caused, or is likely to cause, serious injury or death to the patient, and therefore, constitutes an immediate jeopardy within the meaning of Health and Safety Code Section 1280.1	E 485	The Team reports to the Pharmacy and Therapeutics Committee, which is a medical staff committee, and the information is reported to the Board of Governors by the Medical Executive Committee. **3. POLICY AND PROCEDURES** **Action: Revision of Hospital Policy "Medication – Orders" Policy No. MM.414** The house-wide policy, "Medication – Orders" No. MM.414 will be revised to include the following verbiage: Orders that state "give in divided doses" must be clarified with the practitioner as to the total daily dose and the exact dose and frequency of the dose(s) to be administered. This change requires pharmacy staff to clarify with the ordering physician all orders written in this manner. This policy change will help safeguard against errors when calculating the medication dosage for a patient. **Education:** A draft revision of policy "Medication – Orders" policy No. MM.414 will be presented at Senior Leadersip attended by Nursing directors on June 23, 2011. The revised policy will be reviewed at the Pharmacy and Therapeutics Committee meeting on June 29, 2011. On June 30, 2011 the Director of Pharmacy will educate Hospital directors including Nursing directors on the policy changes via electronic mail. The pharmacy staff will be educated in person on June 30, 2011. Medical Staff will be educated on the updated policy via memorandum and a copy of the revised policy will be distributed to all physicians on staff on July 1, 2011.	6/20/11

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E 485		E 485	**Responsible Person:** Director of Pharmacy. **Monitoring:** Starting July 1, 2011, the effectiveness of the policy change will be monitored for 90 days by reviewing the Pharmacy Intervention Log where all the physician contacts are documented. Additional monitoring will be performed as needed based on the results of the 90 day review. Detailed reports for Colistimethate will be analyzed by the Pharmacy Clinical Coordinator to ensure that proper contact with the prescriber has been initiated in cases where contact has been deemed necessary. The outcome of the monitoring will be reported to the Multidisciplinary Medication Safety Team as part of the Hospital's quality reporting process. **Action: Medication Event Dashboard** In order to analyze and trend errors, the Pharmacy has developed an aggregate medication event dashboard. The dashboard presents overall errors broken down by node(medication administration, prescribing, dispensing, and transcription) as well as an overall error run chart. This dashboard was presented at the Hospital's Quality Performance Council ("QPC") in July 2010 and is now a standing agenda item at the quarterly QPC meeting chaired by the Hospital's Deputy Chief of Staff. The report is also presented at the Pharmacy and Therapeutics Committee every 2 months. (The QPC functions as the Hospital's Quality Improvement Committee.) **Education:** The change in error reporting format was presented at Quality Performance Council on July 2010.	07/20/10

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E 485		E 485	**Responsible Person**: Director of Pharmacy. **Monitoring:** The QPC and Pharmacy and Therapeutics Committee will monitor the dashboard results at their respective meetings, as described above, and will make recommendations based on the findings from their review. The results of this review and any actions proposed will be reported at the Multidisciplinary Medication Safety Team meetings on a monthly basis and to the Quality Performance Council on a quarterly basis. **Action: Ongoing Medication Incident Review** The Chair of the Department of Medicine reviews all medication incident reports on an ongoing basis. The reports are analyzed by him and forwarded to the Multidisciplinary Medication Safety Team for any follow up. This ongoing review of medication occurrences facilitates early recognition and action by the appropriate parties. **Education:** The Multidisciplinary Medication Safety Team was educated regarding the ongoing review by the Chair of Department of Medicine in October 2010. **Responsible Person:** The Chair of the Department of Medicine. **Monitoring:** The Director of Quality is responsible for forwarding the reports to the Chair of the Department of Medicine. The Chair initials the reviewed reports or acknowledges receipt of reports electronically.	10/20/10

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E 485		E 485	Monitoring of completed reviews will be done for 90 days by the Director of Quality to ensure review is completed consistently and reminders issued to complete in case of a delay. Additional monitoring will be performed as needed based on the results of the 90 day review. The ongoing monitoring is reported to the Multidisciplinary Medication Safety Team as part of the Hospital's quality reporting process. The Multidisciplinary Safety Team audits are reported to the Pharmacy and Therapeutics Committee using the Medical Staff reporting structure to Medical Executive Committee and the Hospital Board of Directors.	