

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050133	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 09/13/2013
NAME OF PROVIDER OR SUPPLIER Rideout Memorial Hospital		STREET ADDRESS, CITY, STATE, ZIP CODE 726 4th St, Marysville, CA 95901-5656 YUBA COUNTY		
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	<p>The following reflects the findings of the Department of Public Health during an inspection visit:</p> <p>Complaint Intake Number: CA00327421 - Substantiated</p> <p>Representing the Department of Public Health: Surveyor ID # 26611, HFEN</p> <p>The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility.</p> <p>Health and Safety Code Section 1280.1(c): For purposes of this section "immediate jeopardy" means a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient.</p> <p>T22 DIV5 ART-70263(g)(2) Pharmaceutical Services General Requirement</p> <p>(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</p>		<p>Incident #327421 6WVT11 survey end date: 10/4/2012. "Immediate jeopardy" which was declared on 9/27/12 and abated on 10/3/12 for a pattern of systemic deficient practices in medication safety.</p> <p>Corrective Actions Taken: To ensure continued compliance with State and Federal laws and regulations, we have taken the following actions:</p> <p>The facility failed to ensure that medications were given as ordered: #1. Patient given 10 times the ordered dose of Methadone; #2. Patient potentially given eight times the intended dose of morphine sulfate; and #3. Patient was not administered Narcan as ordered to reverse the respiratory depressant effects of methadone and morphine.</p> <p>In accordance with the Immediate Jeopardy which was declared on 9/27/12, this Plan of Correction, which was developed collaboratively with the Director of Pharmacy, Nursing Directors, Chief Clinical Officer, Chief Nursing Officer and</p>	9/27/12

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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE *Monica H. Anderson, Ph.D.* TITLE *VP, Quality Management* (X6) DATE *06/27/14*

By signing this document, I am acknowledging receipt of the entire citation packet, Page(s) 1 thru 9

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findings above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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	<p>person lawfully authorized to prescribe or furnish and shall be recorded promptly in the patient's medical record, noting 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.</p> <p>(2) Medications and treatments shall be administered as ordered.</p> <p>Based on observation, staff interview, and clinical record and document review, the facility failed to ensure that medications were given as ordered to Patient 34 when:</p> <p>Patient 34 was given 10 times the dose of Methadone (a long-acting narcotic pain medication) than was ordered; the narcotic was transcribed incorrectly to the medication system as 25 milligrams (mg) instead of 2.5 mg, as ordered.</p> <p>Patient 34 was not administered Narcan (an antidote used to reverse adverse effects of medications) as ordered, to reverse the respiratory depressant effects of the over administration of methadone and morphine.</p> <p>Giving medications inconsistent with physician orders put the patient at risk for developing adverse effects related to excessive use, such as respiratory depression, unresponsiveness, and death. The licensee's noncompliance with T22 DIV5 ART-70263(g)(2) requirements for licensure caused or was likely to cause, serious injury or death to the patient. Patient 34 died on [REDACTED] at 7:30 am.</p>		<p>other members of the executive team, all RN staff were retrained on medication safety policies & procedures that related to verification of orders, clarification of medication orders especially when therapeutic duplication is present, and new requirements for assessment prior to narcotic administration. The hospital trained the Nursing leadership team (consisting of nursing directors, supervisors and clinical educations) then those individuals trained each RN. Each RN was required to complete a post-test which included clinical scenarios related to their area of practice. In addition, each RN signed an attestation statement acknowledging their responsibility to practice in accordance with the training with the understanding that failure to comply would result in coaching or progressive discipline per hospital policy.</p> <p>The verification process for new orders was changed to require the RN to verify the new order from a computer together with the original</p>	9/29/11 through . Nov 2012

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	<p>Findings:</p> <p>Patient 34's record was reviewed. Patient 34 was an 83 year old, admitted to the hospital on [REDACTED] 12 for diarrhea and abdominal cramping and had a history of heart failure, chronic kidney disease, and pulmonary hypertension. (A condition in which high blood pressure in the lungs makes the heart work harder). According to the medication history, Patient 34 had acetaminophen (Tylenol) and gabapentin (non-narcotic medication for nerve pain) ordered for pain.</p> <p>On [REDACTED] 12 at 10:15 am, a physician's note was written indicating there had been a discussion regarding Patient 34's DNR/DNI (do not resuscitate, do not intubate) and that a form was signed. The same note documented that the patient's gastric tube (a feeding tube inserted into the stomach) was discontinued, other medications were stopped, and pain medications were increased.</p> <p>a. On [REDACTED] 12 at 10:30 am, an order for "pain management" was written that included Methadone 2.5 mg to be given every 12 hours (hrs) sublingually (under the tongue).</p> <p>According to LexiComp Online, a pharmaceutical reference, Methadone is a long acting pain medication that has a long half-life, which means it stays in the body for a long time. In a young healthy adult, it can take about 200 hrs (approximately eight days) to eliminate the</p>		<p>physician order (as opposed to verifying the order from the hand-held barcode scanner device). In accordance with the Immediate Jeopardy plan of correction, the Chief and Nursing Officer required the charge nurses to verify all new orders (rather than the care nurse). This process continued for approximately 2 months until Nursing Leadership was satisfied that the care nurses could effectively resume this duty without an adverse effect on medication safety.</p> <p>The Information Systems department created an e-mail alert to all nursing directors and other key individuals which are generated any time a reversal agent is dispensed from the automated medication dispensing cabinet. The nursing directors and / or pharmacy staff research the circumstances to determine if the use was related to an adverse drug event. The Critical Care director also reviews the shift report for any Rapid Response Team (STARRT alert) activation on a daily basis, Monday - Friday, (weekend events are</p>	<p>9/27/12 and on-going</p> <p>9/30/12</p>

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	<p>medication from the body. According to the drug labeling information, it is directed to use methadone with caution in debilitated patients as there is a greater potential for critical respiratory depression, even at therapeutic dosages. Another concern is using methadone in an elderly person as the elderly may be more sensitive to adverse effects.</p> <p>Methadone has a boxed warning, which is the strongest warning that certain contraindications or serious warnings, particularly those that may lead to death or serious injury, may be required by the FDA to be added to the labeling of the drug. The warning indicates that severe respiratory depression has occurred with administration of methadone. It also directs to use extreme caution during treatment initiation, dose titration and conversion from other opioid agonists to methadone.</p> <p>Patient 34 was 83 years old with multiple medical problems and no current medication history of taking narcotics.</p> <p>In an interview and record review on 9/27/12 at 10 am, the Director of Pharmacy (DP) confirmed Patient 34's record contained no documented justification for ordering Methadone for pain considering the history of medication use for Patient 34.</p> <p>On 9/27/12 at 10 am, review of the facility's pharmacy computer system revealed that the methadone order was entered erroneously for 25 mg instead of 2.5 mg (ten times higher than what</p>		<p>reviewed next business day)to determine if a STaRRT alert was due to any adverse drug event.</p> <p>The nurse who administered the incorrect dose of Methadone and who failed to document the waste of Roxanol was a contract RN – following investigation of this event, her contract was terminated. The nurse who failed to administer the Narcan as ordered was educated on the indications for and side effects of the medication and was formally counselled for failing to administer the medication per physician order.</p> <p>The process for charge nurse verifying new orders was implemented to assure that new orders are initiated in a timely manner. Charge Nurse review was done concurrently. In November 2012, based on data reported by the Charge nurses, the Nursing Management team agreed to resume the previous process of the primary care RN verifying all new orders concurrently. All orders from the shift are reviewed by a nurse from</p>	<p>10/5/12</p> <p>9/27/12</p> <p>Nov 2012</p>	

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	<p>was intended) into the medication system.</p> <p>Consequently, according to the [REDACTED] 2012 Medication Administration Record (MAR) for Patient 34, 25 mg of methadone was given (Ten times the dose that was prescribed).</p> <p>On 9/27/12, review of the Accudose (automated dispensing cabinets, where medications are stored and electronically tracked) revealed that three syringes of methadone (10 mg each) were removed for Patient 34 on [REDACTED] 12 at 12:02 pm.</p> <p>The facility's policy titled, "Medication Administration Hospitalwide," approved 9/24/12, was reviewed and included the following: "the right medications (bolded and italicized by the facility for added emphasis) shall be administered to the right patient, in the right dosages, at the right time, using the right methods."</p> <p>This facility's policy was not implemented as Patient 34 received 10 times the methadone dose that was ordered for her. The facility failed to administer the methadone as ordered in violation of T22 DIV5 ART-70263(g)(2).</p> <p>b. On [REDACTED] 12 at 10:30 am, in addition to the above Methadone order, Patient 34's physician ordered Roxanol (oral morphine sulfate, a short acting pain medication) as follows: 2.5 mg every hr for pain scale 0-3/SOB (shortness of breath); 5 mg every hr for pain scale 4-7/SOB; 10 mg every hr for pain 8-10/SOB.</p> <p>On 9/27/12 at 10 am, during an interview and record</p>		<p>each shift at the 12-hr chart check to be sure all orders have been initiated and carried out.</p> <p>The Information Systems department together with the Pharmacy built hard stop alerts (must be answered before proceeding) in the Pharmacy order entry system which requires the pharmacist to answer key questions prior to entering new orders for pain medications. These questions are designed to identify potential therapeutic duplication in advance of the new medication being added to the patient's pharmacy profile. In addition, hard stop alerts were built into the bedside barcode scanning devices requiring the RN to answer questions related to prior narcotic administration, current level of consciousness, respiratory rate, blood pressure and pain level prior to narcotic administration.</p> <p>Again as part of the Immediate Jeopardy Plan of Correction, processes were implemented to assure that pharmacist entered orders were double-checked by a 2nd</p>	<p>9/27/12</p> <p>9/27/12</p>	

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	<p>review, the DP confirmed there was no clinical justification for ordering duplicate pain medications (Methadone and Morphine) as Patient 34 was previously only taking acetaminophen and gabapentin, and there was no evidence of prior narcotic use.</p> <p>Review of Patient 34's MAR revealed that on [REDACTED] 2 at 1412 (2:12 pm), about 2 hours after the methadone dose, a morphine dose was administered and documented as 2.5 mg. However, review of the access record from the Accudose medication dispensing unit showed that one (1) milliliter was removed (one milliliter has 20 mg of morphine). There was no documented evidence of the disposition of the remaining 17.5 mg.</p> <p>The facility's policy titled, "Medication Administration Hospitalwide," approved 9/24/12, was reviewed and included the following: "The following medication doses shall be double checked with a second licensed nurse or physician prior to administration. This includes verification of medication name, dosage, route and scheduled administration time by a second licensed nurse, physician or a pharmacist: ...Oral liquid Opiates (e.g. Roxanol) [bolded and italicized by the facility for added emphasis] ...Both staff administering and witnessing will document the double check on the Medication Administration Record (MAR) by initialing or electronically signing."</p> <p>The nurse that administered the medication was not available for interview.</p>		<p>licensed person. Initially this was accomplished by utilizing RN staff in pharmacy to double-check until such time as contract pharmacists were brought in to perform this function. To date, all pharmacist entered orders are double-checked by a 2nd licensed pharmacist.</p> <p>Corrective Actions Taken:</p> <p>The hospital by implementation of this plan of correction, is in compliance with the standards related to Administration of Drugs.</p> <p>#1: Physician education was performed on the equivalent dosing for opioids and posted on the Physician's portal as a reference. The MEC reviewed issues related to physician prescribing practices for narcotics, therapeutic duplication, and role of the physician in assessing and managing adverse drug events. The general medical staff were educated via e-mail by the Chief Medical Officer. Education was performed for pharmacists on opioid equianalgesic</p>	<p>3/19/13</p> <p>10/15/12</p> <p>10/5/12</p>

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	<p>On 9/27/12 at 10 am, Director of Pharmacy was asked about the disposition of the 17.5 mg of morphine and stated that there was no electronic or manual documentation of wasting the 17.5 mg. Therefore, it could not be confirmed that Patient 34 was administered 2.5 mg of morphine.</p> <p>The requirements for double signature for wasting controlled substance is delineated in the facility's policy titled, "Controlled Substance Hopsitalwide," dated 2/20/12. The policy included the following directive: "Two licensed practitioners are required for wasting all controlled substance. All or part of a controlled drug can be wasted. Documentation of the wastage should be completed when the controlled substance is wasted."</p> <p>Patient 34's record revealed that she had become unresponsive after she was administered 25 mg of methadone, at 10 times the intended dose, and potentially 20 mg of morphine about two hrs later.</p> <p>c. On [REDACTED] 12 at 2054 (8:54 pm), Patient 34 had an order for Narcan 0.4 mg to be given now and repeat every half hr until responsive, times four doses.</p> <p>According to LexiComp Online, Narcan is a rescue agent for opiate/opioid type medication that reverses sedation and respiratory depression associated with excessive use of opiate/opioid type medications like morphine and methadone that reverses sedation and respiratory depression.</p>		<p>dosing and a pharmacokinetics comparison of opioid medications. 100% of pharmacist entered orders are double checked for accuracy by a second pharmacist to ensure the accuracy of order entry, clear indications if there are duplicate therapies, appropriateness of dosage, frequency and overall medication management of the patient. 100% of staff were educated via any one of the following: the weekly huddle, staff meetings, one on one communications and written memoranda.</p> <p>Follow-up monitoring to prevent recurrence: A summary of 100% of pharmacist interventions for incomplete or unclear orders, therapeutic duplications and appropriateness of dosage & frequency are tracked and trended. These interventions are reported on the Med Safety Dashboard, which is reported to the Medication Safety Committee, Hospital Safety Committee, Pharmacy</p>	<p>October 2012</p> <p>10/9/12</p> <p>10/4/12</p> <p>Oct 2012</p> <p>2/21/13</p>	
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	<p>Narcan is metabolized and eliminated from the body very fast, therefore, is it usually given in frequent dosing, every few minutes. According the drug labeling information, Narcan is given as follows: "Initial: 0.4-2 mg; may need to repeat doses every 2-3 minutes; after reversal, may need to readminister dose(s) at a later interval (i.e., 20-60 minutes) depending on type/duration of opioid. If no response is observed after 10 mg total, consider other causes of respiratory depression. ...Continuous infusion (should be considered) ... For use with exposures to long-acting opioids (e.g., methadone), sustained release product ..."</p> <p>Review of the [REDACTED] 2012 MAR for Patient 34 revealed that two doses of Narcan were administered to Patient 34 on [REDACTED] 12 at 2115 (9:15 pm) and 2151 (9:51 pm). There was no documented evidence that the other two doses were administered.</p> <p>On 9/27/12 at 10 am, during a concurrent interview and record review, the DP confirmed there was no documented evidence that the pharmacist that processed the Narcan order questioned the dose or the frequency of the order.</p> <p>Review of the Accudose medication dispensing unit Narcan usage report confirmed only two doses were removed on [REDACTED] 12 at 2111 (9:11 pm) and 2152 (9:52 pm). The first Narcan dose was administered about 20 minutes late. The second dose was not given within 30 minutes; it was given about 15 minutes late. Narcan is metabolized and</p>		<p>and Therapeutics and the Board's Quality Council</p> <p>100% of pharmacist entered orders are double checked for accuracy by a second pharmacist.</p> <p>All incorrectly entered or inappropriate orders are tracked and trended by the pharmacy and pharmacy staff are individually educated on their order entry errors.</p> <p>Coaching, counseling and ultimately progressive discipline will be implemented for those that do not remediate and conform to policy and this plan of correction.</p> <p>The primary care nurse now verifies all new & changed orders in Patient Safe Solutions (computer) system (PSS) after entered by the pharmacist.</p> <p>The care nurse also reviews and verifies 100% of physician orders for medications prior to medication administration.</p> <p>The review of 100% orders is</p>	<p>10/4/12</p> <p>Oct 2012 and on-going</p> <p>9/29/12 and on-going</p>

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	<p>eliminated from the body very fast, thus delay in administering the medication in minutes is very significant. Narcan is given in doses of 0.4-2 mg. Because of its fast clearance, it may need to be repeated every 2-3 minutes. Narcan is given in doses as high as 10 mg to achieve the desired reversal effect.</p> <p>The nurse did not administer Narcan, in accordance with the physician order. Instead, Narcan was given twice instead of the four times. There was no documented evidence that Patient 34 was responsive to justify not administering the subsequent Narcan doses. Hence, the facility failed to administer Narcan as ordered in violation of T22 DIV5 ART-70263(g)(2).</p> <p>Patient 34's record revealed that she had become unresponsive after she was administered 25 mg of methadone, at 10 times the intended dose, and potentially 20 mg of morphine about two hrs later. Patient 34 was prescribed Narcan, a rescue agent, yet the order was not carried out. Patient 34 died c [REDACTED] 2 at 7:30 am.</p> <p>The licensee's noncompliance with T22 DIV5 ART-70263(g)(2) requirements for licensure has caused, or was likely to cause, serious injury or death to the patient.</p>		<p>retrospective with the Charge Nurse review.</p> <p>The charge nurse reports the findings to the Unit Director, and CNO.</p> <p>Persons Responsible: Chief Clinical Officer Chief Nursing Officer Chief Quality Officer Director of Pharmacy</p> <p>Corrective Actions Taken: #2: 100% of hospital staff and physicians were education on Managing Pain and alternatives to opioids through the Pharmacy Newsletter and medical Staff Newsletter.</p> <p>Nurses completed a medication safety education module and completed a post-test that included questions related to safe use of narcotics.</p> <p>All pharmacist entered orders are double checked for accuracy by a second pharmacist. All incorrectly entered or inappropriate orders are tracked and trended by the pharmacy and pharmacy staff are individually</p>	<p>Nov 2012</p> <p>Oct 2012 and on-going</p> <p>Oct 2012 and on-going</p>

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			education on their order entry errors. Errors found are reported to the Medication Safety Committee and the Quality Council of the Board. Pharmacists document interventions to clarify incomplete, unclear, ambiguous or illegible orders including therapeutic duplication and do not use abbreviations.	10/2/12
			The pharmacy department provides a summary of the pharmacist interventions for all incomplete or unclear orders, therapeutic duplications and appropriateness of dosage & frequency are tracked and trended. These interventions are reported on the Med Safety Dashboard, which is reported to the Medication Safety Team, the Safety council, Pharmacy and Therapeutics and the Board's Quality Council.	10/1/2012
			The narcotic surveillance program includes an audit that samples from all Acudose discrepancies and validating that a controlled substance dose was either given or properly wasted. A narcotic surveillance program	10/4/12 and on-going

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CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050133	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 09/13/2013
NAME OF PROVIDER OR SUPPLIER Rideout Memorial Hospital		STREET ADDRESS, CITY, STATE, ZIP CODE 726 4th St, Marysville, CA 95901-5656 YUBA COUNTY		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
			<p>review of the "over and under" Acudose report was added to address controlled substances that were removed from the Acudose where any remaining dose was not charted as given or wasted. Nursing directors and the nurse are emailed this information for follow-up action. Coaching, counseling and ultimately progressive discipline will be implemented for those that do not remediate and conform to policy and this plan of correction.</p> <p>Follow-up monitoring to prevent recurrence: On a monthly basis, nursing directors are given a list of all employees working on their unit who have caused a discrepancy in Acudose to track and trend employee compliance over time. This list also includes when a controlled substance has not been properly wasted. Medical Staff noncompliance will be tracked via reports to the CMO and through the OPPE process with follow-up by the Department Chief or MEC. Monthly Reports are provided to the Med Safety Committee and</p>	<p>2/21/13</p> <p>10/18/12</p> <p>10/18/12</p>

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			<p>the Quality Council of the governing Board. Coaching, counseling, and ultimately progressive discipline will be implemented for those that do not remediate and conform to policy and this plan of correction.</p> <p>Persons Responsible: Director of Pharmacy Director of Education Chief Nursing Officer Chief Clinical Officer</p> <p>Corrective Actions Taken: #3. The High Risk Medication Policy was updated to include naloxone monitoring requirements that include frequency of vital signs and physician re-evaluation of the patient. Nursing staff was educated on the policy revision and frequency of vital signs. 100% of staff were educated via any one of the following: the weekly huddle, staff meetings, one on one communications and written memoranda.</p> <p>Follow-up monitoring to prevent</p>	2/21/12	

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			<p>recurrence:</p> <p>The use of a reversal agent ("trigger drug"), which includes naloxone and flumazenil, are reviewed at least three times per week in order to track and trend 100% accuracy in medication ordering, medication administration and physician follow-up after the dose was administered. These results are reported to the Continuous Survey Readiness Team, the Safety Council and the Board's Quality Council Committee.</p> <p>Physician's not in compliance are reported to the Practitioner Excellence Committee.</p> <p>Reversal agents naloxone and flumazenil usage is reported monthly on the Medication Safety Dashboard, which is reported to the Medication Safety Team, Safety Council, Pharmacy and Therapeutics and the Board's Quality Council.</p> <p>A summary of the pharmacist interventions for incomplete or unclear orders, therapeutic duplications and appropriateness of dosage & frequency are tracked and trended.</p> <p>These interventions are reported on</p>	1/15/13	Jan 2013
					10/30/13

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			<p>the Medication Safety Dashboard, which is reported to the Medication Safety Term, Safety Council, Pharmacy and Therapeutics and the Board's Quality Council. Coaching, counseling and ultimately progressive discipline will be implemented for those that do not remediate and conform to policy and this plan of correction.</p> <p>Persons Responsible: Director of Pharmacy Director of Education Chief Nursing Officer Chief Clinical Officer</p>	<p>1/22/13 and on-going</p> <p>2/21/13</p>

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