

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050492	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	LICENSING CODE _____	(X3) DATE SURVEY COMPLETED 11/06/2008
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NAME OF PROVIDER OR SUPPLIER CLOVIS COMMUNITY MEDICAL CENTER	STREET ADDRESS, CITY, STATE, ZIP CODE 2755 HERNDON AVENUE, CLOVIS, CA 93611 FRESNO COUNTY
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(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	Name	Date	Time
	<p>The following reflects the findings of the California Department of Public Health during the investigation of Entity Reported Event #CA 00166149.</p> <p>Administrative Penalty Number: 040005635</p> <p>Inspection was limited to the specific Entity Reported Incident event investigated and does not represent the findings of a full inspection of the facility.</p> <div style="background-color: black; width: 100%; height: 20px; margin: 5px 0;"></div> <p>California Code of Regulations Division 5, Chapter 1, Article 7 Administration. 70701. Governing Body.</p> <p>(a) The governing body shall:</p> <p>(7) Require that the medical staff establish controls that are designed to ensure the achievement and maintenance of high standards of professional ethical practices including provision that all members of the medical staff be required to demonstrate their ability to perform surgical and/or other procedures competently and to the satisfaction of an appropriate committee or committees of the staff, at the time of original application for appointment to the staff and at least every two years thereafter.</p> <p>Based on staff interviews, clinical record review, administrative document review, and the Nursing 2005 Drug Handbook, the hospital failed to ensure</p>		<p>The statements made on the plan of correction are not an admission and do not constitute agreement with the alleged deficiencies herein.</p> <p>This plan of correction constitutes Community Medical Centers written credible allegation of compliance for the deficiencies noted.</p> <p>Corrective action plan CA 00166149</p> <p>T22 DIV5 CH1 ART7-70701(a) Governing Body</p> <p>(7) The governing body shall require that the medical staff establish controls that are designed to ensure the achievement and maintenance of high standards of professional ethical practices including provision that all members of the medical staff be required to demonstrate their ability to perform surgical and/or other procedures competently and to the satisfaction of an appropriate committee or committees of the staff, at the time of original application for appointment to the staff and at least every two years thereafter</p> <p>Finding: 1) Failure to ensure the medical staff established controls designed to ensure the achievement of professional and ethical practices when two attending physicians failed to recognize the need to monitor the effects of warfarin to a patient for whom they shared clinical responsibility.</p> <p><u>Governing Body</u></p> <p>a. How the corrective action will be accomplished, both temporarily and permanently.</p>		David R. Beard	12-17-08	9:45 a.m.

Reviewed By: David R. Beard Name: _____

POC ACCEPTABLE
YES NO

Medical Staff & Governing Body POC is acceptable 12/14/08

Event ID: I4QB11 11/26/2008 7:26:26AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: DAVID R BEARD TITLE: VP/CNO (X6) DATE: 12/10/08

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	<p>Continued From page 1</p> <p>medical staff established controls that were designed to ensure the achievement and maintenance of high standards of professional ethical practices when the facility failed to:</p> <p>1. Ensure the medical staff established controls that were designed to ensure the achievement and maintenance of professional ethical practices when two of two attending physicians (Doctor (DR) 1 and DR 2) failed to recognize the need to monitor the effects of Coumadin (generic name is warfarin - a potentially dangerous medication which would prevent the blood from clotting) being administered to a patient for whom they shared clinical responsibility. (Patient A)</p> <p>2. Provide planning, implementation and evaluation of medical care when Patient A was given Coumadin (generic name is warfarin - a potentially dangerous medication which would prevent the blood from clotting) by seven of eight Registered Nurses (RN's) and one Licensed Vocational Nurse (LVN) without evidence of a ProThrombin (PT) and an International Normalized Ratio (INR) (PT - normal range 12.0 to 14.7 and INR normal range 0.8 to 1.2 according to the facility's laboratory reference ranges) tests (blood tests to determine if the dose of Coumadin was appropriate or too large. Patient A's PT was 167.1 and the INR was greater than 20). Patient A was given the medication for eleven days without benefit of a blood test to determine whether the dose was appropriate or too large. If it was an incorrect dose it would cause internal bleeding. (RN's 1, 2, 3, 4, 5, 6, 7 and LVN 1)</p>		<p>1) Clovis Community Medical Center (CCMC) Chief Executive Officer (CEO) directed the Chief Nursing Officer and Corporate Patient Safety Officer to report the event to California Department of Public Health (CDPH). The event was reported to CDPH on 10/10/08.</p> <p>2) CCMC CEO immediately directed fast track review of the event through hospital Quality Patient Safety Committee on 10/23/08 and at Clovis Medication Safety Committee on 10/27/08.</p> <p>3) CCMC CEO ensured that the event was immediately reported to Peer Review on 10/10/08.</p> <p>4) CCMC CEO notified the Corporate Chief Executive and Chief Operating Officers and the Chief Quality Officer who then notified the Board of Trustees of the event and ensured that all issues identified were incorporated into the quality assurance process for immediate resolution.</p> <p>b. The title or position of the person responsible for the correction. CCMC CEO</p> <p>c. A description of the monitoring process to prevent recurrence of the deficiency. Actions reviewed and completed by CEO as of 10/27/08</p>	<p>10.10.08</p> <p>10.23.08</p> <p>10.27.08</p> <p>10.10.08</p> <p>10.10.08</p> <p>10.27.08</p>

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	<p>Continued From page 2</p> <p>3. Develop and implement written policies and procedures for the establishment of safe and effective systems for the dispensing and use of high risk drugs such as Coumadin (generic name is Warfarin - a potentially dangerous medication which would prevent the blood from clotting).</p> <p>Findings:</p> <p>1. Patient A was admitted to the facility on 9/26/08 for a complaint of shortness of breath by DR1. The History and Physical performed by DR 1 on 9/26/08 included a diagnosis of atrial fibrillation (rapid heart beat). On 9/27/08, DR 2 wrote an order for Warfarin 5 milligrams (mg.) to be given every day.</p> <p>The Clinical Pharmacist (Cl Phr) on 10/29/08 at 9:34 a.m. stated she had consulted on Patient A during the normal course of her duties. She stated she had reviewed the patient's chart and had recommended the responsible physician should write an order to obtain the appropriate laboratory tests which would allow for monitoring the effects of the Coumadin being administered to Patient A. She stated the values from the tests were necessary to ensure the safety of Patient A and the quality of medical care provided to Patient A. She stated she never spoke directly to the physician caring for Patient A and to the best of her knowledge the order for recommended labs was never written.</p> <p>On 10/29/08 at 11:30 a.m., during an interview, DR 1 stated he had assumed care for Patient A when</p>		<p>d. The date the immediate corrective action will be accomplished.</p> <p>10/10/08 through 10/27/08</p> <p>Medical Staff</p> <p>a. How the corrective action will be accomplished, both temporarily and permanently.</p> <p>1) Physicians involved were immediately referred to Medical Staff through the Peer Review Process on 10/10/08. The Medicine Advisory committee's peer review group developed performance improvement plans for both physicians. These plans have and continue to be reviewed by the Medical Executive Committee and reported to the Board of Trustees.</p> <p>2) A letter was sent by the Chief Quality Officer and Physician Chair of Quality Patient Safety Committee to Clovis Community Medical Center Physicians alerting them to the new Warfarin Hard Stop Process on 10/21/08.</p> <p>3) Pharmacy and Therapeutics and Medical Executive Committees approved on 10/30/08 that pharmacists will order a PT/INR on any patient receiving Warfarin who does not have a lab order by the physician. The pharmacist does not prescribe the drug. The pharmacist verifies baseline labs (PT/INR) and contacts the physician to communicate and/or request dose as necessary.</p> <p>4) Per CDPH Pharmacy Surveyor recommendation, a Medical Staff</p>	<p>10.27.08</p> <p>10.10.08</p> <p>10.21.08</p> <p>10.30.08</p> <p>10.30.08</p>

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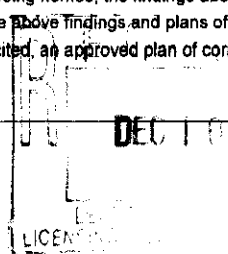
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	<p>Continued From page 3</p> <p>she was admitted on 9/26/08 at 3:20 a.m. DR 1 stated he had arranged for DR 2 to assume care of Patient A on 9/27/08 as DR 1 would be out of town. DR 1 stated he was unaware that DR 2 had written an order for Coumadin in his absence. DR 1 was unaware of Patient A receiving Coumadin on a daily basis when he resumed responsibility for care of Patient A on 9/29/08. DR 1 stated DR 2 did not tell him that Coumadin was being administered to Patient A. DR 1 stated he did not thoroughly review the chart of Patient A when he resumed responsibility of care for Patient A on 9/29/08. DR 1 stated, although he had not written the order for Coumadin as the attending physician of Patient A, it was his responsibility to check the medications being administered. DR 1 stated it was his responsibility to insure appropriate laboratory studies had been ordered to insure quality medical care and patient safety. DR 1 stated he was directly responsible for the lack of quality care which resulted in the failure of appropriate laboratory tests being requested for more than a week's time. DR 1 stated he had failed in his responsibility to communicate with DR 2 regarding the details for Patient A's care.</p> <p>On 10/29/08 at 12:55 p.m., during an interview, DR 2 stated he had assumed care of Patient A on 9/27/08. DR 2 stated he had written an order for Coumadin on 9/27/08 and had never written an order for the appropriate lab tests or the appropriate monitoring of lab tests. DR 2 stated he briefed DR 1 and told him Patient A was receiving Coumadin on a daily basis when DR 1 resumed responsibility of Patient A on 9/29/08. DR 2 stated he was</p>		<p>process for Hand-Off Communication was developed by the Chief Quality Officer and approved on 10/30/08 by Clovis Facility Executive Committee.</p> <p>The process was explained and a verification letter was sent to Clovis Medical Staff on 11/3/08 by Medical Staff Office.</p> <p>Compliance of 92% has been achieved as of 12/9/08</p> <p>The Quality Director will continue to track and monitor weekly for physician communication and compliance.</p> <p>b. The title or position of the person responsible for the correction.</p> <p>Quality Director</p> <p>c. A description of the monitoring process to prevent recurrence of the deficiency.</p> <p>1) Medical Staff Office verified fax confirmation receipt of the Warfarin Hard Stop Process letter by physicians.</p> <p>2) Quality Director will maintain records of letter and approvals by Medical Executive Committee</p> <p>3) Medical Staff Office verified fax confirmation receipt of the Hand-Off Communication Process letter to physicians.</p> <p>Compliance of 92% has been achieved as of 12/9/08</p>	<p>11.3.08</p> <p>12.9.08</p> <p>ONGOING</p> <p>10.21.08</p> <p>11.3.08</p> <p>12.9.08</p>

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	<p>Continued From page 4</p> <p>directly responsible for the lack of quality care which resulted in a failure of the appropriate laboratory tests being requested.</p> <p>On 10/29/08 at 11:32 a.m., during an interview, the Chief Executive Officer (CEO) stated he was ultimately responsible for oversight of the medical staff as a means of ensuring quality medical care and patient safety. The CEO stated he was aware of the lack of communication between DR 1 and DR 2 which resulted in a failure of appropriate laboratory tests being requested for more than a week's time. The CEO stated he was unaware DR 1 had failed to thoroughly review the chart of Patient A when he resumed responsibility of care on 9/29/08. The CEO stated he had ultimate responsibility for the oversight of the medical staff with regard to the quality of care rendered and lack of patient safety for Patient A.</p> <p>2. Patient A was admitted to the facility on 9/26/08 for complaint of shortness of breath by Doctor 1 (DR 1). The History and Physical performed by DR1 on 9/26/08 included a diagnosis of atrial fibrillation (rapid heart beat). On 9/27/08, Doctor 2 (DR 2) wrote an order for warfarin (brand name is Coumadin - a potentially dangerous medication which would prevent the blood from clotting) 5 milligrams (mg.) to be given every day.</p> <p>From 9/27/08 through 10/1/08 at 9:00 p.m., RN 3, RN 4, RN 5, and RN 6 administered Warfarin 5 mg. to Patient A. On 10/2/08 at 9:00 p.m. LVN 1 administered warfarin 5 mg. to Patient A. On 10/3/08 at 9:00 p.m., 10/4/08 at 9:00 p.m., and</p>		<p>The Quality Director will continue to track and monitor weekly for physician communication and compliance.</p> <p>d. The date the immediate corrective action will be accomplished.</p> <p>*Peer Review submission *Warfarin Hard Stop Process letter *Hand-Off Communication letter *Monitoring</p> <p>Finding: 2) Failure to provide planning, implementation and evaluation of medical care when patient was given warfarin by eight nurses without evidence of lab tests to determine if the dose was appropriate.</p> <p><u>Nursing</u></p> <p>a. How the corrective action will be accomplished, both temporarily and permanently.</p> <p>1) The Nurse Managers counseled the nurses who administered Warfarin to the patient.</p> <p>2) On 10/10/08, The Nurse Managers implemented a Hard Stop Process in collaboration with the Pharmacy Manager.</p> <p>(a) All new Warfarin orders must have a baseline PT/INR and CBC recorded prior to administering the medication. If the labs are not ordered, the nurse will call the physician and obtain lab orders. The pharmacy will not dispense the medication without</p>	<p>ONGOING</p> <p>10.10.08 10.21.08 11.3.08 12.9.08 AND ONGOING</p> <p>10.30.08</p> <p>10.10.08</p>

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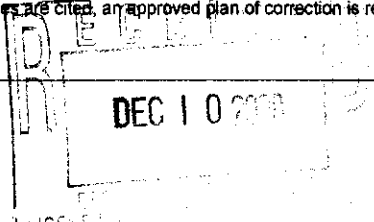
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	<p>Continued From page 5</p> <p>10/5/08 at 9:00 p.m., RN 1 administered warfarin 5 mg. to Patient A. On 10/6/08 at 9:00 p.m., RN 7 administered warfarin 5 mg. to Patient A. On 10/7/08 at 9:00 p.m., RN 2 administered warfarin 5 mg. to Patient A. There was no documented evidence of a PT and INR test in Patient A's clinical record for 11 doses of warfarin.</p> <p>During an interview on 10/29/08 at 2:40 p.m., LVN 1 stated it is the responsibility of the nurse administering warfarin to check a patient's PT and INR before giving it.</p> <p>During an interview on 10/29/08 at 2:55 p.m., RN 7 stated Patient A should have had a baseline PT and INR and daily PT and INR's before giving her warfarin. RN 7 stated Patient A did not have a PT and INR at the time RN 7 gave the medication.</p> <p>During an interview on 10/29/08 at 3:25 p.m., RN 2 stated it is a nurse's responsibility to check the PT and INR before giving Warfarin. RN 2 stated "I don't think I saw the INR before I gave the warfarin".</p> <p>An excerpt taken from the Nursing 2005 Drug Handbook contained the following under the listing for Coumadin: "Nursing Considerations-Draw blood to establish baseline coagulation parameters before therapy...PT and INR determinations are essential for proper control... Give warfarin (Coumadin) at same time daily. INR range for chronic atrial fibrillation is 2 to 3."</p> <p>A review of Patient A's Medication Administration Record revealed the following documentation</p>		<p>baseline labs obtained and reviewed.</p> <p>(b) The daily dose of Warfarin is not administered unless a PT/INR is drawn and documented on the MAR for that day. If there is not an INR ordered, the Nurse obtains an order from the physician and reviews lab results prior to administration of Warfarin. The Nurse contacts the physician with lab results and obtains a new order for Warfarin if needed.</p> <p>After 10/30/08, the Nurse contacts the pharmacist in the event a lab order (PT/INR) is missing. Pharmacy will not dispense the daily dose of Warfarin until the PT/INR lab is verified by Nursing. The Medication Carts are then stocked by Pharmacy with the daily dose of Warfarin.</p> <p>3) No Warfarin is stocked in the Automated Dispensing Unit at CCMC beginning 10/10/08.</p> <p>4) Beginning 10/10/08 all Nurses in the ICU, Telemetry and Med-Surg were educated prior to the start of their shift on the Hard Stop Process, Warfarin dosing, drug-drug/nutrient interactions, signs/symptoms of Warfarin reactions and actions required for monitoring and pharmacist/physician notification.</p> <p>5) Reference provided to nursing of symptoms of over anti-coagulation: melena, petechiae, microscopic hematuria, oozing from superficial injuries such as blood draws, IV sites, bleeding from the gums after</p>	<p>10.30.08 AND ONGOING</p> <p>10.10.08</p> <p>10.10.08 THRU 11.3.08</p> <p>10.30.08</p>

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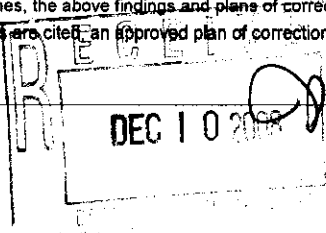
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	<p>Continued From page 6</p> <p>included on each daily printout of the medication Coumadin: "Drug/Nutrient education required/Coumadin Drug/Drug Interaction."</p> <p>During an interview on 10/29/08 at 3:00 p.m., the Chief Nursing Officer (CNO) stated that although the information advising "Drug/Nutrient education required/Coumadin Drug/Drug Interaction" was visible to each nurse who read the order and gave the medication, they didn't act on it.</p> <p>3. On 10/29/08 at 9:30 a.m., the Clinical Pharmacist (Cl Phr) said Pharmacist (Phr) 1 entered an order for warfarin (brand name is Coumadin - a potentially dangerous medication to decrease blood clotting) into the computer for Patient A. Computer entries by a pharmacist were part of the dispensing process. The physician's order written on 9/27/08 in the medical record was for warfarin 5 mg (milligrams) daily. The Cl Phr said she wrote on 9/30/08 in Patient A's medical record recommendations for Patient A's physician to order an INR test. She also wrote in Patient A's medical record there was a drug-drug interaction between amiodarone (for irregular heart rhythms), which Patient A was receiving, and warfarin. The Cl Phr said the hospital did not have a formal policy and procedures concerning warfarin.</p> <p>At 10:15 a.m. on 10/29/08, the Phr Mgr said the hospital did not include warfarin in its high risk/high alert drugs policy and procedures.</p> <p>On 10/29/08 a review was conducted of the hospital policy titled Medications - High Alert/High Risk with</p>		<p>brushing teeth and excessive menstrual bleeding. Coffee ground emesis and nosebleeds are also signs. Any of these symptoms must be reported to the physician immediately.</p> <p>6) On 10/30/08, the Pharmacy and Nursing Managers revised and expanded the Medication High Risk/High Alert policy: (a) Medications- High Risk/High Alert policy was expanded to include drugs recommended by the Institute of Healthcare Improvement (Getting Started Kit: Prevent Harm from High-Alert Medications, How-to Guide). The following listed drugs/categories include: (i) Insulin IV Infusion, Heparin Infusion and Bolus, Concentrated Electrolytes (Sodium, Magnesium and Potassium), Neuromuscular Blocking Agents, Vasopressors Agents, Warfarin, chemotherapy, and all Epidurals.</p> <p>7) The MAR was revised on 10/30/08 to include the statement for Warfarin, "High Alert Med: Record daily PT/INR. MAR co-signature (RN, LVN, Mid-Level Provider) and patient education required."</p> <p>8) Beginning 10/30/08, all CCMC Nurses were educated by the Nurse</p>	<p>10.30.08</p> <p>10.30.08</p> <p>10.30.08 11.3.08</p>

Event ID:I4QB11

11/26/2008

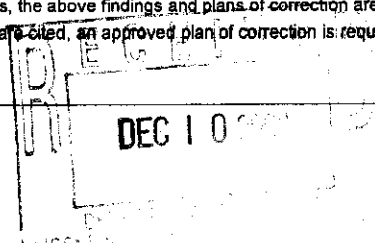
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NAME OF PROVIDER OR SUPPLIER CLOVIS COMMUNITY MEDICAL CENTER		STREET ADDRESS, CITY, STATE, ZIP CODE 2755 HERNDON AVENUE, CLOVIS, CA 93611 FRESNO COUNTY		
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	<p>Continued From page 7</p> <p>an effective date of 11/2/07 listed 10 categories of drugs. It did not include warfarin or the category of drugs which decrease blood clotting (anticoagulants). The policy and procedures titled Medication Orders - Pharmacist Review read, "...If there are questions and/or concerns, the physician will be contacted to discuss these concerns." Further, they read, "If there are questions or concerns with the medication prescribed, the physician will be contacted before administration to the patient." Listed in the document were nine items but patient safety was not included.</p> <p>Patient A received warfarin, 5 mg, daily for 11 days from 9/27/08 until 10/7/08 according to the medication administration records (MAR). The medical records did not document that a clotting test (INR or International Normalized Ratio) had been ordered until 10/8/08. An INR is used to monitor the effects of Warfarin for the dual purposes of adjusting patients' doses and preventing bleeding.</p> <p>On 10/29/08 at 10:48 a.m. the physician for Patient A, Doctor (DR) 1, said he did not see the recommendations which were written in Patient A's medical record by the CI Phr. He said, "I overlooked it. It was my responsibility" for reviewing the recommendations and it was "a lack of quality care." DR 1 said "I would order a baseline INR." A baseline INR was one which was ordered before a patient began receiving warfarin.</p> <p>On 10/29/08 at 10:49 a.m., Dr. 2 said he was aware of the drug interaction with amiodarone and</p>		<p>Managers on the Medications - High Risk/High Alert policy.</p> <p>Nursing education was also expanded to include the Emergency Department, PACU, Procedural areas and Surgery on the Warfarin Hard Stop Process. All educational classes were mandatory and completed by 11/20/08</p> <p>9) All new nurses hired receive training on the Warfarin Hard Stop process and Medications-High Risk/High Alert policy prior to administration of medications.</p> <p>10) The Medications - High Risk/High Alert policy compliance is monitored by Nursing and Pharmacy daily for all identified drugs.</p> <p>(a) The Nursing Unit Clinical Supervisor (or designee) identifies all patients on High Risk/High Alert medications.</p> <p>(b) The Nursing Unit Clinical Supervisor (or designee) reviews compliance for each medication and completes the monitoring tool. Any medication compliance issues are immediately communicated to pharmacy and the attending physician for review and intervention.</p> <p>(c) The monitoring tool is submitted to the Nurse Manager for review</p> <p>(d) The Nurse Manager will submit a monthly report to Quality Patient Safety Committee for unit compliance until 100% compliance rate is achieved for 3 months.</p>	<p>10.30-11.20.08</p> <p>ONGOING</p> <p>11.5.08 AND ONGOING</p> <p>1/2009</p>

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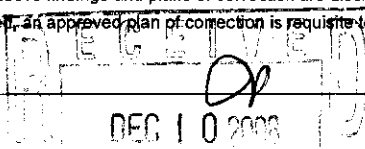
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	<p>Continued From page 8</p> <p>warfarin but was not aware of the other potential drug interactions with drugs Patient A was receiving.</p> <p>On 10/29/08 at 12:50 p.m., DR 2, who wrote the order for warfarin said, he did not order an INR test before ordering the drug. He said it was a regular practice to order an INR and view the results before administering the first dose of warfarin. He stated, "I overlooked the need to order INRs" and it was "my responsibility for not getting INRs. He stated, "I know I made a mistake."</p> <p>On 10/29/08 a review was conducted of the manufacturers' literature for warfarin which was approved by the Federal Food and Drug Administration (FDA) which contained a boxed warning. The warning related the drug can cause major or fatal bleeding. Lexicomp, a drug database, listed the following drugs which may increase the effects of Warfarin on clotting: amiodarone, acetaminophen (for pain relief), propoxyphene (for pain relief), and antiplatelet agents (aspirin). Patient A received amiodarone and aspirin from 9/27/08 through 10/9/08 and propoxyphene and acetaminophen on 10/2, 10/3, 10/6/10/7 and 10/8/08.</p> <p>On 10/29/08 at 4:00 p.m., the Pharmacist Manager (Phr Mgr) said there was no documentation Phr 1 had contacted the physician about the order for warfarin.</p> <p>The cumulative effects of physician failure to order the PT and INR for baseline use of anticoagulants</p>		<p>b. The title or position of the person responsible for the correction.</p> <p>Chief Nursing Officer and Nurse Managers of ICU, Telemetry, Med-Surg, and Emergency Department</p> <p>c. A description of the monitoring process to prevent recurrence of the deficiency.</p> <p>1) The Nurse Managers monitored for 100% compliance by nurses for education on Warfarin Hard-Stop Process (beginning 10/10/08) and Medication High risk/alert policy (beginning 10/30/08) Compliance rate at 100%.</p> <p>2) Beginning 10/10/08 through 1/2009, the Pharmacist performs concurrent daily review with the bedside nurse utilizing the Warfarin Flow Sheet. Daily monitoring will be performed until 100% compliance rate is achieved for 3 months .</p> <p>3) Beginning 11/3/08, concurrent daily review by the Nursing Unit Clinical Coordinator (or designee) of all High Risk/High Alert medications for compliance with policy until 100% compliance rate is achieved for 3 months.</p> <p>4) This is reported to the Nurse Manager, reviewed by the Chief Nursing Officer and Quality Patient Safety Committee.</p>	<p>10.10.08</p> <p>10.30.08</p> <p>12.4.08 THRU 1/2009</p> <p>11.3.08 THRU 1/2009</p>

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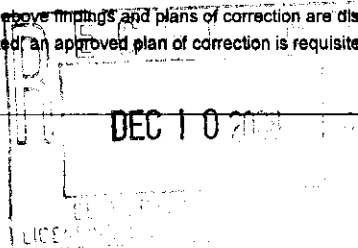
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	Continued From page 9 such as warfarin; pharmacist not following through with their recommendation; nurses administering warfarin without PT and INR baseline; lack of oversight by administration; and no policy and procedure for high alert-high risk use of anticoagulant: resulted in Patient A's PT being abnormally prolonged and the INR being critically high. These failures contributed to the death of Patient A, who expired on 10/9/08 after suffering a massive bleeding into her brain as indicated by her Computed Tomography Scan dated 10/9/08.		<p>d. The date the immediate corrective action will be accomplished.</p> <ul style="list-style-type: none"> *Nurses counseled *Hard stop process implemented *No Warfarin in Pyxis *Education - Hard Stop Process / and Bleeding symptoms *Education - Medications High Risk/High Alert Policy *Education - New Nurses *Monitoring <p>Finding: 3) Failure to develop and implement written policies and procedures for the establishment of safe and effective systems for the dispensing and use of high risk drugs such as warfarin.</p> <p>Pharmacy</p> <p>a. How the corrective action will be accomplished, both temporarily and permanently.</p> <ol style="list-style-type: none"> 1. Pharmacy Manager counseled the dispensing pharmacist for this incident on medication orders and pharmacist review per policy. 2. Pharmacy Manager counseled the clinical pharmacist for this incident on the need to communicate significant clinical recommendations directly to the physician. 3. Pharmacy initiated a hard stop process for Warfarin and did NOT dispense to any patient (hospital wide) without verifying a baseline CBC, PT and INR. <p>From 10/10/08 through 10/30/08, pharmacists contacted the physician for a lab order if the physician did not</p>	<p>10.30.08 10.10.08 10.10.08 10.10.08</p> <p>10.30-11.5.08</p> <p>ONGOING 1/2009</p> <p>10.10.08</p> <p>10.10.08</p> <p>10.10.08</p> <p>10.30.08</p>

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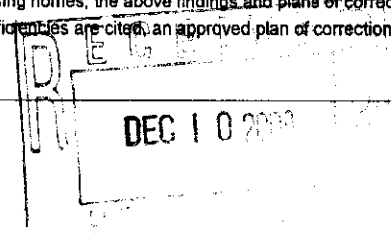
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			<p>write a PT/INR order. The pharmacist did not prescribe the drug. The pharmacist verified baseline labs (PT/INR) and when applicable, contacted the physician to communicate and/or request:</p> <ul style="list-style-type: none"> a. Warfarin dosage adjustments based on the lab values. b. Clinically significant drug-drug interactions c. INR results (if INR is above goal range) prior to dispensing the Warfarin to the patient. If the pharmacist could not reach the physician, Warfarin was not dispensed until a physician was reached. The pharmacist would contact the physician on-call and proceed through the Medical Staff Chain of Command until a physician could be contacted. <p>4. On 10/30/08, Medical Staff Committees; Pharmacy and Therapeutics and Medical Executive approved authorization for pharmacists to order a PT/INR on any patient receiving Warfarin in the event they did not have a lab order by the physician. The pharmacist did not prescribe the drug. The pharmacists verified baseline labs (PT/INR) and if applicable, contacted the physician to communicate and/or request:</p> <ul style="list-style-type: none"> a. Warfarin dosage adjustments based on the lab values. b. Clinically significant drug-drug interactions c. INR results (if INR is above goal range) prior to dispensing 	10.30.08

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DEC 10 2008

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			<p>Warfarin to the patient. If the pharmacist could not reach the physician, Warfarin was not dispensed until a physician reached. The pharmacist would contact the physician on-call and proceed through the Medical Staff Chain of Command until a physician could be contacted.</p> <p>5. The Pharmacy and Nursing Managers developed and initiated a "Warfarin Flow sheet" used for daily patient quality assurance tracking which monitors the patient's response to Warfarin. The flow sheet is used collaboratively by Pharmacy and Nursing to review and document the patient's response to Warfarin. Upon the patient's discharge, the Warfarin Flow Sheet is secured in the Pharmacy.</p> <p>(a) The clinical pharmacist evaluates and completes the "Warfarin Flow Sheet" for all patients on the drug. During daily rounds, the pharmacist has the bedside nurse complete the "Warfarin Flow Sheet" from the nursing perspective documenting assessment for any signs of bleeding. The pharmacist reviews and documents the daily INR prior to Warfarin being dispensed. The pharmacist returns the Warfarin Flow Sheet to pharmacy where it is stored in the Clinical Pharmacy Anti-Coagulation Therapy Tracking binder until</p>	10.10.08 THRU 11.16.08

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			Warfarin, and all Epidurals.	
			b) The Medication Orders-Pharmacist Review policy was revised to include pharmacist activation of the physician chain of command on 11/3/08.	11.3.08
			5) On 10/30/08 all Pharmacists were educated by the Pharmacy Manager on the Medications -High Risk/High Alert policy including:	10.30-11.3.08
			a) Drug classifications/High alert drugs	
			b) Pharmacy actions to be taken for each drug	
			6) Efforts to recruit 2 additional clinical pharmacists were expedited. Viable candidates were identified during October and interviews began 11/04/08. Offer extended to candidate 1 on 11/04/08, but offer declined. Offer extended to candidate 2 on 11/12/08, awaiting decision by candidate. Offer extended to candidate 3 on 12/3/08, candidate accepted offer.	10.30.08 AND ONGOING
			7) Any new pharmacists will receive training on the Warfarin Hard Stop process and high risk/high-alert medication policy prior to medication processing.	10.30.08 AND ONGOING
			8) On 10/23/08, the Warfarin event was discussed at Quality Patient Safety Committee.	10.23.08
			On 10/27/08, the Warfarin event was discussed at the facility Medication Management Committee.	10.27.08

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			10/10/08 all pharmacists on shift were educated. Pharmacists on vacation or leave were educated prior to the beginning of their first shift back. All new pharmacists will receive this education.	10.10.08

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