DEPARTMENT OF HEALTH & HUMAN SERVICES



CENTERS FOR MEDICARE & MEDICAID SERVICES
CONSORTIUM FOR QUALITY IMPROVEMENT AND SURVEY & CERTIFICATION OPERATIONS
WESTERN DIVISION OF SURVEY AND CERTIFICATION

SENT BY OVERNIGHT MAIL

IMPORTANT NOTICE - PLEASE READ CAREFULLY

December 7, 2011

Terry Belmont, Chief Executive Officer University of California Irvine Medical Center 101 City Drive South Orange, CA 92868

RE:

CMS Certification Number (CCN): **05-0348** (previously Medicare Provider Number)

Dear Mr. Belmont:

Hospitals accredited by the Joint Commission (JC) are "deemed" to meet Medicare Conditions of Participation (COPs) with certain exceptions, not pertinent here. See 42 C.F.R. § 488.4 (a). However, if a complaint validation survey results in a finding that the hospital is out of compliance with one or more of the COPs, the hospital will no longer be deemed to meet any COP. See 42 C.F.R. §488.7(d).

The California Department of Public Health (CDPH), Orange County District Office, the State Medicare survey agency, reported serious deficiencies from the August 23, 2011 complaint validation survey of University of California Irvine Medical Center, authorized by this office. Specifically, University of California Irvine Medical Center did not comply with the following three (3) Conditions of Participation (COPs):

42 C.F.R. § 482.12 Governing Body

42 C.F.R. § 482.21 QAPI (Quality Assessment and Performance Improvement)

42 C.F.R. § 482.25 Pharmaceutical Services

During this same visit on August 15, 2011, the CDPH survey team identified Immediate Jeopardy (IJ) situations in Pharmaceutical Services, 42 C.F.R. § 482.25. University of California Irvine Medical Center presented a finalized plan to the survey team on August 16, 2011 and the Immediate Jeopardy situation was abated.

Page 2 – University of California Irvine Medical Center (CCN: 050348) (Complaint Validation Survey conducted August 23, 2011)

Consequently, effective the date of this letter we are removing your status as a provider deemed to meet Medicare COPs and placing you under the CDPH survey jurisdiction until you demonstrate full compliance. See 42 C.F.R. §488 7(d). This means that the hospital is now subject to all applicable participation and enforcement requirements and may be subject to termination of its Medicare provider agreement.

A description of the deficiencies found by the August 23, 2011 survey is set forth on the enclosed Statement of Deficiencies, Form CMS-2567.

You need to submit evidence documenting actions you have taken to correct these deficiencies. Please submit your evidence of correction to address the survey findings to <u>this San Francisco</u> <u>Regional office and the CDPH, Orange County District Office, Licensing and Certification</u>, by close of business, within ten (10) days of receipt of this letter.

The evidence of correction is to be entered on the right side of Form CMS-2567, opposite the deficiency, and must be signed and dated by the administrator or other authorized official.

The evidence of correction of each item must contain the following:

- 1. How the correction was accomplished, both temporarily and permanently for each individual affected by the deficient practice, including any system changes that must be made.
- 2. The title of position of the person responsible for correction, e.g. Administrator, Director of Nursing or other responsible supervisory personnel.
- 3. A description of the monitoring process to prevent recurrences of the deficiency, the frequency of the monitoring and the individual(s) responsible for the monitoring.
- 4. The date when the immediate correction of the deficiency will be accomplished. Normally this will be no more than thirty (30) days from the date of the exit conference.

If we determine that the submission is timely, credible and otherwise acceptable, we will authorize CDPH to conduct a resurvey. If this survey finds that the hospital meets all applicable Medicare Conditions, deemed status will be restored. See 42 C.F.R. §488.7(e)(3). If we do not receive an acceptable, timely submission, or if a resurvey finds that the hospital is not complying with any COP, we will notify you that we are initiating action to terminate the facility's Medicare provider agreement. See 42 C.F.R. §488.7(d). In the meantime, the removal of deemed status does not limit your ability to bill Medicare, nor does it affect JC accreditation.

Copies of this letter are being sent to the JC, the CDPH-Orange County District Office and Medicaid agency.

Page 3 – University of California Irvine Medical Center (CCN: 050348) (Complaint Validation Survey conducted August 23, 2011)

If you have any questions, please contact Patricia Jung of my staff at (415) 744-3753.

Sincerely,

Rufus Arther, Manager

Non-LTC Survey, Certification & Enforcement Branch

Western Division of Survey and Certification

Enclosure (50 pages CMS-2567)

cc:

The Joint Commission

CDPH – Orange County DO

Title XIX

University of California, Irvine • Healthcare

Office of Risk Management 101 The City Drive, Rte. 153 Bldg. 53, Ste. 100 Orange, CA 92868

December 20, 2011

Mr. Rufus Arther, Manager
Non-LTC Survey, Certification & Enforcement Branch
Western Division of Survey and Certification
Department of Health & Human Services
Centers for Medicare & Medicaid Services
90 7th Street, Ste. 5-300(5W)
San Francisco, CA 94103-6707

Subject:

CMS Certification Number (CCN): 05-0348 Evidence of Correction of Cited Deficiencies Survey Completion Date: August 23, 2011

Dear Mr. Arther:

The attached Form 2567 reflects credible documentation that all deficiencies cited on the survey ending August 23, 2011 have been corrected and that the University of California Irvine Medical Center is now in full compliance with all Medicare Conditions of Participation.

As you review this evidence, please take note of the following significant improvements made to the hospital's Pharmaceutical Services and Patient Safety programs:

- The implementation of a Pump Safety Committee to oversee all aspects of medication delivery pumps which includes, but is not limited to the assessment of pump technology, the education of health care providers in the use of pumps, the implementation of smart pump safeguards such as medication libraries, and the standardization of work flow, through and including the development of policies governing pump usage.
- 2. The implementation of an executive-level Patient Safety Steering Committee that is charged with overseeing timely completion of improvement efforts across the organization, prioritizing error reduction activities, and identifying cross-discipline trends and patterns in actual or potential errors.

If you have any questions relative to this Plan of Correction, please contact Nance Hove, Director of Risk & Regulatory Affairs at (714) 456-5676.

Sincerely,

Terry A. Belmont

Chief Executive Officer

cc: California Department of Public Health

Licensing & Certification Division
Orange County District Office

Orange County District Office

PRINTED: 09/13/2011 FORM APPROVED OMB NO. 0938-0391

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| | | ntered the hospital at 1015 The hospital identified their 85. | | | | | |
| | was notified of Imm health and safety of medications admini infusion pumps (act months ago). There | stered by newly acquired quired approximately 3 was no hospital-wide training | | | | | |
| | was not developed of the pumps. On 7 stop" alert (a progra programmer the rat | policy and procedure (P&P) and approved for the safe use /25/11, MD X overrode a "soft imming alert informing the e and/or dose was high but b) for Thymoglobulin (an | | | | | |
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| | overridden) progran to prevent life threa received 100 millign | e medication and could not be need into the infusion pump tening overdoses. Patient 37 ams (mg) of Thymoglobulin ad of over 6 hours which | | | | | |
| - | could have contribu | ted to his death. | | | | | |
| ABOBATOR | Y DIRECTOR'S OR PROVID | R/SUPPLIER REPRESENTATIVE'S SIGN | IATURE | | TITLE | | (X6) DATE |
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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. (See instructions.) Except for nursing homes, the findings stated 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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| A 000 | * On 7/25/11, the his similar safety issue hospital was unable competent in accur medication infusion medication used for This specific pump (the hospital has not pumps from all patin Neonatal Intensive programmed the puyear old (Patient 52 dose of Precedex the prescribed dose. The micrograms/kilogramicrograms per howeight. Patient 52 mithin an hour due to Patient 52 survived drop in heart rate the medications (medications (medications must be pregistered nurses wappropriate pump of demonstration. B. Dosage, concented to the concentration of the co | that occurred on 6/15/11. The to ensure that MD K was ately programming the pump for Precedex (a redation during procedures). did not contain a drug library ow removed these type of ent care areas except the Care Unit). MD K ump incorrectly and the 10 c) received an intravenous that was over 30 times the prescribed dose was 2 ms/hour (mcg/kg/hr) or 6 ur based on Patient 52's body beceived a dose of 200 mcg to the programming error. The incident but experienced a last required two rescues attons used to reverse the or his heart rate to stabilize. Thours, the immediate d when the hospital presented which included the following: programmed only by the have completed ompetency with return tration and flow rates should urrent drug library (contains usage and rate limits) that was | A (| 000 | | |

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| A 000 | required for any add D. Soft limits or stothat standard dosing soft limits might be with caution. If a sopractitioner must reand pump program Hard limits or stops lethal medication do overridden. The presolve this discrep E. Independent do for initial programm programming of introdeliver opiates, a chemotherapy. Guidelines: A. Pump safety tean oversight of compliate throughout the hosp and the frequency obe reviewed quarter to improve compliant Training: Registered nurses to immediately. No regallowed to program completing the 8/17 Sign in sheets and socillected to validate. Anesthesiologists, registered nurse and required to use the was not in the library Officer, in collaboration. | ministration by basic mode. The system of t | Α : | 000 | | | |

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| A 043 | 2. Ensure medicate the QAPI committee reference A276. 3. Ensure the QAPI risk, high volume, puto infusion pump sates and adverse events related implemented preverse for patient safety. Comparison of 43 sampled reference A405 #2. 6. Ensure a safe en administration. Cross. | program set priorities for high problem prone activities related afety. Cross reference A285, program provided analysis of ated to infusion pumps and antive/improvement measures cross reference A288. Cal staff enforced its bylaws to gy physicians provided daily pass reference A353. Ininistration of medications for patients (Patient 39). Cross over the program of the patients of the patients and nursing staff training was | A 043 | INFUSION PUMP SAFETY (Cross referent A Pump Safety Committee was created as a of the Medication Safety Committee and choverseeing and optimizing all aspects of purincluding: the assessment of pump technolo education of health care providers utilizing the implementation of smart pump safeguar medication libraries, soft stops, hard stops, a standardization of workflow through the deand implementation of appropriate policies and quality/safety monitoring of pump related The Pump Safety Team reviews all adverse associated with pumps and identifies specific wide changes to enhance safety. Compreher medication libraries, including a robust set of soft stops have been developed for Critical Anesthesia, Chemotherapy, Emergency Depand general medical/surgical settings. A spewith an appropriate library, is used for neon All libraries are constantly reviewed and reresponse to changes in medication use and repotential for programming errors. Infusion phave been revised and improved five times 2011. Monitoring: A comprehensive set of setting-specific indicollected, including the percentage of infusion programmed using the library, the number of encountered, and the number of soft stops employed the Pump Safety Team are over Medication Safety Committee with independence of the Pump Safety Team are over Medication Safety Committee with independence of the Pump Safety Team are over Medication Safety Committee with independence of the Pump Safety Steering Committee with indepe | sub-committed arged with mp use gy; the pumps; ds such as and alerts; the velopment and procedures ed processes, events ic and system usive of hard and Care, partment, edial pump, atal patients, vised in reduce the pump libraries since August icators are ions of hard stops incountered, to continuousles. The reseen by the ident | |
| | | safe drug administration fusion pumps. Cross d A500. | | Responsible Party: Chief Pharmacy Officer Date of Correction: IMPLEMENTATION OF NEW DEVICES | 5 | 08/11/11 |
| A 263 | | ect of these systemic problems ital's inability to ensure the health care in a safe | A 263 | The Quality & Safety Oversight Committee approve the implementation of all signification medication delivery devices (such as implementation of medication medication for model of infusion pumps). The assures that appropriate policies, procedure are in place PRIOR to implementation and appropriate safety monitoring activities durimplementation process. | nt changes plementation of the Committee and training the established | r |
| | maintain an effectiv | evelop, implement and e, ongoing, hospital-wide, assessment and performance | | Monitoring: The activities of the Quality & Oversight Committee are overseen by direct Governing Body. Responsible Party: Chief Pharmacy Office: Date of Covertion: | t reports to the | 08/31/11 |

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| A 263 | the program reflect hospital's organizationspital department those services fur arrangement); and to improved health and reduction of many the hospital must evidence of its QAThis CONDITION Based on interview, the hospit effective, ongoing and performance | erning body must ensure that its the complexity of the ation and services; involves all ints and services (including nished under contract or it focuses on indicators related in outcomes and the prevention | A 263 | Prior to the regulatory visit, more than 99% completed required Baxter pump training an competency. Since 8/17/11, no RN including received a patient assignment prior to compl pump training and competency validation. Monitoring: Nursing Education monitors train an ongoing basis. Responsible Party: Chief Nursing Officer Completion Date: TAG A263 MEDICATION ERROR REVIEW AND RITHE enhanced medication error identification place for approximately a year prior to this on six care area based error identification accommittees reporting to the hospital's Medic Committee. This model has been very effect the systems issues that underlie actual and pmedication errors. This process identified the of pump errors and an improvement effort viat the time of survey. Since the survey, an esafety oversight committee (Patient Safety Scommittee) has begun weekly meetings to completion of improvement efforts, to prior reduction activities and identify cross-discippatterns in actual and potential errors. Mem Committee include the Chief Medical Offic Dean for Clinical Operations, the Chief Phathe Chief Nursing Officer and staff member for error identification and reduction. | d demonstrated g contract RNs, letion of Baxter ining compliance in growth and in growth and in growth and review cation Safety tive identifying totential here-emergence was underway executive-level Steering assure the timely itize error of the er, The Associat macy Officer, | 08/17/11 |
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| A 263 | patient safety. The ensure a system w pump programming hospital. Cross reference 4. The QAPI programpropriate "hard a medication adminisin place in a promp safety. Cross reference All the QAPI program including contract in regarding the use of Cross reference All the cumulative efficient of quality environment. 482.21(a)(1) QAPI identify and reduce This STANDARD Based on interview hospital failed to ensystems in place to medication errors. lead to unsafe medication infusion understand the progression acting upon the | e QAPI program failed to ras developed to monitor for g compliance throughout the grence A266, A285. In am failed to ensure that and soft stops" for the stration pump libraries were put of manner to provide for patient ence A491. In am failed to identify all RNs, nurses, had not been educated of medication infusion pumps. 500. If these systemic problems pital's inability to ensure the health care in a safe | | 263 · | is in place PRIOR to implementation and es appropriate safety monitoring activities duri implementation process. Monitoring: The activities of the Quality & Soversight Committee are overseen by direct Governing Body. Responsible Party: Chief Pharmacy Officer Date of Correction: EDUCATION AND COMPETENCY Educational activities related to new policy/development, including the validation of ini ongoing competence of appropriate staff me physicians, is overseen by the Quality and Soversight Committee. Monitoring: The activities of the Quality and Oversight are overseen by direct reports to the Govern Responsible Party: Chief Executive Officer | f hard and care, artment, cial pump, tal patients. ised in educe the ump libraries ince August 20 cators are ons f hard stops accountered, to continuously is. The seen by the dent mittee. must now at changes lementation of the Committee and training tablished ing the safety Forcess tial and embers and cafety Committee ing Body. | 08/11/11 |
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| A 266 | Findings: 1. On 8/16/11, a m provided by Pharm total of 331 medica the hospital from 2 interview with Pharmstarting at 1250 hospital average of 25 medeach patient each hospital averages. Thus, 300 patients administered each months equals 7,5 doses. So, of app administered to pa 2/1/11 and 8/14/1 reported. An Emergency Dereport for May 2018/18/11. The reported administered to pa 7 here were 110 pcontaining 54 row. So, 54 x 110 = 5,5 ED during May 20 would equal 35,64 for 6 months. On 8/18/11, a reverence for the ED that 9 errors were estimated 35,000 during 6 months, | nedication error report was 1. The report identified that a ation errors were reported in /1/11 to 8/14/11. During an rm I and the CNO on 8/18/11 burs, they stated that an dications were administered to day. They also stated that the about 300 patients per day. 3 x 25 doses = 7,500 doses 4 day. Projecting that for 6 500 x 30 days x 6 or 1.35 million froximately 1.35 million doses atients in the hospital between 1, there were 331 errors Repartment (ED) transaction 11 was provided by Pharm I on rt identified all the medications atients in the ED for May 2011. ages in the report each s of administered medications. 240 doses administered in the 11. Projected for 6 months that 10 doses administered in the ED few of the medication error from 2/1/11 to 8/14/11 identified reported by the ED. Out of an doses administered in the ED there were 9 reported errors. Global Trigger Tool Shows That | A | 266 | All RN's, including contract nurses, are requised Baxter pump computer based training at competency via a hands-on return demonstra patient assignment. Since 8/17/11, no confreceived a patient assignment prior to compite Baxter pump education and competency Monitoring: The Staffing Office monitors cassignments on a daily basis to ensure all apeducation is completed. Responsible Party: Director, Staffing & Pla Completion Date: TAG A266: (cross reference TAG A043) MEDICATION ERROR REVIEW AND R. The enhanced medication error identificating a committee. This model has been very effethe systems issues that underlie actual and medication errors. This process identified of pump errors and an improvement effort at the time of survey. Since the survey, an safety oversight committee (Patient Safety Committee) has begun weekly meetings to completion of improvement efforts, to pric reduction activities and identify cross-disc patterns in actual and potential errors. Mer Committee include the Chief Medical Officer patient for crior identification and reduction. Monitoring: The Governing Body receives reports from the hospital's Quality & Safet Committee, which in turn, oversees the furthe Patient Safety Steering and Medication Committees. Responsible Party: Chief Medical Officer Date of Correction: | attion prior to tract RN has letion of validation. ontract RN propropriate cement ESOLUTION: on process, in survey relied and review lication Safety cetive identifying potential the re-emergence was underway executive-level Steering a surve the timel oritize error ipline trends and mbers of the coer, The Associa larmacy Officer, ers responsible aregular monthly by Oversight notioning of | 08/17/11 v |
| | Adverse Events in | Hospitals May be Ten Times | İ | | | | - |

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| A 266 | published in Health pages 581 to 589. closed medical rechospitals between, reviewed using the Improvment's Glob found that Safety In Voluntary Reporting 90 percent of the armong hospitalized showed: a) 38% of medication errors; to 5.3 medication errors; to 5.3 medication estay. The interview with I described above reaverage, 300 paties and 7,500 medication bospital each day. million doses adminuted would yield 274,000 data would yield 30 about 110,000 error hospital stay per parmore recent HA studivided by 10 times 17 times the annual hospital in 2011. Evolution 200 days per paties (300 divided by 20 year. That was still reported by the hospital stay the protection of the still reported by the hospital stay the still reported by the st | Affairs (HA) dated 4/12/11, The study identified that ords for 795 patients from 3 10/1 and 10/31/04, were Institute for Healthcare al Trigger Tool. The study idicators and Hospital g "fail(ed) to detect more than dverse events that occur d patients." The study also identified adverse events were b) each patient was subjected errors during his/her hospital Pharm I and the CNO evealed that there were, on the ints in the hospital each day ion doses administered in the Thus 7,500 x 365 equal 2.74 instered per year. The IOM of errors per day x 365 or irs per year. If a reasonable attent was 10 days, using the udy would yield a total of (300 is 365) 10,950 errors or almost elized number reported by the iven if a very long average stay ent were used, that would yield times 365) 5,475 errors per more than 8 times the number spital. | A: | 266 | of the Medication Safety Committee and ch overseeing and optimizing all aspects of puin including: the assessment of pump technolo education of health care providers utilizing: the implementation of smart pump safeguar medication libraries, soft stops, hard stops, a standardization of workflow through the devand implementation of appropriate policies procedures; and quality/safety monitoring of pump relat The Pump Safety Team reviews all adverse associated with pumps and identifies specific wide changes to enhance safety. Compreher medication libraries, including a robust set of soft stops have been developed for Critical Anesthesia, Chemotherapy, Emergency Depand general medical/surgical settings. A spewith an appropriate library, is used for neon All libraries are constantly reviewed and reresponse to changes in medication use and a potential for programming errors. Infusion phave been revised and improved five times. Monitoring: A comprehensive set of setting-specific indicollected, including the percentage of infusion programmed using the library, the number of concountered, and the number of soft stops ethics data is used by the Pump Safety Team continuously improve education and perfect pump librariactivities of the Pump Safety Team are over Medication Safety Committee with independent of Correction: IMPLEMENTATION OF NEW DEVICES The Quality & Safety Oversight Committee approve the implementation of all signification medication delivery devices (such as impnew brand or model of infusion pumps). The assures that appropriate policies, procedures in place PRIOR to implementation and eappropriate safety monitoring activities during implementation process. Monitoring: The activities of the Quality & Oversight Committee are overseen by directions and eappropriate after an overseen by directions. | arged with mp use gy; the pumps; ds such as and alerts; the evelopment and ed processes. events ic and system usive of hard and Care, or artment, ed pump, atal patients. vised in reduce the comp libraries since August icators are ions of hard stops no countered. to es. The useen by the ident is a must now at changes lementation of e Committee s and training stablished ing the Safety | 08/11/11 |
| | While the error rate | es from the different studies | | | | | |

Facility ID: CA060000071 .

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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| | OF DEFICIENCIES F CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) M A. BUI | | PLE CONSTRUCTION G | (X3) DATE SURVEY COMPLETED | |
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| A 266 | vary, even the lower using the HA study number of annualizationspital in 2011. Githan 5,000 errors would 662 (annualize hospital in 2011, the number of errors or not being reported. 2. On 8/15/11 at 1 for the policy and phospital monitors the infusion pumps, he P&P for this but we will be responsible the pump." Pharm was investigating in overrides and he state the pharmacy department." On 8/15/11, review revealed the patienthad a kidney transpuring surgery, an Thymoglobulin 100 over 6 hours. Accosummary, "A senion year resident) programming demedication overdor over a one hour perhour period. The primedication in its dring "soft limit" (soft sto | was more than 8 times the was more than 8 times the wed errors reported by the iven the HA study that more were likely happening but that ed) errors were identified by the ere are a potentially significant occurring in the hospital that are | A | 266 | Responsible Party: Chief Pharmacy Officer Date of Correction: | | 08/31/11 |

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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| A 266 | administered. Then | ge 11 e was no programmed "hard ng alert that will not allow the | A2 | 266 | | | |
| | administration of th | e medication and cannot be I for this medication in the | | | | | |
| A 070 | there were retrospe ensure programmir stop" overrides wer "Not at this time bu Pharm I, the compa pumps did not prov hospital to perform the company one to they would be out of several days to train | hours, Pharm I was asked if active audits of the pumps to a was accurate and "soft e being evaluated. He replied, to we intend to." According to any who supplied the infusion ide adequate training for the the monitoring. He spoke with two weeks ago and was told on Thursday 8/18/11 for the pharmacy staff. | ٨ | 176 | TAG A276: MEDICATION ERROR REVIEW AND R | | |
| A 276 | (ii) Identify opportuchanges that will le This STANDARD is Based on interview hospital failed to us | PI IDENTIFY IMPROVEMENT use the data collected to] nities for improvement and ad to improvement. s not met as evidenced by: vs and document reviews the e medication error data system weaknesses in order | | 210 | The enhanced medication error identificating place for approximately a year prior to this on six care area based error identification a committees reporting to the hospital's Medicommittee. This model has been very effect the systems issues that underlie actual and medication errors. This process identified to for pump errors and an improvement effort at the time of survey. Since the survey, an safety oversight committee (Patient Safety Committee) has begun weekly meetings to completion of improvement efforts, to prior reduction activities and identify cross-disc patterns in actual and potential errors. Men | survey relied and review ication Safety ctive identifying potential the re-emergence was underway executive-level Steering assure the timely oritize error ipline trends and | |
| | to improve the qual Findings: 1. The Medication 9 | | | | Committee include the Chief Medical Offi Dean for Clinical Operations, the Chief Ph the Chief Nursing Officer and staff member for error identification and reduction. Monitoring: The Governing Body receives reports from the hospital's Quality & Safety Committee, which in turn, oversees the fun | cer, The Associat armacy Officer, ers responsible regular monthly y Oversight | e |
| | 8/15 and 8/16/11 re of the minutes were | espectively. Appended to each e reports entitled "Medication ERP 11 Elements." Each of the | | | Committees. Responsible Party: Chief Medical Officer Date of Correction: | | 09/18/11 |

| | OF DEFICIENCIES F CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | 1 | ULTIPL LDING | LE CONSTRUCTION | (X3) DATE SURVEY COMPLETED | |
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| A 276 | Continued From pa | age 12. | Α. | 276 | | | <u>.</u> |
| | 2009 to April 2010 (MER1) report. The MSC meeting. The * Under Prescribing related May 2009 to April 2 comments under A * Under Administration related Month - May 2009 comments under a was no evidence of errors nor any iden | C meeting contained the May Medication Error Review here were no minutes for this e MER1 report read: Ig, "Analysis: Number of Medication Events by Month - 2010." There were no assessment or Actions. Action, "Analysis: Number of the Medication Events by to April 2010." There were no assessment or actions. There of any discussion of medication ntification of system(s) in could provide opportunities for | | A CARLON COMMENT OF THE PARTY O | | | |
| | 2009 to July 2011 minutes read: "Revupdated trending raction required." T discussion of the esystem(s) weaknes * Under Administr Administration relaministration relaministratio | (MER2) report. The MSC view med error reports, eports, and determine if further here was no evidence of any errors nor any identification of sses. The MER2 report read: ration, "Analysis: Number of ated Medication Events by to July 2011. Assessment: de errors fairly consistent over s. Several errors associated inister medication as ordered /S not monitored, or not given), ated with pump programming, are as of concern. There were led as to why medications were as ordered. There was no neat errors occurred with pump | | | | | |

| STATEMEN | T OF DEFICIENCIES OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | | | E CONSTRUCTION | (X3) DATE SU COMPLE | |
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| A 276 | discussion of why imention of a commicaused the errors is evidence of what a modify existing systeduce or eliminate them from recurrin. * Under Dispensin Dispensing related July 2009 to July 2 number of events is Actions: Continue There was no evidence why. There was discussion of the traction(s) taken to in During a meeting was no evidence of commonalities of the system of the four most from a) Wrong Dose was no evidence in the above four error of the errors report was no evidence in minutes, reviewed these errors were in the system of the errors were in the system of the errors were in the system of the errors were in the error were in the erro | ere was no evidence of a the errors occurred nor any non thread or theme which to occur. There was no ction(s) needed to be taken to terms or develop new ones to extense errors and prevent g. g, "Analysis: Number of Medication Events by Month -011. Assessment: Consistent in this category reported in July. To monitor." The ence of what errors occurred is no evidence of any rends among the errors nor any emprove processes. With Pharm I and Pharm II on 0840 hours, both agreed there if any discussion of the errors. The from 2/1/11 to 8/14/11, all and reviewed on 8/16/11, all and reviewed on 8/16/11, all of 331 errors reported. Equently recurring errors were: e - 23% are 19% are (omitted) - 16% | A. | 276 | | | |

| (2) m 1 4 1 m 1 | TO LOW MICHIONIA | CA MEDIONAD OFFICE | | | | |
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| A 276 | Continued From pa | age 14 | A 276 | | · | |
| | opportunities to im- reduce or eliminate administration erro | | · | TAG A285: MEDICATION ERROR REVIEW AND R | | |
| A 285 | Focus on high-risk problem-prone are Consider the incide of problems in those | set priorities for its evement activities that high-volume, or as; ence, prevalence, and severity | A 285 | The enhanced medication error identification place for approximately a year prior to this on six care area based error identification a committees reporting to the hospital's Medicommittee. This model has been very effect the systems issues that underlie actual and medication errors. This process identified the form of survey. Since the survey, and safety oversight committee (Patient Safety Committee) has begun weekly meetings to completion of improvement efforts, to prior reduction activities and identify cross-discipatterns in actual and potential errors. Men Committee include the Chief Medical Office. | survey relied nd review ication Safety stive identifying potential he re-emergence was underway executive-level Steering assure the timel ritize error pline trends and thers of the | |
| | quality of care. This STANDARD Based on interview hospital failed to en pumps (these pummedication errors trisk of harm) that of libraries allow for plimits to prevent mappropriately programonitored for complimits to prevent mapped to the program of the program | is not met as evidenced by: v and record review, the nsure that medication infusion ps are associated with hat expose patients to a high ontained drug libraries (drug rogramming dose and rate edication overdose) were ammed for patient safety and bliance throughout the hospital. ailed to ensure PCA pump ted and acted upon in a y addressed and resolved the | | Dean for Clinical Operations, the Chief Phathe Chief Nursing Officer and staff member for error identification and reduction. Monitoring: The Governing Body receives reports from the hospital's Quality & Safety Committee, which in turn, oversees the funthe Patient Safety Steering and Medication Committees. Responsible Party: Chief Medical Officer Date of Correction: | armacy Officer, rs responsible regular monthly v Oversight ctioning of | |
| | | 104 hours, during an interview or of Pharmacy, stated the | <u>.</u> | | | |

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| *************************************** | OLIMATE ON OTH | TEMPME OF DEFICIENCIES | . 167 | | PROVIDER'S PLAN OF CORREC | TION ! | (X5) |
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| A 285 | pumps (except in the that contained drug updating the progra library since medicand always changing stops' and 'hard stops' and 'hard stops' and 'hard stops' that should have "have says to go." the policy and programmed with the policy and programmed word hospital monitors to | sing medication infusion ne neonatal intensive care unit) ne libraries. "We are constantly amming of medications into the ation information is dynamic ng. We are incorporating 'soft ops' if we can. We have ations to program and to do hen asked if all medications hard stops" had been hese stops Pharm I stated, made good progress but still When Pharm I was asked for edure (P&P) on how the ne safe use of these pumps, | | 285 | INFUSION PUMP SAFETY A Pump Safety Committee was created as a of the Medication Safety Committee and cha overseeing and optimizing all aspects of pum including: the assessment of pump technolog education of health care providers utilizing put the implementation of smart pump safeguard medication libraries, soft stops, hard stops, a standardization of workflow through the deal and implementation of appropriate policies and quality/safety monitoring of pump related. The Pump Safety Team reviews all adverse associated with pumps and identifies specific wide changes to enhance safety. Comprehen medication libraries, including a robust set of soft stops have been developed for Critical Canesthesia, Chemotherapy, Emergency Depand general medical/surgical settings. A spewith an appropriate library, is used for neon All libraries are constantly reviewed and reversponse to changes in medication use and repotential for programming errors. Infusion p | arged with inp use gy; the pumps, is such as and alerts; the velopment and procedures; ed processes. events c and system issive of hard and care, isartment, cial pump, atal patients. rised in educe the pump libraries | |
| | will. The Pump Saf for reviewing the or was asked if the horizon inappropriate progrestated, "We will in a department needs." On 8/15/11, review revealed the patienthad a kidney transpouring surgery, and Thymoglobulin 100 over 6 hours. Accosummary, "A senion year resident) programmart pump that contained the medication over the intended six horizontained the medican alert that the "se exceeded." The ale | not have a P&P for this but we sety Team will be responsible verrides of the pump." Pharm I pepital was investigating ramming overrides and he the future but the pharmacy to be trained first." of Patient 37's medical record at was a 63 year old male who plant surgery on 7/25/11. Order was given to administer ang intravenously to infuse rained to the hospital's incident or anesthesia resident [third rammed a [Brand Name] pontains a drug library to deliver a one hour period instead of our period. The pump, which incident in its drug library sent oft limit" [soft stop] was eart was overridden by MD X a was administered. There was | | | have been revised and improved five times second to the control of | icators are ions of hard stops incountered, to continuously es. The reseen by the ident mittee. must now at changes lementation of the Committee s and training stablished ing the Safety | 08/11/11 |

Facility ID: CA060000071

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| A 285 | medication. On 8/15/11 at 1145 | ard stop" entered for this hours, Pharm I was asked if | A 2 | 85 | Responsible Party: Chief Pharmacy Officer Date of Correction: | | 08/31/11 |
| | ensure programmir stop" overrides wer "Not at this time bu Pharm I, the compa pumps did not provhospital to perform the company one to they would be out of several days to traistated the Thymog | ective audits of the pumps to any was accurate and "soft to being evaluated. He replied, it we intend to." According to any who supplied the infusion ride adequate training for the the monitoring. He spoke with the two weeks ago and was told on Thursday 8/18/11 for an the pharmacy staff. Pharm I lobulin infusion was labeled in the label was printed, "Give | | | · | | |
| | "We found PCA (Poump errors in 5/1" PCA pumps were confusion pumps, sind by patients to provipumps offered the administer pain metasis but under a suprevent abuse or or Pump Safety Team errors continue to ceducation. Seven F | 405 hours, the CNO stated, atient Controlled Analgesia) I which had occurred in 4/11." different than medication ace PCA pumps were utilized de pain medication. PCA patients the ability to self dication on an as needed pecific dose and schedule to verdosing. According to the a minutes, dated 7/14/11, "PCA occur despite intensive nurses PCA errors were reported over is. Two of these seven errors is last two weeks." | | | | | |
| - . | dated 8/11/11, "PC despite intensive no | ump Safety Team minutes A errors continue to occur urses education. PCA error ersistent failures in the | | | | | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | IDENTIFICATION NUMBER: | | (X2) MULTIPLE CONSTRUCTION | | | RVEY FED |
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| AND PLAN (| OF CORRECTION | IDENTIFICATION NONDER | A. BUI | LDIN | G | l c | |
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| | PROVIDER OR SUPPLIER | IRVINE MED CENTER | | 10 | REET ADDRESS, CITY, STATE, ZIP CODE 01 CITY DRIVE SOUTH DRANGE, CA 92868 | | |
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| A 288 | independent double pump was program meeting to occur in documented recomperformance in this 482.21(c)(2) QAPI [Performance impressed analyze their cause actions and mechal and learning through This STANDARD Based on staff interperformance Impressed on staff interperformance Impressed in the performance of potential secondary to the many many many. Findings: 1. On 8/1/11, an accepted by the hore ported that on 7/2 infuse Thymogloburing back over 36 a kidney transplant resident (MD X), or alert features and pump. This resulted infused over one hinstructions on the believed there may | e checks at the time a PCA med or reprogrammed. Next 19/11." There were no mendations made to improve shigh risk area. FEEDBACK AND LEARNING overment activities must track adverse patient events, as and implement preventive inisms that include feedback ghout the hospital. Is not met as evidenced by: erview and record review, the overment Committee failed to hisms that included feedback ghout the hospital to prevent initial adverse patient events hisprogramming of infusion diverse patient event was spital to the Department. It was 25/11, a medication order to alin 100 mg by intravenous to minutes to Patient 37 during the surgery. An anesthesiology wer rode the pump's safety misprogrammed the infusion d in the medication being our instead of six hours per medication label. The hospital thave been connection exition misadministration and | | 288 | TAG A288: INFUSION PUMP SAFETY A Pump Safety Committee was created as a of the Medication Safety Committee and choverseeing and optimizing all aspects of pur including: the assessment of pump technologeducation of health care providers utilizing the implementation of smart pump safeguam medication libraries, soft stops, hard stops, a standardization of workflow through the deand implementation of appropriate policies and quality/safety monitoring of pump relate. The Pump Safety Team reviews all adverse associated with pumps and identifies specific wide changes to enhance safety. Compreher medication libraries, including a robust set of soft stops have been developed for Critical (Anesthesia, Chemotherapy, Emergency Depand general medical/surgical settings. A spewith an appropriate library, is used for neon All libraries are constantly reviewed and revresponse to changes in medication use and rotential for programming errors. Infusion phave been revised and improved five times 2011. Monitoring: A comprehensive set of setting-specific indicollected, including the percentage of infusion programmed using the library, the number of encountered, and the number of soft stops et This data is used by the Pump Safety Team improve education and perfect pump libraric activities of the Pump Safety Team are over Medication Safety Committee with independentives by the Patient Safety Steering Committees by the Patient Safety Steering Committee to time constraints in regulatory reporting the hospital self-reported the Thymoglobuling mis-administration before it had the opportuits investigation. The case was internally reviphysicians. In addition, the hospital had the by four external physicians, all from non-Ucperforming transplant programs at academic of Thymoglobulin did not result in either the or injury to the patient. | arged with np use gy; the pumps; ds such as and alerts; the velopment and procedures ed processes. events ic and system nsive of hard and Care, brial pump, atal patients. vised in reduce the pump libraries since August cators are ons of hard stops neountered. to continuously es. The seen by the dent mittee. ng requirements n mity to complete viewed by two case reviewed crelated, highly credical center is-administration | 08/11/11 |

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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| | incident of medicat May 2011. An incident of who re sedative medication misprogramming of the hospital staff repumps was limited and not throughour infusion pumps we no P&P in place to the pumps to preventhere was no evident monitor programmed termine if the hospital incidents described "We're still in the sinfuse potassium of electrolyte and pot infusion) or magnemuscle contraction at whatever rate with mode." Interviews with other floors were conducted. | eport, this was the second cion misadministration since lent on 6/15/11 involved a ceived 30 times the normal in dose, secondary to fan infusion pump. of hospital documentation and ealed retraining/reeducation of egarding the use of the infusion to the anesthesia department in the hospital where the re widely being use. There was serve as guidelines for use of each any possible future errors, ence of a system in place to ing of infusion pumps to espital's actions were sufficient farmming problems. O hours, RN J, charge nurse of RN J), stated that none of the een reeducated regarding the se infusion pumps since the diabove. RN J further stated, ame situation where we could chloride (essential body entially deadly medication for esium sulfate (medication for esium sulfate) and the basic er RNs from different nursing cited. Cross reference A500 | | 288 | IMPLEMENTATION OF NEW DEVICES The Quality & Safety Oversight Committee approve the implementation of all significan in medication delivery devices (such as implew brand or model of infusion pumps). The assures that appropriate policies, procedures is in place PRIOR to implementation and estappropriate safety monitoring activities duri implementation process. Monitoring: The activities of the Quality & Oversight Committee are overseen by direct Governing Body. Responsible Party: Chief Pharmacy Officer Date of Correction: On August 16-17, 2011 a clinical update and program was developed and provided to all including contract nurses, which included in guidelines and education on the Pump Safet of assigned staff completed the re-education to receiving a patient assignment. Monitoring: The Staffing Office monitors coassignments on a daily basis to ensure all apeducation is completed. Staff RN competent annually. Responsible Party: Chief Nursing Officer Date of Completion | t changes ementation of e Committee and training tablished ng the Safety reports to the I re-education nurses, edication librar y policy. 100% program prior ontract RN propriate | 08/31/11 08/17/11 |
| A 353 | 482.22(C) MEDICA | AL STAFF BYLAWS | , A | JUJ | | | (|

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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| A 353 | Continued From pa | age 19 | Α: | 353 | 3 | j | |
| • | | nust adopt and enforce bylaws consibilities. The bylaws must: | | | | | y |
| | Based on interview hospital failed to er enforced bylaws to sampled patients (I | is not met as evidenced by: vs and record review, the nsure the medical staff ensure safety for 2 of 43 Patients 37 and 39). This is medical practice in the | | - | | | : |
| : | Findings: | | | | | | |
| | Patient 37, he cam for a kidney transpirecord revealed that anesthetic assessmand was taken to the 0742 hours. An int Z and MD I on 8/18 MD X and MD I was 1000 hours on 8/23 supervising MD X, anesthesia, she as questions regarding 37. MD X told MD the case. MD Z stareturned periodical X and to verify that MD X stated he was Thymoglobulin, (a lacute organ rejections of the case of this drug only months earlier at a | e to the OR (operating room lant on 7/25/11. The medical at Patient 37 had a prement at 0731 hours on 7/25/11 ne operating room (OR) at review was conducted with MD of 11 at 0900. An interview with seconducted at approximately of 11. MD Z, the physician stated following induction of ked MD X if there were any githe management of Patient Z he was "comfortable" with lated that she left the OR but left to review Patient 37 with MD the patient was stable. The sto initiate an infusion of medication used to prevent on). MD X stated that he had once before, approximately 6 different location during his ted that he would infuse the | | | TAG A353 (cross reference TAG A500) The Supervision policy of the Department of was not followed by MD X, who is a trained investigation was conducted and disciplinar taken against MD X for not following depart written policies. Re-training for all departm on policies and procedures, was initiated an place regularly and prior to Grand Rounds. Monitoring: Is being conducted on an ongoing Responsible Party: Chair, Department of An Date of Completion: | e (resident). An y actions were trmental ental members, d is taking ng basis. | 08/18/11 |

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| A 353 | Thymoglobulin ove the infusion pump, the medication ove Thymoglobulin must physicians and infuprevent acute drug knowledge of a hos requiring 6 hour infurance and infuprevent acute try made by MD intraoperative recohours, revealed "Lanti thymocyte, IC When interviewed unaware or unwilling." | age 20 r 4 hours, but in programming he made an error and infused r 1 hour. (By hospital policy, at be used only by experienced used over a 6 hour interval to reactions.) MD X denied spital or pharmacy policy usion of the medication. An X into the anesthesia rd at 1104 hours to 1204 ymphocyte immune globulin, infusion, 100 mg over 1 hr." on 8/23/11, MD X seemed us to infuse the medication over | AS | 353 | INFUSION PUMP SAFETY A Pump Safety Committee was created as of the Medication Safety Committee and cloverseeing and optimizing all aspects of pump including: the assessment of pump technole education of health care providers utilizing the implementation of smart pump safegua medication libraries, soft stops, hard stops, standardization of workflow through the deand implementation of appropriate policies and quality/safety monitoring of pump relative pump Safety Team reviews all adverse associated with pumps and identifies specified changes to enhance safety. Comprehemedication libraries, including a robust set soft stops have been developed for Critical Anesthesia, Chemotherapy, Emergency Deand general medical/surgical settings. A spwith an appropriate library, is used for neor | narged with mp use ogy; the pumps; rds such as and alerts; the evelopment and procedures; ted processes. e events fic and system ensive of hard and Care, partment, ecial pump, natal patients. | · |
| | gas results for Pati During interview or obtaining a set of a resultant oxygen le normal range and to Patient 37 was four X stated that he hat level of the patient, the slightly acid lev 1416 hours, the an administration of given reversal agent use general anesthesia MD X proceeded to breathing tube from This was in violation Anesthesia rules a trainee physician to anesthesiologist, in | cord revealed an entry of blood ent 37 just prior to 1340 hours. In 8/23/11 MD X recalled interial blood gases. The wel was found to be below the the acid-base balance of and to be in the acid range. MD in discovers of the discovers of the oxygen and took no action to correct el of Patient 37's blood. At esthesia record revealed bycopyrrolate, (an anesthesia did to awaken patients from the airway) of Patient 37. In of the Department of the discovers of the original to the airway of the terminal to be page the attending of this case, MD Z, to be ergence from anesthesia. | | | All libraries are constantly reviewed and re response to changes in medication use and potential for programming errors. Infusion have been revised and improved five times 2011. Monitoring: A comprehensive set of setting-specific induction collected, including the percentage of infus programmed using the library, the number encountered, and the number of soft stops. This data is used by the Pump Safety Team improve education and perfect pump librar activities of the Pump Safety Team are ove Medication Safety Committee with indeper reviews by the Patient Safety Steering Con Responsible Party: Chief Pharmacy Officer Date of Correction: | reduce the pump libraries since August dicators are sions of hard stops encountered. It to continuously ies. The reseen by the adent muittee. | 08/11/11 |

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| A 353 | he turned away from extubation, for a perseconds, to do his stated that he had attending anesthes that he was aware prior to extubating I noted his failure to from Patient 37 to emedical record. He from his computer. When interviewed a stated that trained into turn away from and extubation may staff anesthesiologishe entered the optime page from MD 2 incardiac compression MD 2 instructed MI Patient 37. MD I are was a verbal rule in Anesthesia that an turn away from a premergence of the panesthesia. The hospital failed and department of | on 8/23/11, MD X stated that in the patient, following priod of possibly 10-30 electronic charting. MD X forgotten" to page the lologist, MD Z. MD X stated of his failure to page MD Z Patient 37, however, he only do so when he turned away enter data into the electronic then sent a page to MD Z on 8/18/11, MD Z and MD I ohysicians in anesthesia must a patient following extubation, y not be performed unless a list is present. MD Z stated erating room, having received X, to find that Patient 37 had allow and called a "code blue." D X to immediately initiated external ons and called a "code blue." D X to immediately reintubate in the Department of anesthesiologist was not to attent following extubation and patient from general | A | | MD X, in an isolated occurrence, deviated for department's extubation policy. As indicated disciplinary action was taken against MD X, did not follow written departmental policy. A residents and faculty (Attending) participated re-education of the policy, including that of n supervision. There is now also a pre-extubation is disetween the resident and Attending. This pro incorporated into the post operative process a documented as part of the AlMS (Anesthesia Management System). Monitoring: Is conducted on an ongoing basi Responsible Party; Chair, Department of Ane Completion Date: | previously, a resident who all departmenta i in a esident on verbal iscussed cess has been and is Information | |

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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| A 353 | and Physical, dated stated, "Pertinent precorded at the time permit continuity of entry will show the Whenever possible problems should be progress notes and orders as well as re Progress notes should should be progress notes and progress notes should should be progress notes and progress notes should be progress notes and pro | Medical Staff under History d 9/27/10, on page 9; no. 5 progress notes shall be e of observation, sufficient to f care and transferability. Each date and time of each note. e each of the patient's clinical e clearly identified in the d correlated with specific esuits of tests and treatment. all be written at least daily and varranted by the patient's | A | 353 | | | |
| | 15, no. 11 stated, to doubt or question patient or believes needed and has no shall call this to the superior who in turn the Attending Physresolved, she may Chief Patient Care the Chief Patient Care the Chief Patient Chief practitioner has Cl On 8/17/11, review showed the patien (electrical device to 7/28/11. On 7/29/1 underneath the patien documented in the was no evidence to | General Conduct of Care, page of a nurse (RN) has any reason in the care provided to any that appropriate consultation is of been obtained, the nurse attention of the nurse's in may discuss the matter with sician and if the matter is not then refer the matter to the Services Officer. If warranted, care Services Officer may bring ttention of the Clinical wherein the responsible inical Privileges." of Patient 39's medical record thad a pacemaker insertion or regulate heart beat) on 1, a hematoma (bruise) cemaker dressing was a nursing notes. However, there he cardiology team examined om 7/29/11 to 8/2/11. | | | TAG A353: (Cross reference TAG A043) Members of the Cardiology team were re-erequirement to write daily progress notes. Monitoring: Random chart audits were conceriod of 30 days to ensure daily document by the Cardiology team was present. 100% was noted. Responsible Parties: Chief, Division of Cardiology team to Chief Administrator, Content of Completion: | ducted for a ation of care compliance | 08/30/11 |

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| A 353 | On 8/18/11 ar 1309 took care of Patien was interviewed. Sabout the huge her cardiology resident team in the patient pacemaker dressir note written. The Noncology, who wanded the attendin Again, the cardiologatient but there we have pacemaker sal readjust the pacemaker sal readjust the patient | age 23 Shours, RN K, the nurse who ta 39 post pacemaker insertion, he stated she was concerned matoma. She called the senior RN K saw the cardiology is room, inspecting the ag but there was no progress lursing Supervisor of physician was also notified gy team did rounds on the as no progress note written. This is representative came to maker program to better the sheart beats but she was not to team knew about it or not. | A | 353 | | | |
| A 397 | sedative, was well-medical record and wristband. On 7/23 Ativan as the paties agitated during a Creference A405. 482.23(b)(5) PATI A registered nurse of each patient to accordance with the specialized qualific nursing staff available. This STANDARD Based on observations in the staff of the staff and the staff are staff and the staff are staff a | dicine allergy to Ativan, a documented throughout the dwas written on the patient's 8/11, Patient 39 was given in twas becoming more code Blue situation. Cross ENT CARE ASSIGMENTS must assign the nursing care other nursing personnel in the patient's needs and the cations and competence of the able. Is not met as evidenced by: ations and interviews, the insure one of three sampled (RNs) were competent to on doses for patients (RN L). | A | 397 | TAG A397: SAFE MEDICATION ADMINISTRATION Safe medication administration is an expecta UC Irvine RN's. The competency for safe m administration (which includes dosage calcu- validated during orientation and on an ongoi Ongoing education is conducted based on re- iand noted trends. Monitoring: Randomized medication pass at include dosage calculations) are conducted p identify any deficits. Responsible Party: Chief Nursing Officer Date of Completion: | ation of all tedication tedications) is ting basis, ti | Ongoing |

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| A 397 | , | nge 24 ad to unsafe patient care. | A 397 | | | |
| A 398 | 8/18/11, starting at was asked if she w doses. RN L said y unit provide care to sometimes must vice chemotherapy. RN in pounds and a m per kilogram. This calculate the dose L was unable to ca confirmed by the C 482.23(b)(6) SUPE STAFF Non-employee lice in the hospital must procedures of the I nursing service must procedure and evo of non-employee n within the responsion. This STANDARD Based on record rhospital failed to eneducate and test the sampled registry R worked at the hospital would be used control to the control of the sampled registry R worked at the hospital failed to eneducate and test the sampled registry R worked at the hospital failed to eneducate and test the sampled registry R worked at the hospital failed to eneducate and test the sampled registry R worked at the hospital failed to eneducate and test the sampled registry R worked at the hospital failed to eneducate and test the sampled registry R worked at the hospital failed to eneducate and test the sampled registry R worked at the hospital failed to eneducate and test the sampled registry R worked at the hospital failed to eneducate and test the sampled registry R worked at the hospital failed to eneducate and test t | e Oncology nursing unit on 0830 hours, staff nurse RN L as able to calculate medication es. The RNs in the Oncology of cancer patients and alidate the doses of cancer L was given a patient's weight edication dose in milligrams was sufficient information to for a patient in milligrams. RN loculate the dose. This was encology nursing supervisor. ERVISION OF CONTRACT insed nurses who are working at adhere to the policies and mospital. The director of lest provide for the adequate aluation of the clinical activities ursing personnel which occur bility of the nursing services. Is not met as evidenced by: eview and staff interview, the neuron a process was in place to be competence of one of one N and all registry nurses who bital on the use of new infusions did not ensure the pumps rectly and safely by nurses ations and infusions to | A 398 | TAG A398 (cross reference TAG A04 All contract nurses, are required to conpump computer based training and detecompetency via a hands-on return den a patient assignment. Since 8/17/11, n received a patient assignment prior to the Baxter pump education and competed Monitoring: The Staffing Office monit assignments on a daily basis to ensure education is completed. Responsible Parties: Chief Nursing Office monitoring of Director, Staffing Completion Date: | mplete the Baxter monstrate nonstration prior to o contract RN has completion of stency validation. tors contract RN all appropriate | 08/17/11 |

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| | AME OF PROVIDER OR SUPPLIER UNIVERSITY OF CALIFORNIA IRVINE MED CENTER (X4) ID SUMMARY STATEMENT OF DEFICIENCIES STREET ADDRESS, CITY, STATE, ZIP CODE 101 CITY DRIVE SOUTH ORANGE, CA 92868 PROVIDER'S PLAN OF CORRECTION | | | | | | | |
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| A 398 | Findings: On 8/18/11 at 0800 personnel files was personnel file for R nurse. The file comanswer sheet. The the nurse's compet pumps that were planswer sheet was been scored to show and was qualified to the All hospital nurses test and classes who work with the pump programming. The provided to show F to ensure proper using the Assistant I Placement. RN I's him. The Assistant Direction of the surveyor minimum passing added that copies information had be nurses who worked completed tests we scored prior to beir The Assistant Direction of the surveyor minimum passing added that copies information had be nurses who worked completed tests we scored prior to beir The Assistant Direction of the surveyor minimum passing added that copies information had be nurses who worked completed tests we scored prior to beir The Assistant Direction in the person of the surveyor minimum passing added that copies information had be nurses who worked completed tests we scored prior to beir The Assistant Direction of the surveyor minimum passing added that copies information had be nurses who worked completed tests we scored prior to beir The Assistant Direction of the surveyor minimum passing added that copies information had be nurses who worked completed tests we scored prior to beir The Assistant Direction of the surveyor minimum passing and the provided tests we scored prior to beir The Assistant Direction of the surveyor minimum passing and the provided tests we scored prior to beir The Assistant Direction of the provided tests we scored prior to beir The Assistant Direction of the provided tests we scored prior to beir The Assistant Direction of the provided tests we scored prior to beir The Assistant Direction of the prior to beir The Assistant Direction of the prior to beir The Assistant Direction of the prior to be prior to beir The Assistant Direction of the prior to be | hours, review of hospital initiated. Review of the N I showed he was a registry tained a completed test test was given to determine tency to use the new nfusion ut into use on 6/23/11. The test dated 7/1/11, and had not ow if RN I had passed the test or use the pumps. Were given a computer based here the nurses were able to be to ensure its proper use and re was no documentation RN I had taken the pump class see and programming. Thours, an interview was done Director of Staff and Patient answer sheet was shown to Director was asked how wif RN I was qualified to numps since there was no test had passed or failed the test correct then scored the test in ors. The score was 80%, the score. The Assistant Director of this test and pump en forwarded to all the registry dat the hospital. The ere to be sent to his office to be not placed in the personnel files ctor stated that registry nurses he new pumps in different | A | 398 | | 3. | | |

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| (X4) ID PREFIX TAG | (EACH DEFICIENC) | NTEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF CO (EACH CORRECTIVE ACTION CROSS-REFERENCED TO THE DEFICIENCY) | N SHOULD BE: | (X5) COMPLETION DATE |
| A 398 | Continued From pa | ge 26 | A 39 | 98 | | |
| A 404 | a list of the registry the hospital and the the new pumps. The provided by the time hospital. | ctor was requested to provide nurses that provide care at eir tested competency for using his information had not been e the survey team exited the | A 40 | 04 | | |
| | administered in acc State laws, the ord practitioners respo | als must be prepared and cordance with Federal and ers of the practitioner or nsible for the patient's care as 82.12(c), and accepted ce. | | | | |
| | Based on interview hospital failed to en an antibiotic) was a with California Cod Section 70263(g)(2 | is not met as evidenced by: v and record review, the nsure that Metronidazole (ME - administered as in accordance le of Regulations, Title 22, by which states medications all be administered as ordered. | | | | |
| | Findings: | | | | | |
| | (SICU) on 8/18/11, Medication Admini Patient 50 was rev year old with a pre Clostridium difficile Lexi-comp, a natio information source toxic and causes of | | | TAG A404: The RN caring for the patient reported ordered by the physician differed from patient was receiving at home. The mending clarification/verification of the from the physician. The standard of put the dosage is correct prior to administ Monitoring: None required Responsible Party: Chief Nursing Office. | n the dosage the ledication was held the medication dosage tractice is to ensure tration | |
| | During an interview nurse, she stated to | v with RN P, the patient's he physician's order for the ME | | Date of Completion: | iloo. | None Required |

| CENTERS FOR MICDIOARCE & MICDIOARD C | | | (V2) MI | ILTIPLE CONSTRUCTION | CONSTRUCTION (X3) DATE SURVEY | | |
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| | OF DEFICIENCIES OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | ' | | COMPLET | | |
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| NAME OF P | ROVIDER OR SUPPLIER | | | STREET ADDRESS, CITY, STATE | ZIP CODE | | |
| | • | CONTRACTOR OF STATE | - | 101 CITY DRIVE SOUTH | | | |
| UNIVERS | SITY OF CALIFORNIA | A IRVINE MED CENTER | | ORANGE, CA 92868 | | | |
| (X4) ID PREFIX TAG | (EACH DEFICIENC | ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL SC (DENTIFYING INFORMATION) | ID PREFD TAG | CROSS-REFERENCED | OF CORRECTION ACTION SHOULD BE TO THE APPROPRIATE ENCY) | (X5) COMPLETION DATE | |
| | | 0.7 | | 0.4 | | | |
| A 404 | Continued From pa | | A 4 | 104 | | | |
| | was written at 0630 | hours (nearly 3 hours before | | | £" . | | |
| | this interview). At the | 910 hours the MAR showed had still not been given. RN P | | | 1 | | |
| | mat the medication | had not yet administered ME | | | | | |
| | to Patient 50. | , had hot you darningto. on him | | TAG A405: | | | |
| A 405 | 482.23(c)(1) ADMI | NISTRATION OF DRUGS | A 4 | MEDICATION ERROR REV | TEW AND RESOLUTION: | | |
| | | ļ | | The enhanced medication error | | | |
| | All drugs and biolo | gicals must be administered | | on six care area based error id | lentification and review | | |
| | by, or under super | vision of, nursing or other dance with Federal and State | | committees reporting to the h Committee. This model has b | | | |
| | | ns, including applicable | • | the systems issues that underl | ie actual and potential | | |
| | | ents, and in accordance with | | medication errors. This proce | | | |
| | | ical staff policies and | | at the time of survey. Since the | | : | |
| | procedures. | · | | safety oversight committee (P | atient Safety Steering | | |
| | | t to a soul hour | | Committee) has begun weekly completion of improvement e | | y | |
| | This STANDARD | is not met as evidenced by: ws and record reviews, two of | | reduction activities and identi | fy cross-discipline trends and | | |
| | five medical record | is reviewed regarding the use | | patterns in actual and potential Committee include the Chief | | te | |
| | of patient controlle | d analgesia (PCA) pumps were | | Dean for Clinical Operations, | | | |
| | not in compliance | with approved policies and | | the Chief Nursing Officer and for error identification and re | | | |
| | procedures (Patier | nts 42 and 44). Noncompliance | | Monitoring: The Governing I | Body receives regular monthly | | |
| | with P&Ps as gene | eral guidelines could harm | | reports from the hospital's Qu | | | |
| | | n, the hospital failed to ensure I patients did not receive | | Committee, which in turn, ov the Patient Safety Steering an | | | |
| | | nich an allergy was listed in the | | Committees. | | | |
| | medical record. (P | | | Responsible Party: Chief Me | dical Officer | 00110111 | |
| | | , | <u> </u> | Date of Correction: | | 09/18/11 | |
| [| Findings: | | | NA CONTRACTOR | • | | |
| | 4 44 0050 5 | 0/40/44 during a masting | | PUMP DOUBLE CHECK The hospital's Medication Ad | | | |
| | | on 8/18/11, during a meeting, rsing Research stated that, | | revised to streamline workflo | | | |
| | according to the h | ospital's P&Ps, the use of | | independent double check. | | | |
| | PCAs (pumps - us | sed by patients to self | | MONITORING: Randomized conducted to validate complia | | | |
| | administer narcoti | cs within prescribed limits) | | Responsible Party: Chief Nur | | | |
| | require a second l | RN signature to validate the | | Date of Completion: | one onton | 09/19/11 | |
| | 1, 1 | nmed and administered | | | | 1 | |
| | correctly. | | | , | | | |
| 1 | 1 | | 1 | 1 | | i | |

| CENTERS FOR MEDICARE STATEMENT OF DEFICIENCIES | | (X1) PROVIDER/SUPPLIER/CLIA | | 1ULTII | PLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED | |
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| | FCORRECTION | IDENTIFICATION NUMBER: | A. BU | ILDIN | G | C | |
| | | 050348 | B. Wil | NG | | 08/23 | |
| | ROVIDER OR SUPPLIER | IRVINE MED CENTER | | 11 | REET ADDRESS, CITY, STATE, ZIP CODE 01 CITY DRIVE SOUTH DRANGE, CA 92868 | | |
| (X4) ID PREFIX TAG | (FACH DEFICIENC) | ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION) | ID PREF TAC | ·ΙΧ | PROVIDER'S PLAN OF CORREC (EACH CORRECTIVE ACTION SHO CROSS-REFERENCED TO THE APPI DEFICIENCY) | OULD BE | (X5) COMPLETION DATE |
| A 405 | reviewed with Phan Specialist on 8/17/Patient 42 was recin the PACU. The indicated a second programming of the Specialist stated the electronic record with RN cannot (him or programming in the Clinical Nurse Speprimary RN document in the computer further confirmed for Patient 42's record | dical record for Patient 42 was multi and the Clinical Nurse 11 starting at 1125 hours. eiving a narcotic using a PCA text on the computer screen I RN had double checked the e PCA. The Clinical Nurse hat because of the way the works in the PACU, a second herself) validate the PCA e electronic record. The scialist explained that the hents the name of the second er. The Clinical Nurse Specialist there was no documentation in the which identified that a second ted the programming and | A | 405 | INFUSION PUMP SAFETY A Pump Safety Committee was created as a of the Medication Safety Committee and choverseeing and optimizing all aspects of puincluding; the assessment of pump technolo education of health care providers utilizing the implementation of smart pump safeguar medication libraries, soft stops, bard stops, standardization of workflow through the deand implementation of appropriate policies and quality/safety monitoring of pump relat The Pump Safety Team reviews all adverse associated with pumps and identifies specification libraries, including a robust set soft stops have been developed for Critical Anesthesia, Chemotherapy, Emergency Dejand general medical/surgical settings. A spewith an appropriate library, is used for neon All libraries are constantly reviewed and reresponse to changes in medication use and potential for programming errors. Infusion bave been revised and improved five times 2011. | arged with mp use gg; the pumps; ds such as and alerts; the velopment and procedures; ed processes. events fic and system asive of hard and Care, partment, acial pump, atal patients. vised in reduce the pump libraries | |
| | record for Patient was receiving a na was started in the nursing flow sheet screen. (This flow document contain record and scanne Thus a hand writte can be viewed on Clinical Nurse Speinitials or signature anywhere else in who programmed pump. This was contained to the containe | irme the electronic medical 44 was reviewed. Patient 44 arcotic also by a PCA. The PCA Intensive Care Unit (ICU). The was reviewed on the computer sheet is a hand written ed in the hard copy medical ed into the electronic record. En signature or initial of the RN the computer screen). The exialist stated there were no es on the nursing flow sheet or the patient's record identifying and administered the PCA onfirmed by Pharm III. | | | Monitoring: A comprehensive set of setting-specific indicollected, including the percentage of infus programmed using the library, the number encountered, and the number of soft stops of This data is used by the Pump Safety Team improve education and perfect pump librariactivities of the Pump Safety Team are ove Medication Safety Committee with independence by the Patient Safety Steering Committee of Correction: | ions of hard stops encountered. to continuously ies. The rseen by the adent unittee. | 08/11/11 |
| | 2. Per record reviewmedicine allergy (| ew on 8/17/11, Patient 39's Ativan, a sedative medication) | | | , | | |

| | | - CHILDIONID CERTICES | , , , , , | | | | |
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| | T OF DEFICIENCIES OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) M A. BUI | | PLE CONSTRUCTION G | (X3) DATE SU COMPLE | |
| | | 050348 | B. WI | √1G | | 1 | C 3/2011 |
| | PROVIDER OR SUPPLIER SITY OF CALIFORNIA | A IRVINE MED CENTER | | 10 | REET ADDRESS, CITY, STATE, ZIP CODE 01 CITY DRIVE SOUTH DRANGE, CA 92868 | | |
| (X4) ID PREFIX TAG | (EACH DEFICIENC) | ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION) | ID PREF TAG | | PROVIÉER'S PLAN OF CORRE (EACH CORRECTIVE ACTION SH CROSS-REFERENCED TO THE APP DEFICIENCY) | OULD BE | (X5) COMPLETION DATE |
| A 405 | of the hard copy m H&P, and all the copy and all the copy as oncology, cardioneurosurgery and proceeding caused the patient. On 7/23/11, a Codoresuscitation team complained to his withen became unresusted approximate intravenous line was of Ativan was admidose .5 - 4 mg.). Proceeding to Medical Intensive hours. At 1950 hours on 7 documented the pafixed and dilated at to display abnormation of possible brain decamination notes no doll's eyes react There were no reflex extremities. Patient posture to pain. Support of the complete to pain. Support of the patient 39's wife, the versed (another seintravenously while sedated. During the resident physician of the patient physician of the patient physician of the patient and was able to the patient and w | ted. It was listed on the front edical record, on the admitting possible to the process of the edical record, on the admitting possible to the process of the process of the process of the process of the edical record, and to be hyperactive. Blue was called for the edition note, the allergy to Ativan to be hyperactive. Blue was called for the edition of the edition of the process of the edition of the editi | Α. | | SAFE MEDICATION ADMINSTRATION reference TAGs A043, A353) Use of Ativan was concluded to be appropericumstance. The patient's medical record allergy to Ativan with a hyperactivity react verified by the patient's wife. As the patient the physician's clinical judgment was the bativan outweighed the risks of hyperactivity patient was intubated prior to Ativan admin patient oxygenated well and showed no evolution to the physician's clinical judgment was intubated prior to Ativan admin patient oxygenated well and showed no evolution to the patient was intubated prior to Ativan admin patient oxygenated well and showed no evolution adverse outcomes associated with medications. Trends, if identified, are reported to a complete the properties of Completion: EDUCATION AND COMPETENCY Educational activities related to new policy development, including the validation of in ongoing competence of appropriate staff in physicians, is overseen by the Quality and Oversight Committee. Monitoring: The activities of the Quality and Safety Oversight Committee are overseen by direct reports to Governing Body. Responsible Party: Chief Executive Officer Date of Correction: | riate in this I indicated an tion. This was at was coding, enefit of ty. The bistration. The idence of ety Committee code response rted to the r r/process titial and tembers and Safety ersight to the | None Required |

| | | (X1) PROVIDER/SUPPLIER/CLIA | (X2) MU | LTIPLE CONSTRUCTION | (X3) DATE SU | RVEY |
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| | OF DEFICIENCIES F CORRECTION | IDENTIFICATION NUMBER: | A. BUIL | | COMPLET | TED |
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| A 450 | confused and all ophysician then yell saying, "Go ahead reasons!" Further consultation notes because they felt obecoming agitated 482.24(c)(1) MED! All patient medical complete, dated, twritten or electronices provided, consisted procedures. This STANDARD Based on observative, the hospital consent form was patients (Patient 1 inaccurate care before the search of | stated Patient 39 "goes beserk, ver the place." The resident ed back to the Code Blue team, it is not for respiratory review of the Medicine team showed, the Ativan was given concerned because he was during the code. ICAL RECORD SERVICES record entries must be legible, imed, and authenticated in ic form by the person oviding or evaluating the service int with hospital policies and is not met as evidenced by: ation, interview and record al failed to ensure the informed legible for one of 43 sampled 4). This could result in eing delivered. 3 hours, the preoperative area are Director of Surgical Services, and preparing non English are Director of Surgical Services. 60 hours, the Operation ent for Patient 14 read, "Wound ist, possible repair indons, possible vein graft vs. or graft site, possible wound | A 4 | TAG A450 The surveyor reviewed the information to the initiation of the surging Multiple checks of correct procedure the organization's efforts to eliminate surgery. Most important are the pand the time-out processes. The procedure of the described in the hospital's Surgic policy includes verification of an and signed consent document. Topportunity to clarify any illegible document. For procedures occument is pre-procedure verification is patient is moved into the OR and the patient's representative to correct procedure, using the indocument, is also repeated as par procedure time out. This process recognized efforts to eliminate was surgery and has built-in quality a Monitoring: The hospital's Patier Committee reviews reports of no hospital's Surgical/Procedural Veidentify potential trends. Responsible Party: Chief Medical Date of Completion: | ical verification process. dure are done as part of inate wrong site/side pre-procedure verification pre-procedure verification pre-procedure verification accurately completed his allows for the le wording in the consent ring in the main OR, a performed before the l involves the patient or infirm their understanding to undergo. Verification informed consent rt of the formal pressupports nationally wrong site/side and safety checks. In Safety Steering in-compliance with the erification policy to | |
| | | nt, incision and drainage left ve (illegible word), possible | | * · · · · · · · · · · · · · · · · · · · | | |

| <u> </u> | O FUR WEDICARE | Q MEDICAID OFF A JOEG | - | | | | -1.4514 |
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| | ROVIDER OR SUPPLIER | IRVINE MED CENTER | | 10 | EET ADDRESS, CITY, STATE, ZIP CODE 01 CITY DRIVE SOUTH RANGE, CA 92868 | 30,20 | |
| (X4) ID PREFIX TAG | (EACH DEFICIENC) | ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION) | ID PREF TAG | IX | PROVIDER'S PLAN OF CORREC (EACH CORRECTIVE ACTION SHO CROSS-REFERENCED TO THE APPE DEFICIENCY) | ULD BE | (X5) COMPLETION DATE |
| A 490 | assisted during the revealed the patier explanation about the word was not of the word about the stated it should reamade no sense for orthopedic residen interviewed and stapatient was inconsistent was that meet the need institution must have registered pharma under competent of the word interview at the consistent was inconsistent was inconsistent was not of the word wa | se." The interpreter who interview of the patient at did not receive any the part of the consent where clearly written. To hours, RN F and RN G were the unclear word. They both ad as "take;" however, "take" any type of surgery. MD A (and the the explanation to the istent based on what was sent. To the patients of the patients of the patients. The we a pharmaceutical services are a supervision. The medical staff developing policies and inimize drug errors. This elegated to the hospital's ceutical service. To the met as evidenced by: The medical record, and ument review, the hospital at pharmaceutical services and complete oversight that the patients and prevented | | 450 | TAG A490: INFUSION PUMP SAFETY A Pump Safety Committee was created as a of the Medication Safety Committee and choverseeing and optimizing all aspects of purincluding: the assessment of pump technoloeducation of health care providers utilizing the implementation of smart pump safeguar medication libraries, soft stops, hard stops, standardization of workflow through the de and implementation of appropriate policies and quality/safety monitoring of pump relat The Pump Safety Team reviews all adverse associated with pumps and identifies specifivide changes to enhance safety. Comprehen medication libraries, including a robust set soft stops have been developed for Critical Anesthesia, Chemotherapy, Emergency Dejand general medical/surgical settings. A spewith an appropriate library, is used for neon All libraries are constantly reviewed and reresponse to changes in medication use and potential for programming errors. Infusion | arged with mp use ggy; the pumps; rds such as and alerts; the velopment and procedures; ted processes. e vents fix and system nsive of hard and Care, partment, ecial pump, natal patients. vised in reduce the | - |
| | significant medicar | uon ono. | | | have been revised and improved five times 2011. | since August | 1 |

| <u> </u> | RS FOR MEDICARE | & MEDICAID SERVICES | | | · · · · · · · · · · · · · · · · · · · | OMD 140. | |
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| NAME OF P | ROVIDER OR SUPPLIER | | | | REET ADDRESS, CITY, STATE, ZIP CODE | | |
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| A 490 | MD X accurately prinfusion pump for Timedication administransplants to prevent following the instruction of the hospital failed overrode the "soft salert informing the dose is high but ca. Thymoglobulin, that programming alert administration of the overridden) was propump so life threat occur. Patient 37 results after the could Cross reference As 2. Pharmaceutical safe and appropriate medication devices overdose of a medication devices overdose of a medication the administration could hard stop" alert (a allow the administration could hard stop alert (a allow the administration could hard stop" alert (a allow the administration could hard stop alert (a allow the administration could hard stop alert (a allow the administration could hard stop alert (a allow the administration could hard stop). * On 8/15/11 at 15 was notified of Imminealth and safety of medications administrations administration administrations administration administrations administration administrations administration administr | services failed to ensure that rogrammed the medication Thymoglobulin (an intravenous stered during kidney ent kidney rejection) by ctions on the medication label to ensure that when MD X stop" alert (a programming programmer the rate and/or in be overridden) for it a "hard stop" alert (a that will not allow the medication and cannot be ogrammed into the infusion ening overdoses would not eceived 100 milligrams (mg) of it one hour instead of over 6 have contributed to his death. 500. services failed to ensure the te use of medications and ication, Thymoglobulin as a utical services failing to eation infusion pump with a programming alert that will not ation of the medication and en). A "hard stop" alert for this ave prevented the overdose. | A | 490 | Monitoring: A comprehensive set of setting-specific indic collected, including the percentage of infusion programmed using the library, the number of encountered, and the number of soft stops entry in the soft at a is used by the Pump Safety Team at improve education and perfect pump librarie activities of the Pump Safety Team are overs Medication Safety Committee with independency of the Pump Safety Team are overs Medication Safety Committee with independency of the Pattern Safety Steering Committee approach of Correction: IMPLEMENTATION OF NEW DEVICES The Quality & Safety Oversight Committee approve the implementation of all significant in medication delivery devices (such as impnew brand or model of infusion pumps). The assures that appropriate policies, procedures is in place PRIOR to implementation and estappropriate safety monitoring activities duri implementation process. Monitoring: The activities of the Quality & Oversight Committee are overseen by direct Governing Body. Responsible Party: Chief Pharmacy Officer Date of Correction: MEDICATION ADMINISTRATION Due to time constraints in regulatory report the hospital self-reported the Thyrnoglobuli mis-administration before it had the opport its investigation. The case was internally rephysicians. In addition, the hospital had the by four external physicians, all from non-Uperforming transplant programs at academic All six reviews independently opined the mof Thymoglobulin did not result in either th or injury to the patient. | must now t changes lementation of e Committee and training tablished ing the Safety reports to the inity to complet viewed by two case reviewed C related, highly medical center is-administratio | e v |

| STATEMENT | OF DEFICIENCIES OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | ļ | E CONSTRUCTION | | (X3) DATE S COMPLE | |
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| ANDICARO | , 55111251751 | | A, BUILDING B, WING | | | 1 | C 3/2011 |
| • | ROVIDER OR SUPPLIER | 050348 A IRVINE MED CENTER | 101 | ET ADDRESS, CITY, CITY DRIVE SOU LANGE, CA 9286 | TH | 1 00/2 | SILUY |
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| A 490 | on these pumps. A was not developed of the pumps. On stop" alert (a programmer the racould be overridde intravenous medic kidney transplants kidney). There was programming alert administration of the overridden program to prevent life thre received 100 millig | e was no hospital-wide training policy and procedure (P&P) and approved for the safe use 7/25/11, MD X overrode a "soft amming alert informing the ate and/or dose was high but n) for Thymoglobulin (an ation administered during to prevent rejection of the new is no "hard stop" alert (a that would not allow the me medication and could not be ammed into the infusion pumpatening overdoses. Patient 37 grams (mg) of Thymoglobulin ead of over 6 hours which | A 490 | | | | |
| | similar safety issumospital was unable competent in accumedication infusion medication used for This specific pumple (the hospital has repumps from all partient 50 programmed the programmed the programmed the programmed the programs of (Patient 50 dose of Precedex prescribed dose, micrograms/kilogramicrograms per health patient 52 survive Patient 52 survive | hospital was investigated for a e that occurred on 6/15/11. The le to ensure that MD K was trately programming the n pump for Precedex (a or sedation during procedures). It is did not contain a drug library now removed these type of tient care areas except the e Care Unit). MD K coump incorrectly and the 10 (2) received an intravenous that was over 30 times the The prescribed dose was 2 ams/hour (mcg/kg/hr) or 6 our based on Patient 52's body received a dose of 200 mcg e to the programming error. It is that required two rescue | | | | | |

| STATEMENT | OF DEFICIENCIES | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | 1 | | E CONSTRUCTION | (X3) DATE SI COMPLE | |
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| AND PLAN O | F CORRECTION | IDENTIFICATION NUMBER: | | LDING | | | C |
| | | 050348 | B. WIN | | | | 3/2011 |
| | ROVIDER OR SUPPLIER | IRVINE MED CENTER | i | 101 | ET ADDRESS, CITY, STATE, ZIP CO CITY DRIVE SOUTH (ANGE, CA 92868 | DE | |
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| | | | | | DESTOREMENT. | <u> </u> | <u>:</u> |
| A 490 | * On 8/16/11 at 16 jeopardy was abate a plan of correction A. Pumps must be registered nurses appropriate pump demonstration. B. Dosage, conce be chosen from a medications with cappropriate for the C. Basic mode (padose and rate whe library) could only Verification by and required for any action of the soft limits might be with caution. If a spractitioner must rand pump programment of the presolve this discrete. Independent designed. | cations used to reverse the for his heart rate to stabilize. 15 hours, the immediate ed when the hospital presented in which included the following: programmed only by who have completed competency with return intration and flow rates should current drug library (contains losage and rate limits) that was ecare area. Althway to enter a medication and the medication was not in the be used in rare situations. When practitioner was to be diministration by basic mode, tops were alerts which indicated ing had been exceeded. While the overridden, this must be done off limit appeared, the re-verify the medication order mining for accuracy, is were alerts of potentially doses that cannot be rescriber must be contacted to epancy. Ouble check was to be required | | 490 | | | |
| | programming of into deliver opiates, chemotherapy. Guidelines: A. Pump safety te oversight of comp | ming and changes to the ntravenous infusion pumps used anticoagulants, insulin and earn should be responsible for bliance with this policy spital. Reports regarding alerts | | | | | and the state of t |

| STATEMENT | OF DEFICIENCIES OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPL A. BUILDING | E CONSTRUCTION | (X3) DATE S COMPL | |
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| | ROVIDER OR SUPPLIER | A IRVINE MED CENTER | 101 | ET ADDRESS, CITY, STATE, ZIP C CITY DRIVE SOUTH LANGE, CA 92868 | CODE | |
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| A 490 | be reviewed quarte to improve complia Training: Registered nurses immediately. No reallowed to program completing the 8/1 Sign in sheets and collected to validate Anesthesiologists, registered nurse a required to use the was not in the libraries Anesthesia reside programming verificants and the libraries Anesthesia reside programming verificants and the libraries and th | of basic mode utilization would erly and actions would be taken ance and assure patient safety. Itraining was to occur egistered nurse would be an an infusion pump without 7/11 education packet. It staff sheets would be the completion of training. Itraining was to occur egistered nurse would be the completion of training. It staff sheets would be the completion of training. It is a complet | | | | |
| | The cumulative en resulted in the hor | ffect of these systemic problems spital's inability to ensure the | | | | |

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| | ે provision હૃદયાંઘાાાંપ્ર ે environment. | health care in a safe | | | | | |
| A 491 | | ACY ADMINISTRATION | Α | 491 | TAG A491: | ; | |
| , , , , , , | | | | | INFUSION PUMP SAFETY | | |
| | The pharmacy or o | drug storage area must be | | | A Pump Safety Committee was created as a of the Medication Safety Committee and ch | | |
| | administered in ac professional princi | cordance with accepted | | | overseeing and optimizing all aspects of pu | mp use | |
| | professional princip | pros. | | | including: the assessment of pump technological education of health care providers utilizing | | |
| | This STANDARD | is not met as evidenced by: | | | the implementation of smart pump safeguar medication libraries, soft stops, hard stops, | | |
| | Based on interview | w and medical record review, | | | standardization of workflow through the de | velopment | |
| | the hospital failed | to ensure that pharmaceutical safe and appropriate use of | | | and implementation of appropriate policies and quality/safety monitoring of pump relat | | |
| | medications and m | nedication-devices for three of | | | The Pump Safety Team reviews all adverse | events | |
| | 43 sampled patien | ts (Patients 37, 39 and 52). | | | associated with pumps and identifies specifi wide changes to enhance safety. Comprehe | ic and system | |
| | Patient 37 received | d an overdose of a | | | medication libraries, including a robust set | of hard and | |
| | Thymoglobulin as | a result of pharmaceutical | | | soft stops have been developed for Critical Anesthesia, Chemotherapy, Emergency De | | |
| | services failing to | program the medication | | | and general medical/surgical settings. A spe | ecial pump, | |
| | ston" alert for this | n a "hard stop" alert. A "hard medication could have | | | with an appropriate library, is used for neor All libraries are constantly reviewed and re | | |
| | prevented the ove | rdose. Patient 52 was given an | | | response to changes in medication use and | reduce the | |
| | overdose of Prece | dex as a result of | | | potential for programming errors. Infusion have been revised and improved five times | since August | |
| | pharmaceutical se | ervices not ensuring an | | | 2011. | | i |
| | anesthesia resider | nt was competent when edication infusion pump. | | | Monitoring: A comprehensive set of setting-specific ind | icatore are | |
| | Nursing staff misp | laced an applicator for eye | | | collected, including the percentage of infus | ions | |
| | medication Patient | t 39 brought in from home for | | | programmed using the library, the number encountered, and the number of soft stops of | | |
| | treatment and pre- | vention of comeal (eye) ulcers. | | | This data is used by the Pump Safety Team | to continuously | |
| | | | | | improve education and perfect pump librar activities of the Pump Safety Team are ove | | |
| | Findings: | | | | Medication Safety Committee with indepen | ndent | |
| | 1. On 8/15/11. Pat | tient 37's medical record was | | | reviews by the Patient Safety Steering Con | литее. | |
| | reviewed. Patient | 37 was admitted to the hospital | | | Responsible Party: Chief Pharmacy Officer | * | |
| | on 7/25/11 for a ki | idney transplant. An order was | | | Date of Correction: | | 08/11/11 |
| | given to administe | er Thymoglobulin 100 mg | | | | | |
| | intravenously, to it | nfusion over 6 hours. According cident summary, "A senior | | | | | |
| | anesthesia reside | nt (third year resident) | | | | | |
| | programmed a em | part nump to deliver the | | | · · | | 1 |

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| A 491 | intended six hour p contained the med an alert that the "so pump's alert was o medication admini- stop" for this medic | pone hour period instead of the period. The pump, which ication in its drug library sent off limit " was "exceeded." The verridden by MD X and the stered. There was no "hard cation programmed in the ne resident physician from | A 4 | IMPLEMENTATION OF NEW DITTHE Quality & Safety Oversight Coapprove the implementation of all s in medication delivery devicess (sunew brand or model of infusion purassures that appropriate policies, pris in place PRIOR to implementation appropriate safety monitoring activitimplementation process. Monitoring: The activities of the Quality of the Qual | mmittee must now ignificant changes ch as implementation of nps). The Committee occdures and training on and established ities during the uality & Safety | |
| | the Director of Pha 'hard stop' progran are constantly upd medications into the 'soft stops' and 'ha hundreds of medic this takes time. We progress but still h | | · | Responsible Party: Chief Pharmacy Date of Correction: | officer | 09/18/11 |
| | the anesthesiology no "hard stop" pro for Thymoglobulin overdose would no On 7/25/11, the ho similar safety issue hospital was unab | O hours, MD I, the director of department, stated there was agrammed in the infusion pump. "If there was a 'hard stop,' the of occur." Despital was investigated for a de that occurred on 6/15/11. The lee to ensure that MD K was rately programming the | | | | |
| | medication infusion medication used for This specific pump (the hospital has not pumps from all particular programmed the prog | n pump for Precedex (a preceder sedation during procedures). It did not contain a drug library low removed these type of tient care areas except the | | | | The same of the sa |

| CILINIT | (3) OIT MEDIOMITE | T WILDIO, ID OLIVIOLO | | | | | | |
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| A 491 | Continued From particles of the application to be at Without the applicator was administer the eye applicator was applicator to administer the eye applicator was applicator to administer the eye applicator was | over 30 times the prescribed ed dose was 2 ms/hour (mcg/kg/hr) or 6 ur based on Patient 52's body received a dose of 200 mcg to the programming error. If the incident but experienced a nat required two rescue cations used to reverse the for his heart rate to stabilize. Inadmitted to the hospital on the home medications that was similarly many medication that used an inster the gel into the patient's ication moistens the eyeballs er damage to the patient's or was needed to hook the gel ble to administer in the eyes. Sator, it would be impossible to medication. During Patient he 7th floor Telemetry Unit, the lost and so there was no gel | · A | 491 | This incident was an isolated occurrence an systemic occurrence. If a patient is missing medication delivery device, the Pharmacy I will obtain a new device for the patient, or i feasible, find an available and suitable there alternative for the patient. Monitoring: Is conducted on an ongoing ba review of incident reports to identify trends issues. Responsible Party: Chief Pharmacy Officer Chief Nursing Officer | part of all of a Department f not upeutic sis through a or systemic | | |
| | On 8/18/11 at 1305 K who took care of gel applicator was the eye applicator screens at the nurs | t further abrasions of the cer. hours, in an interview with RN Patient 39, she stated the eye lost for one day. RN K found in between the EKG telemetry ses' station. RN K and the r of Oncology were unable to | | | Date of Completion: | · | 08/22/11 | |

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| | and not put back w 482.25(b) DELIVE In order to provide biologicals must be accordance with al consistent with Fee This STANDARD Based on interview document review, MD X accurately p infusion pump for instructions on the failed to ensure the "soft stop" alert, th programmed into t threatening overdo 37 received 100 m Thymoglobulin ove hours which could The hospital also f throughout the hos pumps. The hospit and implemented in This resulted in tw- receiving overdose patients put at risk 52). Findings: 1. On 8/15/11, Par reviewed. Patient 3 | edication applicator was there with the medication. RY OF DRUGS patient safety, drugs and a controlled and distributed in applicable standards of practice, deral and State law. is not met as evidenced by: w, medical record and the hospital failed to ensure rogrammed the medication. Thymoglobulin by following the medication label. The hospital at when MD X overrode the at a "hard stop" alert was the infusion pump so life as would not occur. Patient alled to train their nursing staff spital on the use of the infusion tal failed to ensure a policy and eived approval by the all committees was developed for use of the infusion pumps of 43 sampled patients as of medications and other of overdose (Patients 37 and tient 37's medical record was 37 was a 63 year old male | A 45 | | e and charged with tts of pump use technology; the trilizing pumps; safeguards such as d stops, and alerts; the th the development policies and procedures; mp related processes adverse events as specific and system omprehensive bust set of hard and Critical Care, ency Department, as. A special pump, for neonatal patients. d and revised in use and reduce the infusion pump libraries re times since August cific indicators are of infusions number of hard stops t stops encountered. The are overseen by the independent ing Committee. | |
| | | 37 was a 63 year old male spital on 7/25/11 for a kidney | | | | |

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| A 500 | Continued From pa | age 40 | A : | 500 | | | |
| | transplant. An orde Thymoglobulin 100 over 6 hours. Acco summary, a senior programmed a small medication over a contained the medical an alert that the 'so | r was given to administer mg intravenously to infuse rding to the hospital 's incident anesthesia resident ert pump to deliver the one hour period instead of the period. The pump, which ication in its drug library, sent off limit was exceeded." The en by MD X and the medication | | | | | |
| | Record, Patient 37 mg. on 7/25/11 at Patient 37 was in meart beat). At 143 extubated (breathin hours, Patient 37 bfully aroused), stopreintubated. At 144 desaturate (when toxygen) with a hea above 60). Cardior was started. Patier mg to increase his stabilized within a stransported to the patient died shortly 2011. On 8/15/11 at 1104 (Director of Pharnow uses only [Brand Name) purideliver small doses | received Thymoglobulin 100 1104 hours. At 1123 hours, formal sinus rhythm (normal 2 hours, the patient was ng tube removed). At 1445 lecame obtunded (could not be lead breathing, and had to be lead breathing, and had to be lead breathing and had to | | | MEDICATION ADMINISTRATION Due to time constraints in regulatory rep- the hospital self-reported the Thymoglob mis-administration before it had the oppo- its investigation. The case was internally physicians. In addition, the hospital had to by four external physicians, all from non performing transplant programs at acade. All six reviews independently opined the of Thymoglobulin did not result in either or injury to the patient. | ulin ortunity to complet reviewed by two the case reviewed -UC related, highly mic medical center emis-administratio | i · · · · · · · · · · · · · · · · · · · |

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| A 500 | been no policy and approved for the use According to Califo 22, Section 70263 (pharmacy and the committee of equivalent develop written polestablishment of sign procurement, stora and use of drugs a in consultation with professionals and responsible for the implementations of approved by the graph shall be approved medical staff where Pharm 1 was asked audits of the pumpaccurate and "soft evaluated. He replinated to." According manufacturer did to the hospital pharmacy monitoring. He spot to two weeks ago on Thursday 8/18/pharmacy staff. For the thing of the pumpaccurate and the pharmacy staff. For the thing of the pumpaccurate and the pharmacy staff. For the thing of the pumpaccurate and the pharmacy staff. For the pharmacy staff is the pharmacy staff. For the pharmacy staff is the pharmacy staff. For the pharmacy staff is the pharmacy s | put 3 months ago. There has procedure developed and se of these pumps." Immia Code of Regulations, Title (c)(1): "The committee grapeutics committee, or a valent composition) shall licies and procedures for afe and effective systems for age, distribution, dispensing and chemicals. The pharmacist in other appropriate health administration shall be development and for procedures. Policies shall be overning body. Procedures by the administration and re such is appropriate." The difference were retrospective as to ensure programming was a stop" overrides were being lied, "Not at this time but we are the provide adequate training to a staff for them to perform the oke with the manufacturer one and was told they would be out the for several days to train the | A | 500 | IMPLEMENTATION OF NEW DEVICES. The Quality & Safety Oversight Committe approve the implementation of all signification medication delivery devices (such as impressed in medication process). The activities of implementation and eappropriate safety monitoring activities during mentation process. Monitoring: The activities of the Quality & Oversight Committee are overseen by direct Governing Body. Responsible Party: Chief Pharmacy Office Date of Correction: EDUCATION AND COMPETENCY Educational activities related to new policide development, including the validation of it ongoing competence of appropriate staff in physicians, is overseen by the Quality and Oversight Committee. Monitoring: The activities of the Quality and Oversight are overseen by direct reports to the Goverseen by dir | e must now ant changes plementation of the Committee as and training stablished ring the a Safety at reports to the r | 09/18/11 |

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| as is required by the hospital's policy and procedure. "MD X said he forgot to page the faculty." * On 8/17/11 at 0910 hours, MD I, the director of the anesthesiology department, stated there was no "hard stop" programmed in the infusion pump for Thymoglobulin. "If there was a 'hard stop,' the overdose would not occur." He also stated, the anesthesiology department reviewed the case and initiated a root case analysis (RCA). "At this time the RCA is incomplete." A RCA is an investigation of an incident to determine the cause(s) and when resolved restores patient safety. * On 8/18/11 at 0900 hours, during an interview MD Z stated she walked into the operating room after Patient 37 was extubated at 1432 hours, and found him pale and not breathing. She gave the order to MD X to reintubate Patient 37 and ordered epinephrine 1 mg by intravenous push. She also started chest compressions and called a Code Blue (notifying staff this patient is in a medical emergency). "The patient was back in less than a minute and eventually transferred to ICU." On 8/18/11 at 0916 hours, MD I stated, "if MD Z did not come back to the room, Patient 37 would be dead and not four days later." * On 8/23/11 at 1005 hours, during an interview MD X stated he has given it over four hours. When asked why four hours when on the label of the medication it stated to infuse over six hours, he stated he has given it over four hours, he stated that fin 12/10, he didn't program the pump but the attending anesthesiologist programmed the pump and he believes it was given over four hours. | | as is required by the procedure. "MD X faculty." * On 8/17/11 at 09 the anesthesiology no "hard stop" progfor Thymoglobulin, the overdose would the anesthesiology and initiated a root time the RCA is indinvestigation of an cause(s) and where safety. * On 8/18/11 at 09 MD Z stated she wafter Patient 37 war and found him pakethe order to MD X ordered epinephring She also started to Code Blue (notifying medical emergence less than a minute ICU." On 8/18/11 at 10 MD Z did not commould be dead and * On 8/23/11 at 10 MD X stated he programmed to infuse Thymoglobulin, he asked when thymoglobulin, he 12/10, he didn't programmed the anesthe and the stated in the didn't programmed the anesthe and the stated in the didn't programmed the stated in the st | said he forgot to page the 10 hours, MD I, the director of department, stated there was grammed in the infusion pump "If there was a ' hard stop,' d not occur." He also stated, department reviewed the case case analysis (RCA). "At this complete." A RCA is an incident to determine the resolved restores patient 00 hours, during an interview walked into the operating room as extubated at 1432 hours, e and not breathing. She gave to reintubate Patient 37 and he 1 mg by intravenous push, hest compressions and called a ng staff this patient is in a cy). "The patient was back in and eventually transferred to at 0916 hours, MD I stated, "if e back to the room, Patient 37 d not four days later." 105 hours, during an interview rogrammed the infusion pump obulin over four hours. When ours when on the label of the en it over four hours before, in the last time he administered the stated 12/10. He stated that in regram the pump but the resiologist programmed the pump | | | | |

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| AND PLAN C | F CORRECTION . | IDENTIFICATION NUMBER: | A. BU | LDIN | IG | COWFLE | |
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| A 500 | medication the time "During the first yeto Lexicomp on line drug information si Thymoglobulin has associated with its states, "Should onlexperienced in imredication car or life-threatening warnings mea the medication car or life-threatening warning is the stro and Drug Administ MD X added he for programmed the mattending anesther patient 37, he replied in the complex turned his being the program on perior that is the complex turned his programmed the program of the p | he administered the e before that, he stated, ar of my residency." According e, a well-known and respected te for healthcare professionals, a black box warning use. The black box warning y be used by physicians nunosuppressive therapy for nal transplant patients." Black n that medical studies indicate ries a significant risk of serious adverse events. The black box ngest warning the FDA (Food tration) issues. und out days later that he nump to infuse the medication ead of the four hours he sked why he did not notify the siologist before extubating ied that he intended to but ssage. "I would routinely page ny mind was distracted by other resonally." After the extubation, ack on Patient 1 to document uter. MD Z walked in the room ent pale and not breathing. was concerned about Paient 37 on warfarin (a blood thinning the procedure, he stated, "The warfarin but on aspirin and to the Pre-Anesthesia record extent 37 was taking the ulants prior to admission: | A | 500 | The supervision policy of the Department was not followed by MD X, who is a train investigation was conducted and disciplina against MD X for not following department policies. Re-training for all departmental refaculty (Attending) on policies and proced conducted on a regular basis, prior to Gran Monitoring: Ongoing Responsible Party: Chair, Department of A Date of Correction: | ee (resident). An ary actions taken atal written esidents and ures is d Rounds. | |

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| A 500 | hospital was unable competent in accur medication infusion medication used fo This specific pump (the hospital has no pumps, from all part MD K programmed year old Patient 52 of Precedex that w prescribed dose. The micrograms/kilogramicrograms per howeight. Patient 52 within an hour due Patient 52 survived drop in heart rate the medications (medications in heart rate). On 8/15/11 at 1500 (CEO) was notified the health and safe medications admirinfusion pumps (acago). There was not these pumps and pumps. On 8/16/11 at 1618 | that occurred on 6/15/11. The eto ensure that MD K was rately programming the pump for Precedex (a r sedation during procedures). did not contain a drug library ow removed these type of tient care areas except NICU). If the pump incorrectly and 10 received an intravenous dose as over 30 times the he prescribed dose was 2 ams/hour (mcg/kg/hr) or 6 four based on Patient 52's body received a dose of 200 mcg to the programming error. If the incident but experienced a that required two rescue cations used to reverse the for his heart rate to stabilize. The incident but experienced a for his heart rate to stabilize. The incident but experienced a for his heart rate to stabilize. The incident but experienced a for his heart rate to stabilize. The incident but experienced a for his heart rate to stabilize. The incident but experienced a for his heart rate to stabilize. The incident but experienced a for his heart rate to stabilize. The incident but experienced a for his heart rate to stabilize. The incident but experienced a for his heart rate to stabilize. The incident but experienced a for his heart rate to stabilize. The incident but experienced a for his heart rate to stabilize. The incident but experienced a for his heart rate to stabilize. | A | 500 | Prior to the regulatory visit, more than 99% completed required Baxter pump training at competency. Since 8/17, no RN, including received a patient assignment prior to compump training. Monitoring: Training is verified before patifor all contract RNs; training is verified by during orientation for all new RN hires Responsible Party: Chief Nursing Officer Date of Correction: EDUCATION AND COMPETENCY Educational activities related to new policy development, including the validation of in ongoing competence of appropriate staff mphysicians, is overseen by the Quality and the competence of the second competence of the contraction of | nd demonstrated contract RNs, letion of Baxter ent assignment the Nurse Manage //process ittal and embers and | |
| | jeopardy was abat and implemented | ed when the hospital presented a thorough plan of correction. | | | Oversight Committee. Monitoring: The activities of the Quality and Oversight are overseen by direct reports to the Govern | | |
| | hours. The RN sta | erviewed on 8/17/11 at 0900 ted she was trained in the use puumps a few months ago. | | | Responsible Party: Chief Executive Officer Date of Correction: | | 08/31/11 |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MUL A. BUILD | TIPLE CONSTRUCTION | (X3) DATE S COMPLE | TED |
|--|--|--|----------------------|--|-----------------------------------|--|
| | | 050348 | B. WING | | | C 3/2011 |
| | ROVIDER OR SUPPLIER | RVINE MED CENTER | s | TREET ADDRESS, CITY, STATE, ZI 101 CITY DRIVE SOUTH ORANGE, CA 92868 | | |
| (X4) ID · PREFIX TAG | (FACH DEFICIENC) | ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF (EACH CORRECTIVE AC CROSS-REFERENCED TO DEFICIEN | TION SHOULD BE THE APPROPRIATE | : (X5) COMPLETION DATE |
| A 500 | The RN stated it was in the basic mode; drugs to the pump. When asked if she information regard the initial training, to the initial training, to the initial training, to the was a resource use of the pump. It program in the basic non-library drug, to program in all the process required a RN, RN E stated in the use of the pum the basic mode. The basic mode. The basic mode information if he rewither the initial training, information he had drugs to the pump | as not optimal to use the pump however, adding oncology library was a work in progress. had received any updated ing the use of the pump since the RN stated, no she had not. Viewed on 8/17/11 at 0905 ted he was trained to be a new infusion pump, meaning to the other nursing staff in the The RN stated, when mp he had not encountered a is not in the library. The RN mode had to be used for a new infusion pump asked if this in double check with another was unaware if the P&P for the RN stated he would have the programmed dose of a received a "soft stop" alert, thad received any updated ing the use of the pump since the RN stated the only if received was the addition of library. | A 50 | | | |
| | hours. The RN sta use of the new info The RN stated mo were in the pump's mode was availab the library. The RN another RN was re | viewed on 8/17/11 at 0930 ated he had been trained in the susion pump a few months ago. Let of the medications he used is library; however, the basic le if the medication was not in a stated no double check with equired for the use of the basic eded to be careful. When asked | | | | - Company of the comp |

| STATEMENT OF DEFICIENCIES | | (X1) PROVIDER/SUPPLIER/CLIA | (X2) MI | (X2) MULTIPLE CONSTRUCTION | | (X3) DATE S COMPL | | |
|---------------------------|--|--|---|----------------------------|--|----------------------|--|--|
| AND PLAN C | F CORRECTION | IDENTIFICATION NUMBER: | A. BUIL | .DING | | | С | |
| | | 050348 | B. WIN | G | | 08/2 | 23/2011 | |
| | ROVIDER OR SUPPLIER | A IRVINE MED CENTER | STREET ADDRESS, CITY, STATE, ZIP CODE 101 CITY DRIVE SOUTH ORANGE, CA 92868 | | | | | |
| (X4) ID PREFIX TAG | (FACH DEFICIENC | ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION) | ID PREFI TAG | | PROVIDER'S PLAN OF CO (EACH CORRECTIVE ACTION CROSS-REFERENCED TO THE DEFICIENCY) | I SHOULD BE | (X5) COMPLETION DATE | |
| A 500 | when programming double check with RN E stated, other additions made to | soft stop" alert was received the pump, the RN stated a another RN was not required. than notices regarding the the pump library, he had anal information regarding the | Α 5 | 500 | | | | |
| | hours. The RN sta unit had been add- infusion pump so s basic mode. Whe stop" alert was rec pump, the RN stat not encountered a ask another RN or assistance. The R additional informat | riewed on 8/17/11 at 0955 fed medications used on her ed to the library of the the new she had not needed to use the n asked the procedure if a "soft reived when programming the ed she did not know, she had n alert. RN B stated she would call on a super user RN for N stated she had not received tion or training on the pump ining a few months ago. | | | | | and the same of th | |
| A1004 | hours. The RN strategies had to use the new infusion pumple. RN was required, she received a "so programming, the the order but a do not required. The additional information pump since the in | viewed on 8/17/11 at 1015 ated, although she would physician's medication order if a basic mode to program the b, no double check with another When asked the procedure if off stop" alert during RN stated she would recheck uble check by another RN was RN stated she had not received tion regarding the use of the itial training. ATIENT POST-ANESTHESIA | | 004 | | | | |
| | [The policies mus provided for each | t ensure that the following are patient:] | | | | | | |

| STATEMENT OF DEFICIENCIES | | (X1) PROVIDER/SUPPLIER/CLIA | (X2) N | IULTIF | PLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED | | |
|---------------------------|---|---|-------------------|---|--|--|------------------------------|--|
| AND PLAN O | F CORRECTION | IDENTIFICATION NUMBER: | A. BU | LDING | G | С | | |
| | | 050348 | B. WII | 4G | | 08/23 | /2011 | |
| | NAME OF PROVIDER OR SUPPLIER UNIVERSITY OF CALIFORNIA IRVINE MED CENTER | | | STREET ADDRESS, CITY, STATE, ZIP CODE 101 CITY DRIVE SOUTH ORANGE, CA 92868 | | | | |
| "(X4) ID PREFIX TAG | (FACH DEFICIENC) | ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION) | ID PREF TAC | | PROVIDER'S PLAN OF CORREC (EACH CORRECTIVE ACTION SHO CROSS-REFERENCED TO THE APP DEFICIENCY) | OULD BE : ! | (X5) COMPLETION - DATE | |
| A1004 | An intraoperative at This STANDARD Based on interview hospital failed to exacurately reflecteduring adverse real anesthesia for one including the patie. (Patient 37). This continuity of the patient had a large of the patient should be patient be an anesthesiology real and quality of responsive oxygenation), doc reattached and was anesthesia vital sides aturation and a though it was docted as a shortly bradycardia with in the last blood preper the anesthesis mmHq measured | is not met as evidenced by: ws and review of records, the nsure an anesthesia record d the sequence of events actions or difficulties during of 43 sampled patients, nt's response to treatments could lead to unsafe anesthesia ioperative period. If review of Patient 37 showed cidney transplant surgery on 1435 hours. A Code Blue ardiopulmonary arrest) was arrs by the scrub technician after hing tube was removed by the sident. The rate, rhythm, depth or sident. The rate, rhythm, depth or sensor to measure umented as "not reading," was as recorded at 100%. The gns graph did not show oxygen abnormally slow heart beat umented "patient noted to after extubation, sinus neart rate of 32." essure before the resuscitation, a graphic chart, was 80/60 before 1430 hours. This was a | A1 | 004 | MD X, in an isolated occurrence, deviated department's documentation policy. As ind disciplinary action was taken against MD 2 did not follow written departmental policy, all departmental residents and faculty (Atte policies and procedures is conducted on an prior to Grand Rounds. Monitoring: Compliance with departmental monitored on an ongoing basis Responsible Party: Chair, Department of A Date of Correction: | icated previously K, a resident who Re-training for Inding) on all regular basis | | |
| | decrease from the | e blood pressure of 110/60 at 1410 hours. A unit of red | | | | | | |

| STATEMENT OF DEFICIENCIES | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | | ULTIPLE | CONSTRUCTION | | (X3) DATE SURVEY COMPLETED | |
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| AND PLAN O | | | | LDING NG | | C 08/23/2011 | | |
| NAME OF S | ROVIDER OR SUPPLIER | 050348 | D. V. | | ET ADDRESS, CITY, STATE, ZIP CODE | | 3/2013 | |
| | | IRVINE MED CENTER | | 101 | CITY DRIVE SOUTH ANGE, CA 92868 | | | |
| (X4) ID PREFIX TAG | /EACH DEFICIENC | ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION) | ID PREF TAG | 1 | PROVIDER'S PLAN OF CORR (EACH CORRECTIVE ACTION S CROSS-REFERENCED TO THE AI DEFICIENCY) | HOULD BE | (X5) COMPLETION DATE | |
| A1004 | Infusing Dopamine medication that as dose [1-5 mcg/mir increase heart rate doses), remained graphic chart desp 32 beats per minu the Code Blue and 7/25/11, though the reading and a hear commenced." | using at 1421 hours. The drip (an intravenous sists in kidney perfusion at low all and a pressor agent to e and blood pressure at higher unchanged on its rate on the bite the reported heart beat at the and low blood pressure. Per dianesthesia record dated e patient had a blood pressure intrate, "chest compressions" | A1 | 004 | | | | |
| | normal arterial blot test to measure or determine how we and 1230 hours. A showed an abnormis 80-100) with an balance. Per the sintervention documented or any follow monitor the blood Instead, Patient 3 removed) by MD | the anesthesia record showed 2 and gases (ABG-arterial blood exygen and carbon dioxide to sell lungs are working) at 1130 at 1300 hours, the ABG results mal oxygen level at 65 (normal abnormal blood acid/base anesthesia record, there was no mented to improve the oxygen rup test that was done to gas and acid/base balance. 7 was extubated (breathing tube X at 1432 hours without the proval of MD Z, the attending | | | | | | |
| | He stated he turn 10-30 seconds at documentation el "overlooked" the | 00 hours, MD X was interviewed, ed away from Patient 37 for fer extubation to enter his ectronically. He stated he had oxygen level of the ABG, and correct the acid level. | | The state of the s | . • | | | |
| | The last set of vit | al signs were recorded at 1550 perative summary showed "no | | | | | | |

| CENTER | KS FOR MEDICARE | & MEDICAID SERVICES | | | | 1 | 0000-0001 |
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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) M A. BUI | | PLE CONSTRUCTION | (X3) DATE S COMPLE | TED |
| | 050348 | | | vG | | C 08/23/2011 | |
| NAME OF P | ROVIDER OR SUPPLIER | | | í | EET ADDRESS, CITY, STATE, ZIP CODE | | |
| UNIVERSITY OF CALIFORNIA IRVINE MED CENTER | | | | E | 11 CITY DRIVE SOUTH RANGE, CA 92868 | | |
| (X4) ID PREFIX TAG | (EACH DEFICIENC | ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL .SC IDENTIFYING INFORMATION) | ID PREF TAG | | PROVIDER'S PLAN OF CORRE (EACH CORRECTIVE ACTION SI- CROSS-REFERENCED TO THE AP DEFICIENCY) | IOULD BE | (X5) COMPLETION DATE |
| A1004 | significant event w complications." Th | ith no cardiovascular e inaccurate anesthesia record tronically by MD Z, the | A1 | 004 | | | |
| | | | | ************************************** | | - | |
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| | | | | 1000 | | | |
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