The following reflects the findings of the Department of Public Health, formally referred to as the Department of Health Services, during an investigation of COMPLAINT NO: CA00132637

Representing the Department of Public Health were:

- Pharm.D, Pharmacist Consultant
- MD, Medical Consultant
- RN, Health Facilities Nurse
- Evaluator

1280.1(a) HSC Section 1280
If a licensee of a health facility licensed under subdivision (a), (b), or (f) of Section 1250 receives a notice of deficiency constituting an immediate jeopardy to the health or safety of a patient and is required to submit a plan of correction, the department may assess the licensee an administrative penalty in an amount not to exceed twenty-five thousand dollars ($25,000) per violation.

1280.1(c) HSC Section 1280
For purposes of this section, "immediate jeopardy" means a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient.

DEFICIENCY CONSTITUTING IMMEDIATE JEOPARDY

ALPHABETICAL LIST OF ABBREVIATIONS:
- am - morning
- cc - cubic centimeter

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

050625

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

DATE SURVEY COMPLETED


NAME OF PROVIDER OR SUPPLIER

CEDARS-SINAI MEDICAL CENTER

STREET ADDRESS, CITY, STATE, ZIP CODE

8700 BEVERLY BLVD., LOS ANGELES, CA 90048  LOS ANGELES COUNTY

PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)

Continued From page 1

DPH - Department of Public Health
IJ - immediate jeopardy
INR - international normalized ratio
iu - international units
IV - intravenous
mg - milligram
ml - milliliter
NE - north-east
NS - normal saline
pm - evening
PTT - partial thromboplastin time
PT - protime
RE - regarding
RN - Registered Nurse
u - units
# - number
= - equals
> - greater than
5R's - five rights

Based on interview with staff, inspection of the facility, and review of documents, the facility failed to establish, consistently implement, and adequately educate staff regarding policies and procedures for the safe and effective use of an anticoagulant, blood thinner - heparin, affecting three of seventeen reviewed patients. In summary:

A. For Patients One, Two, and Three who were housed in a general pediatric unit (4NE), doses of heparin 10,000 units per milliliter were administered on November 18, 2007 instead of the facility approved pediatric protocol dose of heparin 10 units per milliliter to keep intravenous lines free of blood clots. It was stated by the Facility

Event ID:7BS511  3/18/2008  12:20:10PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE  TITLE  (X6) DATE

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

**NAME OF PROVIDER OR SUPPLIER**
CEDARS-SINAI MEDICAL CENTER

**STREET ADDRESS, CITY, STATE, ZIP CODE**
8700 BEVERLY BLVD., LOS ANGELES, CA 90048  LOS ANGELES COUNTY

<table>
<thead>
<tr>
<th>(X4) ID</th>
<th>(X5) COMPLETE</th>
<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PREFIX</td>
<td>DATE</td>
<td></td>
</tr>
<tr>
<td>TAG</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Summary Statement of Deficiencies**
(EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)

<table>
<thead>
<tr>
<th>ID</th>
<th>PREFIX</th>
<th>TAG</th>
<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</th>
</tr>
</thead>
</table>

**Continued From page 2**

Pharmacist Administrator during an interview on November 20, 2007 at 2:40 pm, that 100 vials of heparin 10,000 units per milliliter were delivered, mistakenly, instead of heparin 10 units per milliliter by Pharmacy Technicians One and Two to the 4NE unit on November 18, 2007 at 11:00 am. Heparin 10,000 units per milliliter is one thousand times the unit strength concentration compared to heparin 10 units per milliliter.

Upon facility discovery of the medication error, about 12 hours later, on November 18, 2007 between 10:00 to 11:00 pm, 86 of the 100 vials of heparin 10,000 units per milliliter were retrieved, unused, prior to the end of day on November 18, 2007.

An interview with the Facility Nursing Administrator One and Facility Pharmacist Administrator on November 20, 2007 at 3:00 pm revealed that contrary to facility policies and procedures for medication administration involving the " 5-Rights " (Right Patient, Right Medication, Right Dose, Right Route, and Right Time), up to 14 vials of the injectable heparin 10,000 units per milliliter were, *possibly administered * to three patients in the 4NE pediatric unit. Patients One, Two, and Three subsequently required additional monitoring due to an elevated blood clotting laboratory value (PTT), indicative of potential adverse bleeding. In addition, Patients One and Two also required two administrations of an injectable antidote, Protamine sulfate 25mg, respectively to reverse the overdose of heparin.

Event ID:7BS511  3/18/2008  12:20:10PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE  TITLE  (X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findings above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.
B. It was stated during an interview with Facility Nursing Administrator One and the Facility Pharmacist Administrator on November 20, 2007 at 4:00pm that heparin was discussed and re-identified within the hospital as a "high-alert, high-risk medication" that could cause patient harm such as an adverse consequence of bleeding. It was further stated that additional safety precautions by the implementation of a new heparin pharmacy policy and procedure was established at that time on March 13, 2007 that created special green-colored, alert labeling for bulk, floor stock heparin in the pharmacy. This labeling procedure was to be implemented within the pharmacy to remind staff that floor stock heparin to be dispensed out of the pharmacy, must be double checked by pharmacy staff prior to delivery to the nursing units. However, further interview with the Facility Pharmacist Administrator revealed that as of November 20, 2007, no written policy and procedure outlining the special green-colored, alert labeling existed or was formally approved by the medical center.

An inspection of the pharmacy on November 20, 2007 revealed that five of the seven heparin storage areas of various concentrations, including the heparin 10,000 units per milliliter were not labeled with the special green-colored, alert label. In addition, interview with the Facility Pharmacist Administrator on November 20, 2007 at 4:15pm, revealed that contrary to the double checking, safety precaution policy and procedure, the floor stock heparin that was sent to the 4NE pediatric unit on November 18, 2007 was not double checked.
Continued From page 4

by pharmacy staff before dispensing. The 100 vials of heparin 10,000 units per milliliter were then transported out of the pharmacy by Pharmacy Technicians One and Two to the nursing unit ' s floor stock for patient use without any verification by a staff Pharmacist. It was also observed on November 20, 2007 that the drug storage box in the pharmacy department containing the bulk heparin 10,000 units per milliliter vials continued to be stored directly adjacent to heparin doses of varying concentrations, without any special alerts for the pharmacy staff.

During the inspection of the pharmacy, an interview with Pharmacy Technician Six on November 20, 2007 at 4:00 pm was conducted regarding the pharmacy procedure for floor stocking of drugs. It was noted that he was not aware of the double checking procedures for heparin floor stock dispensing.

C. It was stated during an interview with Facility Nursing Administrator Two on November 20, 2007 at 3:45 pm, that RN Three, " spoke to staff as a whole " in the 4NE pediatric unit on November 18, 2007 at approximately 11:00 pm regarding this incident and proper medication administration. Facility Nursing Administrator Two stated that she
 " spoke to staff " in the 4NE unit on November 19 & 20, 2007 at approximately 7:00am regarding, " looking at all medications when taking them from any source, verifying it is the right medications and dose for the right patient prior to administering to the correct patient. "
Continued From page 5

However, unlike prior facility based education programs that were reviewed, as of November 20, 2007 at 3:45 pm, no organized attendance records with sign-in sheets to ensure a complete staff attendance, written curriculum and teaching plan to ensure consistent information, or staff re-evaluation to ensure competency were available for the 4NE pediatric unit discussions. An interview with Facility Nursing Administrator One on November 20, 2007 at 3:00pm also revealed that additional nursing in-services or competency assessments for all remaining hospital nursing units had not been initiated as yet.

On November 20, 2007 at 5:45pm, the Facility Administrator, Facility Nursing Administrator One, Facility Pharmacist Administrator as well as facility staff in attendance were notified that a situation of immediate jeopardy (IJ) existed due to deficient practices pertaining to the facility ‘s failure to establish, consistently implement, and adequately educate staff regarding policies and procedures for the safe and effective use of the facility identified, high alert, high risk anticoagulant & blood thinner, heparin. This failure resulted in a medication overdose involving three pediatric patients (Patients One, Two and Three) who were administered multiple intravenous flush doses of heparin that were 1000 times the facility approved protocol dose. Moreover, this failure required the facility to initiate immediate therapeutic monitoring and intervention to prevent serious injury or death including the administration of a heparin reversal antidote, Protamine sulfate for 2 of the 3 affected.

Event ID: 7BS511 3/18/2008 12:20:10PM
LABORATORY DIRECTOR’S OR PROVIDER/SUPPLIER REPRESENTATIVE’S SIGNATURE
TITLEx
(X6) DATE
Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findings above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.
Continued From page 6

patients.

These systemic, unsafe medication practices by the facility created a risk of harm for all hospital patients. Facility Nursing Administrator One and the Facility Pharmacist Administrator immediately submitted a proposal to the Department of Public Health (DPH) to remove the IJ. The facility initiated immediate corrective actions.

The IJ was abated approximately 22 hours later on November 21, 2007 at 3:45 pm when DPH determined that the facility was in substantial compliance with their proposed immediate corrective action plan following: 1) Inspections of the pharmacy department and random nursing units, 2) Random interviews with Pharmacy Technicians Three, Four, Five, and Registered Nurses 13, 14, and 15, and 3) A review of facility policy and procedure changes.

Findings:

1. A review of facility documents on November 20, 2007 revealed a joint facility intravenous policy# CCN00088 approved by the Departments of Nursing and Pharmacy for the flushing of pediatric, peripheral intravenous lines and catheters with one milliliter of an anticoagulant (blood thinner) heparin 10 units per milliliter after intravenous medication administrations to prevent blood clot formation that was in effect on November 18, 2007. In addition, a review of the Departments of Nursing and Pharmacy policy# CCN00048 for medication administration outlined aspects of the 5 Rights (5
<table>
<thead>
<tr>
<th>ID</th>
<th>PREFIX</th>
<th>TAG</th>
<th>ID</th>
<th>PREFIX</th>
<th>TAG</th>
<th>PROVIDER'S PLAN OF CORRECTION</th>
<th>(X5) COMPLETE DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Continued From page 7**

Rs) of medication administration including, " Before administering a medication, the medication to be administered must be verified as the correct one based on the medication order and product label for the correct patient ...and verified that the medication is being administered at the proper time, in the prescribed dose, by the correct route and documented immediately."

However, a review of clinical records on November 20, 2007 revealed three of seventeen pediatric patients (Patient One, Two, and Three) in the 4NE pediatric unit on November 18, 2007 that received peripheral intravenous line flushes with heparin 10,000 units per milliliter instead of the facility approved dose of heparin 10 units per milliliter.

a.) Patient One: An interview with Facility Nursing Administrator One on November 20, 2007 at 3:00pm and Registered Nurse Two on November 27, 2007 at 11:20am as well as review of Physician One's and Physician Four's progress notes revealed that Patient One had received incorrect flush doses of heparin 10,000 units per milliliter instead of the facility protocol to flush with heparin 10 units per milliliter following intravenous medication administration.

A progress note by Physician Five on November 19, 2007 at 3:00 am documented, " I was called to evaluate patient by RN staff at 9:15 pm secondary to oozing from heel stick site. At 10:50, my charge RN notified me of a possible adverse effect as the usual heparin 10 units / 1 ml vial was restocked with heparin 10,000 units / 1 ml vial " A progress

---

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findings above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.
Continued From page 8

note dated November 19, 2007 at approximately 1:00-2:00 pm by Physician One stated,
"Received wrong dose heparin reportedly at 10,000 iu/ml instead of 10 iu/ml apparently twice."
A physician's note by Physician Four dated November 24, 2007 at 5:52 pm stated,
"given an overdose of approximately 20,000 units x frequency unknown heparin for flushing of line."

It was stated during an interview with Registered Nurse Two on November 27, 2007 at 11:20 am that,
"even at the start of her evening shift at 7:00 pm on November 18, 2007, she and Registered Nurse Sixteen observed that Patient One seemed to be bleeding with visible oozing from an intravenous site on the arm and from a heel stick."

Further interview with Registered Nurse Two revealed that,
"she charted a heparin flush dose administered at 7:15 pm on November 18, 2007 but cannot remember if she read the label on heparin vial."

It was stated during an interview with Registered Nurses One and Seven on November 27, 2007 at 9:30 am and 10:50 am respectively that Patient One received a heparin flush at approximately 11:00 am during the day shift. However, contrary to facility policy# CCN00084, the heparin administration was not documented on Patient One's medication administration record. Further interview with Registered Nurses One and Seven also revealed that they could not recollect the dose of heparin.

Upon discovery of this heparin medication error on November 18, 2007 between 10:00 to 11:00 pm,
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

**NAME OF PROVIDER OR SUPPLIER**: CEDARS-SINAI MEDICAL CENTER  
**STREET ADDRESS, CITY, STATE, ZIP CODE**: 8700 BEVERLY BLVD., LOS ANGELES, CA 90048  
**LOS ANGELES COUNTY**

---

<table>
<thead>
<tr>
<th>ID</th>
<th>PREFIX</th>
<th>TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Continued From page 9</strong></td>
</tr>
</tbody>
</table>

Blood clotting laboratory tests were ordered and results including the partial thromboplastin time (PTT), prothrombin time (PT) and international normalized ratio (INR) were all reported to be elevated on November 19, 2007 at 3:00 am at PTT>200 seconds (laboratory heparin normal = 78-115 seconds), PT=83.9 seconds (laboratory normal = 10.6 - 14 seconds), and INR=27.2 (laboratory normal = .8 - 1.3) A review of a progress notes by Physicians Four and Eight on November 19, 2007 at 3:00 am and 9:30 am respectively disclosed that two doses of a heparin reversal antidote, Protamine sulfate 25mg were administered on November 19, 2007 at 12:05 am and 9:30 am.

A review of a progress note by Physician One dated November 20, 2007 at approximately 1:00-2:00 pm revealed that the "heparin overdose was resolved " as indicated by normal blood clotting values of PT=13.1 seconds and PTT=36 seconds. A review of a progress note by Physician Seven dated November 26, 2007 at 1:34 pm revealed that Patient One was, "stable and doing well and laboratory blood clotting values were within normal limits at PTT = 32 seconds (laboratory heparin normal = 78-115 seconds), PT = 12.2 seconds (laboratory normal = 10.6 - 14 seconds), and INR= 1 (laboratory normal = .8 - 1.3)

b) Patient Two: An interview with Facility Nursing Administrator One on November 20, 2007 at 3:00pm and Registered Nurses Two, Three, and Sixteen on November 27, 2007 as well as review of Physician One’s and Physician Three’s progress
Continued From page 10

notes revealed that Patient Two had received incorrect flush doses of heparin 10,000 units per milliliter instead of the facility protocol to flush with heparin 10 units per milliliter following medication administration.

A progress note by Physician Five on November 19, 2007 at 2:00 am stated, " I was called to evaluate patient by RN staff at 9:15 pm secondary to oozing from heel stick and IV site. At 10:50, my charge RN notified me that the heparin medication had been stored with heparin 10,000 units / 1ml instead of the usual heparin. "  A progress note dated November 19, 2007 by Physician One between 1:00-2:00 pm stated, " Heparin flush was given with a concentration of 10,000 iu/ml instead of 10 iu/ml; received apparently 2 doses, 8 hours apart. Noticed to be oozing heel stick and umbilicus. Now developed a hematoma at left IV site.

"  A progress note by Physician Four dated November 24, 2007 at 5:54 pm stated," was given 20,000 units overdose, frequency unknown, of heparin flush. "

It was stated during an interview with Registered Nurse Three on November 27, 2007 at 11:50 am that, as evening charge nurse on November 18, 2007, she assisted Registered Nurse Two by preparing a 7:35 pm heparin flush dose by drawing the one milliliter heparin dose into a syringe with one milliliter of normal saline. Registered Nurse Three also stated, " I can ' t be sure that I read the label and concentration of the heparin vial. "

---

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findings above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.
**Continued From page 11**

Further interview with Registered Nurse Two on November 27, 2007 at 11:20 am revealed that Registered Nurse Sixteen was training with her. Registered Nurse Two stated that she received a syringe labeled as heparin that was prepared by Registered Nurse Three and proceeded to hand the syringe to trainee, Registered Nurse Sixteen to administer to Patient Two. It was stated during an interview with Registered Nurse Sixteen on November 27, 2007 at 11:40am that she was informed by Registered Nurse Three that the pediatric 4NE unit used heparin 10 units per milliliter and 1ml of normal saline as a flush. Registered Nurse Sixteen administered the heparin and saline flush solution to Patient Two at 7:45 pm but contrary to facility policy# CCN00048, the heparin administration was not documented on Patient Two’s medication administration record.

It was stated during an interview with Registered Nurse Four on November 27, 2007 at 10:50 am, that she administered a heparin flush for Patient Two on November 18, 2007 at approximately 11:00 am during the day shift but she recalled that it was heparin 10 units per ml with a green top. "Contrary to facility policy# CCN00048, this heparin administration was also not documented on Patient Two’s medication administration record.

Upon discovery of this heparin medication error on November 18, 2007 between 10:00 to 11:00 pm, blood clotting laboratory tests were ordered but an attempt to draw a blood sample to test the partial thromboplastin time (PTT), prothrombin time (PT)
Continued From page 12

and international normalized ratio (INR) was unsuccessful. However, a blood sample from Patient Two's sister Patient One was obtained and both patients were receiving the same type of intravenous medications and heparin flushes. A review of a progress notes by Physician Five on November 19, 2007 at 2:00 am revealed that a decision was made to give a dose of a heparin reversal antidote, Protamine sulfate 25mg on November 19, 2007 at 12:05 am and then repeated at 9:30 am per Physician One's November 20, 2007 progress note.

A review of a progress note by Physician One dated November 20, 2007 at approximately 1:00-2:00 pm revealed that Patient Two was," doing great, bleeding stopped" as indicated by normal blood clotting values of PT=14.1 seconds and PTT=38 seconds. A review of a progress note by Physician Seven dated November 27, 2007 at 11:24 am revealed that Patient Two's, "hematoma resolving and laboratory blood clotting values were reported as PTT = 43 seconds (laboratory heparin normal = 78-115 seconds), PT = 17 seconds (laboratory normal = 10.6 - 14 seconds), and INR=1.7 (laboratory normal = .8 - 1.3).

c.) Patient Three: An interview with Facility Nursing Administrator One on November 20, 2007 at 3:00pm as well as review of clinical records revealed that Patient Three was to receive a flush of heparin 10 units per milliliter as ordered but contrary to facility policy# CCN00088 received up to two doses of heparin 10,000 units per milliliter as a peripheral intravenous flush on November 18, 2007

<table>
<thead>
<tr>
<th>Event ID:7BS511</th>
<th>3/18/2008 12:20:10PM</th>
</tr>
</thead>
</table>

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findings above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.
Continued From page 13

following medication administration.

It was stated during an interview with Registered Nurses Five and Six on November 27, 2007 at 10:15 am and 12:00 noon respectively that contrary to facility protocol for peripheral intravenous flushes, "they do not use heparin for flushing and only use solutions such as normal saline to flush the peripheral lines."

However, a review of a progress note documented by Physician Three on November 19, 2007 at 3:00 am revealed that, "Patient three could have received this flush that was the wrong concentration of heparin ...tests for PT/PTT ordered. An examination of the patient found no signs of bleeding." A review of a progress note documented by Physician Two on November 19, 2007 at 9:00 am revealed that, "inadvertently received 10,000u/cc heparin as IV flush. PT=15.4, INR=1.5, PTT=95. No evidence of bleeding. No need to recheck."

"It was noted that the heparin reversal agent, Protamine sulfate was not administered for Patient Three who was discharged home from the hospital on November 19, 2007 at 4:30pm. A progress note by Physician Nine on November 19, 2007 at 10:00 am stated, "Patient states she feels good and wants to go home."

2. An interview with the Facility Pharmacist Administrator on November 20, 2007 at 2:40 pm and Pharmacy Technicians One and Two on November 27, 2007 at 12:50 and 1:10 pm revealed...
Continued From page 14

that 100 vials of heparin 10,000 units per milliliter were delivered, mistakenly, instead of heparin 10 units per milliliter by Pharmacy Technicians One and Two to the 4NE unit on November 18, 2007 between 10:00-11:00 am. Upon discovery of the medication error involving Patients One, Two, and Three on November 18, 2007, approximately twelve hours later between approximately 10:00-11:00 pm, 86 of the 100 vials of heparin 10,000 units per milliliter were retrieved, unused, prior to the end of day on November 18, 2007.

Further interview with Facility Nursing Administrator One and Facility Pharmacist Administrator on November 20, 2007 at 2:40 pm revealed that 6 of the 14 vials from the original 100 vials of heparin 10,000 units per milliliter that were delivered were used on Patients One, Two, and Three. It was further stated by Facility Nursing Administrator One and the Facility Pharmacist Administrator that 8 of the 14 remaining vials were probably wasted and not used. An expanded clinical record review for all remaining patients in 4NE on November 18, 2007, (Patients 4,5,6,7,8,9,10,11,12,13,14,15,16,&17) revealed that 9 of the 14 patients did not have an intravenous line and 5 of the 14 patient ' s blood clotting value (PTT) for heparin were within normal laboratory limits.

3. A review of facility policy# INPT-059 for the management of high-risk or high-alert medications revealed a procedure dated September 2005 that identified anticoagulants as being " involved in a high percentage of medication errors. " It was stated during an interview with the Facility Nursing
Continued From page 15

Administrator One and the Facility Pharmacist Administrator staff on November 20, 2007 at 3:00pm that heparin had been re-identified on March 13, 2007 by the facility medical staff as a "high-alert, high-risk medication" that could cause patient harm such as an adverse consequence of bleeding.

An interview with the Facility Pharmacist Administrator on November 20, 2007 at 4:00 pm revealed the facility implemented additional safety precautions for heparin with a new pharmacy policy and procedure that was established on March 13, 2007 that created special green-colored, alert labeling for bulk, floor stock heparin that stated, "EFFECTIVE 3/13/07 - ALL HEPARIN STOCK ORDERS ARE TO BE DOUBLE CHECKED BY A SECOND INDIVIDUAL." This labeling procedure was to be implemented within the pharmacy to remind staff that floor stock heparin that is dispensed out of the pharmacy must be double checked by pharmacy staff prior to delivery to the nursing units. However, further interview with the Facility Pharmacist Administrator revealed that no formalized, written policy outlining the special green-colored, alert labeling existed to effectively communicate this procedure to pharmacy staff nor was this procedure approved by the medical center.

Moreover, an inspection of the facility pharmacy on November 20, 2007 at 4:00 pm revealed that five of the seven heparin storage areas of various concentrations such as 10 units per milliliter vials, 100 units per milliliter vials, 1000 units per milliliter vials, as well as intravenous heparin solutions of
Continued From page 16

25,000 units per 500 milliliters were not labeled with the special green-colored, alert labeling. Further inspection also noted that the bulk supply of heparin 10,000 units per milliliter vials also were not labeled with the special green-colored, alert labeling and continued to be stored with and directly adjacent to the other heparin doses of varying concentrations, without any special alerts for the pharmacy staff.

A review of facility documents including Pharmacy and Therapeutics committee meeting minutes, dated December 12, 2006, revealed an agenda item listing facility look-alike and sound-alike medications. A review of the medication listed revealed that heparin was not identified as a look-alike and sound-alike medication. However, an inspection of the facility vials for heparin 10 units per milliliter and 10,000 units per milliliter revealed two similar vials, identical in dimensions, that were both labeled with font color backgrounds that were varying shades of blue and black. An interview with the Pharmacy Technicians One and Two on November 27, 2007 at 12:50 pm and 1:10 pm revealed that medications that were identified as look-alike and sound-alike would be further distinguished with special red labeling, lettering, as well as physically separated from it's look-alike or sound-alike.

An interview with the Facility Pharmacist Administrator and Pharmacist One on November 20, 2007 at 4:15pm and Pharmacy Technicians One and Two on November 27, 2007 at 12:50 and 1:10 pm revealed that contrary to the double
Continued From page 17

checking, safety precaution policy and procedure, the floor stock heparin that was sent to the 4NE pediatric unit on November 18, 2007 was not double checked by pharmacy staff before dispensing. It was also stated that the vials of heparin 10 units per milliliter and heparin 10,000 units per milliliter were stored on the same shelf, next to each other, and without any special identifying labeling.

The 100 vials of heparin 10,000 units per milliliter were transported out of the pharmacy by Pharmacy Technician One to the 4NE Pharmacy Satellite and then subsequently transported to the nursing station by Pharmacy Technician Two, ultimately to the 4NE nursing unit's floor stock for patient use. It was stated by both Pharmacy Technicians One and Two during the November 27, 2007 interviews, that contrary to the policy and procedure for double checking of the heparin, the 100 vials of heparin 10,000 units per milliliter were not double checked and left the pharmacy without any verification by a staff Pharmacist. It was also stated by Technicians One and Two that they did not recall reading the labels of the 4 boxes containing 25 vials each of heparin 10,000 units per milliliter.

4. It was stated during an interview with Facility Nursing Administrator Two on November 20, 2007 at 3:45 pm, that RN Three, "spoke to staff as a whole" in the 4NE pediatric unit on November 18, 2007 at approximately 11:00pm regarding this incident and proper medication administration. Facility Nursing Administrator Two also stated that she "spoke to staff" in the 4NE pediatric unit on
Continued From page 18

November 19 & 20, 2007 at approximately 7:00 am regarding, "looking at all medications when taking them from any source, verifying it is the right medications and dose for the right patient prior to administering to the correct patient. " These discussions involved one to one verbal instructions with nursing staff and did not include documentation, sign-in sheets, staff competency re-evaluation or a teaching plan.

A review of prior facility based education programs in the 4NE unit revealed organized attendance sheets with written in-service curriculum. Examples of the prior in-service topics included calcium gluconate intravenous administration, & changes in proton pump inhibitor formulary changes that was conducted on July 27, 2007 as well as an in-service topic of when to draw drug levels that was conducted on June 16, 2007.

During an interview with Facility Nursing Administrator One on November 20, 2007 at 3:00 pm, it was stated that intravenous flush policy# CCN00088 had been replaced with a new policy on November 19, 2007 whereby normal saline would only be used for the flushing of pediatric, peripheral intravenous lines and catheters. A review of facility documents on November 20, 2007 revealed no documentation of sign-in sheets or curriculum regarding in-services to nursing staff regarding this policy and procedure change.

5. On November 20, 2007 at 8:30 pm, Facility Nursing Administrator One, and the Facility Pharmacist Administrator submitted a proposal to
Continued From page 19
the Department to remove the IJ and initiated corrective actions that included:

a. All high alert drugs as identified by the hospital that are dispensed to nursing floor stock will always be checked by two licensed pharmacy staff members;
b. All heparin 10,000 units per milliliter vials will be immediately sequestered and stored in a separate location from other drugs;
c. All boxes of heparin will always be stickered with an additional green alert that it must be double checked prior to dispensing;
d. All heparin, a high alert drug will always be double checked by two licensed pharmacy staff members before dispensing;
e. The heparin double check will be documented on the floor stock list, including date, time, and initials;
f. Ongoing audits for at least the following 6 months will be conducted to ensure compliance, in addition to the monthly unit inspections;
g. Immediate in-services to all pharmacy staff regarding policy changes for high alert drugs such as heparin will be conducted with documented curriculum and attendance;
h. Immediate competency in-services to all nursing staff regarding medication administration with documented attendance, curriculum, and post-test;
i. Immediate in-services to all nursing staff regarding policy changes for high alert drugs such as heparin and venous access flushes with documented attendance and curriculum;
j. Immediate medication pass observations on
Continued From page 20

the nursing units with randomly chosen nursing staff with documented findings to be provided to DPH and the Medication Safety Committee;

k. The medication pass observations will be included in all future weekly tracer processes;

l. Vice President of Nursing Services and Director of Pharmacy will ensure immediate and sustained compliance with the above listed improvements.

Following additional inspections, interviews, and record reviews that determined the facility was in substantial compliance with their proposed immediate corrective action plan, the IJ was abated on November 21, 2007 at 3:45 pm prior to the facility’s survey exit on November 27, 2007 at 3:00 pm. A review of facility documents verified that as of November 27, 2007, approximately 200 hospital pharmacy and 1, 388 current nursing staff had been in-serviced with competency assessments regarding all aspects of the facility's IJ abatement plan.

This violation involved multiple failures by the facility to adhere to established policies & procedures for safe medication use. A policy and procedure protocol for the flushing of pediatric, peripheral intravenous lines with heparin 10 units per milliliter was not followed. A policy and procedure involving the 5 Rights of medication administration including the administration of the right medication at the right dose to the right patient was not followed. A policy and procedure to re-emphasize the facility identified high-alert, high-risk medication heparin with pharmacy warning labels, segregation and double checking was not fully formalized,
### Statement of Deficiencies and Plan of Correction

**Name of Provider or Supplier:** CEDARS-SINAI MEDICAL CENTER  
**Street Address, City, State, Zip Code:** 8700 BEVERLY BLVD., LOS ANGELES, CA 90048  
**Los Angeles County**

**Continued From page 21**

implemented and followed. A policy and procedure involving the documentation of all administered medications such as heparin onto a medication administration record was not followed.

These policy and procedure failures resulted in preventable medication errors involving three patients, (Patient One, Two, and Three) who were given multiple doses of the wrong heparin concentration of 10,000 units per milliliter to flush a peripheral intravenous line requiring immediate therapeutic monitoring and intervention to prevent serious injury or death. These violations caused, or were likely to cause, serious injury or death to the patients who received the wrong medication. The facility systemic practices involving these failures to follow facility policies & protocols also had a potential to affect all patients in the hospital.

---

**Event ID:** 7BS511  
**Date:** 3/18/2008 12:20:10PM  
**Laboratory Director’s or Provider/Supplier Representative’s Signature:**  
**Title:**  

---

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