

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

RECEIVED  
CA DEPT OF PUBLIC HEALTH

RECEIVED  
SAN DIEGO NORTH DISTRICT  
IMAGING & CERTIFICATION

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050100	(X2) MULTIPLE CONSTRUCTION A. BUILDING 1. ALTIMA	(X3) DATE SURVEY COMPLETED  03/27/2014
NAME OF PROVIDER OR SUPPLIER  Sharp Memorial Hospital		STREET ADDRESS, CITY, STATE, ZIP CODE: 7901 Frost St, San Diego, CA 92123-2701 SAN DIEGO COUNTY		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
	<p>The following reflects the findings of the Department of Public Health during an inspection visit:</p> <p>Complaint Intake Number: CA00335919 - Substantiated</p> <p>Representing the Department of Public Health: Surveyor ID # 22363, HFEN</p> <p>The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility.</p> <p>Health and Safety Code Section 1280.1(c): For purposes of this section "immediate jeopardy" means a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient.</p> <p>The following reflects the findings of the California Department of Public Health during the investigation of an entity reported incident. Complaint Number: CA00335919 The investigation was limited to the specific self-reported event investigated and does not represent the findings of a full inspection of the facility. Representing the Department of Public Health: Health Facilities Evaluator Nurse 22363 and 12766. Health and Safety Code Section 1280.1 (c) For purposes of this section "immediate jeopardy" means a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious</p>		<p>Immediate safety measures and precautions addressing patient safety and the provision of a safe environment in the Interventional Radiology (IR) suite were taken:</p> <ol style="list-style-type: none"> <li>1. Additional security straps/belts (medical immobilizers) were purchased to accommodate patients with larger girths and/or body mass index (BMI).</li> <li>2. A new process was developed and implemented: Prior to entry into the IR Suite, patient BMI is assessed. For those patients with a BMI &gt; 35, the Imaging Manager and assigned IR Radiologist confer to determine the optimal location for the ordered procedure (i.e., IR vs. OR with use of bariatric table + portable C-arm imaging equipment). <ul style="list-style-type: none"> <li>• When IR is determined to be the optimal location, the Imaging Manager and IR team evaluate and implement safe patient placement on the IR table.</li> <li>• All IR staff were educated on the above new process via staff meetings and 1:1 review.</li> </ul> </li> <li>3. An IR Department Guideline was created, further supporting patient safety in the IR setting via the utilization of medical immobilizers for <i>all</i> patients regardless of BMI, level of mental, or use of sedation. <ul style="list-style-type: none"> <li>• Education was provided to all IR staff.</li> </ul> </li> <li>4. An Imaging Competency, "(GE) Innova 4100 Table (Philips) Integris" was created. The competency addresses patient safety within the context of table use. <ul style="list-style-type: none"> <li>• Education was provided to all IR staff.</li> </ul> </li> </ol>	<p>12/10/12</p> <p>12/10/12</p> <p>12/19/12</p> <p>12/19/12</p>

Event ID MIPH11

3/27/2014

8:23 07AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

*Joan M. Eng* Director, Regulatory Affairs

4/10/14

By signing this document, I am acknowledging receipt of the entire citation packet. Page(s) 1 thru 8

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

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	<p>injury or death to the patient. Informed Adverse Event Notification Health and Safety Code Section 1279.1. (c) The facility shall inform the patient or the party responsible for the patient of the adverse event by the time the report is made. The CDPH verified that the facility informed the patient, or the party responsible for the patient, of the adverse event by the time the report was made. Health &amp; Safety Code Section 1279.1 (a) A health facility licensed pursuant to subdivision (a), (b), or (f) of Section 1250 shall report an adverse event to the department no later than five days after the adverse event has been detected, or, if that event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, not later than 24 hours after the adverse event has been detected. Disclosure of individually identifiable patient information shall be consistent with applicable law. (b) For purposes of this section, "adverse event" includes any of the following: (7) An adverse event or series of adverse events that cause the death or serious disability of a patient, personnel, or visitor.</p> <p>California Code of Regulations, Title 22, Division 5, Chapter 1. 70215(c) The nursing plan for the patient's care shall be discussed with and developed as a result of coordination with the patient, the patient's family, or other representatives, when appropriate, and staff of other disciplines involved in the care of the patient. The facility failed to provide for the safety of Patient</p>		<p>5. The BMI evaluation process (#2 above) was modified based upon quality assessment data to the following: The IR RN and IR Radiologist performing the procedure assess every patient's BMI. If the BMI <math>\geq</math> 35, the IR team consult with the IR Radiologist re: optimal procedural location for patient safety and imaging quality. • Education was provided to all IR staff re: the modified evaluation process. Monitoring: 1. A 10-month electronic medical record (EMR) documentation audit of IR patients was completed to ensure Imaging Manager and IR Radiologist notification occurred for patients with a BMI <math>\geq</math>35. Outcome: 1) zero patient falls; 2) 160 (6%) of the 2612 IR patients screened had a BMI <math>\geq</math>35; 100% had EMR documentation that Imaging Manager and IR Radiologist consultation occurred. 2. A randomized prevalence audit consisting of one day/month X 4 months was completed post-process modification (#5 above) to ensure IR team and IR Radiologist consultation occurred. Outcome: 1) zero patient falls; 2) 6 (13%) of the 47 IR medical records audited had a BMI <math>\geq</math> 35; 100% had EMR documentation that IR team and IR Radiologist consultation had occurred. Responsible Party: Manager, Imaging</p>	<p>11/25/13</p> <p>9/26/13</p> <p>4/1/14</p>

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	<p>1 while she was undergoing the insertion of a peripherally inserted central catheter (PICC) line in the Interventional Radiology (IR) department. This resulted in Patient 1 falling off a treatment table in the interventional radiology service area during the insertion of the PICC line, and sustained a fracture of the 8th thoracic vertebrae requiring an additional surgical procedure to repair the fracture.</p> <p>Findings:</p> <p>Patient 1 a 73 year old woman, was transferred from a long term care facility and admitted to the Sharp Memorial Hospital on [REDACTED] 12 with a chief complaint of abdominal pain and abdominal distention.</p> <p>Per the admission history and physical dated [REDACTED] 2, Patient 1 had been "bedridden for the last 3 years " and included the following additional diagnosis:</p> <ol style="list-style-type: none"> <li>1. Chronic respiratory failure with ventilator assistance</li> <li>2. Obesity induced hyperventilation syndrome</li> <li>3. Severe chronic obstructive pulmonary disease (emphysema)</li> <li>4. Super morbid obesity</li> <li>5. Atrial fibrillation (Irregular heartbeat)</li> <li>6. Cardiomyopathy (enlarged heart)</li> <li>7. Chronic kidney disease, stage 4 to 5.             <ol style="list-style-type: none"> <li>8. Pulmonary hypertension</li> <li>9. History of stroke</li> <li>10. Loss of mobility</li> <li>11. Peripheral neuropathy (nerve damage causing numbness and pain in hands and feet).</li> </ol> </li> </ol> <p>The progress notes dated [REDACTED] 2 indicated the patient had, "Acute asterixis (a motor disorder</p>			

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	<p>characterized by jerking movements of the hands and arms) as well as myoclonus jerks (involuntary twitching of a muscle or a group of muscles)."</p> <p>On [REDACTED] 2, Patient 1 was moved to the surgical intensive care unit (SICU) due to continuing hypotension (low blood pressure) and a medication (dopamine) was needed to maintain her blood pressure, according to the physician's progress notes dated [REDACTED] 2 at 7:02 a.m. The same progress notes indicated Patient 1 had an, "Altered level of consciousness: Lethargic (sluggish and tired). She is at least morbidly obese."</p> <p>On [REDACTED] 2 at 2:30 p.m., Patient 1 was medicated intravenously (IV) with Benadryl 25 mg (antihistamine) for itching, with Dilaudid 0.5 milligrams (mg) for pain, and with Zofran 4 mg for nausea/vomiting, according to the electronic medical record (EMR). At 2:40 p.m. Patient 1 was transferred to the IR department for a PICC line insertion.</p> <p>(PICC lines are inserted in the arm through the skin into a large vein. The catheter is threaded through this vein until it reaches a large vein near the heart. PICC lines are used for long term antibiotic therapy, because they can be left in place for a long period of time.)</p> <p>According to the ICU nurse (RN 1), Patient 1 was on an inflatable mattress that was used to slide her onto the IR table. The mattress was then deflated. No security straps or bells were used. RN 1 stated she did not recall ever taking anyone Patient 1's size to the IR room. Patient 1 was medicated again at 3:45 p.m. with Dilaudid IV for pain.</p> <p>Physician 1 was interviewed on 1/17/13 at 10:00 a.m. and verified he was responsible for the</p>			

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	<p>insertion of the PICC line on [REDACTED] 12. Physician 1 described the patient was already prepped and draped when he entered the room. Physician 1 stated he assumed the patient was strapped down, and he attempted to insert the PICC line on Patient 1's right side but was unsuccessful. Another attempt was made to access the left arm of Patient 1 and during the process Physician 1 said that just as he was trying to pass the catheter over the wire on the left side, Patient 1 fell off the table.</p> <p>As a result of the fall from the IR table onto the floor, Patient 1 sustained a fracture of the 8th thoracic vertebrae as described in the post fall radiology report dated [REDACTED] 12.</p> <p>According to the Trauma Progress Notes dated [REDACTED] 12, "The patient's family refused ORIF (open reduction internal fixation - surgical repair of the fracture). I have explained the potential complications related to not having her back stabilized ...pneumonia, paraplegia (paralysis), sepsis (blood infection) all potentially leading to death."</p> <p>According to the Trauma Progress Notes dated [REDACTED] 12, "The only option that has a chance of letting her heal and get better is operative despite the high mortality (death rate) associated with operation and anesthesia. The patient will die a lingering death (without) operative intervention and will become paraplegic at some point despite careful turning."</p> <p>The surgeon noted on [REDACTED] 12, "...the family and the patient through continued conversation with me as well as the trauma team has decided to proceed with operative intervention .. the estimated mortality was greater than 50% in addition to the operation</p>			

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	<p>itself. However, I did explain the risk of mortality with non-operative management likely nearly 100 % with non-operative care. After serious discussion with family, they really felt that the right means of treating (Patient 1) at this point despite her significant complication risk was to proceed with operative intervention with stabilization of her fracture to allow her to mobilize ..."</p> <p>Patient 1 went to surgery on [REDACTED] 12, for surgical repair of the spine with insertion of hardware and fusion of the spine.</p> <p>Staff members from the IR department were interviewed on 12/19/12 at 2 p.m. The lead RN 2 and the lead technician (LT 1) confirmed they assisted Physician 1 on [REDACTED] 2 with the procedure. According to RN 2 and LT 1, all patients that were placed on the IR table were secured with belts. RN 2 and LT 1 said Patient 1 would have been secured, but the straps would not fit around her girth. Patient 1 had a documented weight of 328 pounds and height of 61 inches.</p> <p>The manufacturer's instruction manual was reviewed in the form of a CD ROM. According to the CD ROM instructions entitled, Movement of Patient on the Table, "In addition, it is recommended to use restraints, such as Velcro straps ..." The instructions show a picture of a patient on the table with Velcro straps across shoulders and legs.</p> <p>Administrative Staff were present at the 12/19/12 interview with RN 2 and LT 1, and stated that in retrospect Patient 1 should have been taken to the bariatric room (a room with the proper equipment to accommodate obese patients). During this same interview, Regulatory Staff stated there was no safety program in the IR Department related to the</p>			

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	<p>safety or strapping of patients to the table.</p> <p>On 9/26/13 at 11:30 a.m., both RN 2 and the Radiology Manager were re-interviewed related to the fall event. At the time of the incident ( ) RN 2 stated the use of safety restraints was based upon an assessment of "the patients level of mentation or if sedation was needed and/or observed prior to the procedure." RN 2 stated the Patient 1 was alert and oriented when she arrived for the procedure on 12. RN 2 stated the use of the available safety restraints were inadequate due to the girth of Patient 1.</p> <p>The assessment documentation provided by RN 3 on 2 at 3:09 PM prior to the procedure indicated Patient 1 had no neurological problems, and the safety precautions were addressed based on the medication use. The nursing notes assigned to the assessment provided "Pt was alert oriented and cooperative. Consent was signed and pt was assisted to x-ray table."</p> <p>The IR table measured 131 inches in length. The width of the head (top) was 8 inches, the trunk (center) portion of the table was 18 inches wide, and the bottom was 26 inches wide.</p> <p>The facility placed Patient 1 on an IR table that measured at its narrowest point 18 inches and failed to provide any safety measures or precautions. Patient 1 fell to the floor during the procedure, fracturing thoracic vertebrae, which required surgical intervention to repair.</p> <p>Per the discharge summary dated 13, Patient 1 was subsequently discharged to a long term acute care facility 13. The extent of the disability related to the fall, and surgical repair of the thoracic vertebrae fracture could not be</p>				

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4	<p>determined at the time of discharge.</p> <p>The facility's failure to ensure the radiology and nursing departments coordinated with each other to develop an effective plan of care to provide a safe environment for Patient A's IR procedure is a deficiency that has caused, or is likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of the Health and Safety Code Section 1280.1(c).</p> <p>This facility failed to prevent the deficiency(ies) as described above that caused, or is likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code Section 1280.1(c).</p>			
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