

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA240000100	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED C 12/01/2008
--	--	--	--

NAME OF PROVIDER OR SUPPLIER ARROWHEAD REGIONAL MEDICAL CENTER	STREET ADDRESS, CITY, STATE, ZIP CODE 400 NORTH PEPPER AVENUE COLTON, CA 92324
--	--

(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
--------------------	--	---------------	---	--------------------

E 000 Initial Comments

The following reflects the findings of the California Department of Public Health during the investigation of a entity reported event.

Entity reported event number: CA00170371

Representing the California Department of Public Health: [REDACTED] HFEN

The inspection was limited to the specific entity reported incident investigated and does not represent the findings of a full inspection of the facility.

One deficiency was written as a result of entity reported event number CA00170371.

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 and therefore constitutes Immediate Jeopardy under the Health and Safety Code section 1280.1.

E 347 T22 DIV5 CH1 ART3-70223(b)(2) Surgical Service General Requirements

(b) A committee of the medical staff shall be assigned responsibility for:
(2) Development, maintenance and implementation of written policies and procedures in consultation with other appropriate health professionals and administration. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate.

This Statute is not met as evidenced by:

E 000

E 347

Immediate Corrective Action:

- 1) Re-educate 100% of the Operating Room Staff on the OR Policy #141.08 "Counts: Sponges, Sharps, and Instruments", with emphasis on the required minimum of three (3) counts at all required intervals. Education provided by the Staff involved in the incident.

12/6/08

09 JUL 15 AM 10:52

Licensing and Certification Division

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

STATE FORM

Holly Ramos

HL
5/2/09

Holly Ramos, R.N., B.S.N., M.H.A.
Associate Hospital Administrator
Professional Services

(X6) DATE

12-14-08

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA240000100	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED C 12/01/2008
NAME OF PROVIDER OR SUPPLIER ARROWHEAD REGIONAL MEDICAL CENTER		STREET ADDRESS, CITY, STATE, ZIP CODE 400 NORTH PEPPER AVENUE COLTON, CA 92324	
(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
E 347	<p>Continued From page 1</p> <p>Based on interview, and record review, the facility failed to implement written policies and procedures (P&P) for counting of surgical sponges (a procedure in which all surgical sponges are counted to ensure that none were left inside the patient) which resulted in Patient 1 suffering unnecessary pain, and another major surgical procedure to remove a retained sponge. The surgical procedure had the potential of Patient 1 suffering major complications, and/or requiring her to have a hysterectomy.</p> <p>Findings:</p> <p>An unannounced visit was made to facility on 12/1/08 at 3:15 PM to investigate an entity reported adverse event regarding a surgical sponge (a sterile folded gauze used during a surgical procedure to wipe up bleeding or to locate sources of bleeding) that was left in a patient after a surgical procedure.</p> <p>The Associate Hospital Administrator (AHA) was met and informed of the purpose for the visit. The clinical record for Patient 1 was requested and reviewed.</p> <p>Review of the clinical record on 12/1/08 for Patient 1 showed an History and Physical (H&P) dated 10/16/08 that showed she was a 26 year-old female that had no significant previous medical problems and no children.</p> <p>According to the pre-op H&P she had a "left complex large ovarian ((female reproductive gland) cyst (a sack filled with fluid on the ovary). The patient had no history of previous surgeries.</p> <p>Further review of the clinical record revealed an Operative Note also dated 10/16/08 at 10:07 AM</p>	E 347	<p>Monitoring: Perform daily chart audits for compliance with documentation of counts to include sponges, instruments, and/or sharps, according to OR Policy #141.08, OR Nursing Staff will participate in these chart audits. 2/06/08</p> <p>Responsible Party: OR Nurse Manager</p> <p>2) Conduct a Multi-disciplinary Root Cause Analysis with the OR Staff involved in the incident. 12/17/08 (Documentation on File)</p> <p>3) Install racks for holding sponge counters to facilitate all members of the Surgical Team to view and count used sponges 12/16/08</p> <ul style="list-style-type: none"> 100% of OR Staff educated on the new process for counting sponges on the racks. 2/06/09 (Documentation on file) <p>4) Circulating Nurse and Scrub Tech involved in this case received Formal Discipline for not following hospital policy and procedures. 2/06/09 (Documentation on file)</p>

09 JAN 15 2009 10:52

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA240000100	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED C 12/01/2008
NAME OF PROVIDER OR SUPPLIER ARROWHEAD REGIONAL MEDICAL CENTER		STREET ADDRESS, CITY, STATE, ZIP CODE 400 NORTH PEPPER AVENUE COLTON, CA 92324	
(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)
E 347	Continued From page 2 that indicated Patient 1 had a surgical procedure at the facility to remove bilateral ovarian cysts (a tumor (usually benign) of the ovary. According to the Operative Note Patient 1 had her right ovary and fallopian tube removed. The surgeon dictated "...due to vascularity and difficulty of removal of the cyst wall from the ovary tissue itself, we (the surgical team)found that it was impossible to maintain the integrity of the ovary as well as persistent bleeding was noted (this is the area where the sponge was left). According to the Operative Note surgical sponges were used during the procedure and the sponge count was documented as being correct. Review of the Discharge Summary on 12/1/08 that was dated 10/19/08 at 7:19 AM revealed documentation that showed Patient 1 was discharged home on 10/19/08 with lifting restrictions. Further review of Patient 1's clinical record revealed that on 11/19/08 the patient returned to the facility's surgery clinic for a follow-up appointment and was complaining of constant abdominal pain in the right upper quadrant (RUQ) of her abdomen and constipation. Patient 1 was sent to the (Emergency Department (ED) and an abdominal CT scan (device that takes pictures of internal body parts) was done. The reason given for the CT scan was because Patient 1 had been "suffering from abdominal pain and constipation." Review of the CT scan report dated 11/19/08 on	E 347	<u>Monitoring Process:</u> Conduct random unannounced direct observation audits of actual counts being performed during surgical cases. A minimum of 30 count audits will be performed monthly. <u>Responsible Party:</u> OR Nurse Manager 5) The following policies will be reviewed by 100% of the OR Staff on a monthly basis to avoid "Never Events" 2/10/09 <ul style="list-style-type: none"> • OR Policy #141.08 "Counts, Sponges, Sharps, and Instruments". • OR Policy #177.22 "Use of Electro-Surgical Units". • Administrative Operational Policy #650.07 "Side-Site Verification". • Administrative Operational Policy #300.02 "Patient Notification of Medical Error (Unanticipated Outcome)". <u>Monitoring Process:</u> Assistant Nurse Manager will ensure that all of the above policies are reviewed with signed acknowledgement on 100% of the OR Staff. 2/10/09

091115 15 4115 52
 STATE OF CALIFORNIA
 DEPARTMENT OF PUBLIC HEALTH
 LICENSING AND CERTIFICATION DIVISION

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA240000100	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED C 12/01/2008
NAME OF PROVIDER OR SUPPLIER ARROWHEAD REGIONAL MEDICAL CENTER		STREET ADDRESS, CITY, STATE, ZIP CODE 400 NORTH PEPPER AVENUE COLTON, CA 92324	
(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)
E 347	Continued From page 3 12/1/08 revealed that the Radiologist had documented "...retained sponge in the right mid abdomen with large abscess cavity (a collection of pus, usually associated with infection)." Further review of the clinical record revealed that on 11/19/08 the ED physician diagnosed Patient 1 with an "abdominal abscess with sponge intraabdominal s/p(status post) abd (abdominal) surgery 10/16/08," and was readmitted to the facility for surgery to remove the retained sponge. Review of the pre-op H&P dated 11/19/08 revealed that Patient 1 had been in constant abdominal pain, and had been suffering with constipation since her surgery on 10/16/08. The physician documented her "pain was five out ten, on a scale of one to ten in the right upper area of her stomach. Patient 1 also suffered a weight loss." The physician further documented that Patient 1 had an "abdominal abscess with sponge intraabdominal (in the abdomen) S/P (after) abdominal surgery 10/16/08", and that she would be admitted for an exploratory laparotomy (a large cut made in the abdomen to expose the internal organs for examination) to remove the sponge, and possible bowel resection (procedure where part of the large or small bowel is removed)." The Pre-Anesthesia Assessment dated 11/19/08 indicated Patient 1 had lost ten pounds since the last surgery, and that the patient was complaining of sharp abdominal pain. The consent dated 11/19/08, signed by Patient 1, the surgeon, and a witness, indicated she was	E 347	<u>Responsible Party:</u> OR Nurse Manager 6) Submit a request to the Hospital Wide Quality Management Committee, to initiate a Performance Improvement project to monitor compliance with surgical counts in the OR. 2/05/09 <u>Monitoring Process:</u> The results of the Performance Improvement activities and findings will be reported to: Operative and Other Invasive Procedure Committee; Hospital Wide Quality Management Committee; Medical Executive Committee and the Governing Body on a quarterly basis. 4/02/09 <u>Responsible Party:</u> OR Manager <u>QAPI</u> Develop the OR QAPI Plan for the monitoring and reporting of compliance related to sponge sharps and instrument counts: 1. Developed data collection tool on-going 2. Conduct chart audits for compliance with counts, as well as the appropriateness of counts relevant to the type of surgical procedure. on-going

09 JUN 15 AM 10:52

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA240000100	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED C 12/01/2008
NAME OF PROVIDER OR SUPPLIER ARROWHEAD REGIONAL MEDICAL CENTER		STREET ADDRESS, CITY, STATE, ZIP CODE 400 NORTH PEPPER AVENUE COLTON, CA 92324	
(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)
E 347	<p>Continued From page 4</p> <p>going to have an "operative laparotomy, possible foreign body removal, drainage of abscess, possible total abdominal hysterectomy."</p> <p>Review of the Operative Note on 12/1/08 revealed that on 11/19/08 Patient 1 had surgery at the facility to remove from her abdomen the sponge that was seen by the Radiologist on the CT scan.</p> <p>According to the Operative Note a single sponge was found and removed from Patient's 1's abdomen and an abscess caused by the retained sponge was drained.</p> <p>During an interview with the Associate Hospital Administrator (AHA) on 12/1/08 at 3 PM, she stated the facility was concerned that a surgical sponge had been left in Patient 1.</p> <p>The AHA stated the Circulating Nurse (CN), and the Scrub person (SP) "only did two counts", during Patient 1's surgical procedure on 10/16/08.</p> <p>The AHA further stated, "during the 10/16/08 surgery, the CN and SP counted the sponges before starting the procedure, and after the procedure. They did not count prior to closing the abdominal cavity (as required per facility's surgical count P&P)."</p> <p>The AHA stated "the surgical count P&P had been revised in January 2008. The surgical staff attended an in-service in January 2008. During the in-service, the attendees were given a copy of the new surgical count P&P."</p> <p>The AHA went on to say that the facility "was in the process of "re-educating" the surgical staff about the correct procedure for doing surgical</p>	E 347	<p>3. Conduct unannounced direct observation for compliance with counts, and the removal of all sponges, lap sponges and sharps out of the OR suite at the end of a surgical procedures.</p> <p>4. Implement the use of hanging sponge bags in every OR suite for soiled sponges and lap sponges.</p> <p>5. Report results of PI Project to QMC on a quarterly basis.</p> <p>6. Share results of PI Project with OR Staff during monthly staff meeting.</p>
			<p>on-going</p> <p>12/16/08</p> <p>4/02/09</p> <p>4/20/09</p>

Responsible Party:

OR Nurse Manager

09 JUL 15 AM 10:52

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA240000100	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED C 12/01/2008
NAME OF PROVIDER OR SUPPLIER ARROWHEAD REGIONAL MEDICAL CENTER		STREET ADDRESS, CITY, STATE, ZIP CODE 400 NORTH PEPPER AVENUE COLTON, CA 92324	
(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)
E 347	Continued From page 5 counts. The surgical staff are required to attend an in-service that will review the surgical count P&P. During the in-service, they will watch an Association of Operating Room Nurses (AORN) video that demonstrates the correct procedure for counting sponges, instruments, etc." During an interview with the Assistant Operating Room Nurse Manager (AORNM) on 12/1/08 at 4:45 PM, she stated, "they (the CN and SP) have worked together a long time, had become nonchalant (unconcerned)." The AORNM stated "I believe the CN trusted the SP to count. I don't believe they (the CN and SP) did a visual count, where each sponge is located and seen by both the CN and SP." Review of the facility's policy and procedure (P&P) on 12/1/08 titled Counts: Sponges, Sharps, and Instruments, Policy No. 141.08 Issue 2 last revised 01/2008, indicated: 1. The facility developed this protocol using established guidelines and recommendations from the Association of Operating Room Nurses (AORN) and other references in order to provide the community with the highest standard of care in Surgical Nursing (Policy page 1). 2. All counts are completed audibly by the Scrub Nurse/Technician and Circulating Nurse while each item is being viewed... All counts are documented on the OR (operating room) Record by the Circulating Nurse" (Policy A. Procedure page 1). 3. The Circulating Nurse is responsible for obtaining and verifying the surgical counts. The Scrub person is responsible for counting with the	E 347	

09 JUL 15 AM 10:52
 LICENSING DIVISION

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA240000100	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED C 12/01/2008
NAME OF PROVIDER OR SUPPLIER ARROWHEAD REGIONAL MEDICAL CENTER		STREET ADDRESS, CITY, STATE, ZIP CODE 400 NORTH PEPPER AVENUE COLTON, CA 92324	
(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)
E 347	Continued From page 6 Circulating Nurse. Obtaining an accurate surgical count is a team effort and all the parties involved in the surgical case have a professional, legal, and ethical obligation to the patient and the community at large. Surgical staff will fulfill this obligation to the satisfaction of all team members involved in order to assure patient safety and quality nursing practices" (Policy B. Responsibilities page 1). 4. Surgical sponge counts refer to, but are not limited to, laparotomy sponges... Sponges will be counted on all surgical procedures" (Procedures A. 1. page 1); and All sponges will be separated by the scrub and counted audibly with the Circulator or another RN (registered nurse) (Procedures A. 2. page 1). 5. Surgical counts will be accomplished (a) audibly by the Scrub Nurse/Technician and in the presence of the Circulating Nurse, (b) prior to the surgical start,... (e) prior to the closure of a cavity within a cavity, (f) prior to the closure of any deep or large incision or body cavity, ... (h) Final count is mandatory and is defined as occurring after skin closure" (E. Application 1. page 4 and 5). 6. The Circulating Nurse is responsible for the nursing activities in the operating room and for obtaining and documenting the surgical counts. It is the Circulating nurse's responsibility to document (a) the types of counts (sponge, sharp, instrument, miscellaneous), (b) the number of counts, (c) the results of the counts...(F. Documentation 1. page 5). The facility failed to implement written policies and procedures for counting of surgical sponges, which resulted in Patient 1 suffering unnecessary pain, and having to undergo another major	E 347	

09 JUL 15 AM 10:52
 LICENSING DIVISION

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA240000100	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED C 12/01/2008
--	--	--	---

NAME OF PROVIDER OR SUPPLIER ARROWHEAD REGIONAL MEDICAL CENTER	STREET ADDRESS, CITY, STATE, ZIP CODE 400 NORTH PEPPER AVENUE COLTON, CA 92324
--	--

(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
--------------------	--	---------------	---	--------------------

E 347	Continued From page 7 surgical procedure to remove a retained sponge and drain an abscess caused by the retained sponge.	E 347		
-------	---	-------	--	--

09 JUL 15 AM 10:52
 LICENSING AND CERTIFICATION DIVISION