CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050121	A. BUILDING _____ B. WING _____	04/09/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Adventist Health Hanford	115 Mall Dr, Hanford, CA 93230-5786 KINGS COUNTY

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	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00569261 - Substantiated Representing the Department of Public Health: Surveyor ID # 2697, HFEN The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility. Health and Safety Code Section 1280.3(g): 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. Health and Safety Code 1279.1 b) For purposes of this section, "adverse event" includes any of the following: (1) Surgical events, including the following (D) Retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained. Title 22, California Code of Regulations, Division 5, Chapter 1, Article 3, Section 70223 (b)(2): Surgical Services General Requirements 70223 (b) (2) (b) A committee of medical staff shall be assigned responsibility for:		Preparation and execution of this plan of correction, does not constitute an admission or agreement of the facts alleged or conclusion set forth on the Statement of Deficiencies. The following constitutes Hanford Community Hospital dba Adventist Health Hanford's credible allegation of compliance. CMS POC ACCEPTABLE YES ☐ NO ☐ Reviewed By: _____ Name Fax _____ Original _____ Facility Notified Name: ADVENTIST HEALTH HANFORD Date: 5/1/19 Time: 1500 Notified By: ISAAC SMITH Name Rev. Spec. Title 22, California code of Regulations, Division 5, Chapter 1, Article 3, Section 70223(b)(2): Surgical Services General Requirements 70223(b)(2)	

Event ID:6B8H11 4/10/2019 11:26:36AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE _____ TITLE Regulatory Specialist (X6) DATE 4/24/19

By signing this document, I am acknowledging receipt of the entire citation packet. Page(s). 1 thru 14

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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	(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 administration and medical staff where such is appropriate. Nursing Service Policies and Procedures 70213 (a) (4) (d) (a) Written policies and procedures for patient care shall be developed, maintained and implemented by the nursing service. (4) (d) Policies and procedures which require consistency and continuity in patient care, incorporating the nursing process and the medical treatment plan, shall be developed and implemented in cooperation with the medical staff. Health and Safety Code 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. Deficiency Constitutes Immediate Jeopardy Based on interview, clinical and administrative document review, Hospital A failed to follow the Operating Room (OR) policy and procedure for, "Sponge, Sharps, and Instrument Counts", when a (Brand Name viscera retainer) (VR-a disposable, oblong, rubbery device used to retain and shield tissue and organs during closure of the abdominal incision) was unintentionally left in the surgical site of Patient (Pt) 1 following a surgical procedure at Hospital A on 12/6/17.		Title 22, California code of Regulations, Division 5, Chapter 1, Article 3, Section 70223(b)(2): Surgical Services General Requirements 70223(b)(2) (continued from prior page) The responsible party for the corrective action is the Director of Surgical Services. Plan of Correction: On January 16, 2018, during a mandatory staff meeting, Surgical Services staff was re-educated on the Instrument Count Corporate Standard Policy titled: Sponges, Sharps and Instrument Counts. This policy provides guidelines for performing sponge, sharps and instrument counts in all surgical procedures. These counts are performed to account for items and to ensure that the patient is not injured as a result of a retained foreign body. In addition, staff was also re-educated on the following items: *New HIGH ALERT label attached to the outside of the (Brand Name viscera retainer) package what notifies staff of special instructions required for handling of such instrument. *Management of additional or contaminated items during a surgical case. *AORN Guidelines for the risk and prevention of Retained Surgical Items (RSI). *Brand Name viscera retractor use *Use of the designated white board in OR rooms to document any additional items opened during a surgical procedure.	

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	This failure caused Pt 1 to return to Hospital A's Emergency Department (ED) for evaluation of drainage and odor coming from the surgical site. Pt 1 was discharged from Hospital A's ED, and then went to Hospital B's ED less than 24 hours later complaining of surgical site opening. Pt 1 chose to then return to Hospital A where she required subsequent hospitalization for a second surgery, 23 days later, on 12/29/17. This caused Pt 1 preventable pain, an additional surgical wound, and emotional distress. The VR was identified as the retained foreign object and was removed during the second surgery. Findings: The "Operative Report", dictated by Surgeon (S) 1, indicated Pt 1 was admitted to Hospital A on 12/6/17, for a Laparoscopic Ventral Herniorrhaphy with mesh (a surgical procedure using small cameras to correct an abdominal hernia by applying a mesh-type material to reinforce the abdominal wall. An abdominal hernia is a weakening of abdominal muscles that causes a bulge and protrusion of underlying organs). The operative report indicated, "Recurrent ventral hernia...much larger than estimated on CT, [computerized tomography (CT) scan combines a series of X-ray images taken from different angles around your body and uses computer processing to create cross-sectional images (slices) of the bones, blood vessels and soft tissues inside your body] containing small bowel noted at laparoscopy, unsuitable for laparoscopic repair. Procedure done open [cutting an incision in the skin] ..."		Title 22, California code of Regulations, Division 5, Chapter 1, Article 3, Section 70223(b)(2): Surgical Services General Requirements 70223(b)(2) (continued from prior page) Any Surgical Services staff that was unable to attend the staff meeting was provided meeting minutes and education pieces via email to ensure 100% of staff received the necessary information. This information was also distributed to all nursing supervision staff. Surgeon re-education occurred during a Surgery Committee meeting of the medical staff. The Corporate Standard Policy: Sponge, Sharps and Instrument Counts was reviewed. The use of a viscera retractor and methods for anchoring the FISH ring when the view is obscured was also discussed. Monitoring and Compliance: A complete retrospective chart audit occurred over a 30 day period, from January 16, 2018 through February 16, 2018. These chart audits consisted of 10 random charts and addressed instrument count verification and proper documentation in the patient medical record, per policy. All 10 random charts were found to be 100% compliant. This date was reported to the Surgery Committee then subsequently reported to the Quality Committee of the medical staff which is part of the Quality Assurance Performance Improvement Plan (QAPI).	

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	The "Intraoperative Report" (A report that tracks events that occur during a surgery-this includes all hospital personnel present and all instruments and materials used during surgery.), dated 12/6/17, indicated all surgical counts (the process of counting any item that may be retained in a patient during a surgical procedure) were correct and, "Patient is free from unintended retained foreign objects." The "Discharge Summary", dictated by Medical Doctor (MD) 1, dated 12/11/17, indicated Pt 1 was discharged home with the abdominal surgical wound having staples and three drains (medical devices used to drain bodily fluids from surgical sites) to the incision, and had been, "Cleared [to go home] by general surgery." An office/clinic note from S 1, dated 12/19/17, indicated Pt 1 was seen by S 1 for a follow-up appointment. The staples and three drains were removed and Pt 1 was told to follow-up with S 1 in a month at the clinic. The "Emergency Department (ED) Physician Notes" from Hospital A, dated 12/25/17 at 11:28 p.m., indicated, Pt 1 was seen by Nurse Practitioner (NP) (a registered nurse who is qualified through advanced training to assume some of the duties and responsibilities formerly assumed only by a physician) 1. NP 1's note indicated, "Pt [1] noted odor to surgical incision yesterday and possible opening of incision today." The "ED Physician Notes" from Hospital A, dated		Title 22, California code of Regulations, Division 5, Chapter 1, Article 3, Section 70223(b)(2): Surgical Services General Requirements 70223(b)(2) (continued from prior page) Over the next 30 days, between January 16, 2018 and February 16, 2018, 10 random surgical cases were observed. The observer notes consisted of verification that all instrument counts were complete and accurate. The observations concluded 100% compliance with surgical instrument counts. This data was reported to the Surgery Committee and then subsequently reported to the Quality Committee of the medical staff which is part of the Quality Assurance Performance Improvement Plan (QAPI).	

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	12/26/17 at 12:26 a.m., indicated Pt 1 was seen by Physician's Assistant (PA) (a person certified to provide basic medical services usually under the supervision of a licensed physician) 1. PA 1's note indicated, "... pt. [1] states her significant other noticed 'white' at wound opening and odor while changing dressing... attempted to contact [S 1] w/out success... started on abx [antibiotics]... no further w/u [workup] or admission [to hospital] anticipated at this time...stable for discharge [home]..." Pt 1 was discharged from Hospital A's ED 12/26/17 at 1:44 a.m. ED records from Hospital B, dated 12/27/17 at 1:42 p.m., indicated, "...Pt [1] presents to the facility with a complaint of incision site opened... says she went to [Hospital A] due to her wound opening, was given abx and sent home... came here [Hospital B] to be evaluated... Patient reports fever and chills last several days..." The "Radiology Report" from Hospital B, dated 12/27/17 at 10:21 p.m., indicated, "... CT abdomen...Intra-abdominal surgical hardware is in the left side of the abdomen..." The ED "Discharge Summary" from Hospital B, dated 12/28/17 at 12:12 a.m., indicated, "...the patient reports having surgery at [Hospital A] on 12/6/17...on the 25th she noticed the incision was opening at the level of the umbilicus [belly button] ... the patient noticed serous discharge from the wound and decided to come to [Hospital B] ...a CT scan showed retained [VR] ... her surgeon was contacted and she will now be transferred to [Hospital A] for			

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	further surgery ..." Pt 1 returned to Hospital A on 12/29/17. The "History and Physical", dated 12/29/17, at 7:19 a.m., dictated by S 1, indicated, "...pt. ended up at [Hospital B] ... On CT possible intra-abdominal Foreign Body noted... possible removal foreign body..." The "Operation/Procedure Report" from Hospital A, dated 12/29/17 at 1:01 p.m., indicated, "...PROCEDURE: Removal intra-abdominal/peritoneal foreign body... PREOPERATIVE DIAGNOSIS: Subcutaneous wound abscess, right side of abdomen... Possible retained foreign body... DESCRIPTION OF PROCEDURE: ...I did encounter what was felt to be a palpable foreign body. This was grasped and it turned out to be the retained foreign body [Brand Name] silastic bowel retractor which had been utilized at the patient's initial surgery... RN was called in to the OR to place a wound VAC (therapeutic device using a negative pressure vacuum dressing to promote wound healing) ..." On 1/19/18 at 12:05 p.m., during an interview with Hospital A's Circulating Registered Nurse (CRN-an OR nurse who assists in managing nursing care of a patient during surgery) 1 stated on 12/6/18 he was the relief circulating RN for the surgery on Pt 1.. CRN 1 stated during the surgical case S 1 requested a (VR). CRN 1 stated he did not know what a (VR) was, (he was a new nurse and this was his first case that involved the use of this device) and the OR tech (an allied health professional working as part of the team delivering surgical care,			

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	assisting the doctor with maintaining surgical field and providing equipment requested by doctor to use during surgery) told him where to find the device in the storage cabinet. CRN 1 stated he was nervous and when he started to pass the (VR) to the sterile table, the device fell on the floor. CRN 1 stated he got a second (VR) from the storage cabinet, and passed it onto the sterile field. CRN 1 stated the first (VR) on the floor was thrown into the kick bucket (trash can for used gauze sponges). CRN 1 stated he did not remember whether he wrote either (VR) on the white board (a dry erase board used in the OR to keep track of any instruments or equipment added during a surgery) or not. CRN 1 stated when the count for the first closure was called for, he saw the (VR) in the kick bucket and thought the count was correct. CRN 1 stated the OR tech agreed with the count, forgetting two (VR) were opened for the case. CRN 1 stated he thought the (VR) was accounted for because it was in the kick bucket. On 1/19/18 at 3:05 p.m., during an interview, OR tech 1 stated she did not recall if S 1 asked "Is the (VR) out?" OR tech 1 stated she counted the instruments and sponges and the count was correct. OR tech 1 stated she did not remember the (Brand Name viscera retainer) being counted and it should have been written on the white board as a reminder, but it was not. On 2/20/18 at 10 a.m., during an interview, after the second surgery to remove the retained foreign body, Pt 1 stated, "My back hurts, my shoulders hurt, I've had the aching since the 29th of December.... It's			

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	hard to get comfortable and I have many sleepless nights." Pt 1 stated, "It's taken a toll, I was working, but I haven't worked since December." Pt 1 stated, "I was used to getting up doing things, now I don't want to go anywhere, I've become depressed. I haven't been able to carry my grandchild since the surgery. I can't bend over to pick her up or anything. I have to call someone to pick up anything, I can't do anything for myself. I feel so useless. I've always been an independent person. I've worked 11 years at [Name of employer]. I am a strong person, but I just want this to be over. I started seeing a wound doctor February 2nd, but she said it will be a few months [until completely healed]. I try to walk around, but I have a lot of pain. I do as much as possible, I'm trying to get back [to normal]." On 4/10/18 at 1:45 p.m., during an interview, Hospital A's OR tech 2 stated he relieved the First Assist PA (FAPA-Physician's Assistant trained to assist surgeon during surgical procedures) during Pt 1's first surgery on 12/6/17. OR tech 2 stated he took over, holding retractors (device used to hold the surgical incision open) and helped S 1 with the suturing (stitches holding the edges of a wound or surgical incision together) by pulling the suture material tight to prevent tangling. OR tech 2 stated he did not remember receiving report from the FAPA that a (VR) was used during the surgery. OR tech 2 stated he does not remember seeing the ring or the tail from the (VR) on the surgical drape outside Pt 1's incision. OR tech 2 stated seeing those things would have alerted him to tell S 1 the (VR) was still in the patient. OR Tech 2 stated it was CRN 1's responsibility to write on the White Board any items			

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	added to the sterile field. OR Tech 2 stated he does not remember seeing a (VR) written on the White Board. On 4/10/18 at 2:07 p.m., during an interview, Hospital A's OR Tech 3 stated on 12/29/17, she was in the OR for Pt 1's second surgery for the removal of a retained foreign body. OR Tech 3 stated she asked S 1, "What are we looking for?", and he replied, "It's the (VR)." OR Tech 3 stated she was holding a retractor after S 1 opened Pt 1's incision in the same place as the previous surgery, and put his hand in Pt 1's abdominal cavity. OR Tech 3 stated S 1 felt around and finally located the (VR) in the upper right side inside Pt 1's abdomen. OR Tech 3 stated Surgeon 1 "wiggled" the (VR) and pulled it out intact. On 4/10/18 at 2:28 p.m., during an interview, Hospital A's FAPA stated she was assisting S 1 during Pt 1's surgery on 12/6/17. The FAPA stated she stayed 2 hours past her shift to assist S 1 and then she asked to leave the surgery. The FAPA stated at the time she left the surgery, Surgeon 1 was getting ready to put in the mesh and all he needed was someone to retract and cut sutures. The FAPA stated, OR Tech 2 came in to relieve her. The FAPA stated all staff in the OR involved in any surgical case are responsible to know what is going on at all times. The FAPA stated communication is very important for patient safety and if a (VR) was going to be used during a surgery, she or S 1 would call out "(VR) in" when inserting the device and "(VR) out" when removing it. The FAPA stated she does not remember if that happened in this case.			

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	On 4/11/18 at 12:40 p.m., during an interview, Hospital A's Director of Perioperative Services (DPOS) stated it was her expectation that all instruments, sponges and disposable devices get counted by the scrub tech and circulating nurse, and documented in the electronic medical record and on the white board by the circulating nurse as they are being used during the surgery. The DPOS stated staff is expected to follow hospital policy and procedure and the Association of peri-Operative Registered Nurses (AORN) guidelines for prevention of a retained foreign body. The DPOS stated staff present in the room during the procedure did not remember if the two (VR) were written on the white board or not. There should have been two, the first one that was dropped and contaminated and the second used for the procedure, and there was not. On 4/11/18 at 1 p.m., during an interview, Hospital A's CRN 3 stated she was in the OR during Pt 1's second surgery on 12/29/17 for the removal of a retained foreign body. CRN 3 stated, "I was shocked, I knew something was left inside her but didn't know it was a (Brand Name viscera retainer). On 4/11/18 at 2:05 p.m., during an interview, Hospital A's S 1 stated on 12/6/17, Patient 1 was the last case of the day and the biggest (most complicated) case. S 1 stated the procedure was set up as a laparoscopic hernia repair but became an open case due to the large hernia. S 1 stated, during the surgery the (Brand Name viscera retainer) was placed over the intestines to prevent suturing the mesh to the bowel, then the mesh was placed on top. S 1 stated, "I know I took my eyes off the			

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	surgical field a couple of times because I moved around the table to do suturing of the fascia [a band of tissue below the skin that covers and encloses muscle and other tissues) starting from the top of the incision to midway and then the bottom of the incision to midway. I do this in a lot of my general surgery cases with big incisions." S 1 stated, "I know I asked for a count as I was closing and someone said correct, so I proceeded to close." S 1 stated he did not recall putting the (Brand Name viscera retainer) in, or pulling it out. S 1 stated, "If the [Brand Name viscera retainer] goes in, the [FAPA] or myself will call it going in, or coming out and I don't remember, I think the [FAPA] may have put it in." S 1 stated, "I realize as the surgeon I am responsible for what happens in the room, but I depend on my staff to keep track of the counts and disposable items, like the [Brand Name viscera retainer]. We all need to agree on the count before closing and verify it." S 1 stated he received a call from Hospital B and was told Pt 1 was there on 12/27/17 with a wound infection which caused pain, odor and drainage from the incisional site and the CT scan showed a retained foreign body in Pt 1's abdomen. S 1 stated, "On 12/29/17, I opened [Pt 1] up and removed the (Brand Name viscera retainer) intact." S 1 stated Pt 1 was discharged home on 1/4/18 with a wound vac, and with orders to be followed by home health. Hospital A's policy titled "SPONGE, SHARPS, AND INSTRUMENT COUNTS" dated 7/25/17, indicated "A. General Considerations: 1. Sponge, needle and miscellaneous item counts must be performed in any circumstance where these items are opened			

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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED 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
	for a procedure ... 6. Sharps and miscellaneous items which have the potential for being retained in a surgical wound should be counted on all procedures ... 13. The OR team may be more vulnerable to distraction in certain instances. Heightened awareness (situational awareness) will be emphasized in situations where the risk of retained items is greater due to the nature of the procedure, i.e., ... patient obesity, multiple surgical teams, shift changes, staff member inexperience. B. Frequency of Sponge and Sharps Counts 1. Sharps (including miscellaneous items) and sponge counts are performed at the following times: ... e. When either the scrub person or circulating nurse is relieved permanently, a count is taken by the relieving person ...D. Procedure for Sponge, Sharps and Instrument Counts ... 3. All sponges, sharps and instruments added to the operative field during surgery ... are counted together and out loud and recorded immediately by the circulating nurse ... 13. The circulating nurse is responsible for: a. recording the count on the count worksheet or on the grease board [white board]. b. Recording the result of the final counts on the Intraoperative record. c. Informing the surgeon and team of the count results ..." The AORN Guideline Essentials titled, "Retained Surgical Items, Guideline at a Glance" dated 2016 indicated, "RN Circulator ... Accurately accounting for items used during a surgical procedure is a primary responsibility of the RN circulator. The RN circulator plays a leading role in implementing measures to account for surgical items ... Scrub Person [OR tech] ... Accurately accounting for			

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DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050121	A. BUILDING _____ B. WING _____	04/09/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Adventist Health Hanford	115 Mall Dr, Hanford, CA 93230-5786 KINGS COUNTY

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	items used during a surgical procedure is a primary responsibility of the scrub person. Maintaining an organized sterile field facilitates accounting for all items during and after the procedure. Standardized sterile setups established by the health care organization's policy reduction variation may lessen the risk of error ... Timing of the Count ... Counts occur at specified times to ensure surgical items are accounted for before the next stage of the surgical procedure, such as before closing of a cavity within a cavity or the skin closure ..." The AORN Guideline Essentials titled, "Retained Surgical Items, Key Takeaways" dated 2016, indicated "All perioperative team members are responsible for the prevention of retained surgical items ... Distractions, noise and interruptions should be minimized during the surgical count ... A systems approach to performance improvement should be used for prevention of retained surgical items ..." The hospital failed to follow their policy and procedure for Operating Room (OR) policy and procedure for "Sponge, Sharps, and Instrument Counts" during a surgical procedure on 12/6/17. This failure directly led to a (Brand Name viscera retainer) being retained in Patient 1 for 23 days. The retained (Brand Name viscera retainer) directly lead to an additional surgical procedure on 12/29/17 to remove the (Brand Name viscera retainer) and additional hospitalization for antibiotic therapy and placement of a wound vac. The hospital's failure resulted in preventable pain, injury and harm. The failure to follow the hospital's policy and procedure			

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Adventist Health Hanford	115 Mall Dr, Hanford, CA 93230-5788 KINGS COUNTY

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	for, "Sponge, Sharps, and Instrument Counts" directly led to the licensee's noncompliance with one or more requirements for licensure. The hospital failed to prevent the deficiencies as described above which caused, or was 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). 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 1280.3(g).			