CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES ANO PLAN OF CORRECTION	(XI) PROVIDER/SUPPUERCUA DENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	()(3)DATE SURVEY COMPLETED
	050537	A. BUILDING _____ B. WING _____	08/05/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS. CITY, STATE, ZIP CODE
Sutter Davis Hospital	2000 Sutter Place, Davis, CA 95616-6201 YOLO COUNTY

acaptable POC 9/14/16

(X4) 1D PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST SE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	D PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS. REFERENCEDTO THEAPPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE

The following reflects the findings of the Department of Public Health during an inspection visit:

Complaint htake Number:
CA00324171 - Substantiated

Representing the Department of Public Health:
Surveyor ID# 29821, HFEN

Their 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.

The hospital detected Adverse Event on 01.10.2012.
The hospital reported Adverse Event to Department on 8.31.2012.
The hospital notified Patient of Adverse Event - no documentation.

Health and Safety Code 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.

Adverse Event Notification - Not Informed

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE Jennifer Maher TITLE CEO, Sutter Davis Hospital (X6) DATE

By signing this document, I am acknowledging receipt of the entire dation packet. Page(s) 1 thru 13

M 9/7/16

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 dsclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findngs 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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	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 failed to inform the patient or the party responsible for the patient of the adverse event by the time the report was made Health and 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 2 hours after the adverse event has been detected. Disclosure of individually identifiable patient information shall be consistent with applicable law. The Department verified the facility failed to report the adverse event to the Department within the mandated time frame. Health and Safety Code Section 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.	1279.1 (c)	Health and Safety Code Section 1279.1 (c) Finding Number 1A: Inform the Patient Finding Number 1A, Responsible Parties: Chief Medical Officer, Chief of Staff, Chief of Surgery, Chief Nurse Executive, Chief Executive Officer, Perioperative Nursing managers Finding Number 1A, Action Plan: Original Action plan was developed and carried out in the summer of 2014 that included OR staff and Surgeon education on Disclosure as well as revision of this particular policy. At this current time, to ensure compliance to the above action plan it was decided to redeploy the action plan due to the passage of time, turnover in personnel and the updating of policies during the normal course of business. Redeployment of Education to Physicians consisting of Read & Sign acknowledgements to all regular staff surgeons of the following polices: "Disclosure of Unanticipated Outcome Information 70-7." All physicians not present (on leave, or on-call) will complete/read/sign within 24hrs of return. Redeployment of Education to OR Nursing and OR support staff, consisting of Read & Sign acknowledgement of the following polices: "Disclosure of Unanticipated Outcome Information 70-7." All staff not present (on leave, or on-call) will complete/read/sign within 24hrs of return to work. Ongoing Culture of Safety Survey Metric: "Willingness to Report" included in September 6-26, 2016 iteration of survey. With this metric we can assess current state of attitudes about disclosure for any improvement projects in this area. Monitoring: 1. If an adverse event occurs, or reportable event occurs, Quality/Risk Management, in coordination with the Perioperative Service Director/management will review record for	8/22/16 8/22/16 Sept 2016 August 2016 through August 2017

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	Health and Safety Code 1280.4 If a licensee of a health facility licensed under subdivision (a), (b), or (f) of Section 1250 fails to report an adverse event pursuant to Section 1279.1, the department may assess the licensee a civil penalty in an amount not to exceed one hundred dollars ($100) for each day that the adverse event is not reported following the initial five-day period or 24-hour period, as applicable, pursuant to subdivision (a) of Section 1279.1. If the licensee disputes a determination by the department regarding alleged failure to report an adverse event, the licensee may, within 10 days, request a hearing pursuant to Section 100171. Penalties shall be paid when appeals pursuant to those provisions have been exhausted. T22 DIV5 CH1 ART3 70213 Nursing Services Policies and Procedure (a) Written policies and procedures for patient care shall be developed, maintained and implemented by the nursing service. These requirements were not met as evidenced by: Based on staff and family interview, medical record and facility document review, General Acute Care Hospital (GACH) 1 failed to: 1. Follow its policy when a patient safety issue, the post-surgical retention of a foreign object (RFO) by Patient 1, was not communicated to Operating Room management, Quality/Risk, or hospital Administration leaders, 2. Show evidence that the retention was disclosed	1279.1 (a), (b), (c or (f) of section 1250	(Continued) clear documentation from physician and/or nursing of event and disclosures made to the patient/family/care provider. This will be monitored for a period of one year (August 2016-August 2017). 2. Patient Safety Reports (PSRs) are monitored continuously through the Sutter Davis patient safety process. PSRs are sent to Administration, Directors, & Managers on a daily and weekly bases, and reviewed/discussed with managers every week during safety huddles (with Quality and the Administration team present). The PSR quarterly report is shared quarterly during the Quality Patient Safety Committee (QPSC) and minutes sent to the Medical Executive Committee monthly for review. Health and Safety Code Section 1279.1 (a), (b), (c) or (f) Finding Number 1B: Reporting: Finding Number 1B, Responsible Parties: Chief Medical Officer, Chief of Staff, Chief of Surgery, Chief Nurse Executive, Chief Executive Officer, Perioperative Nursing managers Finding Number 1B, Action Plan: Original Action plan was developed and carried out in the summer of 2014 that included OR staff and Surgeon education on Reporting Adverse Events as well as revising this policy for any deficiencies. At this current time, to ensure compliance to the above action plan it was decided to redeploy the action plan due to the passage of time, turnover in personnel and the updating of policies during the normal course of business. Redeployment of Education to Physicians consisting of Read & Sign acknowledgements to all regular staff surgeons of the following policy: "High Risk Events and Unusual Occurrences Management and Reporting to Governmental Agencies 70-4." All physicians not present will complete read/sign within 24hrs of return.	Ongoing 8/24/16

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	to Patient 1 or her responsible party, and 3. Report the adverse event to the Department no later than five days after discovery. These failures precluded the Quality/Risk Management and Administration departments from knowledge of the adverse event. If Operating Room management, Quality/Risk representatives or hospital Administration had been apprised that a central venous catheter segment (piece of small tubing threaded into a large chest vein for delivery of medications and fluids) attached to a Port-a-cath (bloodstream venous access device for medication and IV solutions, usually implanted in the upper chest) had broken away during Patient 1's surgery, needed clinical resources could have been mobilized to remove the RFO in timely fashion. Instead, the RFO, later determined to be a catheter piece measuring 6.3 inches, was left inside Patient 1 with no post-operative attempt made to extract it. Patient 1 subsequently developed a blood clot in her lung; physicians determined the retained catheter piece was the likely cause of the clot. Surgical intervention was needed to remove the tubing piece. The failure of the staff and physician to follow hospital policies and procedure to report the retained foreign object to hospital leadership (which resulted in the patient developing a life threatening complication [pulmonary embolus, a blood clot which has traveled to the lungs]) and additional surgery to remove the retained foreign object is a deficiency that has caused or is likely to cause	1279.1 (a), (b), (c) or (f) of sectior 1250 Cont'd T22 DIV 5 CH1 ART3 70213	Redeployment of Education to OR Nursing and OR support staff, consisting of Read & Sign acknowledgement to all regular staff & support staff of the following policy: "High Risk Events and Unusual Occurrences Management and Reporting to Governmental Agencies 70-4". All staff not present (on leave, or on-call) will complete/read/sign within 24hrs of return. Ongoing Culture of Safety Survey Metric: "Willingness to Report" included in September 6-26 2016 iteration of survey. With this metric we can assess current state of attitudes about disclosure for any improvement projects in this area. Monitoring: 1. If an adverse event occurs, or reportable event occurs, Quality/Risk Management, in coordination with the Perioperative Service Director/management will review record for clear documentation from physician and/or nursing of event and disclosures made to the patient/family/care provider of the patient. Perioperative Management will also ensure event reported to Administration & Quality Management and a Patient Safety Report (PSR) completed & submitted to Risk management. This will be monitored for a period of one year (August 2016-August 2017). 2. Patient Safety Reports (PSRs) are monitored continuously through the Sutter Davis patient safety process. PSRs are sent to Administration, Directors, & Managers daily and weekly bases, and reviewed/discussed with managers every week during safety huddles (with Quality and the Administration team present). The PSR quarterly report is shared quarterly during the Quality Patient Safety Committee (QPSC) and minutes sent to the Medical Executive Committee monthly.	8/25/16 Sept 2016 August 2016 through August 2017 Ongoing

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	serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code section 1280.1. These failures also kept pertinent healthcare information from Patient 1 and potentially prevented her from making informed healthcare decisions related to the avoidable RFO. In addition, these failures precluded leadership from timely compliance with regulatory reporting requirements. Findings: 1. Patient 1 was admitted to GACH 1 in January 9, 2012 for intravenous (IV, through a vein) antibiotic administration and wound care. While hospitalized, a surgery to replace a nonfunctional Port-a-Cath was scheduled. During the procedure on 1/10/2012, the surgeon cut the IV tubing attached to the old device, lost hold of the end portion of the tubing in Patient 1's bloodstream and was unable to retrieve it. The surgeon's immediate post-operative note I listed as a complication, "Portion portacath displaced to right ventricle (a heart chamber)." The surgeon's formal dictated operative note read, "The tubing was found and was brought out into the wound...it was grasped...and cut across... It was realized that hemostat [a surgical tool] holding the subclavian [a large vessel in the chest] portion was not holding it and attempts to find this [missing piece of tubing] were unsuccessful. It looked on x-ray that it had displaced into the superior vena cava (large vein which carries blood to the right side of the heart) or		(Continued) T22 DIV 5 CH1 ART3 70213 Nursing Services Policies and Procedure Finding Number 2, Responsible Parties: Chief Medical Officer, Chief of Staff, Chief of Surgery, Chief Nurse Executive, Chief Executive Officer, Perioperative Nursing managers Finding Number 2, Action Plan: Original Action plan was developed and carried out in the summer of 2014 that included OR staff and Surgeon education on Reporting Adverse Events as well as Nursing/Or staff education on revised OR Count and Patient Safety Record Policy. At this current time, to ensure compliance to the above action plan, it was decided to redeploy the action plan due to; the passage of time, turnover in personnel and the updating of policies during the normal course of business. Redeployment of Education to OR Nursing and OR support staff, consisting of Read & Sign acknowledgements to all regular staff & support staff of the following policy: "Patient Safety Record (PSR)-70-6". All staff not present (on leave, or on-call) will complete/read/sign within 24hrs of return. Redeployment of Education to OR Nursing and OR support staff, consisting of Read & Sign acknowledgements to all regular staff and support staff of the following policies: "Count Policy" and "Surgical Count" & addendum A for Bar Code Assisted Technology". All staff not present (on leave, or on-call) will complete/read/sign within 24hrs of return. Ongoing Culture of Safety Survey Metric: "Willingness to Report" included in September 6-26, 2016 iteration of survey. With this metric we can assess current state of attitudes about disclosure for any improvement projects in this	8/25/16 8/25/16 Sept 2016

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	proximal (situated nearer to the center of the body) subclavian..." No further attempts were made to retrieve the IV tubing segment and the event was not referenced in any other part of the medical record. Patient 1 was sent to a nursing home the following day. Patient 1 was admitted to GACH 2 in August 26, 2012 for acute respiratory failure, altered mental status, and chronic lower extremity sores. Review of her medical record indicated imaging studies were done and a pulmonary embolus (PE, blood clot in the lung) was discovered. On 8/28/12, Patient 1's consulting lung specialist wrote, "It appears that the clot may be associated with a retained foreign body as there is evidence that the tip of the catheter is touching the clot. This could be the cause of the PE." The lung specialist contacted Patient 1's primary care physician (PCP) "who was not aware of a foreign body." That day the PCP sent office records to the specialist for review, including a copy of the surgeon's January, 2012 operative note. On 8/31/2012, three days after the RFO was seen on imaging, Patient 1 required transfer to GACH 3 in a nearby city for removal of the catheter piece, which measured 6.3 inches in length. Review of medical literature reflected the serious nature of central venous catheter fragment retention. In an article entitled "Transcatheter Retrieval of Dislodged Port-A-Catheter Fragments: Experience with 47 Cases" [Acta Cardiologica		(Continued) Monitoring: 1. Audits will be conducted of surgical counts (20% of the total amount of surgical procedures per month) to ensure counts are being performed correctly, based on the Sutter Davis hospital policy and procedure called "Count Policy" (effective through 9/30/17). Audits will be a combination of retroactive audits and concurrent audits (July – Oct 2016). J.M. Responsible Parties: Peri-operative management (Nursing). 2. Patient Safety Reports (PSRs) are monitored continuously through the Sutter Davis patient safety process. PSRs are sent to Administration, Directors, & Managers daily and weekly bases, and reviewed/discussed with managers every week during safety huddles (with Quality and the Administration team present). The PSR quarterly report is shared quarterly during the Quality Patient Safety Committee (QPSC) and minutes sent to the Medical Executive Committee monthly.	July-Oct 2016 Ongoing

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Sinica, 2006;Volume 22:221-8], cardiologist authors stated, "...Dislodged broken catheter...can be fatal if the dislodged fragment migrates into the heart...Therefore, the dislodged catheter should be removed as soon as possible...Transcatheter removal (removal using a snare or other device attached to another catheter, which is inserted into the bloodstream] of a dislodged catheter is generally safe... Most of these procedures can be carried out under local anesthesia [numbing the retrieval catheter insertion site] and are well tolerated..."

Physician authors of an article entitled "Endovascular [inside a blood vessel] Foreign Body Retrieval" (Journal of Vascular Surgery, 2007;Volume 57, Number 2; 459-463] wrote, "The dangers of intravascular [within a blood vessel or the blood vessel system] foreign bodies (IVFB) were formally recognized by the Federal Drug Administration (FDA) in a 2008 public health notification. The purpose of the notification as stated was to advise health care providers of serious adverse events associated with unretrieved device fragments...The potential for embolization [clot or other plug such as a catheter fragment caried by the blood from a larger vessel into a smaller one, obstructing circulation] of an IVFB to the heart and pulmonary arteries is a danger that should be a major concern...Mortality of untreated embolization approached 60% due to cardiopulmonary [heart and lung] complications...When an intravascular foreign body is identified, endovascular retrieval should be attempted due to its high success rate and minimal

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morbidity and mortality."

2012 Association of periOperative Registered Nurses (AORN) Standards and Recommended Practices indicated, "Prevention of Retained Surgical Items Recommendation V: Measures should be taken to identify and reduce the risks associated with unretrieved device fragments...Serious adverse events have been associated with unretrieved device fragments. The FDA [federal Food and Drug Administration] defines an unretrieved device fragment as 'a fragment of a medical device that has separated unintentionally and remains in the patient after a procedure.' "

During a 3:17 p.m.,7/16/14 interview, the Operating Room Technician (ORT) assisting the surgeon recalled, 'The tip broke off as we were trying to pull it out;" she recalled seeing it on x-ray in the room. She "vaguely" remembered talking with the circulating Registered Nurse (RN 1) about the event, including a discussion about documentation.

In a 10:47 a.m., 7/15/14 interview, GACH 1's Quality Management Executive (QME) recalled the incident. She indicated that surgery staff was aware a piece of IV tubing had remained inside Patient 1 after the procedure. The QME stated the incident "never got reported to Administration or Quality at the time (January 2012)."

In a 3:05 p.m., 7/15/14 interview, the QME stated that a member of the 1/10/12 surgical team should have completed a report of the event. In a concurrent interview, the Surgical Services Nurse

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Manager (SSNM) stated that if the RN circulating in the operating room became aware that a foreign object had been retained during surgery, the RN should complete an incident report and report the issue to leadership.

Review of the undated "Surgical Count Policy" (last revised 8/11) read, "Intentionally Retained Items:...Complete Patient Safety Report...."

Review of the facility's 10/09 "Quality Assessment Record [OAR]" pol cy indicated, "Types of Incidents to Record:...Patient Events - Documentation of all patient-related occurrences that are in any way unusual in nature. Something that happened to/with a patient that should not have...all high-risk events as outlined below. High-Risk Events...Injuries - e.g...foreign body retention...When an event occurs, personnel witnessing the event will access the online OAR form...and complete all required fields that pertain to the event...IMPORTANT: If the event is a high risk event...the individual completing the OAR must immediately notify the Nursing Supervisor...."

The GACH's 6/10 "Sentinel Event Policy" read, "Sentinel Event Definitions:...Unintended retention of a foreign object in a patient after surgery or other procedure...The Administrator-on-call and Quality Improvement Manager should be called immediately...."

The GACH's investigation concluded that "policy was not followed" and "no event notification was submitted."

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1. Review of Patient 1's medical record from her January 9, 2012 hospitalization reflected no documentation affirming that disclosure of the RFO had been made to Patient 1 or to her responsible party by the surgeon or a hospital representative.

Physician notes reflected that at the time of the GACH 2 lung specialist's discovery of the RFO in August, 2012, he was unable to discuss the RFO's presence with Patient 1 as she was sedated and on a continuous breathing machine. The specialist wrote that he instead spoke with Patient 1's two sons. Yet in interviews discussed below the two sons stated they were unaware of the presence of the RFO.

The QME recalled the event during a 10:47 a.m., 7/15/14 interview. She indicated notification of disclosure was expected to be recorded in the medical record but was not evident in Patient 1's chart. She stated that while there was no written documentation that the presence of a RFO was disclosed to the patient or her responsible party, the surgeon "was adamant" during their investigation that he had made disclosure about the incident. When asked to produce evidence of a comprehensive investigation of the incident, the QME revealed the file containing details of the investigation could not be located.

In a 3:56 p.m.. 7/16/14 interview, the surgeon Medical Doctor 1 (MD 1) recalled making the disclosure the day of the procedure but could not remember whether he spoke with the patient or a

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family member.

In a 10:15 a.m., 7/30/14 interview. Patient 1 was unable to verify that the RFO incident had been disclosed to her in January, 2012.

Two family members, one a designated contact on her January 9, 2012 medical record demographics form, were also asked to verify that disclosure had taken place. In a 10:15 a.m., 7/29/14 interview, Family Member 1(FM 1) stated, "I'm pretty sure no one told (Patient 1]." In addition, she didn't think other family members knew at the time of the incident either; FM 1 only became aware of the RFO when she was advised of its presence in August, 2012.

In a 7:06 a.m., 7/30/14 interview. FM 2 also was unable to verify Patient 1's knowledge of the RFO in January, 2012. FM 2 felt that Patient 1didn't know at the time of occurrence because "she never spoke about it. I think that's something she would have talked to us about." FM 2 added, "No one [physician or hospital representative] talked to us [family members]" at the time of the event. When she learned of the RFO in August, 2012, "that was news to us [family members].We had no idea."

2012 AORN Standards and Recommended Practices read, "V.a.In the event that an unretrieved device fragment is left in the surgical wound...the surgeon should inform the patient of the nature of the item and the risks associated with leaving it in the wound...Health care professionals are encouraged to maintain public confidence by

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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

communicating with patients regarding their treatment and outcomes. Organizations are held accountable for informing patients of their rights when they enter the health care system. V.a. 1. Information provided to the patient should include...material composition of the fragment (if known); size of the fragment (if known); location of the fragment; potential mechanisms for injury (eg, migration [travel to another body part],infection); procedures or treatments that should be avoided...which may help reduce the possibility of a serious injury from the fragment: and risks and benefits of retrieving the fragment as opposed to leaving it in the wound...."

Review of the 5/08 facility policy "Disclosure of Unanticipated Outcome Information "indicated, "It is the policy of [the GACH] to provide our patients with outcome or results information so that knowledgeable decisions may be made regarding future treatment...Examples of 'Unanticipated Outcomes' ...5. A 'never event' as defined by the California Department of Public Health [Health and Safety Code 1279.1,Adverse Events - (b)(1)(D) Retention of a foreign objection a patient after surgery or other procedure)...3. Disclosure must be timely. 'Timely' can indicate a spectrum from 'immediately' to as soon as appropriate support can be obtained for the patient...5. The healthcare professional/physician who informed the patient should document in the medical record that the discussion took place with the patient, or with the patient's representative...with the date, time, and signature, AND 6. The patient's physician should also document in the medical record the plan of

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050537	A. BUILDING _____ B. WING _____	08/05/2016

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	care upon the patient's knowledge and consent..." The GACH's investigation concluded that "policy was not followed." 3. CDPH received a report from GACH 1 on 8/31/12 stating that a foreign object, a section of intravenous tubing from a Port-a-cath, had been retained by Patient 1 after removal and replacement surgery on 1/10/12. In a 10:47 a.m., 7/15/14 interview, the QME confirmed that members of the surgical team were aware of the event at the time it occurred on 1/10/12. She stated that neither the Quality/Risk Management Department nor GACH Administration was apprised of the event until 8/30/12 when the Quality/Risk representative from GACH 2, where Patient 1 was hospitalized, sent notification. The QME acknowledged that GACH 1's adverse event report was made to CDPH on 8/31/14, which was 228 days after the required report within five days of detection. 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).			