

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050599	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  08/30/2012
--	--	--	--

NAME OF PROVIDER OR SUPPLIER  UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER	STREET ADDRESS, CITY, STATE, ZIP CODE 2315 Stockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO 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: CA00319646 - Substantiated</p> <p>Representing the Department of Public Health: Surveyor ID # 27966, 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>1279.1 Health and Safety Code Section (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.</p> <p>1279.1 Adverse Event or Series of Adverse Events (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>70223 Surgical Services General Requirement (b) A committee of the medical staff shall be</p>		<p>UC Davis Medical Center (UCDMC) respectfully submits its Plan of Correction (POC) in response to the Statement of Deficiencies (2567) received on May 23, 2013. This POC constitutes a summary of UCDMC's compliance with the cited regulations. The submission of this POC is not an admission, direct or implied, of any of the allegations or conclusions set forth in the 2567.</p> <p>This plan of correction describes the policies that were created or revised in order to ensure compliance with regulations, accreditation standards, and accepted medical practice. The plan of correction also describes the actions taken to educate staff about the policies and procedures and monitor compliance.</p> <p>UCDMC disputes that the conduct of the three cases constitutes an immediate jeopardy as defined by the California Health and Safety Code, § 1280.1(c): <i>immediate jeopardy means a situation in which the licensee's noncompliance with one or more requirements of licensure caused, or was likely to cause, serious injury or death to the patient.</i> CDPH is correct that some policies were not followed, but those policy violations did not cause, nor were they likely to cause, serious injury or death to any UCDMC patients. Thus, a situation meeting the definition of "immediate jeopardy" did not exist at UCDMC for the following reasons:</p> <p>1. <u>Policy violations did not result in "immediate jeopardy" for UCDMC patients.</u> The three cases that were the focus of the CMS survey in August 2012 constituted the provision of</p>	<p>POC ACCEPTED PL-000009 6/12/13</p>
--	--	--	---	---------------------------------------

3:38:45PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: J. Douglas Kirk, M.D., Assoc. Chief Medical Officer TITLE: Assoc. Chief Medical Officer (X6) DATE: 6/12/13

By signing this document, I am acknowledging receipt of the entire citation packet. Page(s) 1 thru 20

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.

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>050599</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  <b>08/30/2012</b>
NAME OF PROVIDER OR SUPPLIER  <b>UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER</b>		STREET ADDRESS, CITY, STATE, ZIP CODE <b>2315 Stockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO COUNTY</b>		
(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>assigned responsibility for:</p> <p>(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.</p> <p>Based on observation, staff interview and record review, the hospital failed to ensure policies, and therefore processes, governing surgical care were designed, implemented and monitored to ensure the achievement and maintenance of high standards of medical practice and patient care for Patients 1, 2, and 3 as evidenced by:</p> <ol style="list-style-type: none"> <li>1. The failure to implement a process to verify medical staff compliance with safety practices for research activities, including experimental, compassionate and innovative treatments performed on hospital patients, and</li> <li>2. The failure to ensure physicians and nurses were fully educated on the requirements for the approval, scheduling, procurement, processing, labeling, storage, use and disposal of a non-approved biologic (a preparation prepared by a biological process); and</li> <li>3. The failure to provide pre-operative, intra-operative and post-operative surgical care in accordance with hospital policies and acceptable standards of practice, including those of the nationally recognized Association of periOperative Registered</li> </ol>		<p>innovative care to patients with grim prognoses following the diagnosis of glioblastoma multiforme, an aggressive form of brain cancer. The purpose of the care that was provided to these patients was to give them an infection that would trigger an immune response. Properly labeling syringes or educating the OR staff about their roles in handling the biologic should have been done, but the fact that those things were not done is not the reason that the patients developed infections. The infections were the intended outcome of the innovative care. Each of the glioblastoma patients who received the innovative care gave their informed consent to have the procedures. The patients as well as their families understood that the circumstances were extremely dire; that this was not standard care; that the care had not been approved by the FDA or any other state or federal agency; that the procedure involved deliberately infecting the patient's brain in order to trigger a localized and potentially beneficial immune response to attack the deadly form of brain cancer and was essentially untested; and that the potential outcomes were uncertain. The consent process for each case was extensive and detailed. The consent forms, which were signed by each patient and at least one other family member, described the proposed treatment ("implant live gram negative bacteria into the tumor bed and in the bone flap"), and stated there was no proof that the treatment might be beneficial, and that the innovative treatment might be ineffective or even harmful.</p> <p>2. <u>Sixteen months before the August 2012 CMS complaint validation survey, a peer review</u></p>	

Event ID:1K5X11

5/20/2013

3:30:27PM

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>050599</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  <b>08/30/2012</b>
NAME OF PROVIDER OR SUPPLIER  <b>UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>2315 Stockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO COUNTY</b>		
(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>Nurses (AORN), for safety, and</p> <p>4. The failure to conduct a comprehensive investigation, including a root cause analysis, of three related incidents within a six month period that met the hospital's written criteria for adverse and sentinel events (untoward medical occurrences that result in actual or potential harm to patients).</p> <p>The failure to recognize violations of hospital policies and nationally recognized safety standards in the care of Patient 1, who suffered actual harm, resulted in repeated non-compliance which caused actual and potential harm to Patients 2 and 3.</p> <p>Findings:</p> <p>During the period from [REDACTED] 10 to [REDACTED] 11, two neurosurgeons (MD 1, MD 2) performed surgery on three patients (Patients 1, 2, 3) with end stage glioblastoma multiforme (a quickly growing cancerous brain tumor). In addition to the complete or partial removal of the tumors, Patients 1, 2, and 3 underwent implantation of live Enterobacter aerogenes bacteria (a bacteria commonly found in the gastrointestinal tract and defined by hospital policies as a biologic) into the brain and surrounding bone tissue with the intent to create a wound infection that would attack tumor cells. The bacterial agent used had never been tested on humans and both the Institutional Review Board (IRB-an internal university committee that oversaw the protection of human participants in research) and the Food and Drug Administration (FDA-a government consumer protection agency) had not</p>		<p><u>investigation was conducted that prevented further cases from occurring. If an immediate jeopardy situation existed at UCDMC, it was remedied long before the CMS survey and more than two years before the CDPH 2567 was received in May 2013.</u> The neurosurgeons who performed these three cases were given permission to perform the first case by the Chief Medical Officer. There is disagreement among the involved parties whether permission was given to perform the second case, and agreement that permission was not sought from the Chief Medical Officer or Institutional Review Board for the third case. In [REDACTED] 2011, when it was discovered that the third case occurred and no IRB approval had been secured, the UCDMC Medical Staff immediately issued a cease and desist notice to the physicians involved, conducted a peer review investigation, and took appropriate corrective action. No further cases were performed.</p> <p><u>3. To protect patients who are candidates for compassionate or innovative care, creation of an "Innovative Care" policy was initiated in May 2011 to provide a process to address care that is not standard care, but does not fall under the purview of the IRB.</u> At the time that these three cases occurred, UCDMC did not have a policy and procedure in place that formalized the processes surrounding the performance of innovative care. The care provided to these patients involved the implantation of an infectious biologic at the</p>		

Event ID: 1K5X11

5/20/2013

3:30:27PM

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050599	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  08/30/2012
NAME OF PROVIDER OR SUPPLIER  UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 2315 Stockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO 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>formally approved its use in the treatment of human diseases.</p> <p>MD 1 and MD 2 did not inform the Investigational Pharmacy of their plans to use the unapproved biologic and did not seek direction on the pre- or post-operative pharmacologic management of Patients 1, 2, and 3.</p> <p>MD 1 and MD 2 did not inform the physician Director of Peri-operative Services (DPS) or the Operating Room (OR) Manager of their plan to use the experimental biologic and the biologic agent was taken into the OR without proper labeling or instructions for use, handling or disposal.</p> <p>MD 1 and MD 2 had not prepared a post-operative plan for care, which substantially deviated from expected post-operative standards, and did not seek appropriate and timely consults from infectious disease specialists for the management of the intentionally induced infections either before or after the infections developed.</p> <p>The Manager of Medical Staff Administration (AM 1), in an Entrance Conference on 8/27/12 at 8:45 a.m., stated there had been no internal investigation of hospital systems and processes following the surgeries of Patient's 1, 2, and 3. The AM 1 stated medical staff leadership had determined this was a "communications" problem with the involved physicians and had been addressed in Peer Review (a process by which a committee of physicians examines the work of a peer). AM 1 stated medical staff leadership had</p>		<p>surgical site intended to trigger an immune response that would effectively fight the cancer. The fact that the care being provided was innovative but not part of an IRB approved study set it apart from the standard care or clinical research cases that are provided in almost all surgical cases at UCDMC. The deviations from practice that were an inherent part of the innovative care, e.g., implantation of bacteria to cause an infection, as well as withholding of antibiotics to allow the infection to create an immune response, was not within the scope of UCDMC's then-existing policies and procedures governing standard care and human subjects research.</p> <p>Therefore, as a central part of its plan of correction, first submitted in response to the CMS survey in August 2012, UCDMC established new policies and procedures, and revised existing policies, to prevent similar unusual occurrences in the future. The cornerstone of the plan of correction is UCDMC policy 2516, <i>Innovative Care</i>, that defines innovative care, describes the process for getting approval for innovative care, educating staff about the care, and reviewing the process to assure compliance. The innovative care application and Frequently Asked Questions are attached to the policy.</p>		

Event ID: 1K5X11

5/20/2013

3:30:27PM

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050599	(X2) MULTIPLE CONSTRUCTION: A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  08/30/2012
NAME OF PROVIDER OR SUPPLIER  UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 2315 Stockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO 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>determined there were no patient care or safety issues identified.</p> <p>In an interview with the Acting Manager for Quality and Safety (AMQS) on 8/29/12 at 10 a.m., she stated her first knowledge of the three surgical events was when she read it in the newspaper on 7/22/12. The AMQS stated there had been no incident report (a report by a staff member of an unusual occurrence) filed in the cases of Patient 1, 2, and 3. The AMQS stated she reviewed all hospital committee meeting minutes and did not find any discussion of the three surgical cases. She revealed, "I was made aware" Peer Review was being conducted and was not asked to conduct any further investigation as "nothing bubbled up regarding patient care or safety."</p> <p>The Chief Patient Care Services Officer (CPCSO - responsible for nursing services throughout the hospital), in an interview on 8/30/12 at 10 a.m., stated at present she had no knowledge of Patients 1, 2, or 3 other than what she had read in the newspaper. The CPCSO firmly stated, "This is not a quality of care issue" and "It is clear to me it is a research, medical staff issue." The CPCSO stated the events had been reported to the FDA and no nursing action was required. Again, the CPSCO repeated "we only conduct investigations if something is wrong and there was nothing wrong." Continuing on, she further stated "This was an innovative issue brought in by the physicians and nurses are only responsible for [ensuring the patient has] an informed consent. Only Peer Review was necessary." The CPCSO stated it was</p>				

Event ID:1K5X11

5/20/2013

3:30:27PM

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050599	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  08/30/2012	
NAME OF PROVIDER OR SUPPLIER  UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER		STREET ADDRESS, CITY, STATE, ZIP CODE 2315 Stockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO 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>not her expectation for the nurses to question the procedures performed as nurses are not "whistleblowers." The CPSCO stated she felt strongly these were not a sentinel or adverse events and incident reports did not need to be filed. The CPCSO, however, did acknowledge these events should have been discussed with the monthly meeting of the Quality Committee.</p> <p>The current Chief of Neurosurgery (MD 3), in an interview on 8/27/12 at 3 p.m. stated there had been no departmental review of Patient 1, 2, or 3's surgical events. MD 3 acknowledged there was no mechanism to capture activities which were not addressed in research protocols unless reported and "staff must report if they see something."</p> <p>In an interview with the Governing Body (GB - the Dean of the School of Medicine who was also the Vice Chancellor for Human Health Services) on 8/29/12 at 2 p.m., the GB acknowledged there had been no evaluation of the systems that failed.</p> <p>Patient 1: Date of surgery [REDACTED] 10</p> <p>Review of the medical record revealed Patient 1 had failed conventional treatment (surgical removal, radiation and chemotherapy) for a brain tumor between [REDACTED] 2010 and [REDACTED] 2010. In [REDACTED] 2010, Patient 1 developed right side weakness from the recurrence of the brain tumor. Patient 1 consented to an untried and unproven treatment (surgical removal of the tumor with implantation of live bowel bacteria into the brain) to be performed by MD 1 and MD 2 on [REDACTED] 0. Following surgery,</p>			

Event ID: 1K5X11

5/20/2013

3:30:27PM



CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050599	(X2) MULTIPLE CONSTRUCTION: A. BUILDING: _____ B. WING: _____		(X3) DATE SURVEY COMPLETED  08/30/2012
NAME OF PROVIDER OR SUPPLIER  UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 2315 Stockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO 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>Patient 1 experienced life threatening complications and multiple infections which compromised critical life functions (breathing, circulation, consciousness, movement) and which were not managed in accordance with acceptable medical practices.</p> <p>Within five hours of arrival to the recovery room, Patient 1 had seizures, became unresponsive and needed to have an artificial airway (intubation) for suspected bacteria in the blood. Antibiotics were administered from [REDACTED] 0 to [REDACTED] 0 but not continued despite, a) a decline in nervous system function exhibited by an altered level of consciousness, b) a culture from the brain cavity that grew bacteria and c) an imaging study showing the presence of encephalitis (infection of the brain). On [REDACTED] 10, a request was made for an Infectious Disease consult as different types of bacteria had been cultured from urine, lung secretions and a buttocks wound.</p> <p>Between [REDACTED] 10 and his death on [REDACTED] 10, Patient 1 never regained independent breathing, neurologic or feeding functions. On [REDACTED] 10, Patient 1 was described as having septic shock (low blood pressure resulting from bacteria in the blood). On [REDACTED] 10, the physicians confirmed the loss of brain function and Patient 1's family withdrew life support. Shortly thereafter Patient 1 expired.</p> <p>Patient 2: Date of surgery [REDACTED] 10</p> <p>Review of the medical record revealed Patient 2</p>				

Event ID: 1K5X11

5/20/2013

3:30:27PM

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050599	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED  08/30/2012	
NAME OF PROVIDER OR SUPPLIER  UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER		STREET ADDRESS, CITY, STATE, ZIP CODE 2315 Stockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO 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>was diagnosed with a brain tumor in [REDACTED] 2010 and treated with conventional surgery, radiation and chemotherapy. In [REDACTED] of 2010, Patient 2 developed left sided body weakness. A brain imaging test showed recurrence of the tumor. On [REDACTED] 10, MD 1 and MD 2 performed surgery and the same procedure was followed for the implantation of the live bowel bacteria into the brain. During Patient 2's hospitalization, from [REDACTED] 10 to [REDACTED] 0, the left sided weakness increased. On [REDACTED] 0, an imaging test showed increased brain swelling and pressure. On [REDACTED] 10, fluid was taken from the brain cavity and showed the growth of the implanted bacteria. Antibiotics were not administered. Patient 2 was discharged to a Skilled Nursing Facility. During this approximate eleven month period post discharge, increased pressure in the brain and chronic drainage from the infection at the original wound site required additional surgical interventions.</p> <p>Patient 3: Date of surgery [REDACTED] 11</p> <p>Review of the medical record revealed Patient 3 presented to the hospital emergency room on [REDACTED] 11 with recent onset of stabbing neck pain traveling down the right arm and right leg weakness causing falls. An imaging test was suspicious for a large brain tumor. MD 1 provided treatment consultation, offered standard and clinical research trial options, as well as the non-standard experimental treatment performed on Patients 1 and 2. On [REDACTED] 11, MD 1 and MD 2 performed removal of the tumor with implantation of the bowel bacteria into the brain. Patient 3 rapidly</p>			

Event ID:1K5X11

5/20/2013

3:30:27PM



CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050599	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____		(X3) DATE SURVEY COMPLETED  08/30/2012
NAME OF PROVIDER OR SUPPLIER  UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 2315 Stockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO 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>experienced life-threatening effects from the experimental treatment.</p> <p>Immediately following surgery, Patient 3 developed seizures and symptoms of sepsis (a life threatening infection of the blood). After one week, Patient 3 experienced breathing difficulty which required intubation. On the 12th post operative day, Patient 3 began to decline and no longer followed commands. Patient 3 had multiple cultures (brain/spinal fluid, blood) that were positive for the bacteria that had been implanted into the brain cavity. Patient 3 also developed a viral infection of the mouth and a bacterial infection of the urinary tract. Infectious Disease consultants provided no rationale for treating some infections with antibiotics and not others. On [REDACTED] 11, a drain was placed in the brain to reduce increased pressure. The swelling could not be reduced and Patient 3 expired on [REDACTED] 1.</p> <p>1. Failure to verify medical staff compliance with research activities</p> <p>In an interview on 8/27/12 at 10:15 a.m., the Associate Chief Medical Officer (ACMO) stated that any drugs related to research must be dispensed by the Investigational Drug Pharmacy (IDP), a division of the hospital Pharmacy. He stated a protocol was being developed for all unusual, innovative or non-standard treatments. The ACMO acknowledged there was currently no process to identify non-standard treatments and verify IRB approval. The ACMO further stated the medical staff currently had no plans to conduct audits to verify</p>		<p><b>#1. Failure to verify medical staff compliance with research activities.</b></p> <p><b>How the correction was accomplished:</b> The Medical Staff developed a policy, <i>Innovative Care</i>, in March 2012 to provide guidance and oversight to Medical Staff members in the innovative use of medical therapies, devices and/or medications in the treatment of patients. The guidelines are intended to minimize the potential risk to both patients and physicians in the delivery of innovative and</p>		

Event ID:1K5X11

5/20/2013

3:30:27PM

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>050599</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  <b>08/30/2012</b>
NAME OF PROVIDER OR SUPPLIER  <b>UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>2315 Stockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO COUNTY</b>		
(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>IRB or FDA approval for non-standard treatments. When asked how the treatments would be identified, the ACMO responded, "By common sense, someone will recognize...such as OR staff."</p> <p>MD 3, in an interview on 8/27/12 at 10:30 a.m., acknowledged the brain tumor treatments given to Patients 1, 2, and 3 were not standard, had never been scientifically studied in humans, had not been proven to be effective and were "highly unprecedented." MD 3 revealed no clear benefit had been defined for Patients 1, 2, and 3 and the treatment used was very high risk for harm.</p> <p>MD 4, the physician Director of Hospital Epidemiology and Infection, was interviewed on 8/28/12 at 4:15 p.m. MD 4 indicated that the infusion of bacteria that routinely inhabit the bowel, but become harmful in other body locations such as the nervous system, was not a standard treatment for brain tumors. MD 4 stated this type of treatment in humans would be investigational and subject to formal approvals, protocols and published experience in animal testing. MD 4 acknowledged that research in humans had not been conducted to determine whether the treatment would be safe, effective or what outcomes were to be expected. MD 4 further revealed there was no source of reference for determining how to isolate the infection in the brain to prevent the development of infections in other body locations.</p> <p>Review of the Medical Staff Bylaws, in place at the time of treatment of Patients 1, 2, and 3, defined the purposes of the medical staff as: "To provide</p>		<p>compassionate care, as well as to further UCDMC's academic mission. The revised policy includes an application that requires the applicant to identify the materials that will be used for innovative care, including unapproved drugs, devices and biologics. The Innovative Care Review Committee will consider this information during the approval process and will ensure that unapproved drugs, devices, and biologics are used safely and in compliance with UCDMC policies and state and federal regulations. The innovative care application process includes the development of a plan for monitoring and evaluating outcomes. The policy requires that the innovative care will be monitored by the Chief Medical Officer to ensure compliance with the approved innovative care plan, minimize or eliminate the continued use of ineffective or unsafe practices, and ensure that the physician and UCDMC meet ethical and legal obligations. The process for applying to provide innovative care, the details that are included in the application, and the oversight of the Medical Staff Organization of the delivery of innovative care that are required in the <i>Innovative Care</i> policy provide the necessary accountability of the Medical Staff to the Governing Body for quality of care and compliance with federal regulations and hospital policies.</p>		

Event ID:1K5X11

5/20/2013

3:30:27PM

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050599	(X2) MULTIPLE CONSTRUCTION: A. BUILDING: _____ B. WING: _____		(X3) DATE SURVEY COMPLETED  08/30/2012
NAME OF PROVIDER OR SUPPLIER  UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 2315 Stockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO 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>that all patients admitted to the hospital...receive quality care and treatment." The bylaws stipulated that medical staff members were required to document their ability to provide patient care and treatment in accordance with generally accepted standards of care. The Bylaws defined the responsibility of the Clinical Department Chairs to establish an ongoing review process to evaluate patient care and ensure department members practice within the privileges (authority) granted. The Bylaws defined the Chief of Staff (COS) or Chief Medical Officer's (CMO) duty to exercise authority to, a) ensure patient welfare took precedence over all other concerns, b) to require consultations when deemed necessary and c) require medical staff to comply with the hospital and medical staff bylaws, rules and regulations, policies and procedures, or face disciplinary action.</p> <p>The CMO, in an interview on 8/28/12 at 3:30 p.m., acknowledged MD 1 approached him for approval to treat Patient 1 in early [REDACTED] 2010 as a single, one time compassionate use of a non-approved biologic. The CMO directed MD 1 to obtain a consultation from the "ethics experts" to concur if the treatment was in the patient's best interest. The CMO stipulated that there be specific documentation in the medical record regarding MD 1's conversations with the IRB. MD 1 was directed to plan with the patient and family for possible complications in order to agree on the scope of treatment and end point of care. The CMO revealed MD 1 did not comply with these instructions prior to Patient 1's surgery and he instructed MD 1 not to perform the treatment on any other patients until</p>		<p>The Medical Staff will be educated about the Innovative Care policy and the application process in at least two ways: electronically via an email that was sent out to all Medical Staff and Resident Medical Staff on November 29, 2012, and at the Medical Staff Executive Committee, Quality and Safety Operations Committee, and clinical department quality and safety meetings by the Quality and Safety Nurse Analysts.</p> <p>The revised policy, new application, and frequently asked questions document are attached to this plan of correction below.</p> <p>Title of responsible person: Chief Medical Officer</p> <p>Description of monitoring process: In all cases of innovative care, all aspects of the innovative care will be assessed during the approval process by the Innovative Care Review Committee and will be monitored when the innovative care is provided. The quality and safety of care provided to patients and compliance with hospital policies and federal regulations will be monitored by the Chief Medical Officer. This will occur for each case of innovative care, but may happen infrequently, as innovative care cases occur infrequently.</p> <p>Date of correction: The revised Innovative Care policy was approved by Medical Staff Executive Committee on November 19, 2012. Education to the Medical Staff began on October 24, 2012.</p> <p><b><u>Policy 2516: Innovative Care</u></b></p>		

Event ID: 1K5X11

5/20/2013

3:30:27PM



CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050599	(X2) MULTIPLE CONSTRUCTION: A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  08/30/2012
NAME OF PROVIDER OR SUPPLIER  UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 2315 Stockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO 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>formal approvals by the IRB and appropriate regulatory agencies was obtained. The CMO acknowledged MD 1 arranged for Patient 2's treatment on [REDACTED] 0 without his knowledge and without complying with his instructions from the prior case. The CMO stated he met with MD 1 and again repeated his instructions not to perform other treatments without approvals. The CMO stated he was notified by the Director of the Pharmacy following the third surgery on [REDACTED] 11 and shortly thereafter learned MD 1 had planned to do five more cases.</p> <p>The CMO stated a "letter of expectation" was sent to MD 1 and MD 2 on 3/17/11 which instructed MD 1 and MD 2 to "cease and desist" research activities. The CMO stated Peer Review (multi-disciplinary physician review) was conducted on 4/18/11 and the determination was made that the "issue" needed to go back to the IRB before the two neurosurgeons would be authorized to perform similar research cases. These letters were maintained in a "shadow" file, not in the credentials files of MD 1 and MD 2.</p> <p>In an interview with the Manager of Medical Staff Administration (AM) 1 on 8/27/12 at 12:45 p.m., she stated the Peer Review for the three surgical cases was presented to the GB at the Governing Advisory Council Meeting on 11/14/11. The AM 1 acknowledged the Peer Review was presented without detail in summary form and the discussion was not included in the minutes of the meeting.</p> <p>MD 1 was interviewed on 8/30/12 at 11:40 a.m. MD</p>		<p><b>I. PURPOSE</b> <i>To provide guidance and oversight to members of the University of California, Davis Medical Center (UCDMC) Medical Staff in the innovative use of medical therapies, devices and/or medications in the treatment of patients. These guidelines are intended to minimize the potential risks to both patients and physicians in the delivery of innovative and compassionate care, as well as to further UCDMC's academic mission. These guidelines are designed to protect patients and to support, not impede, physicians in the consideration of care options.</i></p> <p><b>II. SETTING</b> <i>Medical Center</i></p> <p><b>III. DEFINITIONS</b> <i>Innovative Care--is the application of a therapy, device, or medication to a patient in a manner that departs in a significant way from standard or accepted medical practice in order to enhance the well-being of a specific patient. The sole purpose of innovative care is to benefit the patient, not to collect data to support a hypothesis or theory. Innovative care includes any use of an unapproved drug, biologic or device that is subject to Food and Drug Administration (FDA) expanded access approval. Innovative care also includes unusual or entirely novel off-label uses of FDA approved drugs, biologics or devices, but does not include common off-label use. For the purposes of this policy, innovative care and compassionate care are synonymous.</i> <i>Innovative Care Review Committee: A subcommittee of the UCDMC Quality and Safety Operations Committee. Members are appointed by the Chief of Staff on an ad hoc</i></p>		

Event ID: 1K5X11

5/20/2013

3:30:27PM

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>050599</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  <b>08/30/2012</b>
NAME OF PROVIDER OR SUPPLIER  <b>UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>2315 Stockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO COUNTY</b>		
(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>1 acknowledged formal procedures for the acquisition, handling, use, and disposal of the biologic were not followed for Patients 1, 2, and 3. MD 1 revealed he did not know how much bacteria to implant as there were no prior studies to reference to determine this. MD 1 revealed no post operative plan had been defined to denote the actions to be taken to rescue each patient from life-threatening adverse effects of the treatment. MD 1 further revealed "we told the nursing staff we were going to do this [in the OR]" and "It went against all OR rules."</p> <p>2. Failure to ensure required approval, scheduling, procurement, processing, labeling, storage, use and disposal of a non-approved biologic.</p> <p>MD 1 and MD 2 did not inform the OR of the use of a biologic when scheduling Patient 1, 2, and 3's brain surgeries. The biologic agent was transported from a university animal research laboratory by a university Research Assistant (RA) in an unlabeled vial without instructions for handling, use or disposal. None of the perioperative nurses interviewed stated they were familiar with the term "probiotic" (the term used by the neurosurgeon on two of the three patient Informed Consents), however they never questioned leadership about the definition or the handling, use or disposal of the biologic. None of the OR nurses interviewed, who had either circulated or scrubbed on the three cases, considered informing the Manager of the Operating Room (MOR) of the occurrence of a treatment and processes outside of established OR standards of care.</p>		<p><i>basis each time an application for innovative care is received and may include the Chief Medical Officer (CMO), Associate CMO, and representatives from Pharmacy, Clinical Engineering, Perioperative Services, Patient Care Services, Quality and Safety, and the Institutional Review Board (IRB). Consultations will be sought, as needed, from content experts depending on the subject matter.</i></p> <p><b>IV. POLICY</b> A. UCDCMC recognizes that medical circumstances arise in which non-standard therapies for treatment or novel uses for drugs or devices may be warranted. This policy will assist providers in appropriately identifying innovative care and resolving issues involving planned treatment.</p> <p><i>The primary physician is responsible for determining that a planned treatment is likely to be considered innovative care and to initiate the approval process described in section V.A.</i></p> <p><b>1. The Innovative Care Review Committee will make the final recommendations regarding the innovative care, seeking consultation from ethicists and individuals experienced in both clinical care and research, as needed.</b></p> <p><b>2. Outcomes will be monitored to ensure patient safety and appropriate use of innovative care.</b></p> <p><b>C. The patient will be flagged in the EMR as a recipient of innovative care and the Innovative Care Application form (Attachment A) will be scanned into the EMR.</b></p> <p><b>V. PROCEDURE/RESPONSIBILITY</b> A. Physician Responsibility</p>		

Event ID 1K5X11

5/20/2013

3:30:27PM



CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050599	(X2) MULTIPLE CONSTRUCTION: A. BUILDING: _____ B. WING: _____		(X3) DATE SURVEY COMPLETED  08/30/2012
NAME OF PROVIDER OR SUPPLIER  UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 2315 Stockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO 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>1. acknowledged formal procedures for the acquisition, handling, use, and disposal of the biologic were not followed for Patients 1, 2, and 3. MD 1 revealed he did not know how much bacteria to implant as there were no prior studies to reference to determine this. MD 1 revealed no post operative plan had been defined to denote the actions to be taken to rescue each patient from life-threatening adverse effects of the treatment. MD 1 further revealed "we told the nursing staff we were going to do this [in the OR]" and "It went against all OR rules."</p> <p>2. Failure to ensure required approval, scheduling, procurement, processing, labeling, storage, use and disposal of a non-approved biologic</p> <p>MD 1 and MD 2 did not inform the OR of the use of a biologic when scheduling Patient 1, 2, and 3's brain surgeries. The biologic agent was transported from a university animal research laboratory by a university Research Assistant (RA) in an unlabeled vial without instructions for handling, use or disposal. None of the perioperative nurses interviewed stated they were familiar with the term "probiotic" (the term used by the neurosurgeon on two of the three patient Informed Consents), however they never questioned leadership about the definition or the handling, use or disposal of the biologic. None of the OR nurses interviewed, who had either circulated or scrubbed on the three cases, considered informing the Manager of the Operating Room (MOR) of the occurrence of a treatment and processes outside of established OR standards of care.</p>		<p><i>1. Any physician who wishes to provide innovative care utilizing an unapproved drug, biologic or device must first obtain an IRB determination of whether the innovative use requires FDA expanded access approval or other regulatory approval.</i></p> <p><i>2. To proceed with innovative care approval, the ordering physician will submit a complete innovative care application form (Attachment A) to the CMO for consideration by the Innovative Care Review Committee. The application provides relevant details for consideration including a description of the innovative care, specific consent including unique risks and benefits, a care plan and course of treatment including triggers for care plan changes, and coordination with Pharmacy, Infection Prevention, Laboratory, Perioperative Services, Tumor Board, Bioethics Consultation Committee, Risk Management, if applicable. The application will clearly address billing issues, EMR documentation requirements and staff/team education to protect patient safety and maximize staff competency. The innovative care application will also address the plan for monitoring, outcome evaluation tracking and reporting.</i></p> <p><i>3. If the innovative care application is approved, the physician will document in the medical record the informed consent of the patient/patient's representative reflecting the discussion with the patient or his/her representative and the understanding that the treatment represents a novel approach and has not been fully tested or approved prior to using or administering the innovative care. The physician is also responsible for assuring that all staff participating in the care of the patient</i></p>		

Event ID: 1K5X11

5/20/2013

3:30:27PM



CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050599	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  08/30/2012
NAME OF PROVIDER OR SUPPLIER  UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 2315 Stockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO 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>1 acknowledged formal procedures for the acquisition, handling, use, and disposal of the biologic were not followed for Patients 1, 2, and 3. MD 1 revealed he did not know how much bacteria to implant as there were no prior studies to reference to determine this MD 1 revealed no post operative plan had been defined to denote the actions to be taken to rescue each patient from life-threatening adverse effects of the treatment. MD 1 further revealed "we told the nursing staff we were going to do this [in the OR]" and "It went against all OR rules."</p> <p>2. Failure to ensure required approval, scheduling, procurement, processing, labeling, storage, use and disposal of a non-approved biologic</p> <p>MD 1 and MD 2 did not inform the OR of the use of a biologic when scheduling Patient 1, 2, and 3's brain surgeries. The biologic agent was transported from a university animal research laboratory by a university Research Assistant (RA) in an unlabeled vial without instructions for handling, use or disposal. None of the perioperative nurses interviewed stated they were familiar with the term "probiotic" (the term used by the neurosurgeon on two of the three patient Informed Consents), however they never questioned leadership about the definition or the handling, use or disposal of the biologic. None of the OR nurses interviewed, who had either circulated or scrubbed on the three cases, considered informing the Manager of the Operating Room (MOR) of the occurrence of a treatment and processes outside of established OR standards of care.</p>		<p><i>are informed of the innovative care plan and understand their roles in the treatment of the patient.</i></p> <p><i>4. The primary physician will oversee the prospective monitoring and retrospective review of the innovative care as required by the Chief Medical Officer and/or Innovative Care Review Committee.</i></p> <p><i>B. Chief Medical Officer and Innovative Care Review Committee</i> <i>The CMO will review the application for completeness and convene the Innovative Care Review Committee.</i> <i>The Innovative Care Review Committee is designed for rapid response and flexibility in composition for expertise. The Committee may request assistance and input from the UC Davis Biosafety Committee, Institutional Animal Care and Use Committee (IACUC), Office of Research, Bioethics or other individuals with expertise in ethics, research, and clinical care.</i> <i>If the Committee agrees that the proposed care is innovative and reasonable, approval may be given to proceed. Limitations or modifications to the treatment plan may also be imposed.</i> <i>The approved Innovative Care Application form will be sent to Health Information Management to be scanned into the EMR. The patient's record will be flagged to document that the patient is receiving innovative care.</i> <i>For all approved applications, the CMO will ensure that outcomes are monitored to ensure compliance, minimize the continued use of ineffective or unsafe practices, and ensure that the physician and UC Davis Health System meet ethical and legal obligations.</i></p> <p><b>INNOVATIVE CARE APPLICATION Attachment A</b></p>		

Event ID:1K5X11

5/20/2013

3:30:27PM

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>050599</b>	(X2) MULTIPLE CONSTRUCTION: A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED  <b>08/30/2012</b>
NAME OF PROVIDER OR SUPPLIER  <b>UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER</b>		STREET ADDRESS, CITY, STATE, ZIP CODE <b>2315 Stockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO COUNTY</b>		
(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>1 acknowledged formal procedures for the acquisition, handling, use, and disposal of the biologic were not followed for Patients 1, 2, and 3. MD 1 revealed he did not know how much bacteria to implant as there were no prior studies to reference to determine this. MD 1 revealed no post operative plan had been defined to denote the actions to be taken to rescue each patient from life-threatening adverse effects of the treatment. MD 1 further revealed "we told the nursing staff we were going to do this [in the OR]" and "It went against all OR rules."</p> <p>2. Failure to ensure required approval, scheduling, procurement, processing, labeling, storage, use and disposal of a non-approved biologic</p> <p>MD 1 and MD 2 did not inform the OR of the use of a biologic when scheduling Patient 1, 2, and 3's brain surgeries. The biologic agent was transported from a university animal research laboratory by a university Research Assistant (RA) in an unlabeled vial without instructions for handling, use or disposal. None of the perioperative nurses interviewed stated they were familiar with the term "probiotic" (the term used by the neurosurgeon on two of the three patient Informed Consents), however they never questioned leadership about the definition or the handling, use or disposal of the biologic. None of the OR nurses interviewed, who had either circulated or scrubbed on the three cases, considered informing the Manager of the Operating Room (MOR) of the occurrence of a treatment and processes outside of established OR standards of care.</p>		<p><i>Name of clinician or team</i></p> <p><i>Patient's name, if applicable</i></p> <p><i>Description of innovative use (drug, device, biologic, technique, etc.)</i></p> <p><i>Attach sample consent form, including unique risks and benefits (must consider patient status and ability to give consent)</i></p> <p><i>Care Plan mapping out course of treatment and triggers for changes in plan (e.g., rescue if needed, intubation, code status, etc.)</i></p> <p><i>Does the proposed innovative care involve the use of an investigational drug, device or therapy?</i></p> <p><i>What is the plan for the acquisition, handling, and storage of the item(s) needed for the innovative care?</i></p> <p><i>Is a contract or purchasing agreement in place?</i></p> <p><i>Pharmacy issues/coordination</i></p> <p><i>Infection Prevention issues/coordination</i></p> <p><i>Laboratory issues/coordination</i> <i>Perioperative Services issues/coordination</i> <i>Tumor Board communication</i> <i>Bioethics consultation</i> <i>Risk Management issue</i></p> <p><i>Billing issues</i> <i>EMR documentation requirements (description of device, biologic, technique, etc.)</i> <i>Staff/team education regarding care</i></p>	

Event ID:1K5X11

5/20/2013

3:30 27PM

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050599	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____		(X3) DATE SURVEY COMPLETED  08/30/2012
NAME OF PROVIDER OR SUPPLIER  UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 2315 Stockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO 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>1. I acknowledged formal procedures for the acquisition, handling, use, and disposal of the biologic were not followed for Patients 1, 2, and 3. MD 1 revealed he did not know how much bacteria to implant as there were no prior studies to reference to determine this. MD 1 revealed no post operative plan had been defined to denote the actions to be taken to rescue each patient from life-threatening adverse effects of the treatment. MD 1 further revealed "we told the nursing staff we were going to do this [in the OR]" and "It went against all OR rules."</p> <p>2. Failure to ensure required approval, scheduling, procurement, processing, labeling, storage, use and disposal of a non-approved biologic</p> <p>MD 1 and MD 2 did not inform the OR of the use of a biologic when scheduling Patient 1, 2, and 3's brain surgeries. The biologic agent was transported from a university animal research laboratory by a university Research Assistant (RA) in an unlabeled vial without instructions for handling, use or disposal. None of the perioperative nurses interviewed stated they were familiar with the term "probiotic" (the term used by the neurosurgeon on two of the three patient Informed Consents), however they never questioned leadership about the definition or the handling, use or disposal of the biologic. None of the OR nurses interviewed, who had either circulated or scrubbed on the three cases, considered informing the Manager of the Operating Room (MOR) of the occurrence of a treatment and processes outside of established OR standards of care</p>		<p><i>plan/course of care</i> <i>Plan for monitoring, outcome evaluation, tracking, reporting</i></p> <p><b><u>Innovative Care Frequently Asked Questions (FAQs)</u></b> Attachment B</p> <p><b>Q. Is what I am doing research or innovative care?</b></p> <p>A. Federal regulations define research as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. The purpose of research is primarily to seek new knowledge, to reorder existing knowledge, or to apply existing knowledge to a new situation.</p> <p><i>In contrast, the primary purpose of innovative care is to benefit a patient(s), not to collect data to support a hypothesis or theory. Innovative care is a non-standard procedure or treatment that is solely attempted to enhance the wellbeing of a patient. Innovative care is sometimes called "nonvalidated" treatment, since it has not been formally evaluated for safety or effectiveness.</i></p> <p><b>Q. What kind of oversight is required for research?</b></p> <p>A. Procedures and therapies that are determined to be research require review by the Institutional Review Board (IRB). If you wish to provide innovative care utilizing an unapproved drug, biologic or device, you must first obtain an IRB determination of whether</p>		

Event ID:1K5X11

5/20/2013

3:30:27PM

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050599	(X2) MULTIPLE CONSTRUCTION: A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  08/30/2012
NAME OF PROVIDER OR SUPPLIER  UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 2315 Stockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO 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>1 acknowledged formal procedures for the acquisition, handling, use, and disposal of the biologic were not followed for Patients 1, 2, and 3. MD 1 revealed he did not know how much bacteria to implant as there were no prior studies to reference to determine this. MD 1 revealed no post operative plan had been defined to denote the actions to be taken to rescue each patient from life-threatening adverse effects of the treatment. MD 1 further revealed "we told the nursing staff we were going to do this [in the OR]" and "It went against all OR rules."</p> <p>2. Failure to ensure required approval, scheduling, procurement, processing, labeling, storage, use and disposal of a non-approved biologic</p> <p>MD 1 and MD 2 did not inform the OR of the use of a biologic when scheduling Patient 1, 2, and 3's brain surgeries. The biologic agent was transported from a university animal research laboratory by a university Research Assistant (RA) in an unlabeled vial without instructions for handling, use or disposal. None of the perioperative nurses interviewed stated they were familiar with the term "probiotic" (the term used by the neurosurgeon on two of the three patient Informed Consents), however they never questioned leadership about the definition or the handling, use or disposal of the biologic. None of the OR nurses interviewed, who had either circulated or scrubbed on the three cases, considered informing the Manager of the Operating Room (MOR) of the occurrence of a treatment and processes outside of established OR standards of care.</p>		<p><i>the innovative use requires FDA expanded access approval or other regulatory approval.</i></p> <p><b>Q. What kind of review and monitoring is recommended for innovative care?</b></p> <p><i>A. Innovative care should be monitored prospectively and reviewed retrospectively as described in the Innovative Care policy. For innovative therapy/procedures that present a significant increase in risk over other acceptable alternatives or if the therapy/procedure is so novel or unique that it is not possible to evaluate the risk or benefit, the Innovative Care Review Committee may be organized to review the reasonableness of the proposed treatment and the patient's situation and to make recommendations to the Chief Medical Officer, your department chair, and you.</i></p> <p><b>Q. Does every procedure that diverges from accepted practice fall under the Innovative Care policy?</b></p> <p><i>A. It depends on the degree of deviation and the associated risks. The higher the associated risks, and the larger the divergence from accepted practice, the more important it becomes to consult the IRB and Chief Medical Officer as described in the Innovative Care policy. When in doubt, consult. The Medical Staff Organization, in consultation with the appropriate department chair, is ultimately responsible for determining what kind of monitoring, support or oversight (if any) your activity requires.</i></p> <p><b>Q. What if my approved innovative treatment/procedure is successful and I want</b></p>		

Event ID: 1K5X11

5/20/2013

3:30:27PM

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>050599</b>	(X2) MULTIPLE CONSTRUCTION: A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  <b>08/30/2012</b>
NAME OF PROVIDER OR SUPPLIER  <b>UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>2315 Stockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO COUNTY</b>		
(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>1. acknowledged formal procedures for the acquisition, handling, use, and disposal of the biologic were not followed for Patients 1, 2, and 3. MD 1 revealed he did not know how much bacteria to implant as there were no prior studies to reference to determine this. MD 1 revealed no post operative plan had been defined to denote the actions to be taken to rescue each patient from life-threatening adverse effects of the treatment. MD 1 further revealed "we told the nursing staff we were going to do this [in the OR]" and "It went against all OR rules."</p> <p>2. Failure to ensure required approval, scheduling, procurement, processing, labeling, storage, use and disposal of a non-approved biologic</p> <p>MD 1 and MD 2 did not inform the OR of the use of a biologic when scheduling Patient 1, 2, and 3's brain surgeries. The biologic agent was transported from a university animal research laboratory by a university Research Assistant (RA) in an unlabeled vial without instructions for handling, use or disposal. None of the perioperative nurses interviewed stated they were familiar with the term "probiotic" (the term used by the neurosurgeon on two of the three patient Informed Consents), however they never questioned leadership about the definition or the handling, use or disposal of the biologic. None of the OR nurses interviewed, who had either circulated or scrubbed on the three cases, considered informing the Manager of the Operating Room (MOR) of the occurrence of a treatment and processes outside of established OR standards of care.</p>		<p><b>to repeat it?</b></p> <p><b>A . If you want to repeat the treatment beyond the number of times initially authorized, you should consult with the Chief Medical Officer, who will in turn consult with the Innovative Care Review Committee that initially reviewed your treatment plan under the Innovative Care policy. The Committee will consider whether the treatment should no longer be considered "innovative." However, you should continue to follow this policy for approval of further treatments. Alternatively, the Committee may recommend that any further treatments would be best undertaken as research carried out with IRB approval.</b></p> <p><b>Q. What if I want to publish the outcome of or describe the procedures I've done in a medical journal article?</b></p> <p><b>A. The Federal Office of Human Research Protections (OHRP) has said that "the intent to publish is an insufficient criterion for determining whether an activity involves research." Planning to publish an account of an activity does not necessarily mean that the project fits the definition of research. People seek to publish descriptions of clinical activities that are not research for a variety of reasons. In fact, Kennedy and Eaton (2007) feel that "all innovating physicians should assume a duty...to educate about the impact of their changes on patient care." They go on to say that "If formal research is not conducted...the least that innovating physicians can do is to collect outcome data on their patients and use it to inform themselves and other physicians."</b></p>		

Event ID:1K5X11

5/20/2013

3:30:27PM



CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050599	(X2) MULTIPLE CONSTRUCTION: A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  08/30/2012
NAME OF PROVIDER OR SUPPLIER  UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 2315 Stockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO 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>1. acknowledged formal procedures for the acquisition, handling, use, and disposal of the biologic were not followed for Patients 1, 2, and 3. MD 1 revealed he did not know how much bacteria to implant as there were no prior studies to reference to determine this. MD 1 revealed no post operative plan had been defined to denote the actions to be taken to rescue each patient from life-threatening adverse effects of the treatment. MD 1 further revealed "we told the nursing staff we were going to do this [in the OR]" and "It went against all OR rules."</p> <p>2. Failure to ensure required approval, scheduling, procurement, processing, labeling, storage, use and disposal of a non-approved biologic</p> <p>MD 1 and MD 2 did not inform the OR of the use of a biologic when scheduling Patient 1, 2, and 3's brain surgeries. The biologic agent was transported from a university animal research laboratory by a university Research Assistant (RA) in an unlabeled vial without instructions for handling, use or disposal. None of the perioperative nurses interviewed stated they were familiar with the term "probiotic" (the term used by the neurosurgeon on two of the three patient Informed Consents), however they never questioned leadership about the definition or the handling, use or disposal of the biologic. None of the OR nurses interviewed, who had either circulated or scrubbed on the three cases, considered informing the Manager of the Operating Room (MOR) of the occurrence of a treatment and processes outside of established OR standards of care.</p>		<p><b>How the correction was accomplished:</b> The Research Compliance Coordinating Committee has been formed as an oversight committee that includes representatives of the IRB, Compliance, and the Medical Staff. The multidisciplinary committee will allow for the free flow of information related to compliance with human research safety rules for Medical Staff members who conduct research activities on hospital patients to ensure the safety of all patients. In addition, the chair of one of the IRBs will serve as a member of the Quality and Safety Operations Committee and will provide a monthly report of the quality issues addressed by the IRBs.</p> <p>Title of responsible person: Chief Compliance Officer</p> <p>Description of monitoring process: The manager of the Medical Staff, who is a member of the Research Compliance Coordinating Committee, will monitor the discussions held at this meeting and track that information is shared between the Medical Staff and the IRB regarding physician compliance with safety rules.</p> <p>Date of correction: The Research Compliance Coordinating Committee met for the first time on November 16, 2012. It meets monthly.</p>		

Event ID: 1K5X11

5/20/2013

3:30:27PM



CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050599	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  08/30/2012
NAME OF PROVIDER OR SUPPLIER  UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 2315 Stockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO 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>1 acknowledged formal procedures for the acquisition, handling, use, and disposal of the biologic were not followed for Patients 1, 2, and 3. MD 1 revealed he did not know how much bacteria to implant as there were no prior studies to reference to determine this. MD 1 revealed no post operative plan had been defined to denote the actions to be taken to rescue each patient from life-threatening adverse effects of the treatment. MD 1 further revealed "we told the nursing staff we were going to do this [in the OR]" and "It went against all OR rules."</p> <p>2. Failure to ensure required approval, scheduling, procurement, processing, labeling, storage, use and disposal of a non-approved biologic</p> <p>MD 1 and MD 2 did not inform the OR of the use of a biologic when scheduling Patient 1, 2, and 3's brain surgeries. The biologic agent was transported from a university animal research laboratory by a university Research Assistant (RA) in an unlabeled vial without instructions for handling, use or disposal. None of the perioperative nurses interviewed stated they were familiar with the term "probiotic" (the term used by the neurosurgeon on two of the three patient Informed Consents), however they never questioned leadership about the definition or the handling, use or disposal of the biologic. None of the OR nurses interviewed, who had either circulated or scrubbed on the three cases, considered informing the Manager of the Operating Room (MOR) of the occurrence of a treatment and processes outside of established OR standards of care.</p>		<p><b>#2. Failure to ensure required approval, scheduling, procurement, processing, labeling, storage, use and disposal of a non-approved biologic</b></p> <p><b>How the correction was accomplished:</b> UCDMC policy 2517, <i>Research and Innovative Care: Operative Room Review</i> was developed to provide a process to review appropriateness of research and innovative care in patients undergoing surgery or anesthesia. The policy provides for communication to Perioperative Services staff regarding research and innovative care cases, a review process, education of staff regarding their roles in the case, communication to surgery schedulers, and other safeguards to ensure that patient's receive safe, approved care and the professional standards are met. The policy is attached to this document below.</p> <p>Title of person responsible: Director of Perioperative Services</p>		

Event ID:1K5X11

5/20/2013

3:30:27PM

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050599	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  08/30/2012
NAME OF PROVIDER OR SUPPLIER  UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 2315 Stockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO 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>In an interview with the RA, on 8/28/12 at 10:30 a.m., she revealed she was asked by MD 2 to produce and transport the biologic material to the hospital to be implanted during the surgeries for Patients 1, 2, and 3. The RA indicated she did not follow any formal written protocols or procedures to package, label and transport the biologic material.</p> <p>In an interview with the Director of the Pharmacy (DOP) on 8/29/12 at 10 a.m., the DOP indicated that existing hospital policies required all drugs and biologic materials be approved for human use by the FDA. The DOP stated that biologic agents intended for patient use would be considered investigational and would require review by the IDP to ensure the integrity, security, labeling, safety and storage requirements in accordance with the manufacturer's recommendations.</p> <p>In review of hospital policies in place at the time of the treatment of Patient's 1, 2, and 3, (██████ 10 to ██████ 11) the following was noted:</p> <p>Policy #1508, titled Distribution of Investigational Drugs addressed the storage and distribution requirements for items maintained outside of the pharmacy, transfer and disposal of the item and labeling requirements.</p> <p>Policy #1509, titled Emergency Treatment Use of an Investigational Drug, Device or Biologic (FDA regulated products) addressed the requirements for use when there was insufficient time to obtain IRB approval before rendering an investigational biologic.</p>		<p>Description of monitoring process: The Nurse Manager of Perioperative Services is responsible for the re-education of Perioperative Services staff regarding policy 2517, and is also responsible for the annual competency assessment of Perioperative Services nursing staff. Following the re-education of nursing staff during the month of December 2012, the Nurse Manager will monitor each case of research or innovative care in the Perioperative Suites and monitor that staff members appropriately advocated for their patients and followed professional practice standards.</p> <p>Date of correction: December 15, 2012</p> <p><b><u>Policy 2517, Research and Innovative Care: Operating Room Review</u></b></p> <p><b>PURPOSE</b> Provide process to review appropriateness of research and innovative use in patients undergoing surgery or anesthesia.</p> <p><b>SETTING</b> UC Davis Medical Center (UCDMC) Operating Room</p> <p><b>POLICY</b> The principal investigator (PI) submits the research protocol or the primary physician submits the approved innovative care application to the Operating Room Manager for review. The review is conducted in consultation with the Medical Director and Assistant Director of Perioperative Services.</p>		

Event ID:1K5X11

5/20/2013

3:30:27PM

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050599	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____		(X3) DATE SURVEY COMPLETED  08/30/2012
NAME OF PROVIDER OR SUPPLIER  UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 2315 Stockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO 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>to save a life. The same requirements applied for dispensing through the IDP and notifying the FDA or other oversight agency. The policy further directed that investigational drugs and biologics intended for the treatment of disease be recognized in the United States Pharmacopoeia (USP), a document which lists all drugs and biologic materials legally approved for sale and use in the United States. The policy further defined innovative use as the application of a ...medication in a manner that departs in a significant way from standard or accepted practice and included unapproved biologics which had IRB approval. In addition, this policy stipulated an independent assessment by an uninvolved physician must be obtained.</p> <p>The new hospital policy ID: #2516 Innovative Use Policy, presented in draft form, was acknowledged by the hospital to have been placed in use to provide direction for the use of an Unapproved Drug, Biologic or Device. Hospital leadership acknowledged this policy had not been approved as yet by the governing body. This policy was similar to the old policy in that it again directed the physician to obtain approval of the use of the biologic from the IRB (or, in an emergency, from the FDA with notification to the IRB). The policy, however failed to require the approval process to be formally documented in writing to avoid any misinterpretation of the approval and to provide evidence of approval to staff working in the OR. In addition, the policy did not address any operational issues including how to acquire, store, handle, use or dispose of the Unapproved Drug or Biologic or</p>		<p><i>If the research or innovative care is appropriate for the OR setting and resources are adequately addressed, the Assistant Director (principle) or Operating Room Manager (backup) issues a letter of approval.</i></p> <p><i>The Medical Director may provide recommendations regarding the safeguarding of patients' rights related to the research/innovative care.</i></p> <p><i>Principal Investigator includes the letter of approval in submission packet to School of Medicine Sponsored Programs as part of the Institutional Review Board or Contracts and Grants submission process.</i></p> <p><i>Operating Room Manager updates list of approved research/innovative care projects which is referenced when research/innovative care patients are scheduled. Schedulers should notify managers of any research subjects/innovative care patients on protocols that have not undergone the review process.</i></p> <p><i>Principal investigator or primary physician identifies patients as research/innovative care subjects when scheduling procedures.</i></p> <p><i>When the PI or primary physician is not the physician scheduling the case (e.g., the anesthesiologist or another physician), then the PI or primary physician must notify the OR manager or Charge nurse that a patient is, or will be, the subject of research or innovative care (when the case is scheduled). This must be done on each and every patient so identified.</i></p> <p><i>Operating room clinical staff must check charts</i></p>		

Event ID 1K5X11

5/20/2013

3:30:27PM

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050599	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  08/30/2012
NAME OF PROVIDER OR SUPPLIER  UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 2315 Stockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO 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>what processes were needed to ensure all environmental and patient safety measures were in place.</p> <p>3. Failure to provide pre-operative, intra-operative and post-operative care in accordance with hospital policies and acceptable standards of practice</p> <p>In an interview with the MOR on 8/27/12 at 10:30 a.m., he stated he was not aware of any issues regarding the use of the non-approved biologic until he was called by the Risk Management office in mid [REDACTED] of 2011, after the third surgery. He stated he talked with the nurses at that time and "found nursing was not involved," "they didn't know anything about it." Although he was concerned that something was brought into the OR without his knowledge, he did not conduct an internal investigation. The MOR stated he had interviewed the nurses involved and they didn't remember anything "changing hands." He stated "they [the neurosurgeons] did something on the sterile field the nursing staff was not involved with." The MOR stated he didn't know what a "probiotic" was or why the nurses had not questioned the use of the word probiotic on the Informed Consent. The MOR stated Patient 1, 2, and 3's cases were never discussed at any hospital committee meetings he attended. The MOR stated it was his belief there was no necessity to develop or revise any policies regarding the use of an unapproved biologic. The MOR stated he did not file an Incident Report (IR) as he was informed the incidents "were being handled by Clinical Affairs." The MOR acknowledged he had not conducted any education</p>		<p><i>of research subjects/innovative care patients for current, signed protocol or innovative care informed consent forms prior to start of procedure.</i></p> <p><b>PROCEDURE/RESPONSIBILITIES</b> <i>Principal Investigator or Primary Physician</i></p> <p><i>Submits research protocol or approved innovative use application to Operating Room Manager for resource review.</i></p> <p><i>Forwards operating room letter of resource approval to the School of Medicine Sponsored Programs office (this step is skipped for innovative care cases).</i></p> <p><i>Identifies research subject or innovative care patients when scheduling operating room time.</i></p> <p><i>Places current, signed protocol informed consent forms or innovative care informed consent form in the medical record for review by operating room staff prior to start of procedure.</i></p> <p><b>Operating Room</b> <i>Manager conducts review of submitted protocols or innovative care in consultation with Assistant Director and Medical Director of Perioperative Services.</i></p> <p><i>Assistant Director or Manager issues letter of approval to principal investigator or primary physician as appropriate.</i></p> <p><i>In conjunction with the Office of Research, maintains a list of approved protocols and innovative care cases.</i></p>		

Event ID: 1K5X11

5/20/2013

3:30:27PM

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>050589</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  <b>08/30/2012</b>
NAME OF PROVIDER OR SUPPLIER  <b>UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER</b>		STREET ADDRESS, CITY, STATE, ZIP CODE <b>2315 Stockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO COUNTY</b>		
(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>what processes were needed to ensure all environmental and patient safety measures were in place.</p> <p>3. Failure to provide pre-operative, intra-operative and post-operative care in accordance with hospital policies and acceptable standards of practice</p> <p>In an interview with the MOR on 8/27/12 at 10:30 a.m., he stated he was not aware of any issues regarding the use of the non-approved biologic until he was called by the Risk Management office in mid [REDACTED] of 2011, after the third surgery. He stated he talked with the nurses at that time and "found nursing was not involved," "they didn't know anything about it." Although he was concerned that something was brought into the OR without his knowledge, he did not conduct an internal investigation. The MOR stated he had interviewed the nurses involved and they didn't remember anything "changing hands." He stated "they [the neurosurgeons] did something on the sterile field the nursing staff was not involved with." The MOR stated he didn't know what a "probiotic" was or why the nurses had not questioned the use of the word probiotic on the Informed Consent. The MOR stated Patient 1, 2, and 3's cases were never discussed at any hospital committee meetings he attended. The MOR stated it was his belief there was no necessity to develop or revise any policies regarding the use of an unapproved biologic. The MOR stated he did not file an Incident Report (IR) as he was informed the incidents "were being handled by Clinical Affairs." The MOR acknowledged he had not conducted any education</p>		<p><i>The OR Manager, in consultation with the PI/Primary Physician, the Assistant Director and Medical Director, will determine the appropriate education and training of OR personnel related to the research/innovative care, and will implement the educational program via the OR educators and CN3 of the specialty.</i></p> <p><i>The OR Manager will identify any deviations from standard operating procedures that are necessary to accomplish the research or innovative care and inform staff of their roles in these deviations.</i></p> <p><i>Surgery Scheduling</i> <i>Appropriately identifies those patients who are research subjects/innovative care patients by information entered on the scheduling request (see policy related to innovative care).</i></p> <p><i>Ensures research/innovative care subjects scheduled for the operating room are on the approved protocol/innovative care list.</i></p> <p><i>Notifies Operating Room Manager and Charge Nurse of any non-approved protocols or patients.</i></p> <p><i>Operating Room Clinical Staff</i></p> <p><i>1. Review operating room chart for copy of current, signed protocol informed consent form for those patients identified as participants in a research/innovative care protocol. Documents study coordinator in chart as well as any treatment or equipment.</i></p> <p><i>Office of Research/School of Medicine</i></p>	

Event ID: 1K5X11

5/20/2013

3:30:27PM

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>050599</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  <b>08/30/2012</b>
NAME OF PROVIDER OR SUPPLIER  <b>UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>2315 Stockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO COUNTY</b>		
(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>what processes were needed to ensure all environmental and patient safety measures were in place.</p> <p>3. Failure to provide pre-operative, intra-operative and post-operative care in accordance with hospital policies and acceptable standards of practice</p> <p>In an interview with the MOR on 8/27/12 at 10:30 a.m., he stated he was not aware of any issues regarding the use of the non-approved biologic until he was called by the Risk Management office in mid [REDACTED] of 2011, after the third surgery. He stated he talked with the nurses at that time and "found nursing was not involved," "they didn't know anything about it." Although he was concerned that something was brought into the OR without his knowledge, he did not conduct an internal investigation. The MOR stated he had interviewed the nurses involved and they didn't remember anything "changing hands." He stated "they [the neurosurgeons] did something on the sterile field the nursing staff was not involved with." The MOR stated he didn't know what a "probiotic" was or why the nurses had not questioned the use of the word probiotic on the Informed Consent. The MOR stated Patient 1, 2, and 3's cases were never discussed at any hospital committee meetings he attended. The MOR stated it was his belief there was no necessity to develop or revise any policies regarding the use of an unapproved biologic. The MOR stated he did not file an Incident Report (IR) as he was informed the incidents "were being handled by Clinical Affairs." The MOR acknowledged he had not conducted any education</p>		<p><b>Sponsored Programs</b></p> <p><i>Check surgical study submission for operating room approval letter.</i></p> <p><i>If approval letter is absent refer principal investigators to the Operating Room Assistant Director or Manager.</i></p> <p><i>Maintain accessible electronic database of research protocols</i></p> <p><b>How the correction was accomplished:</b> UCDMC policy 3091, <i>Labeling of Medications in the Perioperative and Procedural Areas</i> was not followed. The policy was revised to make it clear that it applies to biological products, as has always been the intention but was not previously elucidated. Perioperative Services staff were re-educated about the content of the policy at staff meetings and electronically via an all-staff electronic "Read Mail" file that is required reading for all staff. The "Operating Room Documentation Audit Tool" was designed and routed for review and approval with the audit of appropriate medication labeling practices to begin in early December 2012. The policy is attached below.</p> <p>Title of responsible person: Director of Perioperative Services</p> <p>Description of monitoring process: The "Operating Room Documentation Audit Tool" was designed by the Nurse Manager of Perioperative Services and routed for review and approval by Perioperative Services</p>		

Event ID: 1K5X11

5/20/2013

3:30:27PM



CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050599	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  08/30/2012
NAME OF PROVIDER OR SUPPLIER  UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 2315 Stockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO 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>what processes were needed to ensure all environmental and patient safety measures were in place.</p> <p>3 Failure to provide pre-operative, intra-operative and post-operative care in accordance with hospital policies and acceptable standards of practice</p> <p>In an interview with the MOR on 8/27/12 at 10:30 a.m., he stated he was not aware of any issues regarding the use of the non-approved biologic until he was called by the Risk Management office in mid [REDACTED] of 2011, after the third surgery. He stated he talked with the nurses at that time and "found nursing was not involved," "they didn't know anything about it." Although he was concerned that something was brought into the OR without his knowledge, he did not conduct an internal investigation. The MOR stated he had interviewed the nurses involved and they didn't remember anything "changing hands." He stated "they [the neurosurgeons] did something on the sterile field the nursing staff was not involved with." The MOR stated he didn't know what a "probiotic" was or why the nurses had not questioned the use of the word probiotic on the Informed Consent. The MOR stated Patient 1, 2, and 3's cases were never discussed at any hospital committee meetings he attended. The MOR stated it was his belief there was no necessity to develop or revise any policies regarding the use of an unapproved biologic. The MOR stated he did not file an Incident Report (IR) as he was informed the incidents "were being handled by Clinical Affairs." The MOR acknowledged he had not conducted any education</p>		<p>administration. The audit of appropriate medication labeling practices will be conducted by the charge nurses in Perioperative Services and overseen by the Nurse Manager beginning in early December 2012.</p> <p>Date of correction: December 1, 2012</p> <p><b><u>Policy #3091, Labeling of Medications in the Perioperative and Procedural Areas</u></b></p> <p><b><i>I. PURPOSE</i></b> <i>To outline the process for appropriate labeling of medications and solutions in the perioperative and procedural settings. Errors can result when medications and other solutions are removed from their original containers and placed into unlabeled containers.</i></p> <p><b><i>II. SETTING</i></b> <i>Medical Center</i></p> <p><b><i>III. DEFINITIONS</i></b> <i>A. Medication--Includes any prescription medication, sample medications, biological products, herbal remedies, vitamins, nutraceuticals, over-the-counter drugs, vaccines, diagnostic and contrast agents, radioactive medications, respiratory therapy treatments, parenteral nutrition, blood derivatives, intravenous solutions (plain with electrolytes and/or drugs) and any product designated by the United States Food and Drug Administration (FDA) as a drug.</i></p> <p><i>Solutions--Includes chemicals and reagents such as formaline, saline, sterile water, Lugol's</i></p>		

Event ID:1K5X11

5/20/2013

3:30:27PM

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050599	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  08/30/2012
NAME OF PROVIDER OR SUPPLIER  UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 2315 Stockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO 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>what processes were needed to ensure all environmental and patient safety measures were in place.</p> <p>3. Failure to provide pre-operative, intra-operative and post-operative care in accordance with hospital policies and acceptable standards of practice</p> <p>In an interview with the MOR on 8/27/12 at 10:30 a.m., he stated he was not aware of any issues regarding the use of the non-approved biologic until he was called by the Risk Management office in mid [REDACTED] of 2011, after the third surgery. He stated he talked with the nurses at that time and "found nursing was not involved." "they didn't know anything about it." Although he was concerned that something was brought into the OR without his knowledge, he did not conduct an internal investigation. The MOR stated he had interviewed the nurses involved and they didn't remember anything "changing hands." He stated "they [the neurosurgeons] did something on the sterile field the nursing staff was not involved with." The MOR stated he didn't know what a "probiotic" was or why the nurses had not questioned the use of the word probiotic on the Informed Consent. The MOR stated Patient 1, 2, and 3's cases were never discussed at any hospital committee meetings he attended. The MOR stated it was his belief there was no necessity to develop or revise any policies regarding the use of an unapproved biologic. The MOR stated he did not file an Incident Report (IR) as he was informed the incidents "were being handled by Clinical Affairs." The MOR acknowledged he had not conducted any education</p>		<p><i>B. solution, radiopaque dyes, glutaraldehyde and chlorhexidine.</i></p> <p><i>C. Applicable locations--Any surgical or other procedural setting and includes pre-, intra, and post-operative/procedural components that use medications or solutions including, but not limited to, radiology and other imaging services, endoscopy units, patient care units, surgical suites, prep areas, pre-operative holding and Post Anesthesia Care Unit (PACU).</i></p> <p><i>D. Immediately--no intervening activity, without any break in the process</i></p> <p><b>IV. POLICY</b></p> <p><i>A. Labeling occurs when medication or solution is transferred from original packaging to another container. It is unacceptable to pre-label empty syringes.</i></p> <p><i>B. Labels must include the name, strength of the medication or solution, and amount (if not apparent from the container). Expiration date must be included on the label when the product is not used within 24 hours or the product expires in less than 24 hours. Expiration date/times must be placed on products that are prepared and kept ready for emergency cases. It is acceptable to use purchased, pre-filled, pre-labeled syringes such as on procedure trays.</i></p> <p><i>C. Expiration time for propofol is six hours from the time it is drawn up. Products prepared by pharmacy in a sterile hood will have an expiration date/time on the label. Products drawn up by the anesthesiologist or operating room personnel will be given a 24 hour</i></p>		

Event ID: 1K5X11

5/20/2013

3:30:27PM

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050599	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  08/30/2012
NAME OF PROVIDER OR SUPPLIER  UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 2315 Stockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO 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>what processes were needed to ensure all environmental and patient safety measures were in place.</p> <p>3. Failure to provide pre-operative, intra-operative and post-operative care in accordance with hospital policies and acceptable standards of practice</p> <p>In an interview with the MOR on 8/27/12 at 10:30 a.m., he stated he was not aware of any issues regarding the use of the non-approved biologic until he was called by the Risk Management office in mid [REDACTED] of 2011, after the third surgery. He stated he talked with the nurses at that time and "found nursing was not involved," "they didn't know anything about it." Although he was concerned that something was brought into the OR without his knowledge, he did not conduct an internal investigation. The MOR stated he had interviewed the nurses involved and they didn't remember anything "changing hands." He stated "they [the neurosurgeons] did something on the sterile field the nursing staff was not involved with." The MOR stated he didn't know what a "probiotic" was or why the nurses had not questioned the use of the word probiotic on the Informed Consent. The MOR stated Patient 1, 2, and 3's cases were never discussed at any hospital committee meetings he attended. The MOR stated it was his belief there was no necessity to develop or revise any policies regarding the use of an unapproved biologic. The MOR stated he did not file an Incident Report (IR) as he was informed the incidents "were being handled by Clinical Affairs." The MOR acknowledged he had not conducted any education</p>		<p><i>expiration date/time unless the product expires in less than 24 hours.</i></p> <p><i>D. All labels are verified both verbally and visually by two qualified individuals when the person preparing the medication is not the person administering the medication.</i></p> <p><i>E. No more than one medication or solution is labeled at one time.</i></p> <p><i>F. Any medications or solutions found unlabeled are immediately discarded.</i></p> <p><i>G. All original containers from medications or solutions remain available for reference in the perioperative/procedural area until the conclusion of the procedure.</i></p> <p><i>H. All labeled containers on the sterile field are discarded at the conclusion of the procedure.</i></p> <p><i>I. At shift change or break relief, all medications and solutions both on and off the sterile field and their labels are reviewed by entering and exiting personnel.</i></p> <p><i>J. The only exception to the labeling requirement is if during the peri-operative or peri-procedural process, a solution or medication (either in the sterile field or out) is poured, drawn into a syringe, or otherwise removed from its original container and immediately administered by a qualified individual. For example, the anesthesia provider may draw up a medication and immediately administer and/or dispose of the entire contents of the syringe without leaving the area or moving to another function prior to administration or disposal.</i></p>		

Event ID:1K5X11

5/20/2013

3:30:27PM

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050599	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  08/30/2012
NAME OF PROVIDER OR SUPPLIER  UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 2315 Stockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO 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>what processes were needed to ensure all environmental and patient safety measures were in place.</p> <p>3. Failure to provide pre-operative, intra-operative and post-operative care in accordance with hospital policies and acceptable standards of practice</p> <p>In an interview with the MOR on 8/27/12 at 10:30 a.m., he stated he was not aware of any issues regarding the use of the non-approved biologic until he was called by the Risk Management office in mid [REDACTED] of 2011, after the third surgery. He stated he talked with the nurses at that time and "found nursing was not involved," "they didn't know anything about it." Although he was concerned that something was brought into the OR without his knowledge, he did not conduct an internal investigation. The MOR stated he had interviewed the nurses involved and they didn't remember anything "changing hands." He stated "they [the neurosurgeons] did something on the sterile field the nursing staff was not involved with." The MOR stated he didn't know what a "probiotic" was or why the nurses had not questioned the use of the word probiotic on the Informed Consent. The MOR stated Patient 1, 2, and 3's cases were never discussed at any hospital committee meetings he attended. The MOR stated it was his belief there was no necessity to develop or revise any policies regarding the use of an unapproved biologic. The MOR stated he did not file an Incident Report (IR) as he was informed the incidents "were being handled by Clinical Affairs." The MOR acknowledged he had not conducted any education</p>		<p><b>V. PROCEDURE</b></p> <p><b>A. Develop area specific procedures that meet the labeling requirements outlined in this policy.</b></p> <p><b>B. Verify that staff members follow procedures related to labeling of medications and solutions.</b></p>		

Event ID:1K5X11

5/20/2013

3:30:27PM

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050599	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____		(X3) DATE SURVEY COMPLETED  08/30/2012
NAME OF PROVIDER OR SUPPLIER  UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 2315 Stockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO 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>what processes were needed to ensure all environmental and patient safety measures were in place.</p> <p>3. Failure to provide pre-operative, intra-operative and post-operative care in accordance with hospital policies and acceptable standards of practice</p> <p>In an interview with the MOR on 8/27/12 at 10:30 a.m., he stated he was not aware of any issues regarding the use of the non-approved biologic until he was called by the Risk Management office in mid [REDACTED] of 2011, after the third surgery. He stated he talked with the nurses at that time and "found nursing was not involved," "they didn't know anything about it." Although he was concerned that something was brought into the OR without his knowledge, he did not conduct an internal investigation. The MOR stated he had interviewed the nurses involved and they didn't remember anything "changing hands." He stated "they [the neurosurgeons] did something on the sterile field the nursing staff was not involved with." The MOR stated he didn't know what a "probiotic" was or why the nurses had not questioned the use of the word probiotic on the Informed Consent. The MOR stated Patient 1, 2, and 3's cases were never discussed at any hospital committee meetings he attended. The MOR stated it was his belief there was no necessity to develop or revise any policies regarding the use of an unapproved biologic. The MOR stated he did not file an Incident Report (IR) as he was informed the incidents "were being handled by Clinical Affairs." The MOR acknowledged he had not conducted any education</p>		<p><b>#3. Failure to provide pre-operative, intra-operative, and post-operative care in accordance with hospital policies and acceptable standards of practice.</b></p> <p><b>How the correction was accomplished:</b> The standards of professional practice call for providers to act as a patient advocate, seek specialized dialogue appropriate to the patient, facilitate communication between health care professionals to enhance patient outcomes, and consult with the appropriate health care providers to determine a need for new treatments. UCDMC Nursing Practice Committee ensures that the standards of professional practice are outlined and measured in the nursing competencies that are specific to each patient care setting. The surveyors did not find deficiencies with UCDMC's policies or competencies. The correction for this deficiency is re-education of staff regarding the expectation that Perioperative Services staff will advocate for patients who are receiving care that is innovative or part of a research protocol. Policy 2517, <i>Research and Innovative Care: Operating Room Review</i>, has established a process to be followed to provide for communication to Perioperative Services staff regarding research and innovative care cases, a review process, education of staff regarding their roles in the case, communication to</p>		

Event ID: 1K5X11

5/20/2013

3:30:27PM

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>050599</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED  <b>08/30/2012</b>
NAME OF PROVIDER OR SUPPLIER  <b>UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER</b>		STREET ADDRESS, CITY, STATE, ZIP CODE <b>2315 Stockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO COUNTY</b>		
(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>for the nursing staff on standards of care, practice, safety or conduct in the OR following these events.</p> <p>The Director of Peri-operative Services (DPS), in an interview on 8/29/12 at 11 a.m., stated he first learned about the surgeries after the third case. The DPS stated he made assumptions at the time that this would be handled in Peer Review. The DPS stated he never addressed these surgeries as being outside of expected OR standards of care.</p> <p>In a subsequent interview conducted with the MOR on 8/30/12 at 8:50 a.m., he stated he did not recall a request from the Compliance Office to review OR policies and procedures. In review of the current OR policies and procedures, there was no reference to a) how staff would verify the approval of a non-standard, non-approved biologic, or b) what steps staff would take to ensure the safe scheduling, acquisition, packaging, use, handling and disposal of a biologic.</p> <p>That afternoon, after being presented with evidence of several documented e-mails, the MOR recalled a meeting held with two Compliance staff members on 9/27/11 whereby he was instructed to draft a policy that would prevent anyone from bringing in unapproved substances to the OR. In an e-mail on 7/13/12, ten months later, the MOR responded he and the Assistant Manager had determined the "IRB policies covered this" and no new policy was created.</p> <p>In an interview with the RA on 8/28/12 at 10:30 a.m., she stated MD 2 had told her the biologic</p>		<p>surgery schedulers, and other safeguards to ensure that patient's receive safe, approved care and the professional standards are met.</p> <p><b>Title of person responsible:</b> Director of Perioperative Services</p> <p><b>Description of monitoring process:</b> The Nurse Manager of Perioperative Services is responsible for the re-education of Perioperative Services staff regarding policy 2517, and is also responsible for the annual competency assessment of Perioperative Services nursing staff. Following the re-education of nursing staff during the month of December 2012, the Nurse Manager will monitor each case of research or innovative care in the Perioperative Suites and monitor that staff members appropriately advocated for their patients and followed professional practice standards.</p> <p><b>Date of correction:</b> December 15, 2012</p> <p><b>How the correction was accomplished:</b> The Medical Staff developed a policy, <i>Innovative Care</i>, in March 2012 to provide guidance and oversight to Medical Staff members in the innovative use of medical therapies, devices and/or medications in the treatment of patients. The guidelines are intended to minimize the potential risk to both patients and physicians in the delivery of innovative and compassionate care, as well as to further</p>	

Event ID: 1K5X11

5/20/2013

3:30:27PM



CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050599	(X2) MULTIPLE CONSTRUCTION: A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  08/30/2012
NAME OF PROVIDER OR SUPPLIER  UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 2315 Stockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO 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>agent had been approved for use on Patients 1, 2, and 3. The RA, who was in the OR for the surgeries of Patients 1 and 2, stated both surgeons spoke to the surgical team and told them to keep the bacteria isolated from other "tools". The RA said she observed the scrub nurse "clear off the bench" and the solution being poured into a bowl. The RA stated the surgical staff asked her during the procedure if it was safe to handle "the material." She replied, "yes," if it was handled correctly without a spill.</p> <p>In an interview with the Infection Prevention Manager (IPM) on 8/27/12 at 2:53 p.m., she stated she learned of the three neurosurgeries "from the newspaper." She identified the organism as a bacteria "rarely seen in the hospital." The IPM stated no one had asked her for any policies, procedures or clarification either before or after this was published. The IPM stated it was "unlikely [Infection Prevention Leadership] would have approved" the use of the biologic had advance knowledge of its proposed use been known. The IPM "hoped" appropriate handling, cleaning and disposal of the bacteria had been done. She described safe handling as needing to have included guarding the bacteria's container "to prevent a spill." The IPM indicated the Infection Prevention Department would have followed the post-operative clinical care of the patients, had notification of the procedures been received.</p> <p>MD 4, in an interview on 8/28/12 at 4 p.m., revealed he expected formally approved research protocols to be established prior to any innovative treatment</p>		<p>UCDMC's academic mission. The UCDMC policy on <i>Innovative Care</i> was revised in September 2012 to include an application with questions about contracts, agreements, and the plan for acquiring, handling, and storing the items needed for innovative care. The process for applying to provide innovative care, the details that are included in the application, and the oversight of the Medical Staff Organization of the delivery of innovative care that are required in the <i>Innovative Care</i> policy provide the necessary accountability of the Medical Staff to the Governing Body for quality of care and compliance with federal regulations and hospital policies.</p> <p>Title of person responsible: Chief Medical Officer</p> <p>Description of monitoring process: In all cases of innovative care, the use of unapproved drugs, devices and biologic materials used for the innovative care will be assessed by the <i>Innovative Care</i> Review Committee during the approval process. The acquisition, storage, handling, use and disposal of drugs, devices, and biologic materials will be addressed. For the next four months, all approved innovative cases will be reported to the Quality and Safety Operations Committee, including outcomes and monitoring reports. Thereafter, it will be the responsibility of the Chief Medical Officer to ensure that outcomes are monitored. This will occur for each case of innovative care, but may not happen frequently, as innovative care cases occur infrequently.</p> <p>Date of correction: The revised <i>Innovative Care</i></p>		

Event ID: 1K5X11

5/20/2013

3:30:27PM

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050599	(X2) MULTIPLE CONSTRUCTION A- BUILDING: _____ B- WING: _____	(X3) DATE SURVEY COMPLETED  08/30/2012
NAME OF PROVIDER OR SUPPLIER  UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER		STREET ADDRESS, CITY, STATE, ZIP CODE 2315 Stockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO 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>in order to define the pre-operative, intra-operative and post-operative plan of care including the safe use of the biologic. He expected treatments to be FDA approved, channeled through the IDP, with clear instructions for the handling, use and disposal of the product MD 4 acknowledged the three surgical cases, all which involved serious infection, had not been discussed at any Infection Control Committee meeting.</p> <p>4. Failure to conduct a comprehensive investigation for an adverse or sentinel event</p> <p>In multiple interviews previously referenced, hospital leaders stated they did not believe the use of a bacterial agent never tested on humans and not approved for use in the treatment of human diseases, introduced without OR staff prior knowledge or education, to intentionally cause a serious infection with no post-operative plan for treatment on three separate occasions was an adverse event.</p> <p>In review of a hospital policy ID: #1440 titled Sentinel Events, dated 5/10/10, a sentinel event was defined as "an unexpected occurrence or health care associated infection resulting in death or serious physical or psychological injury or the risk thereof." The policy further directed the occurrence be evaluated with the established criteria defined which included: "C. There has been more than one event of the same type within a six month period or D. The nature of the event could potentially undermine public confidence in the hospital." The policy stipulated the individual most</p>		<p>policy was approved by the Medical Staff Executive Committee on November 19, 2012. The education of the Medical Staff began on October 24, 2012.</p> <p><b>#4. Failure to conduct a comprehensive investigation for an adverse or sentinel event.</b></p> <p>CLARIFICATION: On page 20 of the 2567, it reads "In review of a hospital policy ID: #1513, titled <i>Reporting Serious Adverse Events</i>, there was also definition of specific adverse outcomes that would qualify to be reported as an adverse event. This included: 'B. Patient death or serious disability associated with the use of a .... biologic provided by the hospital.'"</p> <p>A key element of the descriptive language in policy #1513, the word "contaminated," has been omitted in the 2567.</p> <p>UCDMC policy 1513, <i>Reporting Serious Adverse Events</i>, requires reporting of an adverse event in which the following occurs: "Patient death or serious disability associated with the use of a <u>contaminated</u> drug, device or biologic provided by the hospital."</p> <p>The California Health and Safety Code, section 1279.1(b)(2)(A) identifies this type of reportable adverse event as: <i>Patient death or serious disability associated with the use of a</i></p>	

Event ID 1K5X11

5/20/2013

3:30 27PM

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050599	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____		(X3) DATE SURVEY COMPLETED  08/30/2012
NAME OF PROVIDER OR SUPPLIER  UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 2315 Stockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO 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>directly involved .... will be responsible for reporting submitting an incident report. The policy further directed: "If the event is determined to be a sentinel event, a root-cause analysis will be conducted."</p> <p>In review of a hospital policy ID: #1513 titled Reporting Serious Adverse Events, there was also definition of specific adverse outcomes that would qualify to be reported as an adverse event. This included: "B. Product or device events, including the following 1. Patient death or serious disability associated with the use of a...biologic provided by the hospital."</p> <p>A non-approved biologic was used on three patients without proper FDA and hospital approvals over a six month period. In accordance with statute and per hospital policy ID #1513, the facility failed to identify these surgeries as adverse events, and failed to report the events in a timely manner as required by statute. The cumulative effect of the failures identified in this document, caused, or was likely to cause, serious injury or death to the patients.</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>		<p><u>contaminated drug, device, or biologic provided by the health facility when the contamination is the result of generally detectable contaminants in the drug, device, or biologic, regardless of the source of the contamination or the product.</u></p> <p>The materials used in these three cases were not contaminated and therefore do not meet the State or UCDMC adverse event reporting criteria.</p> <p><b>How the correction was accomplished:</b> All UCDMC patient care staff were re-educated about the content of policy 1440, <i>Sentinel Events</i>, and policy 1466, <i>Confidential Incident Reports</i>, reminding them to report any practices that they observe or learn about that they believe are unsafe or depart from what they believe are acceptable standards of practice. Staff can report events by notifying their supervisors or filing an incident report. Incident reports can be filed in the electronic incident reporting system, or to a supervisor, who will create a report on the electronic incident reporting system. Incident reports are electronically routed to Risk Management, Quality and Safety, and the manager who is assigned responsibility for that category of incident reports, for review and appropriate action.</p> <p>Title of responsible person: Chief Medical Officer, Chief Patient Care Services Officer, Director of Pharmacy, Director of Perioperative Services</p>		

Event ID:1K5X11

5/20/2013

3:30:27PM

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050599	(X2) MULTIPLE CONSTRUCTION: A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  08/30/2012
NAME OF PROVIDER OR SUPPLIER  UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 2315 Stockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO 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>directly involved ... will be responsible for reporting submitting an incident report. The policy further directed: "If the event is determined to be a sentinel event, a root-cause analysis will be conducted."</p> <p>In review of a hospital policy ID: #1513 titled Reporting Serious Adverse Events, there was also definition of specific adverse outcomes that would qualify to be reported as an adverse event. This included: "B. Product or device events, including the following: 1. Patient death or serious disability associated with the use of a...biologic provided by the hospital."</p> <p>A non-approved biologic was used on three patients without proper FDA and hospital approvals over a six month period. In accordance with statute and per hospital policy ID #1513, the facility failed to identify these surgeries as adverse events, and failed to report the events in a timely manner as required by statute. The cumulative effect of the failures identified in this document, caused, or was likely to cause, serious injury or death to the patients.</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 12801(c).</p>		<p>Description of monitoring process: UCDMC Risk Management oversees the incident reports on a daily basis. Monthly, the Patient Safety Events Committee will review a report of the incident reports from the previous month that breaks out the incident reports into categories, and provides detail of all incident reports flagged as causing harm to a patient or having the potential to cause harm to a patient. This activity will allow the Patient Safety Events Committee to systematically monitor incident reports that may identify practice that is unsafe or departs from acceptable standards of practice and do further study to ensure that unsafe practice is addressed and prevented.</p> <p>Date of correction: June 1, 2013</p>		

Event ID: 1K5X11

5/20/2013

3:30:27PM