California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CA220000031	A. BUILDING _____ B. WING _____	09/24/2007

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CSF MEDICAL CENTER	505 PARNASSUS AVE SAN FRANCISCO, CA 94143

(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
A 000	Initial Comments The following reflects the findings of the Department of Public Health during a Full Validation Survey. State of California CDPH - L&C NOV 21 2007 Daly City Dist. Office Representing the Department of Public Health: [redacted] Pharmaceutical Consultant [redacted] Pharmaceutical Consultant [redacted] Pharmaceutical Consultant [redacted] Medical Consultant [redacted] Health Facilities Evaluator Nurse [redacted] Health Facilities Evaluator Nurse [redacted] Health Facilities Evaluator Nurse [redacted] Dietician 1280.1(a) Health and Safety Code Section 1280 (a) If a licensee of a health facility licensed under subdivision (a), (b), or (f) of Section 1250 receives a notice of deficiency constituting an immediate jeopardy to the health or safety of a patient and is required to submit a plan of correction, the department may assess the licensee an administrative penalty in an amount not to exceed twenty-five thousand dollars ($25,000) per violation. 1280.1(c) Health and Safety Code Section 1280 (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.	A 000	**Corrective Action (A 334-a):** By midnight on September 20, 2007 UCSF Medical Center conducted a 100% review and reconciliation with physician orders of all Medication Administration Records (MAR)/Medication Prescription Record (MPR) on every inpatient at Mount Zion and at Moffitt/Long hospitals. Between midnight of September 20, 2007 and the morning of September 21, 2007, extra RN staff were deployed throughout the Medical Center to double check all orders written over night and transcribed by the bedside nursing staff. By 9:00 am on the morning of September 21, 2007, UCSF Medical Center had deployed additional staff ("transcribers") to each unit to partner with the Medication Safety Nurse to assist with order transcription. Beginning with the 7pm change of shift report on ~~9/20/07, nurses were educated about the new~~ process. This education continued at each change of shift for 7 days. Physicians were informed of the process on 9/20/07 via an email from the CMO, reminding them of the requirements for a complete medication order. Since this time, in order to ensure ongoing accuracy of the MARs, UCSF Medical Center has begun implementation of an automated medication administration record ("aMAR"). The phased aMAR implementation began on 11/15/07. Additionally, transcribers and Medication Safety Nurses (MSN) remain in place to assist with order transcription. Two RNs check all orders and transcription. Additional clarification of ambiguous or incomplete orders is also provided by the pharmacy staff upon review of the scanned	9/20/07 11/15/07
A 334	CCR TITLE 22 DIV5 CH1 ART3 -70263(c) Pharmaceutical Service General Requirements (c) A pharmacy and therapeutics committee, or a	A 334		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE — TITLE — (X6) DATE

11/21/07

STATE FORM 021189 HJ6K11 If continuation sheet 1 of 11

POC accepted by R. Christensen, reviewed by K. Rubin. 11/30/07

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A 334	Continued From Page 1 committee of equivalent composition, shall be established. The committee shall consist of at least one physician, one pharmacist, the director of nursing service or her representative and the administrator or his representative. (1) The committee shall develop written policies and procedures for establishment of safe and effective systems for procurement, storage, distribution, dispensing and use of drugs and chemicals. The pharmacist in consultation with other appropriate health professionals and administration shall be responsible for the development and implementations of procedures. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate. ~~(2) The committee shall be responsible for the~~ development and maintenance of a formulary of drugs for use throughout the hospital. The above regulations are not met as evidenced by: Based on clinical record review of three patients (Patient 1, 2 and 3), document review, and interview of hospital staff, the hospital failed to ensure that policies and procedures were developed and/or implemented to ensure accurate administration of medications to Patient 2, and minimize adverse medication outcomes for Patient 1 and 3 as evidenced by the following: a. Patient 2 ' s medication administration record (MAR: used by nursing staff to guide the administration of medications to their patients) did not accurately reflect the physician orders which potentially exposed Patient 2 to the excessive effects of medications or deprived the patient of the benefit of medications therapy for those medications which did not appear on the	A 334	order, as necessary. In addition, a multi-disciplinary Transcription Clarification and Standardization Workgroup (composed of Pharmacy, Nursing and Medical Staff representation) was formed on 10/4/07 to standardize transcription throughout the inpatient units. The Nursing Education Department has developed a Transcription Training Competency. All nurses are required to undergo re-education of transcription guidelines in conjunction with the aMAR implementation on their units. **Monitoring:** To ensure accuracy of the MARs matching the MD orders, effective August of 2007, UCSF Medical Center is auditing and reconciling approximately 230 MARs/MPRs weekly. Audit results are reviewed by Pharmacy and the Patient Care Managers. Direct feedback is provided to staff and opportunities for improvement are identified. Audit results are reviewed on a monthly basis at the Medication Safety Committee, Nursing Performance Improvement Executive Committee (NPIEC), and on a quarterly schedule at the Quality Improvement Executive Committee (QIEC), until the aMar is implemented. Once the aMar is implemented the staffing and monitoring plan will be reviewed and revised as needed. **Responsible Party:** Chief Nursing Officer, Chief Medical Officer, Director of Pharmacy **Corrective Action (A 334-b):** Beginning the evening of September 20, 2007, the Worx station system instructions have included a flag on any fentanyl patch dose increase that occurs more frequently than every 3 days after the initial dose or more frequently than	9/20/07

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A 334	Continued From Page 2 MAR. b. Patient 1 received dose increases in fentanyl patch (a potent synthetic opiate narcotic manufactured in patch form that releases the medication in a controlled fashion and is indicated for the management of chronic pain in narcotic tolerant patients whose pain has not been manageable by other means) that were not in accordance with the manufacturer's dosing guidelines and as a result required treatment with a reversal agent, naloxone. c. Review of Patient 3 ' s clinical record on September 22, 2007 at 11:47 a.m. revealed the hospital failed to ensure that a possible adverse reaction to ondansetron (Zofran: used to treat nausea) had been entered onto the physician order sheets by a physician and had been documented on the cover of Patient 3 ' s clinical record, as required by a hospital policy and procedure, so that subsequent physicians and other staff such as pharmacists would be alerted to this reaction. As the reaction was not documented on the cover of the clinical record, a second physician prescribed ondansetron six days later potentially exposing Patient 3 to the drug a second time. Findings: 1. On 9/20/07 at 11:38 a.m., a review of Patient 2 ' s clinical medical record revealed the patient was status post heart transplant in [redacted] 2007 and diagnosed to be immunosuppressed (suppression of the immune system by drug use in order to prevent the rejection of grafts or transplants). A review of Patient 2 ' s Medication Administration Record (MAR) against the current	A 334	every 6 days thereafter, as recommended by the product insert. The flag prompts the pharmacist to contact the ordering physician to confer and discuss treatment alternatives. On 9/20/07, a one time review of all fentanyl patch orders was conducted by a pharmacist. Physicians were informed by email on September 20, 2007 that fentanyl patch increases more frequent than those recommended on the product insert will result in a consultation with a pharmacist. **Monitoring:** All fentanyl patch dose increases are reviewed by a pharmacist for compliance with manufacturer recommendations. **Responsible Party:** Director of Pharmacy **Corrective Action (A 334-c):** On September 22, 2007, UCSF Medical Center conducted a 100% review of each patient's orders to ascertain the allergy status of each patient at Moffitt/Long and Mount Zion campus. Nursing checked the MAR, armband and allergy sticker on the front of the chart to ensure conformance to policy. Any discrepancies identified were clarified with the physician, as appropriate, and documented according to policy. By 0800 September 23, 2007 nursing provided to pharmacy a list of all patients with allergies. On September 23, 2007 pharmacy updated the pharmacy profile for patients with allergies as needed. Beginning September 24, 2007, nursing and physician staff were reeducated to policy and procedure related to allergies.	9/22/07

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A 334	Continued From Page 3 physician orders revealed 9 medication order discrepancies out of a total of 30 medications. The following were the 9 discrepancies found, along with the medication order as written: a. Valgancyclovir (antifungal medication) - patient received 450mg twice a day as documented on the MAR. The current order in the chart was for 450mg daily. The patient received double the dose which could lead to adverse drug consequences. b. Magnesium Oxide (magnesium supplement) - patient received 800mg twice a day as documented on the MAR. The current order in the chart was for 800mg daily. The patient received double the dose which could lead to adverse drug consequences. c. Robaxin 500mg every 6 hours as needed for muscle spasm- this medication was listed on the MAR. There was no current order in the chart for the patient to receive this medication. d. Vicodin 1-2 tablets every 6 hours as needed for pain was ordered for the patient on [redacted]2007. This medication was not listed on the MAR so the nursing staff would not know the patient had an order for this medication when needed to treat his pain. e. Zofran 4mg IV every 6 hours as needed for nausea and vomiting was documented on the MAR. There was no current order in the chart for the patient to receive this medication. f. Bisacodyl suppositories 10mg rectally every 12 hours as needed for constipation was ordered on [redacted]2007. This medication was not listed on the MAR so the nursing staff would not know the patient had an order for this medication	A 334	The *Adverse Drug Reaction (ADR) Identification, Reporting and Documentation Policy*, (6.09.01) (see Attachment 1), was revised and approved by the P&T Committee on 11/14/07. The policy stipulates that ADRs requiring specific intervention, increased monitoring, which are potentially life-threatening or cause permanent damage or that are associated with a medication that should not be re-administered are treated in the same manner as allergies (Policy 6.07.18 *Allergy Identification and Documentation*)(see Attachment 2). This requires documentation in the medical record through a physician order which is scanned to pharmacy so that the information is entered into the pharmacy system and the patient's pharmacy profile. Concomitant allergy alerts are implemented (alert sticker on the chart, allergy armband, MAR/flowsheet notations). The policy also stipulates a newly created ADR hotline with the aim to increase the reporting of ADRs by staff. Nurses, physicians and pharmacists were educated regarding the policy changes beginning 11/16/07. **Monitoring:** Beginning September 22, 2007, proper documentation of allergies and ADRs, as described above, was monitored by UCSF Medical Center for a period of seven weeks. On 9/22/07, Medication Safety Nurses performed a 100% review of all patients with documented allergies to ensure conformance to policy. All patients with known allergies and/or serious ADRs were reviewed for proper documentation in the medical record, MAR and presence of an allergy armband. Review showed an increase in compliance from a baseline of	11/14/07

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A 334	Continued From Page 4 when needed for constipation. g. Clonidine (blood pressure medication) 0.3mg three times a day was ordered on [redacted] 2007 with the following blood pressure monitoring parameters, i.e. hold if systolic blood pressure less than 80, pulse less than 55. These parameters were not transcribed on the MAR and the patient might receive this medication when it should have been held. h. Amlodipine (blood pressure medication) 10mg daily was ordered on [redacted] 2007 with the following monitoring parameters, i.e. hold if systolic blood pressure less than 80. This parameter was written on the MAR as hold if systolic blood pressure less than 90. This incorrect parameter could prevent a needed dose from being given. I. Tylenol 650mg every 4 hours as needed for temperature greater than 38.5 or mild pain. According to the facilities plan of correction from a previous survey performed on [redacted] 2007 and dated [redacted] 2007, Tylenol orders should have a maximum daily dose included with each order. The MAR which should have reflected the complete physician order including parameters and maximum doses did not have this maximum daily dose documented. 2. On September 18, 2007 review of Patient 1's clinical record revealed that on [redacted] 2007, a physician ordered that a 25 micrograms per hour (mcg/hr) fentanyl patch be applied to Patient 1. Fentanyl is a potent synthetic opiate narcotic. One available dosage form is a patch that releases the medication at a controlled rate measured in mcg/hr. It is indicated for the treatment of chronic pain that is not adequately controlled by other means. On [redacted] the	A 334	94% up to 99% with each alert element of the policy. **Responsible Party:** Director of Pharmacy and Chief Nursing Officer **Corrective Action (A 334-1):** By midnight on September 20, 2007 UCSF Medical Center conducted a 100% review and reconciliation with physician orders of all Medication Administration Records (MAR)/Medication Prescription Record (MPR) on every inpatient at Mount Zion and at Moffitt/Long hospitals. Between midnight of September 20, 2007 and the morning of September 21, 2007, extra RN staff were deployed throughout the medical center to double check all orders written over night and transcribed by the bedside nursing staff. By 9:00 am on the morning of September 21, 2007, UCSF Medical Center had deployed additional staff ("transcribers") to each unit to partner with the Medication Safety Nurse to assist with order transcription. Beginning with the 7pm change of shift report on 9/20/07, nurses were educated about the new process. This education continued at each change of shift for 7 days. Physicians were informed of the process on 9/20/07 via an email from the CMO, reminding them of the requirements for a complete medication order. Since this time, in order to ensure ongoing accuracy of the MARs, UCSF Medical Center has begun implementation of an automated medication administration record ("aMAR"). The phased aMAR implementation began on 11/15/07.	9/20/07 11/15/07

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A 334	Continued From Page 5 dose was increased to a 50 mcg/hr patch. On [redacted] 2007 the dose was increased to a 75 mcg/hr patch. On [redacted] 2007 the dose was increased to a 100 mcg/hr patch. On [redacted] 2007 the dose was increased to a 150 mcg/hr patch and on [redacted] the dose was reduced to a 75 mcg/hr patch. Review of a physician ' s progress note in the electronic clinical record on September 18, 2007 at 4:21 p.m. revealed that on [redacted] 2007 at 11:32 a.m. a physician noted that the fentanyl patch had been " Increased considerably " yesterday-based on large amount of PRN (as needed) Roxanol (a liquid morphine preparation) use. While writing note, nurse contacted me that RR (respiratory rate: normal rate for an adult, per the Medline Plus Medical Encyclopedia, is 8 to 16 breaths per minute) 7-8 (breaths per minute). Will give Narcan 0.1mg IV X1 (one 0.1 mg dose of the narcotic reversal agent Narcan), hold all PRN po (oral) Roxanol this afternoon and change fentanyl patch back to 75 mcg TD (transdermal: in other words via the patch) q72 (every 72 hours). Will also check RR q1H (every one hour) throughout the afternoon-dose given yesterday around 4 p.m. " On September 18, 2007 at 4:05 p.m. review of the manufacturer ' s package labeling for the fentanyl patch in the Mt. Zion Campus pharmacy revealed the manufacturer documented that (1) each patch could be worn for 72 hours (2) that the initial patch dose could be increased after three days based on supplemental doses of narcotics administered during the three day period. The product labeling documented that after increasing the fentanyl patch dose it may take up to six days to reach a new equilibrium on this new dose and, therefore, patients should wear the new higher dose through two	A 334	Additionally, transcribers and Medication Safety Nurses (MSN) remain in place to assist with order transcription. Two RNs check all orders and transcription. Additional clarification of ambiguous or incomplete orders is also provided by the pharmacy staff upon review of the scanned order, as necessary. In addition, a multi-disciplinary Transcription Clarification and Standardization Workgroup (composed of Pharmacy, Nursing and Medical Staff representation) was formed on 10/4/07 to standardize transcription throughout the inpatient units. The Nursing Education Department has developed a Transcription Training Competency. All nurses are required to undergo re-education of transcription guidelines in conjunction with the aMAR implementation on their units. **Monitoring:** To ensure accuracy of the MARs matching the MD orders, effective August of 2007, UCSF Medical Center is auditing and reconciling approximately 230 MARs/MPRs weekly. Audit results are reviewed by Pharmacy and the Patient Care Managers. Direct feedback is provided to staff and opportunities for improvement are identified. Audit results are reviewed on a monthly basis at the Medication Safety Committee, Nursing Performance Improvement Executive Committee (NPIEC), and on a quarterly schedule at the Quality Improvement Executive Committee (QIEC), until the aMar is implemented. Once the aMar is implemented the staffing and monitoring plan will be reviewed and revised as needed. **Responsible Party:** Chief Nursing Officer, Chief Medical Officer, Director of Pharmacy	

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A 334	Continued From Page 6 applications (of 72 hours each) before any further increase in dosage via the patch was made. During an interview of Staff Member 1 in the Mt. Zion Campus pharmacy on September 18, 2007, he could provide no evidence that supported deviation from the titration schedule as documented by the manufacturer in the product labeling or that pharmacy staff had questioned the dose increase as ordered. 3. On September 22, 2007 at 11:47 a.m., review of Patient 3 's clinical record at the Mt. Zion Campus revealed that the Adult Admit/Transfer Orders dated [redacted] 2007 documented that Patient 3 had no known allergies. The clinical record contained two pre-printed orders for patient controlled analgesia (PCA: allows the patient to self administer pain medication within physician established parameters while under nursing monitoring) dated [redacted] at 7:10 a.m. and [redacted] at 12:25 a.m. respectively. Physician 2 had signed the second set of PCA orders. Both pre-printed PCA order sets also had a space in which any allergies a patient had could be added by the prescribing physician. The prescribing physician had written " NKDA " (no known drug allergies) in the allergy space on both PCA orders sets. Both PCA orders sets pre-printed orders for ondansetron (Zofran: used to treat nausea) to be given intravenously every 6 hours as needed for nausea. Because the orders had been checked on both order sets, the physician had indicated that the patient was to receive this drug as needed to control any nausea the patient may have while on PCA. On [redacted] 2007 at 1:25 p.m. Physician 1 discontinued the Zofran (from the first order set). On [redacted] 2007, at 9:05 a.m., Physician 1 discontinued	A 334	**Corrective Action (A 334-2):** Beginning the evening of September 20, 2007, the Worx station system instructions have included a flag on any fentanyl patch dose increase that occurs more frequently than every 3 days after the initial dose or more frequently than every 6 days thereafter, as recommended by the product insert. The flag prompts the pharmacist to contact the ordering physician to confer and discuss treatment alternatives. Physicians were informed by email on September 20, 2007 that fentanyl patch increases more frequent than those recommended on the product insert will result in a consultation with a pharmacist. On 9/20/07, a one time review of all fentanyl patch orders was conducted by a pharmacist. On 9/20/07, physicians were informed by email that fentanyl patch increases more frequent than those recommended on the product insert would result in a flag by the pharmacy. **Monitoring:** All fentanyl patch dose increases are reviewed by a pharmacist for compliance with manufacturer recommendations. **Responsible Party:** Director of Pharmacy **Corrective Action (A 334-3):** On September 22, 2007, UCSF Medical Center conducted a 100% review of each patient's orders to ascertain the allergy status of each patient at Moffitt/Long and Mount Zion campus. Nursing checked the MAR, armband and allergy sticker on the front of the chart to ensure conformance to policy. Any discrepancies identified were clarified with the physician, as appropriate, and documented according to policy.	9/20/07 9/22/07

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A 334	Continued From Page 7 Zofran again (from the second order set) with instructions to " See AOS " (antibiotic order sheet). Review of the antibiotic order sheet revealed that it too had a space in which the patient ' s allergies, if any, could be filled in and Zofran had been filled in the space. Review of the medication administration record (MAR: used to document the date and time a dose of medication was administered to a resident and the identity of the person administering the dose) revealed that this patient received one 4 mg dose of ondansetron on [redacted]2007 at 7 p.m. All the MARs had a space in which the patient ' s allergies, if any, could be written. All the MARs in Patient 3 ' s clinical record had " ondansetron " written in on this " Allergic to: " space. Other clinical records had been noted during the survey that had red bordered allergy stickers on the front cover of the clinical record on which staff had written in the allergies for those patients but Patient 3 ' s clinical record had no such sticker on the cover. During an interview of Patient 3 on September 22, 2007 at 12:45 p.m. in her room, she stated that one night she felt nauseated and requested Zofran (she only received one dose on [redacted] as documented above). Soon after getting it, she felt numbness in her feet that over a period of 15 to 20 minutes moved up her body until her whole body including her face was involved. She also reported that she had difficulty breathing and that her fingers felt stiff. She reported that she had had the same reaction, only more severe, during a car trip a couple of months prior to her hospitalization. She stated she had that reaction after consuming two cans of a commercially available beverage, however she consumed the beverages at about 11 a.m. and later in the	A 334	By 0800 September 23, 2007 nursing provided to pharmacy a list of all patients with allergies. On September 23, 2007 pharmacy updated the pharmacy profile for patients with allergies as needed. Beginning September 24, 2007, nursing and physician staff were reeducated to policy and procedure related to allergies. The *Adverse Drug Reaction (ADR) Identification, Reporting and Documentation Policy*, (6.09.01) (see Attachment 1), was revised and approved by the P&T Committee on 11/14/07. The policy stipulates that ADRs requiring specific intervention, increased monitoring, which are potentially life-threatening or cause permanent damage or that are associated with a medication that should not be re-administered are treated in the same manner as allergies (Policy 6.07.18 *Allergy Identification and Documentation*)(see Attachment 2). This requires documentation in the medical record through a physician order which is scanned to pharmacy so that the information is entered into the pharmacy system and the patient's pharmacy profile. Concomitant allergy alerts are implemented (alert sticker on the chart, allergy armband, MAR/flowsheet notations). The policy also stipulates a newly created ADR hotline with the aim to increase the reporting of ADRs by staff. Nurses, physicians and pharmacists were educated regarding the policy changes beginning 11/16/07. **Monitoring:** Beginning September 22, 2007, proper documentation of allergies and ADRs, as described above, was monitored by UCSF Medical Center for a period of seven weeks. On 9/22/07, Medication Safety Nurses performed a 100% review of all	11/14/07

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A 334	Continued From Page 8 afternoon but did not have the reaction until about 8 that evening. She had an allergy alert bracelet on her arm listing ondansetron as a medication to which she was allergic and she reported this band had been put on her arm the day after the reaction. On September 22, 2007, at 1:15 p.m. during an interview of Physician 1 on Mt. Zion Campus, he stated that he wrote the orders to discontinue ondansetron on both [redacted] and [redacted] 2007. He stated that he had been called because the resident had complained of rigors (shaking). He was not sure if the patient had had an adverse reaction to ondansetron but after discussing the issue with the nursing staff, he decided to call this an " allergic " reaction. He stated that it would be prudent after a patient has had a reaction soon after getting a drug to discontinue it and to prevent the patient from getting it again unless the need was so great that a test dose would be attempted to see if the patient might tolerate the medication in question. He was notified by the nursing staff on [redacted] 2007 that ondansetron had been prescribed to the patient with a documented allergy to the medication (this was documented on the MARs) and requested that he discontinue the medication which he did. He stated that he depended on the presence of an allergy sticker on the front of the clinical record as well as a review of the Adult Admit/Transfer Orders to determine a patient ' s allergy status. As this adverse reaction occurred after admission, caregivers would have to depend on an " allergy " sticker placed on the cover of this patient ' s clinical record with the offending medication filled in as the first line of prevention for the receipt of this medication. Review of Patient 3 ' s computerized medication	A 334	patients with documented allergies to ensure conformance to policy. All patients with known allergies and/or serious ADRs were reviewed for proper documentation in the medical record, MAR and presence of an allergy armband. Review showed an increase in compliance from a baseline of 94% up to 99% with each alert element of the policy. **Responsible Party:** Director of Pharmacy and the Chief Nursing Officer	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CA220000031	A. BUILDING _____ B. WING _____	09/24/2007

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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A 334	Continued From Page 9 profile in the Mt. Zion Campus pharmacy revealed that Zofran was listed as an allergy. When asked when it had been entered into the profile data base, Staff Member 3 determined that ondansetron had been entered into the allergy field on [redacted]2007, seven days after the original incident and six days after ondansetron had been discontinued on [redacted]2007. On September 22, 2007 at 2:56 p.m. review of the policy and procedure entitled Allergy Identification revealed it stipulated that if allergies are identified during the course of a patient ' s hospital stay, the physician will document the allergy on the physician order sheet which will then be processed and sent to the pharmacy and other departments as necessary. It documented that nursing staff were to affix an allergy sticker on the clinical record cover and note the allergies on the sticker. On September 22, 2007 at 12:33 p.m. during an interview of Staff Member 4 on Mt. Zion Campus, she stated there should have been an allergy sticker on the cover of Patient 3 ' s clinical record (noting ondansetron as an " allergy ") and it was, in fact, not there. Other staff members who were present at the time of the interview of Staff Member 4 all agreed that while the reaction was not an allergic reaction (mediated by antibodies produced by the body after exposure to a foreign substance) it should be noted in allergy fields in and on the clinical record (and by extension, in the computerized pharmacy patient profile) in order to alert physician and other staff members that the patient had had such a reaction in the past. No evidence was provided that the Physician 1 had filled in this adverse reaction in the physician order sheet or that the pharmacy had been notified of this adverse reaction (until seven days	A 334		

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A 334	Continued From Page 10 after the index reaction) as required by the hospital policy and procedure. No allergy sticker had been placed on the cover of the clinical record at the time of the reaction which could have subsequently alerted Physician 2 about the " allergy " so that he could have taken that into consideration when he filled out the pre-printed PCA order set on [redacted] 2007 when he ordered ondansetron for Patient 3 for a second time. The violations have caused or are likely to cause serious injury or death to the patients.	A 334		