STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050079	A. BUILDING _____ B. WING _____	10/19/2007

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
DOCTORS MEDICAL CENTER - SAN PABLO	2000 VALE RD, SAN PABLO, CA 94806 CONTRA COSTA COUNTY

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	California Code of Regulations (CCR) Title-22 70263. Pharmaceutical Service General Requirements (c) A pharmacy and therapeutics committee, or a 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. (1) The committee shall develop written polices 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. Polices shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate. The above Regulations are NOT MET as evidenced by: Based on observation, clinical record review of three open records and four closed records of patients who had been prescribed a fentanyl patch, document review and staff interview, the hospital failed to ensure the development of policies for safe and effective use of Fentanyl Patches to minimize adverse consequences by failing to ensure that pharmacy staff questioned the application of fentanyl patches to a non-opiate tolerant Patient (Patient 400) and failing to develop hospital guidelines for the dosing of this medication outside			

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	Continued From page 1 of the manufacturer's specifications (Patient 401) resulting in an Immediate Jeopardy to patient safety. Findings: 1. On October 18, 2007 at 11:59 a.m., review of Patient 400's clinical record revealed that Patient 400 presented to the Emergency Department on September 28, 2007 with complaint of progressive left-sided weakness. The discharge summary documented that Resident 400 had a diagnosis of right ischemic cerebrovascular accident (stroke) with left-sided hemiparesis (paralysis on the left side of the body) and that he had an acute cardiopulmonary arrest. Review of the Admission Medications - (Home Medications) (used by the hospital to document the medications a patient was taking at home prior to admission) revealed that it listed as needed Tylenol #3 (acetaminophen 325 mg with codeine 30 mg: used to treat pain) at home. There was no indication as to how much Tylenol and codeine he took at home. Review of the Physician Orders revealed that on September 28, 2007 at 5:20 a.m. a physician ordered Vicodin (a pain medication containing 500 milligrams (mg) of acetaminophen and 5 mg of hydrocodone, a narcotic, in each tablet) one tablet every six hours as needed for pain. On September 29, 2007 at 8:35 p.m. a physician ordered morphine (a narcotic pain medication) 2 mg intravenously (IV) every four hours as needed for pain which was subsequently discontinued on September 30th at 1 p.m. at which time a physician ordered a Duragesic			

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	Continued From page 2 Patch (fentanyl patch: a narcotic pain medication) 25 micrograms/hour (mcg/hr) be applied to the chest ever 72 hours. At 7:55 p.m. on September 30, 2007, a telephone order for morphine 2 mg IV every four hours as needed for severe pain was taken from a physician by a nurse. Fentanyl patches contain a potent synthetic opioid narcotic called fentanyl which is released at a constant rate from the patch into the body via the skin. The product labeling for this medication contains a boxed warning. The Federal Register [Food and Drugs: Labeling, 21 CFR □ 201.57(c)(1)] describes boxed warnings as follows: Certain contraindications or serious warnings, particularly those that may lead to death or serious injury, may be required by the FDA to be presented in a box. The boxed warning ordinarily must be based on clinical data but serious animal toxicity may also be the basis of a boxed warning in the absence of clinical data. The boxed warning for the fentanyl patch makes the following points: a. It is indicated for the management of chronic pain that requires around the clock opioid administration for an extended period of time that cannot be managed by other means. b. Because serious or life-threatening hypoventilation (slow rate of breathing) could occur, a fentanyl patch is contraindicated in patients who are not opioid tolerant. c. Opioid tolerance is defined as intake of 60 mg of			

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	Continued From page 3 morphine each day for a week or longer or an equivalent amount of another narcotic. 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) at this time revealed Patient 400 received one tablet of Vicodin at 10:15 p.m. on September 28, 2007, at 11:55 a.m. on September 29, 2007, and at 10:15 a.m. on September 30, 2007 as well as morphine 2 mg IV at 8:50 p.m. on September 29, 2007 prior to the application of a 25 mcg/hr Duragesic (fentanyl) patch at 2 p.m. on September 30, 2007. Patient 400 received a total equivalent dose of 10 mg of oral morphine per day for two days or four percent of the total dose of 420 mg divided over seven days that would be required before a patient would be considered opioid tolerant. On October 18, 2007 at 4:05 p.m. during in interview of the Director of Pharmacy, she stated pharmacy did not determine if Resident 400 was opioid tolerant or question the use of the patch in this patient nor were there any alerts in the pharmacy computerized patient profile system regarding this medication dosage form. 2. On October 19, 2007 at 11:37 a.m. review of Patient 401's clinical record revealed that on September 21, 2007 a physician ordered that a 50 mcg Duragesic patch be placed (for the first time) on the patient and that it be changed every 72 hours. On October 1, 2007 at 9 a.m. the dose was increased to a 75 mcg Duragesic patch every 72 hours. On October 3, 2007 at 8:35 a.m. the dose was increased to a 100 mcg Duragesic patch every			

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	Continued From page 4 72 hours with the stipulation that the new dose be placed when the previous patch was due to be replaced (on October 4, 2007). Review of the MAR at this time revealed that the 75 mcg patch was applied at 10 a.m. on October 1, 2007 and that the 100 mcg patch was applied at 10 a.m. on October 4, 2007. The product labeling for this medication documents that the initial (first time) dose may be increased after 3 days based on the daily dose of supplemental opioid medications required during that period. However, the manufacturer documents that it may take up to six days after a dose increase to reach a new equilibrium, therefore, it is recommended that patients should wear the new higher dose through two cycles of 72 hours each (six days) before further dosage increases are made based on the average daily use of supplemental analgesic (pain medication) use. On October 19, 2007 at 2:39 p.m. review of the MAR from October 1 through October 3, 2007 revealed that Patient 400 did not receive any supplemental doses of opioid pain medication in addition to the regularly scheduled oral combination pain medication (acetaminophen 325 mg/hydrocodone 10 mg) that Patient 401 had been receiving since September 20, 2007. On October 19, 2007 at 2:07 p.m. during an interview of the Director of Pharmacy, she stated there was no evidence in the pharmacy that a pharmacist had called the physician regarding the dosage titration outside of the manufacturer's			

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	Continued From page 5 guidelines as documented in the manufacturer's product labeling available in the pharmacy. The cumulative effect of these systemic problems resulted in the facility's inability to ensure the provision of quality health care in a safe and effective manner. The continued violation(s) has caused, or is likely to cause, serious injury or death to patient(s). On October 18, 2007 at 4:53 p.m. and October 19, 2007 at 3:16 p.m. the hospital administrative staff was informed of the findings regarding Patient 400 and 401 with respect to the use of fentanyl patches as outlined above and the Immediate Jeopardy to patient safety. The administrative staff presented an amended Plan of Correction on October 19, 2007 at 4:30 p.m. which abated the IJ.			

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