

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050225	(X2) MULTIPLE CONSTRUCTION A.  BUILDING B.WING	(X3) DATE SURVEY COMPLETED  06/25/2007	
NAME OF PROVIDER OR SUPPLIER  FEATHER RIVER HOSPITAL	STREET ADDRESS, CITY, STATE, ZIP CODE  5974 PENTZ ROAD, PARADISE, CA 95969 BUTTE COUNTY			
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E 100 Initial Comments

The following represents the findings of the California Department of Public Health, formerly known as the Department of Health Services during a sample validation survey conducted 6/18/07 - 6/25/07.

Representing the Department:  
 Letitia Creighton, HFEN  
Dagmar Bender-Porter, Registered Dietitian

Event ID:R60111

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

8/13/2007

1:45:33PM

TITLE

(X6) DATE

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Everett Davis, Physician  
Robert Menet,  
Pharmacist  
Francia Trout, Medical Records  
Consultant

DEFICIENCY            CONSTITUTING            IMMEDIATE  
JEOPARDY:

E 475 T22 DIV5 CH1 ART3-70263(c)(1)  
Pharmaceutical Service General  
Requirements

(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

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State-2567

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administration and medical staff where such appropriate.	is
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Based on record review, staff interviews, and a review of the hospital's written policies and procedures, the pharmacist in consultation with appropriate hospital staff and committees had not developed guidelines, protocols or policies and procedures, in accordance with accepted standards of practice and State regulations to ensure patient safety for the control, distribution and use of medications in the facility for 5 of 74 patients (Patients 16,41,42,51 and 70).

\* The hospital utilized pre-printed medication order forms that allow for the selection of duplicate drug therapy (as to drug, dosage, route of administration, or indication for use); which lacked clear guidance to

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ensure that these medications would be used safely, in a clear and unambiguous manner. Patients 16, 41, 42, 51 and 70 had multiple orders for opiate analgesics and/or drugs to control nausea and vomiting. (Patient 16 had 8 opiate analgesics and 4 drugs for nausea ordered; Patient 41 had 8 opiate analgesics and 4 drugs for nausea ordered; Patient 42 had 8 opiate analgesics and 4 drugs for nausea ordered; Patient 51 had 8 opiate analgesics and 4 drugs for nausea ordered; Patient 70 had 3 drugs for itching, 1 for nausea, and 3 opiate analgesics ordered.) National organizations for patient safety, such as the Institute for Safe Medication Practices (ISMP), have published reports that show multiple orders for opiates (a class of medications used to treat pain) have a high risk for causing death or serious harm.

\* In order to ensure that medications are used in a safe, consistent and objective manner the accepted

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standard of practice, as established by the ISMP, require limiting the number of medications being ordered for pain control; establishing clear guidelines for the use of specific medications when used for the same reason; the establishment of a system of alerts or warnings when a patient is receiving multiple opiates; and the use of a pain management specialist for high risk patients such as the elderly. The facility lacked guidelines, protocols or policies and procedures for use of high risk medications (opiate analgesics) that ensured these medications would be used in a safe, consistent, and objective and manner. The facility lacked a system of warnings or alerts regarding patients receiving "as needed" multiple medications for the same reason.

\* Patients 16, 41, 42 and 51 were elderly patients who had orders to receive meperidine (an opiate medication used for pain control). The accepted standard of

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practice, as established by recommendations of the ISMP, Lexi-Comp Online (drug information system), and the American Society of Health-System Pharmacists is to avoid the use of meperidine in elderly patients due to an increased risk of adverse effects.

\* The pharmacy department repeatedly failed to identify or remedy duplicate drug therapies; the potential for serious drug interactions or adverse reactions; ensure that the intent of medication orders were clear and unambiguous; or assess for therapeutic appropriateness.

The cumulative effects of these systemic problems resulted in the hospital's inability to ensure the provision of quality health care in a safe and effective manner. At 2:15 p.m., on 6/21/07, the presence of an Immediate Jeopardy was declared and the hospital President/CEO, Vice President Patient Care Services,

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and the Corporate Compliance Officer were notified. This Immediate Jeopardy was brought about by:

Findings:

1. During a review of Patient 70's record on 6/19/07, at 9:20 a.m., a pre-printed set of orders entitled "Routine Standard Orders for L&D (labor and delivery) Continuous Epidural Narcotic Infusion" were noted. The pre-printed orders were designed so that to activate an order for a medication the prescriber would simply check a box for that order. Listed under the heading of "As needed Medications ... " were three medications for "itching" (Benadryl IVP an antihistamine; Narcan [sic] SQ~a drug used to reverse the effects of opiate analgesics; and Nubain IV~an opioid analgesic sometimes used for itching); one medication for "nausea" with two different dosages and routes of administration (Phenergan 1M or IV~an

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antihistamine); and three opiate analgesics for "pain" (Demerol IV, Stadol IV, and Nubain IV).

Patient 70's record indicated that on 6/18/07, at 11 :20 a.m., the anesthesiologist had selected all three as needed "itching" orders; all as needed "nausea" orders (a total of four orders based on dosage and route of administration); and all three as needed "pain" orders. There were no further orders or written policy and procedure to clarify which medication with the same indication for use was to be used first, or how any of the remaining medications within that same group were to be used in relationship to the others. For example: A.) when and why to use Benadryl instead of the Narcan or the Nubain; B.) when or why to administer the Phenergan IM or administer it IV; or C.) when and why to use the Demerol instead of the Stadol or the Nubain.

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In an interview with RN 81 on 6/19/07, at 9:25 a.m., she stated that, "This was this anesthesiologist's usual practice" (selecting all as needed medication orders). When asked as to which medication order was to be used, given the duplications in drug therapy and routes of administration, and under what circumstances, she was unable to provide any further information. She did indicate that, "The orders could be clearer."

2. During a review of Patient 16's record on 6/21/07, at approximately 8 a.m., a pre-printed set of orders entitled "Inpatient Post-Op Orders, Total Knee/Other Knee Surgery" were noted. The pre-printed orders were designed such that to activate a medication order the prescriber would simply check the box(es) for that medication. Checked off under the heading of "Medications ... " were two as needed opiate analgesics for "mild pain" (Lortab 2.5 mg and Lortab 5 mg); one opiate analgesic for "moderate pain" (Percocet 5/325

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one tablet); three opiate analgesics for "severe pain" (Demerol 50 mg or Demerol 75 mg, and Percocet 5/325 two tablets); four medications for "nausea" (Phenergan 12.5 mg 1M or IV, Phenergan 25 mg 1M or IV, Reglan IV, and Zofran IV).

3. A review of Patient 41's record on 6/21/07, at approximately 8 a.m., reflected a pre-printed set of orders entitled "Inpatient Post-Op Orders, Total Knee/Other Knee Surgery" were noted. Checked off under the heading of "Medications ..." were two as needed opiate analgesics for "mild pain" (Lortab 2.5 mg and Lortab 5 mg); one opiate analgesic for "moderate pain" (Percocet 5/325 one tablet); three opiate analgesics for "severe pain" (Demerol 50 mg or Demerol 75 mg, and Percocet 5/325 two tablets); four medications for "nausea" (Phenergan 12.5 mg 1M or IV, Phenergan 25 mg 1M or IV, Reglan IV, and Zofran IV). Additionally, Patient 41 had a Demerol PCA

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(patient controlled analgesia) order with the availability of an additional 10 mg of Demerol every 10 minutes.

4. A review of Patient 42's record on 6/21/07, at approximately 8 a.m., reflected a pre-printed set of orders entitled "Inpatient Post-Op Orders, Total Knee/Other Knee Surgery" were noted. Checked off under the heading of "Medications ..," were two as needed opiate analgesics for "mild pain" (Lortab 2.5 mg and Lortab 5 mg); one opiate analgesic for "moderate pain" (Percocet 5/325 one tablet); three opiate analgesics for "severe pain" (Demerol 50 mg or Demerol 75 mg, and Percocet 5/325 two tablets); four medications for "nausea" (Phenergan 12.5 mg IM or IV, Phenergan 25 mg IM or IV, Reglan IV, and Zofran IV). Additionally, Patient 42 had a Demerol PCA order with the availability of an additional 10 mg of Demerol every 10 minutes (patient controlled analgesia).

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5. A review of Patient 51's record on 6/21/07, at approximately 8 a.m., reflected a pre-printed set of orders entitled "Inpatient Post-Op Orders, Total Knee/Other Knee Surgery" were noted. Checked off under the heading of "Medications ..." were two as needed opiate analgesics for "mild pain" (Lortab 2.5 mg and Lortab 5 mg); one opiate analgesic for "moderate pain" (Percocet 5/325 one tablet); three opiate analgesics for "severe pain" (Demerol 50 mg or Demerol 75 mg, and Percocet 5/325 two tablets); four medications for "nausea" (Phenergan 12.5 mg 1M or IV, Phenergan 25 mg 1M or IV, Reglan IV, and Zofran IV). Additionally, Patient 42 had a Demerol peA order with the availability of an additional 10 mg of Demerol, every 10 minutes (patient controlled analgesia).

On 6/21/07, at approximately 8:20 a.m., interviews with several facility licensed staff indicated that this was this surgeon's "usual practice" (selecting multiple as

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needed medication orders within the same therapeutic category with the same indication for use). When asked as to which medication orders were to be used, given the duplications in drug therapy and routes of administration, and under what circumstances, staff provided different answers such as: "patient preference"; "based on pain assessment" (for pain medications); "depends on what they've used before, and what worked for them." The Medical Unit/Surgical Unit Nursing Director added that, "This has been an issue (multiple as needed medication orders) for some time, and had been previously identified (last fall), and recently discussed in Mayas being a patient safety issue."

During an interview with the facility's Chief of Staff, at approximately 8:30 a.m. on 6/21/07, he stated, "We (physicians) need to cease doing this (prescribing multiple, duplicate as needed medication orders). As a

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1:45:33PM

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050225	(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING	(X3) DATE SURVEY COMPLETED  06/25/2007
NAME OF PROVIDER OR SUPPLIER  FEATHER RIVER HOSPITAL	STREET ADDRESS, CITY, STATE, ZIP CODE  5974 PENTZ ROAD, PARADISE, CA 95969 BUTTE COUNTY		

(X4) 10 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
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group we've talked about it, we've all gotten into the habit. We're slow to change, we get called in the middle of the night." He further stated, "This was my own practice habit" and that, "Your points (this surveyor's comments regarding this unsafe practice) are well-taken and based on solid, evidenced based practice."

Review of the facility's policies and procedures, "Medication Range Orders," and "Medication Administration, High Risk," on 6/21/07 at approximately 10 a.m., reflected that they did not provide guidance for the safe, objective, or consistent use for as needed medications, including opiate analgesics, when more than one drug, dose or route of administration is ordered having the same indication for use.

In an interview on 6/21/07, at approximately 10:15 a.m., the Director of Pharmacy (DOP), stated that he

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had previously communicated (in writing) to facility administrative staff (the Vice President Patient Care Services and Director Quality Resource Management) his concerns related to "too many options (as needed medications) being checked," and that "the Department of Health Services would not find this (practice) acceptable." The DOP further indicated that, "there had been multiple conversations regarding this issue over a period of time going back to last year."

"High-Alert Medications: Safeguarding against Errors, " published by the American Pharmaceutical Association in 1999, concluded that a majority of medication errors resulting in death or serious harm involved a small number of specific medications. The study conducted by the Institute for Safe Medication Practices (ISM P) termed medications having the highest risk of causing injury as "high alert medications." Opiates and narcotics were identified by the ISMP study as having

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the second highest risk of causing serious harm or death.

The 2/22/07 issue of ISMP's "High Alert Medication Feature-Reducing Patient Harm from Opiates" indicated that, "Errors with opiates have led to serious adverse events, including allergic reactions, failure to control pain, over-sedation, respiratory depression, seizures, and death." In order to ensure that opiates are safely and effectively used the ISMP identified several common patient safety risk factors, and recommended the establishment of protocols for pain management that include guidelines for the use of specific analgesics; the reduction of the variety of opiates and other analgesics being ordered for patients; built in alerts or warnings when multiple opiates are being ordered for a patient; and consultation with a pain management specialist for high risk patients such as the elderly.

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Special attention in the ISMP recommendations was given to the use of Demerol (meperidine) in elderly patients or patients with renal (kidney) compromise due to the potential toxic levels of a meperidine metabolite (normeperidine) which may deveiop, leading to irritability, nervousness, agitation, tremors, and seizures. It further recommends that the use of Demerol for pain control be avoided, especially in the elderly and renal-compromised patients, and that it be removed from pre-printed orders. Patient 16 was 74 years old; Patient 41 was 71 years old; Patient 42 was 83 years old and Patient 51 was 65 years old.

In the June 2007 (Volume 64; Issue 11) American Journal of Health System Pharmacy article "Eradicating Analgesic Use of Meperidine in a Hospital" it was stated, "It is indisputably clear today that, in most cases, the risks of using meperidine

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(X2) MULTIPLE CONSTRUCTION A.

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(X5)  
COMPLETE  
DATE

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outweigh the benefits. (This journal is published by the  
American Society of Health-System Pharmacists.)

The cumulative effect of these systemic problems resulted in  
the hospital's inability to ensure the provision of quality  
health care in a safe and effective manner. The violation(s)  
has caused or is likely to cause serious injury or death to the  
patient(s). As a result of these findings, at 2:15 p.m., on  
6/21/07, the presence of an Immediate Jeopardy was  
declared.

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