The following reflects the findings of the California Department of Public Health during the investigation of complaint #CA00268977.

Representing the Department of Public Health: HFEN 1700/17334

The inspection was limited to the specific complaint(s) investigated and does not represent the findings of a full inspection of the facility.

(a) Hospitals and medical staffs shall adopt a written policy on patients' rights

This Statute is not met as evidenced by: Based on staff interview, medical record and policies and procedures (P&P) review the facility failed to ensure that Patient 1 (or the patient's representative) was explained risks, benefits and potential problems and that the patient consented to the medication/treatment with antipsychotic medication (Olanzapine) before receiving the treatment, as per the facility policy and as recommended by the US FDA (Food and Drug Administration).

Findings:

The record review showed that Patient 1 was a 79 years admitted to the hospital on 4/7/11 for observation related to urinary tract infection. The initial diagnoses included history of Alzheimer's with dementia and depression. The course of treatment included...
Department provider's progress note related to dementia showed that "Patient with history of dementia. Appears to be pretty much at baseline. Patient lives in memory care unit. No acute issues at this time. On going evaluation and management of this non-emergent issue per HBS (hospital physician) and PMD (primary care physician)."

The patient was discharged on 4/11/12 to a dementia skilled nursing facility. The review of medications orders and administration showed that on 4/8/11 at 3:05 p.m. an antipsychotic medication Olanzapine 2.5 mg daily was ordered for Patient 1. Review of "Medications Prior to Admission" showed no Olanzapine as the patient's current medication. The Medication Administration Record showed Patient 1 was administered Olanzapine 2.5 mg daily starting on 4/8/12 until discharge on 4/11/11 (four doses were administered). The order was continued for current medications on discharge, indicating that Olanzapine was given "for behavior issues related to dementia."

There was no physician progress note on 4/8/11 related to the assessment of those "behavior issues related to dementia" for which Olanzapine was ordered. There was no documentation of discussing this treatment with the patient's responsible party (the patient was not capable of understanding rights). The 4/8/11 progress note by the prescribing physician indicated, "Patient nonverbal. More awake and alert" and "Patient clinically improving. Continue current medical regimen."

Review of daily nursing flow sheets for Patient 1 between 4/8/11 and 4/11/11 showed no documentation that indicated behavioral issues.

Monitoring:
- Medical records of patients on antipsychotic (Olanzapine) medications with dementia related psychosis will be monitored to ensure that patient's family designated have been informed of the proposed treatment. 11/12 to 1/13
- Any fallout will be addressed immediately with physician.
- Monitoring will continue for three months or until evidence of sustained performance.
- Results of reporting will be reported to Quality Council which reports to Medical Executive Committee for any additional actions.

Accountable Party:
Patient Care Services Director
Pharmacy Director
The nurse's notes included descriptions of the patient such as "pleasant, serene, cooperative."

Review of the record for Patient 1 with the hospital's Risk Management staff on 8/12/12 starting at 8:30 a.m. showed no evidence that the patient of the patient representative received from the prescribing physician information about the risks, benefits and potential problems and that the patient consented to the medication/treatment with antipsychotic medication (Olanzapine) before receiving the treatment.

Review of the policy titled "Patient Rights and Responsibilities (5/28/10) indicated that patient's right included receiving from the practitioner responsible for the patient care complete and current information about any proposed treatment and significant risks involved in this treatment as well as right to refuse treatment.

In an interview on 10/3/12 at 11:40 a.m. the physician who ordered Olanzapine on 4/8/11 (Physician 1) stated that he ordered Olanzapine most likely after the nurses informed him that patient displayed behaviors associated with Alzheimer's and dementia, and also to prevent delirium. The physician stated that he did not always talk with the family about the potential risks/benefits when ordering treatments with psychotropic drugs. However in this case he recalled talking with the daughter (of Patient 1) about ordering Olanzapine and the effects of the drug. However, the physician agreed that the patient's record did not reflect the discussion with daughter or that the patient displayed behaviors that indicated ordering Olanzapine.

The following information was retrieved on 8/20/12 from FDA site
### California Department of Public Health

**Statement of Deficiencies and Plan of Correction**

**Provider/Supplier/GCLA Identification Number:**

CA030000130

**Name of Provider or Supplier:**

Kaiser Foundation Hospital - Sacramento

**Street Address, City, State, Zip Code:**

2025 Morse Avenue, Sacramento, CA 95825

**Date Survey Completed:**

10/03/2012

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**Summary Statement of Deficiencies (Each Deficiency Must Be Preceded by Full Regulatory or LSC Identifying Information):**

E1944

Continued from page 3


"Information for Healthcare Professionals:

Conventional Antipsychotics

FDA ALERT [6/16/2008]: FDA is notifying healthcare professionals that both conventional and atypical antipsychotics are associated with an increased risk of mortality in elderly patients treated for dementia-related psychosis.

In April 2005, FDA notified healthcare professionals that patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death. Since issuing that notification, FDA has reviewed additional information that indicates the risk is also associated with conventional antipsychotics.

Antipsychotics are not indicated for the treatment of dementia-related psychosis.

This information reflects FDA's current analysis of data available to FDA concerning these drugs. FDA intends to update this sheet when additional information or analyses become available. FDA is requiring the manufacturers of conventional antipsychotic drugs to add a Boxed Warning and Warning to the drug's prescribing information about the risk of mortality in elderly patients treated for dementia-related psychosis similar to the Boxed Warning and Warning added to the prescribing information of the atypical antipsychotic drugs in 2005. See the last page of this document for a list of conventional and atypical antipsychotic drugs (the list included Haldol).

Considerations for Healthcare Professionals:
-Elderly patients with dementia-related psychosis treated with conventional or atypical antipsychotic drugs are at an increased risk of death.
-Antipsychotic drugs are not approved for the treatment of dementia-related psychosis.
-Furthermore, there is no approved drug for the treatment of dementia-related psychosis. Healthcare professionals should consider other management options.
-Physicians who prescribe antipsychotics to elderly patients with dementia-related psychosis should discuss this risk of increased mortality with their patients, patients' families, and caregivers.

Review of the P&P titled "Informed Consent Regional Policy for Complex Procedures" (approved on 2/10/09) indicated that "Patients have the right to be provided easily understood information and to decide among all reasonable treatment options, including no treatment. Before consenting to any treatment or procedure, patients have the right to know the relevant risks, benefits, treatment alternatives and potential problems that might occur during recuperation. They also have the right to refuse treatment." The policy indicated that the physician was responsible to ensure that discussion with the patient occurred and that the patient signed the consent form indicating that all necessary information was given and all questions were answered. The policy also indicated that the physician was responsible for documenting the consent process. The policy listed procedures that required informed consent and included "...Medications and/or other therapeutics with potential for particularly severe side effects."