E 000 Initial Comments

The following reflects the findings of the California Department of Public Health during the investigation of complaint #CA00197769.

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.

E1944 T22 Div5 Ch1 ART7-70707(a) Patients' Rights

(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 (Haldol) before receiving the treatment, as per the facility policies and as recommended by the US FDA (Food and Drug Administration).

Findings:
The record review showed that Patient 1 was a 83 years old female seen in the Emergency room by ED physician (MD 1) on 5/07/09 at 3:01 p.m. for altered level of consciousness and frequent urination. Thy physician also noted increased...
agitation, especially after husband called an ambulance. The ED physician noted that per family, the patient gradually declined in function with increasing bouts of agitation with abusive behaviors toward husband and noted "will order Haldol prn (as needed)." The physician assessment included diagnosis of dementia with plan of supportive care "Haldol prn." The patient's past medical history included hypertension, coronary artery disease and atrial fibrillation (abnormal heart rhythm).

Review of a Social Work (SW) Note on 5/7/09 at 12:14 p.m. indicated that "due to the patient's new abusive behaviors to her husband, as reported per family, patient's husband could benefit from plan re (regarding), controlling these behaviors, such as medication management."

In a summary/intervention section, the SW note indicated that per family (the husband and son who was the DPOA) the patient's angry behavior was a new onset last night after the husband made comments about the patient's frequent visits to the bathroom during the night. The SW notes documented that plan for the patient was long term care facility placement for rehabilitation with the husband and son agreeable. There was no documentation of discussing with the family the treatment with psychotropic medications.

Review of the policy titled "Patient Rights and Responsibilities (12/2008)" 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.

Review of nursing flowsheets and progress notes.
showed that Patient 1 was calm and cooperative while in the ED. Review of physician orders and medication administration record showed an order on 5/7/09 at 11:54 a.m. for Haldol 1 mg routine times one, documented as administered to Patient 1 at 11:58 a.m. on 5/7/09.

Review of the discharge (to nursing home) orders showed that the physician documented that the patient was not capable of making decisions. The orders included an order for Haldol 1 mg tablet by mouth as needed for agitation. Section "consent for psychotropic" had an entry "not applicable."

Review of the record for Patient 1 with the hospital's Risk Management staff on 8/10/12 starting at 9:30 a.m. and again on 10/3/12 at about 12 p.m. showed no evidence that the patient or the patient's 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 (Haldol) before receiving the treatment.

In a telephone interview on 10/3/12 at 12:15 p.m. Physician 1 (the physician who prescribed Haldol) stated that before ordering psychotropic medications he usually talks with family and/or patient regarding the potential risks and benefits and on occasion consults with a psychiatrist. However he was not sure that this occurred for Patient 1. The physician confirmed that he did not document in the patient record that he explained the risks associated with the psychotropic medications (Haldol) and that the patient or the responsible family member consented to the treatment.
The following information was retrieved on 8/20/12 from FDA site
<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm124830.htm>:

"Information for Healthcare Professionals:
Conventional Antipsychotics
FDA ALERT [8/10/2008]: 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 drugs' 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
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."
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NAME OF PROVIDER OR SUPPLIER: KAISER FOUNDATION HOSPITAL - SACRAMENTO

STREET ADDRESS, CITY, STATE, ZIP CODE: 2025 MORSE AVENUE, SACRAMENTO, CA, 95825

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[Header: California Department of Public Health]