FOR IMMEDIATE RELEASE

REPORT OF FINDINGS
SAINT JAMES HOSPITAL and HEALTH CENTER— 09-040-9011
HUMAN RIGHTS AUTHORITY— South Suburban Region

[Case Summary: The Authority substantiated the allegation regarding psychotropic medication and made corrective recommendations that were accepted by the service provider. The HRA's public record on this case is recorded below; the provider's response immediately follows the report.]

INTRODUCTION

The Human Rights Authority (HRA), a division of the Illinois Guardianship and Advocacy Commission has completed its investigation into an allegation concerning Saint James Hospital and Health Center. The complaint alleged that an elderly recipient was given psychotropic medication without her informed consent. If substantiated, this allegation would violate the Mental Health and Developmental Disabilities Code (the Code) (405 ILCS 5/100 et seq.) and the Medical Patient Rights Act (410 ILCS 50/3 [a]).

Located in Olympia Fields this 140-bed general hospital and health center is affiliated with the Sisters of Saint Francis Health Services, Incorporated.

METHODOLOGY

To pursue the investigation, the hospital's Medical Director, the Director of Quality Improvement/Accreditation, the Director of Pharmacy, the Manager of Patient Care, the treating physician and two registered nurses were interviewed. The recipient's record was reviewed with her written consent. Relevant hospital policies were also reviewed.

COMPLAINT STATEMENT

According to the complaint, an elderly recipient was admitted to the hospital for abdominal pains. She reportedly showed signs of confusion after she was given medication for a possible blood clot. A family member overheard a nurse tell the recipient that Risperdal would be administered for her confusion. It was alleged that informed consent for the medication was not obtained, but the proposed treatment was still given. It was further reported that the nurse told the family member that older recipients who experience confusion are routinely given Risperdal at the hospital.

FINDINGS

According to the record, the 71-year old recipient signed a general consent for medical treatment upon her arrival to the Emergency Department on February 6th, 2009. The triage nurse noted complaints of epigastric (stomach pains), weakness, nausea and vomiting. The recipient's history included Diabetes Mellitus, Hypertension, Hypertensive Cardiovascular Disease and a kidney transplant. Although the recipient was reportedly no longer insulin dependent, her blood sugar level was 282 when checked. During the recipient's emergency room care, blood work and routine tests were done. Morphine 2 mg, Zofran 4 mg and Nexium 40 mg were administered intravenously (IV). Mycomyst 600 mg orally, which prevents kidney damage due to dyes from certain x-ray procedures, was also given. A Computed Tomography (CT) Scan of the abdomen and pelvis with contrast was done because of a possible abdominal aortic aneurysm threatening to rupture. An abdominal aortic aneurysm is when the large blood vessel that supplies blood to the abdomen, pelvis and legs becomes abnormally large or balloons outward. The record contained a signed consent form for the procedure. The recipient was admitted to a medical unit for further evaluation on that same day.

Nursing notes indicated that the recipient was oriented to the unit and her room upon her arrival on the medical floor. The physician ordered various medications to be administered intravenously and orally. Documentation on February 7th and the 9th referenced that the recipient pulled out the catheter (a tube that allows the administration of intravenous medication) in her arm. On the 9th, a Venous Doppler of the bilateral lower extremities to rule out Deep Vein Thrombosis and Lovenox (a blood thinner medication) 30 mg IV was ordered. Medication records (MAR) reflected that Lovenox was given twice on the order day. On the following morning at 2:35 a.m. a nurse wrote that the recipient was confused about time and place, and she kept getting out of bed. Lovenox was administered later that day and discontinued.

Documentation confirmed that the recipient was given Risperal as reported in the complaint. MARs reflected that Risperdal 0.5 mg orally twice daily was ordered on February 10th, and the medication was administered at 1:17 p.m. and 9:04 p.m. on the order day. According to the Physician Desk Reference, Risperdal is an antipsychotic medication used to treat individuals diagnosed with Schizophrenia and Bipolar Disorder, but the medication may also be used for other purposes such as Anxiety Disorders. On the morning of the 11th, a nursing entry stated that the recipient kept getting out of the bed, and that she was confused about time and place. A CT Scan of the head without contrast was ordered because of her confusion. The same day, the recipient refused Risperdal, and there was no indication that the medication was given over her objections. A Discharge Summary dated February11th stated that an abdominal aortic aneurysm was ruled-out; there were findings of possible diverticular disease and a tiny stone in her gallbladder.

The hospital first responded to the complaint in a letter dated April 1st, 2009 stating that the recipient was admitted to a medical-surgical unit for evaluation of epigastric symptoms. It stated that all consent forms for treatment were signed by the recipient as consistent with the hospital's policy. The letter documented that the recipient does not have a psychiatric history. According to the letter, Risperdal was administered three times, but the dosage given was significantly lower than if the medication had been used as a psychotropic medication. The HRA notes that medication records showed that Risperdal was given only twice. The letter stated that

the recipient's specific consent for the use of psychotropic medication was not considered appropriate under the circumstances.

When the complaint was discussed with the hospital's staff, they said that the recipient was given Lovenox, a blood thinner medication because of a possible blood clot. The Director of Pharmacy explained that the medication can alter a person's mental status if there was bleeding, but this reportedly was not the case. A nurse said that the recipient pulled out her IV lines. She wandered into other recipients' rooms, and she seemed more confused at night. Her room was changed, and she was moved up closer to the nursing station. According to the staff, Risperdal 0.5 mg was administered as "calming medication," and the dosage was significantly lower than if the medication had been given for psychiatric reasons. The Director of Pharmacy said that lower dosages of the medication are usually prescribed for recipients who are confused and anxious. The investigation team was informed that 1-2 mg of Risperdal is usually given for altering a person's behavior.

According to the physician, he has been treating the recipient for 18 years, and he continues to provide post-hospital care to the individual. He stated that the recipient drives herself around, and that she was employed until a few years ago. The physician told the HRA that the recipient presents with a subtle and gradual memory loss. She reportedly would make appointments with him, but sometimes she would forget them. The physician further explained that the CT scan of the recipient's brain showed no acute findings. He stated that the recipient did not object to taking Risperdal, but her family was against the medication. Upon questioning, the physician acknowledged that the recipient lacked decisional capacity to give informed consent for Risperdal, and that the medication information was not provided. He reported that Aricpet was prescribed following her hospital stay. The Authority notes that this medication is used to treat mild to moderate dementia caused by Alzheimer's disease.

The hospital policy entitled "Informed Consent" states that each patient has the right to informed participation in decisions involving his/her health care. According to the policy, informed consent is the process that provides the patient with the knowledge and information needed to determine the type of treatment or intervention that he should have to address his health care problems. The elements that must be included are the nature of the patient's condition and procedures to be performed, the risks, benefits to be reasonably expected of the procedure, the inability of the physician to predict or guarantee results, the irreversibility of the procedure (if appropriate), the likely results if no treatment is performed, and the available alternatives, including their risks and benefits.

According to the Director of Quality Improvement/Accreditation, the hospital does not have a policy that addresses psychotropic medication.

The hospital's "Complaints and Grievances" policy states that every patient shall receive the "Patient Handbook" during the admission process. The handbook includes rights and grievance information. There was no documentation that the recipient filed a grievance with the hospital.

CONCLUSION

According to Section 5/2-102 (a-5) of the Code,

> If the services include the administration of electroconvulsive therapy or psychotropic medication, the physician or the physician's designee shall advise the recipient, in writing, of the side effects, risks, and benefits of the treatment, as well as alternatives to the proposed treatment, to the extent such advice is consistent with recipient's ability to understand the information communicated. The physician shall determine and state in writing whether the recipient has the capacity to make a reasoned decision about the treatment …. If the recipient lacks the capacity to make a reasoned decision about the treatment, the treatment may be administered only (i) pursuant to Section 5/2-107 ….

According to Section 5/1-121.1 of the Code,

> Psychotropic medication means medication used for antipsychotic, antidepressant, antimanic, antianxiety, behavior modification or behavior management purposes is listed in the AMA Drug Evaluations, or Physician's Desk Reference, or which are administered for any of these purposes.

Section 50/3 (a) of the Medical Patients' Rights Act,

> Establishes the right of each patient to care consistent with sound nursing and medical practices, …, to receive information concerning his or her condition and proposed treatment, to refuse any treatment to the extent permitted by law, and to privacy and confidentiality of records except as otherwise provided by law.

The investigation confirmed that Risperdal was administered twice during the recipient's hospital stay. The record contained signed consent for general treatment only, which does not cover unique informed consent requirements under Section 5/2-107 a-5 of the Mental Health Code. There was no documentation that the medication and side effects were discussed with the recipient, that she was given the information in writing or that she had the capacity to provide informed consent. The hospital's letter and the staff asserted that the medication was given for calming purposes. And, the dosage given was significantly lower than if the medication had been used as a psychotropic medication. Regardless, Risperdal is a classic psychotropic medication that was used to change the patient's behavior as defined under the Mental Health Code. Any treatment consent form signed by the recipient at triage or admission clearly did not forecast the use of Risperdal, and she was not provided with the opportunity to be informed of the drug's risks, benefits and side effects regardless of how it was used.

The Authority substantiates that an elderly recipient was given psychotropic medication without her informed consent. This violates Section 5/2-102 (a-5) of the Code, Section 50/3 (a) of the Medical Patients' Rights Act and the hospital's Informed Consent policy.

RECOMMENDATIONS

1. Follow Code requirements and document whether a recipient has the capacity to give informed consent about the proposed treatment and ensure that informed consent is obtained before administering psychotropic medication under Section 5/2-102 (a-5).

2. Follow Section 50/3 (a) of the Medical Patients' Rights Act and the hospital's policy concerning informed consent.

3. Provide recipients with written information regarding psychotropic medications during hospitalization.

4. Train all appropriate staff regarding the Code's treatment process on medication and capacity determinations.

SUGGESTION

1. The hospital should consider developing a policy that addresses the Mental Health and Developmental Disabilities Code's requirements for psychotropic medications, if they are indeed used routinely for patients who experience confusion.

COMMENT

The Authority appreciates the hospital's staff cooperation during the investigation but reasserts that treating with psychotropic medications is authorized and driven by the Mental Health and Developmental Disabilities Code.

RESPONSE

Notice: The following page(s) contain the provider response. Due to technical requirements, some provider responses appear verbatim in retyped format.

St. James
HOSPITAL
and Health Centers

CHICAGO HEIGHTS
1423 Chicago Road, Chicago Heights, Illinois 60411-3483
708/756-1000

OLYMPIA FIELDS
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March 5, 2010

Ms. Judith Rauls, Chairperson
Human Rights Authority
South Suburban Region
P.O. Box 7009
Hines, IL 60141-7009

Re: 09-040-9011

Dear Ms. Rauls:

In response to your correspondence of February 22, 2010, enclosed is our summary of actions taken thus far regarding the above complaint. As the enclosed summary describes, there have been a number of activities to address the issue of psychotropic medication management/patient rights, which have included both the Corporate Compliance Committee as well as strong legal involvement in providing direction for policy development.

You can be assured that the hospital task force, which you referenced in your letter, will continue to meet until the appropriate policies are finalized in this area and staff education is completed.

Please let me know of any questions.

Sincerely,

Seth C. R. Warren
Regional CEO, Sisters of St. Francis Health Services
President, St. James Hospital and Health Centers

WJD:nh
Enc.

cc: William Dwyer, Director, Quality Improvement/Accreditation

St. James
Sisters of St. Francis Health Services

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April 1, 2010

Ms. Judith Rauls
Chairperson
Human Rights Authority
Guardianship & Advocacy Commission
P.O. Box 7009
Hines, IL 60141-7009

Re: Complaint #09-040-9011

Dear Ms. Rauls:

Your March correspondence to Seth Warren, President of St. James Hospital and Health Centers, was forwarded to me for response. As you are aware, I have been coordinating the hospital's efforts to address the recommendations made by the Human Rights Authority as a follow-up to the above complaint. We would like to emphasize that we continue to take the commission's recommendations very seriously, and the hospital has reviewed a number of policy and procedural changes to bring us into the strongest compliance.

The Human Rights Authority request was to be informed of the hospital timeframes for full approval of the various policies being developed as well as the timeframe for staff education when such policies are finalized. We expect the policies to have the appropriate approvals by June 1, with physician and staff education starting at that time. The procedural changes created by these policies will take approximately 2-3 months to be sure all appropriate patient care staff are informed of the process change and understand the importance of such.

In summary, we will continue to move forward with policy development and physician-staff education. We will be happy to keep your agency informed of progress in this important area.

Sincerely,

William J. Dwyer, MSW, MHA

William J. Dwyer, MSW, MHA
Director, Quality Improvement/Accreditation/Regulatory Affairs

WJD:nh

cc: Seth Warren, President, St. James Hospital and Health Centers

St. James
Sisters of St. Francis Health Services

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June 10, 2010

Ms. Judith Rauls
Chairperson
Regional Human Rights Authority
Guardianship & Advocacy Commission
P.O. Box 7009
Hines, IL 60141-7009

Re: Case #09-040-9011

Dear Ms. Rauls:

Your correspondence of May 26 to Seth Warren, President of St. James, has been forwarded to me for a response.

Enclosed is our revised Informed Consent Policy, which addresses the specific requirements when a physician prescribes psychotropic medications. Our Task Force in this important area of concern continues to meet. We have been in contact with Mr. Burnett, of the Guardianship Office, who has provided helpful information regarding the use of psychotropic medications in a general hospital setting. An educational meeting on psychotropic medication administration and patient rights was held on April 21 with Emergency Department physician leadership and a presentation will be done to the Emergency Department physicians on June 28. The Task Force meetings have included Patient Care Services leadership staff as well as hospital education staff. The Task Force is finalizing a procedure which will assure the correct process is followed throughout the hospital when any psychotropic medication is ordered. We are also finalizing an educational program for all physicians that will highlight the changes in the enclosed consent policy.

We are confident that these efforts will result in full compliance with the various medical-legal requirements in this area of psychotropic medication usage. Please feel free to contact me with any questions.

Sincerely,

William J. Dwyer, MSW, MHA
Director, Quality Improvement/Accreditation/Regulatory Affairs

WJD:nh
Enc.

cc: Seth C. R. Warren, President, St. James Hospital and Health Services/
CEO, South Suburban Chicago Region/SSFHS

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September 23, 2010

Ms. Judith Rauls
Chairperson
Regional Human Rights Authority
Guardianship & Advocacy Commission
P.O. Box 7009
Hines, IL 60141-7009

Re: Case #09-040-9011

Dear Ms. Rauls:

In response to your September 16 correspondence to our President, Seth Warren, enclosed is the requested staff training documentation from the inservice held June 28. The attendance records show that the patient rights on psychotropic medication usage was attended by the E.D. physicians and hospital administrative staff.

Please let me know of any questions.

Sincerely,

William J. Dwyer, MSW, MHA
Director, Quality Improvement/Accreditation

WJD:nh
Enc.

cc: Seth C. R. Warren, President, St. James Hospital and Health Services/
CEO, South Suburban Chicago Region, Sisters of St. Francis Health Services