



Department of Health

Three Capital Hill  
Providence, RI 02908-5097

TTY: 711  
[www.health.ri.gov](http://www.health.ri.gov)

August 15, 2014

Thomas Reardon,  
CEO, Interim Administrator  
St. Joseph Health Services of RI  
200 High Service Avenue  
North Providence RI 02904

Dear Mr. Reardon:

The Department of Health concluded an investigation at St. Joseph Hospital regarding another series of circumstances involving the hospitals continuing failure to submit incident and event reports and/or follow-up reports within the statutory time lines or to provide care and services in accordance with the Hospital's written policies and procedures pertaining to "Constant Observation". The Department's findings and Statement of Deficiencies (SOD) are enclosed. Pursuant to the provisions of the "Rules and Regulations for Licensing of Hospitals", the Hospital is required to file a Plan of Correction with the Department within fifteen (15) days.

Also enclosed is a Compliance Order outlining additional conditions I have determined necessary to ensure the ongoing safety for patients St. Joseph Health Hospital. The conditions of the order are effective forthwith.

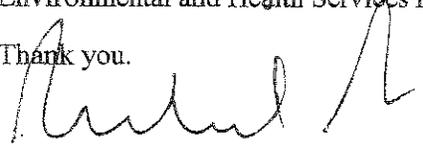
Finally, the Hospital's continued failure to effectively implement policies and practices to ameliorate these particular problems is frustrating and significantly damages the public's perception of safety and the credibility of St. Joseph Hospital's ability to consistently provide for the safety of patients. Subsequently, I believe additional sanctions are needed to highlight the critical nature and importance of these issues. The Hospital is issued a REPRIMAND and is assessed a fine in the amount of ten thousand dollars (\$10,000).

The Hospital is hereby required to submit payment of this fine within thirty (30) days of the receipt of this letter. Address payment to the State of Rhode Island General Treasurer and forward to the Office of Facilities Regulation, 3 Capitol Hill Room 306, Providence RI 02908.

If the Hospital is aggrieved by the discipline set forth in this letter, it may request a hearing on these matters within thirty (30) days.

If you have any questions in these matters, please contact Edward D'Arezzo, Acting Associate Director, Environmental and Health Services Regulations at 222-1624.

Thank you.

  
Michael Fine, M.D.,  
Director of Health

Encl: (1) Statement of Deficiencies  
(2) Amended Immediate Compliance Order

Cc: Samuel S. Lee, Chief Executive Officer, Prospect CharterCare SJHSRI, LLC Board  
Heather Daglieri, Licensing Administrator, BHDDH

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

RHODE ISLAND DEPARTMENT OF HEALTH  
DIVISION OF ENVIRONMENTAL AND HEALTH SERVICES REGULATION  
OFFICE OF FACILITIES REGULATION and  
MICHAEL FINE, MD, IN HIS CAPACITY  
AS DIRECTOR OF HEALTH OF THE STATE OF RHODE ISLAND

V.

ST. JOSEPH HEALTH SERVICES OF RI and  
THOMAS REARDON, CEO,  
IN HIS CAPACITY AS INTERIM ADMINISTRATOR

COMPLIANCE ORDER

Now comes the Director of Health of the State of Rhode Island, and pursuant to Rhode Island General Laws, section 23-17-21 and the Rules and Regulations for Licensing Hospitals (R23-17-HOSP), makes the following Findings and enters the following Order:

1. St. Joseph Health Services of RI (hereinafter the "Hospital") is a hospital located on 200 High Service Avenue in the town of North Providence, which is licensed as a Hospital by the Office of Facilities Regulation within the Department of Health of the State of Rhode Island pursuant to section 23-17-1, et seq of the General Laws of the State of Rhode Island.
2. Pursuant to the Rules and Regulations for Licensing Hospitals (R23-17-HOSP), hereinafter "Regulations" and as a condition of its license, the Hospital is required to submit incident and event reports and/or follow-up reports within specific time lines, timely reporting of allegations of abuse, mistreatment, and neglect, and to provide care and services in accordance with written policies and procedures pertaining to "Constant Observation". The Hospital is further required to comply with all rules and regulations requiring the provision of care and services to all patients in accordance with the prevailing community standard of care and in a manner that ensures the health and safety of individuals.
3. An unannounced on-site review by the Department of Health, on 23 June 2014, indicates that the Hospital failed to report incidents and events in accordance with statutory time lines and failed to provide care and services in accordance with the Hospital's written policies and procedures pertaining to "Constant Observation" or to provide care and services in accordance with the prevailing community standard of care in a manner that ensures the health and safety of individuals and services. The results of this review as set forth in the statement of deficient practice (hereafter "Survey"), a copy of which is attached hereto and made part hereof (Exhibit A), indicates that the Hospital is in violation of the provisions of RIGL Chapter 23-17 and the Regulations.
4. The Department of Health conducted similar reviews of the Hospital in June 2009, December 2011, and March 2013, and documented the Hospital's repeat non-compliance with the incident and events reporting requirements and the Hospital's implementation of written policies and procedures pertaining to "Constant Observation". In spite of the Hospital providing acceptable plans of corrections for each of these events, these same issues continue to prevail and present a continuing and pervasive potential risk to the health and safety of individuals receiving care and services at the Hospital.
5. The Director hereby finds that, based on the Hospitals continued failure to report incidents and events in accordance with statutory time lines and to provide adequate care to patients receiving "Constant Observation", the Hospital is not in conformance with the Regulations and requirements of Hospital licensure.

6. Therefore, based on the foregoing, the Director finds that without intervention of the Department of Health and issuance of this Compliance Order, the health, safety and welfare of the patients of the Hospital will be in jeopardy.

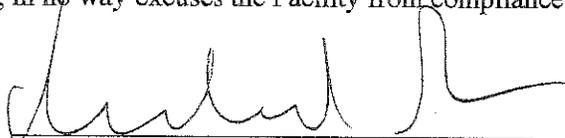
Therefore, in accordance with RI General Law, Chapter 23-17-8.1, the Department of Health enters the following order:

1. St. Joseph Health Services of RI is ordered to engage the services of a independent consultant or consultants, acceptable to the Director of Health to:
  - a. Perform a root cause analysis of the Hospital's incident and event reporting requirements;
  - b. Perform a root cause analysis of the Hospital's policy and procedure regarding patients receiving "Constant Observation" and to specifically assess:
    - i. Measures designed to ensure accountability of staff for patients requiring "Constant Observation" status;
    - ii. Overall communication between staff members regarding coverage during periods of shift change, breaks, unexpected events, etc.
    - iii. Training of staff on "Constant Observation".
    - iv. Staffing levels in the ED and Behavioral units.
    - v. Secure treatment and bathroom area in ED for patients with suicidal ideation.
    - vi. Quality Assurance component for Behavioral Health safety.
  - c. Report to the Hospital and the Director recommendations for plans of correction for sustained compliance and to assist the Hospital with implementation of the Hospitals plan of correction in response to the 6-23-14 inspection report.
  - d. Meet with and report to the Director, as needed, regarding the Hospital's progress.

**The Facility is required to maintain this clinical consultation until the Facility receives official notice of release from the Department.**

Notwithstanding any further actions or sanctions by the Department this order shall remain in effect until further notice.

The Facility may request a hearing in writing to the Department of Health within ten (10) days. A request for hearing in no way excuses the Facility from compliance with the terms of this order.



MICHAEL FINE, MD  
DIRECTOR, Rhode Island Department of Health

CERTIFICATION OF SERVICE

A copy of this Compliance Order was hand-delivered to Thomas Hughes by the undersigned on 8/15/14 and documents receipt of this order.

  
(Signature)

8/15/14  
(Date)

RI Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>HOS00110</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____  B. WING _____	(X3) DATE SURVEY COMPLETED  <b>06/23/2014</b>
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NAME OF PROVIDER OR SUPPLIER  <b>ST JOSEPH HEALTH SERVICES OF RI</b>	STREET ADDRESS, CITY, STATE, ZIP CODE <b>200 HIGH SERVICE AVENUE NORTH PROVIDENCE, RI 02904</b>
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Z 0	INITIAL COMMENTS  A State complaint investigation survey, a follow-up (*EJOO11, 6/20/14) to a previous State complaint investigation survey, and an 'Other' State licensure survey (DDWN11, 6/20/14) were conducted at this facility. Prior deficiencies are recited, and deficiencies relative to the State complaint investigation survey and the 'Other' State licensure survey are also cited .	Z 0		
Z 160	<p>ORGANIZATION &amp; MANAGEMENT 12.2 Organization</p> <p>12.2 Each hospital department and service shall maintain:</p> <p>a) clearly written definitions of its organization, authority, responsibility and relationships; b) written patient care policies and procedures; and c) written provision for systematic evaluation of programs and services.</p> <p>This Requirement is not met as evidenced by: Based on record review, staff interview, and review of hospital policies, it has been determined that the hospital failed to implement the following policies:</p> <ol style="list-style-type: none"> <li>1. "Medical Marijuana", for 1 of 1 relevant sample patients, ID # 4;</li> <li>2. "Documented Informed Consent For AIDS/HIV And Confidentiality", for 5 of 5 relevant sample patients, ID#'s 6, 39, 40, 41 and 42; ;</li> <li>3. "Patient Search Policy", for 1 of 1 relevant sample patients, ID #18;</li> <li>4. "Constant Observation", for 3 of 4 relevant sample patients, ID #'s 2, 27, and 34;</li> <li>5. "Universal Protocol Policy", for 1 of 6 relevant sample patients, ID # 26;</li> <li>6. "Annual Performance Competency Review</li> </ol>	Z 160		

Facilities Regulation  
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE \_\_\_\_\_ TITLE \_\_\_\_\_ (X6) DATE \_\_\_\_\_

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Z 160	<p>Continued From page 1</p> <p>Process", for 6 of 12 relevant sample employees, ID's A, B, C, D, E and F.</p> <p>Findings are as follows:</p> <p>I. The hospital policy, "Medical Marijuana", dated 10/2012, under "Policy Statement" states, under item b:</p> <p>"If the patient is determined to be a licensed card holder, the material in question will be sent home with the patient or the patient's family. In the event that no family members are available to receive the material, it will be disposed of and destroyed.....The pharmacist will contact the patient's prescriber to recommend Marinol (dronabinol) as an oral, FDA (Food and Drug Administration) approved alternative medication to use while the patient is admitted."</p> <p>Review of the clinical record for patient ID #4 reveals that the patient was admitted to the hospital on 3/14/13 for a psychiatric evaluation. The patient presented with a Medical Marijuana Card, and a small amount of marijuana. The patient told staff that there was no significant other to remove the marijuana from the facility, therefore the marijuana was disposed of in the presence of the patient and pharmacy staff in accordance with hospital policy.</p> <p>The record lacked evidence that the patient's physician was contacted by a hospital pharmacist to recommend Marinol during the patient's admission in accordance with the hospital policy.</p> <p>During an interview on 5/27/14 at approximately 2 PM with the Lead Operational Pharmacist, who was present when the marijuana was destroyed, it was revealed that contact with the patient's</p>	Z 160		

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Z 160	<p>Continued From page 2</p> <p>physician regarding prescribing Marinol did not occur.</p> <p>II. The hospital policy, "Documented Informed Consent for AIDS/HIV and Confidentiality", dated 3/2011, under "Policy", item A states:</p> <p>"AIDS tests will only be done with the documented informed consent of the patient... "</p> <p>A review of the clinical record for patient ID #6 reveals the patient was admitted to the facility on 8/2/13 with a question of stroke. While in the hospital the patient had blood work completed which included testing for HIV (human immunodeficiency virus). The medical record lacked evidence of documentation of an informed consent for the HIV testing in accordance with hospital policy.</p> <p>When interviewed on 6/12/14 at approximately 8:30 AM, the ordering physician revealed, "I may have discussed the HIV testing with the patient, but I did not document it; there is an informed consent policy, I usually write it in the record."</p> <p>Review of 4 additional relevant clinical records for patient ID #s 39, 40, 41 and 42 revealed no evidence that informed consent for HIV testing had been obtained in accordance with hospital policy.</p> <p>III. The hospital policy, "Patient Search Policy", dated 8/2010, under "Procedure", Item II, "Patient Search" states:</p>	Z 160		

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Z 160	<p>Continued From page 3</p> <p>"A patient search is performed by two people in the following circumstances: any patient who demonstrates symptoms which suggests the use of contraband drugs."</p> <p>"The patient search is performed as follows":</p> <p>Item b. "The patient removes clothes and will be placed in a hospital gown and the staff member searches the clothing item..."</p> <p>Review of the clinical record for patient ID #18 revealed that the patient was brought to the ED (emergency department) by EMS (emergency medical services). The patient had been found in respiratory arrest after injecting heroin. The patient regained consciousness after treatment. The physician's clinical impression was "heroin overdose".</p> <p>While being monitored in the ED, the patient became unresponsive. The patient responded to treatment. The physician's note reveals, "Patient states s/he found a bag of drugs on the way to the bathroom and used them in the bathroom. Patient still has pants on so it is possible that something was in a pocket..."</p> <p>When interviewed on 6/17/14 at approximately 11:30 AM, the ED Chief revealed, "I feel the care was not optimal, the patient should have been searched."</p> <p>It was determined that the patient was allowed to keep pants on while wearing a hospital gown, and a search for contrabands had not been performed in accordance with the hospital policy.</p>	Z 160		

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Z 160	<p>Continued From page 4</p> <p>IV. The hospital policy, "Constant Observation", dated 6/2013, under "Policy" states:</p> <p>"It is hospital policy to institute a level of Constant Observation for the patient who manifests one or more of the following criteria":</p> <p>Item #2 "Imminent threat to physical or emotional well-being including but not limited to: Reported suicidal/homicidal ideation's."</p> <p>Under, "Definitions," it states:</p> <p>"Constant observation - process of visually monitoring (observing) a patient at all times, regardless of patient activity; goal is to prevent patient from leaving hospital and from causing injury to self or others; may be used with or without patient being in physical restraints."</p> <p>Under, "Procedure", item 5b it states:</p> <p>"Remain with the patient at all times including bathroom visits (door will be left cracked with consideration for privacy but must be visual) and when patients appear to be sleeping focus on visibility of mouth and hands, maintain no more than arms length distance unless otherwise directed..."</p> <p>1. Review of the clinical record for patient ID #2 revealed that the patient was on 1:1 observation. On 4/9/14 at approximately 7:30 AM, the patient could not be found. A search was conducted and the patient was found unharmed at approximately 8:00 AM, in a lower cabinet in the television room.</p> <p>During an interview on 5/28/14 at approximately 3 PM with the Director of Behavioral Health, it was revealed that the person who was assigned to the</p>	Z 160		

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Z 160	<p>Continued From page 5</p> <p>constant observation monitoring of the patient went to assist other staff when another patient had fallen. It was at this time that patient ID #2 was left unattended. The hospital investigation determined that based on review of surveillance video, the patient was in the lower cabinet for approximately 27 minutes.</p> <p>2. Review of the clinical record for patient ID #27 revealed that the patient presented to the ED after an attempted drug overdose. The patient has a psychiatric history of greater than 20 suicide attempts. The documented patient complaint was "major depression and suicidal ideas". The patient was triaged and placed in Room 7. The plan was for the patient to have a psychiatric evaluation.</p> <p>At approximately 11:55 AM, the patient eloped from of the ED. A search by security staff found the patient standing at a bus stop across the street from the hospital. The patient was safely brought back to the hospital ED, and placed in the LSU (low stimulus unit) on 1:1 observation.</p> <p>During an interview on 6/16/14 at approximately 9 AM, the Risk Manager revealed that with hospital investigation the triage nurse had reported that the LSU was full when the patient arrived. It was also reported that the patient should have been on a 1:1 upon arrival to the ED, but there was not enough staff and no bed available in the LSU.</p> <p>When interviewed on 6/18/14 at approximately 1:30 PM, the ED nurse who cared for the patient revealed that the patient stated s/he wanted to commit suicide. However, the patient was left in a room without 1:1 supervision, reportedly due to a lack of sufficient staff.</p>	Z 160		

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Z 160	<p>Continued From page 6</p> <p>3. Review of the clinical record for patient ID# 34 reveals the patient was brought to the ED via EMS for making suicidal statements to his/her father. The patient has a past suicidal attempt in December of 2013.</p> <p>Review of the triage notes reveals the patient did express feelings of depression and thoughts of harming self. The patient was placed on suicide precautions and 1:1 observation.</p> <p>At approximately 2:15 AM the patient was accompanied to the bathroom by the registered nurse. While in the bathroom, the patient opened the other door to the bathroom and fled the ED. The local police were notified, found the patient, and brought him/her back to the ED.</p> <p>During an interview on 6/18/14 at approximately 10 AM with the Risk Manager, she revealed the patient was placed in the "core" area of the ED on arrival. A hallway bathroom was used that has 2 doors, one of which goes to the waiting area. Surveillance video shows the patient was escorted to the bathroom by the RN. The patient was allowed to close the door completely, putting the patient out of view of the RN and security officer. The patient then fled out of the other door leading to the waiting area. The patient was not in full view of staff in accordance with the hospital policy.</p> <p>V. The hospital policy, "Universal Protocol Policy", dated 9/2012, under "Marking the Operative Site", states:</p> <p>"All patients having an invasive procedure/surgical procedure that involve</p>	Z 160		

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Z 160	<p>Continued From page 7</p> <p>laterality... will have their site marked."</p> <p>"The surgeon will mark the site with his initials. The exception to this is Spinal Level, which will be completed as follows:</p> <p>Skin marked at the level of the procedure (e.g. cervical, thoracic, lumbar) The skin mark indicates anterior vs. posterior and right vs. left."</p> <p>Under, "Time-out Process," it states:</p> <p>"An incision will not be made until the circulating nurse or procedure assistant and physician/dentist together along with the SRNA/CRNA/Anesthesiologist (student registered nurse anesthetist/certified registered nurse anesthetist) (if appropriate) actively verifies the surgical information. The physician will initiate "time-out" for the verification process. All staff involved in the procedure (Physician, Anesthesia, Circulating Nurse, Scrub Tech) will pause, take a time-out to verify:</p> <p>The correct patient The correct procedure Correct site/side (confirmed with consent by RN/licensed provider) Physician's initials on procedure site/side visible after prepping and draping, can we see the mark?"</p> <p>Review of the clinical record for patient ID# 26 reveals on 5/22/13 the patient underwent a lumbar and sacral dorsal rami block for right lower back pain.</p> <p>The procedure documentation reveals, "Left L5 (lumbar) and sacral L1, L2, L3 and L4 dorsal rami</p>	Z 160		

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Z 160	<p>Continued From page 8</p> <p>block." The procedure documentation by the physician revealed that at the conclusion of the procedure, it was realized that a left sided injection was performed. This was done despite documentation in the patient's history and physical that his/her pain was principally right sided. Informed consent was for a right sided injection. It was confirmed with the patient that the right side was to be done.</p> <p>Review of the Procedure Assessment/Plan lacks evidence that the site was verified and marked.</p> <p>During an interview on 6/13/14 at approximately 12:15 PM, the Risk Manager revealed in the hospital investigation that it was realized that those involved in the procedure did not actively participate during the time-out. During the time-out, the radiological technician and physician had started the procedure, and the nurse was doing paperwork. There were no site markings in accordance with hospital policy. Additionally, the "Universal Protocol Checklist Non-Operating Room" documentation was not used.</p> <p>When interviewed on 6/17/14 at approximately 12:30 PM, the Chief of Anesthesia revealed the site should have been marked per hospital protocol. During the time-out, everyone is to stop what they are doing and listen to the physician at this time; all in the room should participate during the time-out.</p> <p>During an interview on 6/18/14 at approximately 2:20 PM, the Radiological Technician revealed, "when we do a time out or briefing we should all be in the room. I was not in the room when the time-out was done; I was in the control room entering patient information into the computer." The physician and the nurse were in the room</p>	Z 160		

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(X4) ID 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
Z 160	<p>Continued From page 9</p> <p>and did the time-out without the technician being present.</p> <p>VI. The hospital policy, "Annual Competency Based Evaluation System", dated 7/2010, under "Procedure" item B states:</p> <p>"It is the responsibility of the department manager/supervisor to document performance and assess competency on an ongoing basis on an evaluation and meet with their employees as soon as possible."</p> <p>Also, review of the hospital policy dated 4/2013, entitled "Annual Performance Competency Review Process," under "Policy Statement," states:</p> <p>"A documented annual Performance Review is required of all CharterCARE Health Partner employees in a budgeted position, employees in a per diem position who work 350 or more hours in a year, as well as contracted staff and volunteers..."</p> <p>Review of 6 out of 12 employee files lacked evidence of an annual performance evaluation, (employee ID's A, B, C, D, E and F).</p> <p>ID's A &amp; B lacked an annual performance evaluation for 2012. ID C lacked an annual performance evaluation for 2011 and 2012. ID's D &amp; F lacked an annual performance evaluation for 2012. ID E lacked an annual performance evaluation for 2012 and 2013.</p>	Z 160		

RI Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>HOS00110</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____  B. WING _____	(X3) DATE SURVEY COMPLETED  <b>06/23/2014</b>
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Z 160	Continued From page 10  When interviewed on 6/4/14 at approximately 2:30 PM, the Vice President of Human Resources revealed that the policy is for annual evaluations, and efforts have been made over the years to enforce this policy.	Z 160		
Z 940	<p>PATIENT CARE SERVICES 34.8 Reportable Incidents</p> <p>34.8 Any reportable incident occurring on or after June 30, 1994 shall be reported in writing to the Department of Health within seventy-two (72) hours of when the hospital has reasonable cause to believe an incident has occurred. Any incident(s) occurring prior to June 30, 1994 need not be reported.</p> <p>This Requirement is not met as evidenced by: Based on document review and staff interview, it has been determined that the hospital failed to report, in writing to the licensing agency, reportable incidents within 72 hours for 5 of 18 relevant sample patients (ID#'s 26, 29, 30, 36 and 38).</p> <p>Findings are as follows:</p> <ol style="list-style-type: none"> <li>1. A reportable incident occurring for patient ID# 26 on 5/22/13 was not reported to the licensing agency until 5/28/13.</li> <li>2. A reportable incident occurring for patient ID# 29 on 12/30/13 was not reported to the licensing agency until 1/7/14.</li> <li>3. A reportable incident occurring for patient ID# 30 on 11/7/13 was not reported to the licensing agency until 11/18/13.</li> </ol>	Z 940		

RI Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>HOS00110</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____  B. WING _____	(X3) DATE SURVEY COMPLETED  <b>06/23/2014</b>
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Z 940	<p>Continued From page 11</p> <p>4. A reportable incident occurring for patient ID# 36 on 10/31/13 was not reported to the licensing agency until 11/6/13.</p> <p>5. A reportable incident occurring for patient ID# 38 on 12/8/13 was not reported to the licensing agency until 1/30/14.</p> <p>During an interview on 6/20/14 at approximately 1:30 PM with the Risk Manager, she was unable to provide evidence that the above incidents were reported to the licensing agency within 72 hours as required, and indicated that she frequently gets these reports late from staff.</p>	Z 940		