Safe and Healthy Lives in Safe and Healthy Communities

David R. Gifford, MD, MPH
Director of Health

November 26, 2007

George A. Vecchione
Interim President and Chief Executive Officer
Rhode Island Hospital
593 Eddy Street
Providence, RI 02903

Dear Mr. Vecchione:

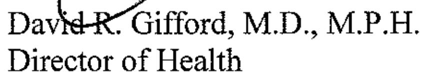
As you know, on Sunday, 25 November 2007 the Department of Health conducted an on-site complaint investigation at Rhode Island Hospital regarding a patient who received a surgical procedure in error. As a consequence of our findings, enclosed is a Statement of Deficiencies (SOD). Pursuant to the provisions 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 an Immediate Compliance Order, the contents of which are effective forthwith.

Lastly, the Hospital is issued a REPRIMAND and is assessed a fine in the amount of fifty thousand dollars ($50,000). The Hospital is hereby required to submit payment of this fine within thirty (30) days of the receipt of this letter. If the Hospital is aggrieved by the discipline set forth in this paragraph, it may request a hearing on these matters within thirty (30) days.

If you have any questions in these matters, please contact me at 222-2231.

Sincerely,



David R. Gifford, M.D., M.P.H.
Director of Health

cc: Alfred J. Verrecchia
Edward A. Iannuccilli, M.D.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 121	(X2) MULTIPLE CONSTRUCTION A. BUILDING ____ B. WING ____	(X3) DATE SURVEY COMPLETED C 11/25/2007

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
RHODE ISLAND HOSPITAL	593 EDDY STREET PROVIDENCE, RI 02902

(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 0	INITIAL COMMENTS A complaint investigation survey was conducted at this facility.	Z 0		
Z 160	ORGANIZATION & MANAGEMENT 12.2 Organization 12.2 Each hospital department and service shall maintain: 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. This Requirement is not met as evidenced by: Based on medical record review, policy and procedure review, and staff interview, it is determined that the hospital failed to ensure compliance with the policy and procedure entitled, "Verification of the Patient's Identity, Procedural Site, and Invasive Procedure Performed Outside the OR", for patient ID # 1. Findings include: The policy and procedure, "Verification of the Patient's Identity, Procedural Site, and Invasive Procedure Performed Outside the OR" states, in part: "The nurse, technologist, or second provider will verify that all appropriate documentation is included in the medical chart: history & physical or preoperative not for inpatients, sign consent form where applicable, and lab work and/or radiographs." Patient ID #1 had CT scans of the head on 11/13/07 and 11/20/07, both revealing a left	Z 160		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 121	(X2) MULTIPLE CONSTRUCTION A. BUILDING ______ B. WING ______	(X3) DATE SURVEY COMPLETED C 11/25/2007
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Z 160	Continued From page 1 subdural hematoma. On 11/23/07 a decision was made to perform a procedure, and signed consent was obtained from the the patient's son, for a "Twist Drill for evacuation of left subdural, possible left Burr Holes, possible craniotomy (Left)". On 11/23/07, the Chief Resident inadvertently initiated the procedure on the patients right side, and after noting the error, completed the procedure on the left side, with good effect. Review of the patient's medical record revealed no evidence that any staff member present during the procedure verified appropriate documentation in accordance with hospital policy. There is no evidence the patient's history & physical, preoperative note, signed consent form, or CT scans were reviewed prior to procedure initiation, although all such forms existed. The hospital Risk Manager stated the nurse was a travel nurse and not familiar with the procedure.	Z 160		
Z 370	PATIENT CARE SERVICES 19.6 Patient Care Management 19.6 The hospital shall provide care and services to all patients in accordance with the prevailing community standard of care. This Requirement is not met as evidenced by: Based on Based on medical record review, policy and procedure review, and staff interview, it is determined that the hospital failed to provide care and services to all patients in accordance with the prevailing community standard of care for patient ID #1. Findings include:	Z 370		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 121	(X2) MULTIPLE CONSTRUCTION A. BUILDING ______ B. WING ______	(X3) DATE SURVEY COMPLETED C 11/25/2007

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
RHODE ISLAND HOSPITAL	593 EDDY STREET PROVIDENCE, RI 02902

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Z 370	Continued From page 2 Patient ID #1 had CT scans of the head on 11/13/07 and 11/20/07, both revealing a left subdural hematoma. On 11/23/07, the Chief Resident inadvertently initiated the procedure on the patients right side (rather than the left side), and after noting the error, completed the procedure on the left side. Refer to findings, Z 160, Section 12.2, Organization, herein.	Z 370		

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

DIRECTOR OF HEALTH
DEPARTMENT OF HEALTH
DIVISION OF FACILITIES REGULATION

IN THE MATTER OF:
RHODE ISLAND HOSPITAL

IMMEDIATE 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 makes the following Findings and enters the following Order:

1. Rhode Island Hospital (hereinafter the "Hospital") is a hospital located on Eddy Street in the City of Providence, County of Providence, State of Rhode Island, which is a 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 regulation and as a condition of its license, the Hospital is required to provide care and services in accordance with written policies and procedures pertaining to invasive procedures. 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 maintains the health and safety of individuals, and to ensure that patients do not undergo unnecessary and/or unwanted procedures

3. A review by the Department of Health, on 21 February 2007, indicated that the Hospital failed to provide care and services in accordance with written policies and procedures pertaining to invasive procedures, and failed to provide care and services in accordance with the prevailing community standard of care in a manner that maintains the health and safety of individuals and services. The hospital further failed to ensure that each patient receiving neursurgery care does not undergo unnecessary and/or unwanted procedures.

4. A review by the Department of Health, on 1 August 2007, indicated the hospital had continued to fail to provide neurosurgery care and services in accordance with written policies and procedures pertaining to invasive procedures, and continued to fail to provide care and services in accordance

with the prevailing community standard of care in a manner that maintains the health and safety of individuals, and continued to fail to ensure that each patient receiving neurosurgery care and services does not undergo unnecessary and/or unwanted procedures.

5. As a consequence of its 1 August 2007 review, the Department of Health issued an Immediate Compliance Order (copy attached and made a part hereof) requiring the Hospital to undertake certain activities.

6. On 23 November 2007 the Hospital informed the Department of Health that a neurosurgery patient had undergone an unnecessary and unwanted procedure.

7. A review by the Department of Health, on 25 November 2007, of a hospital report concerning a patient, and the Hospital's implementation of its adopted policies and procedures regarding the provision of "bedside" neurosurgical procedures indicates the hospital has continued to fail to provide neurosurgery care and services in accordance with written policies and procedures pertaining to invasive procedures, and continued to fail to provide care and services in accordance with the prevailing community standard of care in a manner that maintains the health and safety of individuals, and continued to fail to ensure that each patient receiving neurosurgery care and services does not undergo unnecessary and/or unwanted procedures.

8. The Director hereby finds that, based on the continued failure to provide adequate care to patients receiving neurosurgery, the Hospital is not in conformance with the requirements of licensure.

9. The Director hereby finds that the provision of services in accordance with written policy and procedure and in accordance with the prevailing community standard of care, and ensuring each patient does not undergo unnecessary and/or unwanted invasive procedures is essential to maintain each patient's maximum health, safety and welfare.

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

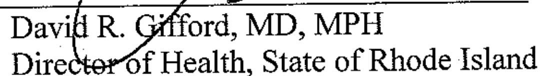
It is hereby **ORDERED**:

Rhode Island Hospital is ordered to

1. Rhode Island Hospital is ordered to assure that an attending physician be in physical attendance throughout the performance of all neurosurgical type procedures in the operating room or elsewhere in the hospital.

2. Rhode Island Hospital is ordered to implement forthwith a revised form known as "Procedure Note (Invasive Procedure Outside of the Operating Room". The revised form shall be required to be completed for all invasive procedures performed outside of the operating room [Note: See Attachment A for the minimum list]. The form shall require separate, primary document confirmation of the correct side (i.e., left versus right) and site of the intended procedure, at a minimum, with the relevant imaging or other study that indicated/confirmed the need for the procedure, the appropriately executed patient consent form assenting to the specific procedure, and the patient's medical record. This form shall require separate completion by the physician and another licensed health professional other than a physician. The Hospital shall revise this form within forty-eight (48) hours of the receipt of this Order and shall file any subsequent revisions of the form with the Department within 48 hours of adoption by the Hospital.
3. Rhode Island Hospital is ordered to report any variance from the requirements established in the amended "Procedure Note (Invasive Procedure Outside of the Operating Room" (see #2, above) relating to procedures performed outside the operating room, such as an "emergency" situation, within twenty-four (24) hours to the Department of Health through the "Incidents and Events" notification process.
4. Rhode Island Hospital is ordered to provide, no later than 15 December 2007, to the Department of Health copies of reports from four consultants to the Hospital, including the "Peri-operative Assessment" and the three reports from neurosurgery consultants.
5. Rhode Island Hospital is ordered to prepare a detailed plan to educate physician staff regarding the Hospital's Policies and Procedures for assuring the right procedure at the right site for the right patient. The plan must include a detailed ongoing competency assessment component. The Hospital shall provide the plan no later than 15 December 2007. Until further notice, the Hospital shall provide the Department with quarterly reports regarding the implementation of the plan and the assessment of physician competency regarding the subject policies and procedures.
6. This Immediate Compliance Order shall be effective immediately upon service.

Entered this 26th day of November, 2007



By____________________________________

David R. Gifford, MD, MPH
Director of Health, State of Rhode Island

Exhibit A

1. Chest tube
2. Thorancentisis
3. Central line placement
4. Arterial line placement
5. Joint Aspiration/injections
6. Craniotomy
7. Kidney biopsy
8. Nephrostomy tubes
9. Lumbar Puncture
10. Liver biopsy
11. Paracentisis
12. Needle Aspiration
13. G-tube reinsertion
14. Suprapubic catheter
15. Tracheostomy
16. Incision & Drainage of abscess

CERTIFICATION OF SERVICE

A copy of the within Immediate Compliance Order was faxed delivered to Kenneth Arnold, Esq., Lifespan General Counsel by the undersigned on the 26th day of November, 2007 at PM.

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