

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 03/25/2011
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 470003	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED C 03/09/2011
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NAME OF PROVIDER OR SUPPLIER FLETCHER ALLEN HOSPITAL OF VERMONT	STREET ADDRESS, CITY, STATE, ZIP CODE 111 COLCHESTER AVE BURLINGTON, VT 05401
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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) COMPLETION DATE
A 000	INITIAL COMMENTS	A 000		
A 466	<p>An unannounced complaint survey, authorized by the Centers for Medicare and Medicaid Services, was completed on 3/9/11. The following deficiency was found.</p> <p>482.24(c)(2)(v) CONTENT OF RECORD - INFORMED CONSENT</p> <p>[All records must document the following, as appropriate:] Properly executed Informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent.</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and record review, the hospital failed to assure that a properly executed informed consent was obtained prior to a procedure requiring conscious sedation for 1 applicable patient in the targeted sample. (Patient # 54) Findings include:</p> <p>Per review of the medical record for Patient #54 on 3/3/11, a consent for treatment for an invasive medical procedure performed under moderate sedation was not properly executed. The consent was not signed by the patient; the document stated "verbal consent" on the patient signature line. A procedure note dated 8/6/10 at 1235 hours stated that informed written consent for the procedure was obtained. During interview on 3/9/11 at 11:30 AM, the physician who performed the procedure confirmed that the report was in error and that he did document 'verbal consent' on the form. Per review on 3/9/11 at 11 AM, the hospital's policy on Informed Consent stated "If the patient or surrogate decision- maker is unable to provide a signature, the responsible provider</p>	A 466	<p>SEE ATTACHED PLAN OF CORRECTION</p>	4/5/2011

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE <i>John J. Norman</i>	TITLE <i>Quality</i>	(X6) DATE 4-5-11
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Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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A 466	Continued From page 1 should record an attestation confirming that the patient or their surrogate has consented to the treatment/procedure after being informed of the risks, benefits, and alternatives. The documentation should be sufficiently extensive to explain why a signature was not obtained. ⁹ There was no attestation note in the medical record on why written consent was not obtained. During interview at 11:40 AM, the Clinical Director of Radiology confirmed that an explanatory note should have documented why written consent was not obtained.	A 466	4/20/11 POC Accepted O. [Signature]		

