



Office of the Attorney General

Agency of Human Services
Department of Mental Health
P.O. Box 70
One Church St., Suite 300
Burlington, VT 05402-0070

[Phone] 802-657-4310
[Fax] 802-657-4322

January 16, 2009

Department of Health & Human Services
Departmental Appeals Board-MS 6132
Civil Remedies Division
Attention: Oliver Potts, Chief
330 Independence Avenue, S.W.
Cohen Building, Room G-644
Washington, D.C. 20201

Richard Shaw, Branch Chief
Northeast Consortium, Division of Survey and Certification
John F. Kennedy Federal Building, Room 2275
Boston, Massachusetts 02203

VIA FEDERAL EXPRESS DELIVERY AND FACSIMILE TRANSMISSION

Re: Vermont State Hospital Request for Hearing

Dear Sirs:

Enclosed, please find the Vermont State Hospital's Notice of Appeal and Request for Hearing.

Respectfully Submitted,

Wendy S. Beinner, A.A.G.
Vermont Department of Mental Health
1 Church Street, P.O. Box 70
Burlington, Vermont 05402-0070
(802) 657-4316
Wendy.Beinner@ahs.state.vt.us

Enc.

cc: Robert Hofmann, Secretary – Agency of Human Services
Michael Hartman, Commissioner – Department of Mental Health
Terry Rowe, Executive Director – Vermont State Hospital

DEPARTMENT OF HEALTH & HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD
CIVIL REMEDIES DIVISION

Vermont State Hospital,)	
)	
Petitioner,)	
)	
v.)	
)	
)	Docket No.
The Centers for Medicare)	
and Medicare Services,)	
)	
Respondent.)	

NOTICE OF APPEAL

NOW COMES Vermont State Hospital, by and through undersigned counsel, pursuant to 42 C.F.R. 498.40, and gives notice of its appeal of the initial determination denying the Vermont State Hospital's ("VSH") application for Medicare participation as a psychiatric hospital and subsequent denial of the Hospital's request for reconsideration of that determination. VSH hereby requests a hearing on this matter before an Administrative Law Judge of the Department of Health and Human Services.

ISSUES, FINDINGS OF FACT, AND CONCLUSIONS OF LAW

As grounds for its request for hearing, VSH disagrees with the decision contained in the letter dated October 1, 2008, and affirmed in the decision dated November 20, 2008, that VSH had significant deficiencies with respect to compliance with the Conditions of Participation when it was initially surveyed on September 18, 2008. VSH contends that the decision to deny VSH's request for participation in the Medicare program was erroneous as a matter of law and fact. VSH contests that the majority of deficiencies cited were factually erroneous. Any deficiencies that did exist were not significant with respect to compliance with the Conditions of Participation, did not reach a conditional level, and therefore did not require CMS to make a determination that the hospital does not meet the

requirements for participation in the Medicare program.

Specifically, VSH alleges that CMS made the following errors in its findings following the September 18, 2008, initial survey:

1. CMS improperly found that the Medicare Condition of Participation found at 42 CFR 482.12 Governing body was not met.

CMS's finding that VSH failed to meet the Governing Body condition is not supported by the evidence. CMS based its conclusion on a finding that VSH lacked compliance with the Conditions of Participation: "Patient Rights", "Medical Records", and "OPO". As set out in detail below, this conclusion was not factually or legally supported. CMS lists subjective and incomplete examples as evidence of non-compliance. This incomplete review led to the incorrect conclusion that this condition was not met.

2. CMS improperly found that the Medicare Condition of Participation found at 42 CFR 482.13 Patient's rights was not met.

- a. CMS erroneously concluded, solely through review of the VSH Grievance Policy, that some patients were denied the ability to pursue resolution of their complaints. CMS wrongly interpreted the language policy, and did not ask for any further information. All grievances are reviewed and resolved. CMS did not investigate whether any grievances in fact had been denied out of hand. If CMS had, they would have found that 100% of grievances were processed.
- b. The CMS finding that the Timely Referral of Grievances standard was not met was not a conditional level violation. In any event, VSH immediately modified its grievance policy to include a referral procedure, and posted the revised procedure to ensure that patients were notified of the change.
- c. CMS's conclusion that VSH did not meet the Grievance Review Time Frames standard was not supported by the facts or law. The seven day requirement is not part of the

condition. It is merely suggested by the CMS interpretive guidelines, but not required.

Furthermore, the policy did include the “seven day timeframe”.

- d. CMS’s conclusion that VSH failed to provide care in a safe setting, in violation of both the Care in a Safe Setting and the Maintenance of a Physical Plant standards is factually erroneous. CMS investigators were simply wrong when they found that many of the cited structures posed an unreasonable risk to patients. These structures have been approved by national experts in patient safety and also are regularly utilized in other hospitals certified by CMS. Reviewers from the United States Department of Justice and the Joint Commission did not cite any safety concerns in their recent reviews. Finally, for those structures that could pose a risk to patients without safety protocols in place, operational plans existed to mitigate that risk. VSH plans to submit significant evidence in this area in its prehearing brief and at hearing.
- e. CMS wrongly found that VSH violated the provision in the Seclusion and Restraint standard that requires reporting of associated deaths. VSH policy did include a requirement that VSH notify all state and federal agencies in the event of such a death.

3. CMS erroneously found that VSH did not meet the Nursing Care Plan standard.

Even though this standard is not cited by CMS as a basis for its refusal to certify VSH, VSH intends to show that it was not out of compliance. VSH will show that its level of accuracy was not problematic (1:31 = 99.992% accuracy), and that, in fact, this patient did receive adequate care.

4. CMS’s Finding that VSH failed to satisfy the Medicare Condition of Participation found at 42 CFR 482.24 Medical Record Services was not supported by the evidence and is wrong as a matter of law.

- a. CMS based its inaccurate conclusion on discussions with VSH staff. Had the investigators reviewed the VSH written policies and procedures, it would have seen that VSH’s medical records reporting structure includes a direct report to VSH leadership. Additionally, VSH has

documentation illustrating: the completion rate for discharge summaries; that it stores medical records on-site for greater than five years, making them readily accessible when needed; and that it ensures that copies of medical records are not released to unauthorized people.

The findings referring to failure to accurately complete all medical entries do not reach the level of conditional violation and should not have been considered as evidence of failure to meet a condition as a matter of law. However, VSH has educated all clinicians to the expectation that medical entries are complete and implemented an education and audit process which includes feedback to reinforce knowledge and practice.

The finding relating to physical examinations is factually wrong. The two documents that were alleged to be missing were retrieved and put in the proper place in the medical record.

- b. CMS's conclusion that VSH failed to meet the standard ensuring that medical records were properly stored and accessible was factually and legally erroneous. All records are stored at VSH for greater than five years. The records referred to in the findings, which take longer to retrieve, are ten years or more old. Further, the finding that the records were minimally protected from water damage was beyond the scope of the survey. There is no specific requirement that records be covered by a "roof", and the risk of fire outweighs the risk of water damage to these records. Finally, all critical records are additionally stored on disc, and not at risk for water damage.
- c. CMS based its finding that VSH failed to have a procedure for ensuring confidentiality of records on incomplete information, and is erroneous. Access to VSH patient records is only granted pursuant to a VSH request. There is no risk that an unauthorized person would gain access to a patient's confidential records.
- d. CMS erroneously found that VSH failed to meet the Medical Record Services and Orders Dated and Signed requirements both as a matter of fact and law. Although a small number of records were found to be incomplete, VSH had a performance improvement process in place

to address these types of errors. The process includes educating all clinicians about the expectation that all medical entries must be complete, and an audit process with feedback to reinforce knowledge and practice. The CMS interpretive guidelines state that, if there is a performance improvement process in place, surveyors must take the process into consideration.

The VSH performance improvement process specifically includes an audit of Certificate of Need forms to ensure that debriefing takes place and that the team considers alteration of the treatment plan based on the information gleaned in the debriefing. However, debriefing is not specifically required by the Conditions of Participation and is not referenced in any standard or condition. So, these findings should not have been included as a matter of law.

- e. CMS's finding that VSH failed to meet the Verbal Orders Authenticated Based on Law standard lacks a factual and legal basis. The above-mentioned performance project is in place to address any signature errors. The process specifically includes a provision addressing the requirement that all orders must be authenticated within 48 hours. The investigators were informed about the existence of the VSH performance improvement process, but they refused to review the plan, any audits or results. The audit shows a rate of 97% completion rate for signatures.
- f. The CMS conclusion that VSH failed to meet the Content of Record standard is erroneous as a matter of fact and law. The two records cited as missing in the findings were retrieved and presented to the investigators, and there was evidence in the record that the exam had occurred. Further, a performance improvement process is in place, which includes educating the clinicians about this requirement and an audit system is in place to monitor compliance.
- g. CMS's finding that VSH failed to meet the Content of Record standard is erroneous as a matter of law and fact. The number of errors found in this area does not amount to a violation of the standard. Further, a performance improvement process is in place, which includes

educating the clinicians about the requirement and an audit system is in place to monitor compliance. The process also includes a protocol that ensures the results of consultative evaluations are included in the medical record.

The reference to the neurological consult for patient #2 is immaterial. The consult was not urgent. The neurologist was aware of the requested consult and planned to see the patient during her regularly scheduled hours of work. VSH has a protocol in place that requires transport to an acute medical-surgical hospital in the event an emergency consult is needed. The reference to the audiologist consult and brain scan order for patient #1 is likewise immaterial. The investigators did not ask for any information relative to these orders. If they had, the treating doctor would have provided clarification, including the fact that the patient had refused both procedures.

- h. CMS improperly found that VSH failed to meet the Secure Storage standard. At the time of the survey, there was indeed a policy and procedure in place that related to secure storage of medications and biologicals. The findings relating to medications that were not secured during the survey did not constitute a conditional violation. Furthermore, immediate corrective action was taken.
- i. CMS improperly found that VSH did not meet the standard requiring that outdated, mislabeled or otherwise unusable drugs must not be available for patient use. Patient #24 was on a short visit, and it is not required that medications for someone on a visit be returned to the pharmacy. The other cited error, relating to the lack of documentation, did not rise to the level of violation of the standard. VSH has a performance improvement process in place in this area.
- j. The CMS finding that VSH failed to meet the Facilities, Supplies and Equipment Maintenance requirement is not supported by the evidence. The problems cited were minimal, did not rise to a conditional violation, and were immediately addressed. In addition, staff has all received

training in this area and a checklist monitoring completion of cleaning tasks has been implemented.

5. CMS improperly found that the Medicare Condition of Participation found at 42 CFR 482.45 Organ, tissue, and eye procurement was not met.

Although a policy addressing organ, tissue and eye procurement was not in place at the time the survey began, an interim policy was implemented prior to the completion of the survey. The surveyors improperly refused to consider the new policy. The policy includes notification of the OPO, and VSH has entered into a Memorandum of Understanding with the NEOB.

In the related area of respiratory care services, VSH has likewise immediately amended its policies to clarify that it does not provide respiratory services and is not in violation of this standard.

6. CMS Neglected to Follow its Published Procedures and Guidelines

By refusing to allow VSH to address any deficiencies found in the initial survey through a corrective action plan, CMS failed to follow its own procedures. VSH should have been allowed the opportunity to present a corrective action plan for approval, to have implemented that plan, and had CMS investigators return to assess whether the plan had been implemented. Instead, immediately following the survey, CMS outright denied the application, not allowing VSH the opportunity to correct any deficiencies prior to the final decision to deny participation.

CONCLUSION

CMS's refusal to certify VSH was in error of law and fact. CMS improperly found that VSH provides substandard quality of care. The sole violation cited by CMS that reaches a conditional threshold is the requirement relative to organ and tissue procurement. VSH immediately offered to fix this problem during the survey, but the investigators refused to consider it. The other deficiencies cited were either not supported by the evidence or were merely a standard violation.

For these reasons, VSH requests an order granting its application for certification in the

Medicare program, and asks that its provider agreement be retroactive to the date of the initial survey. VSH reserves the right to submit further documentation in support of this appeal, and to assert other grounds for appeal which may be discovered through such documentation.

Dated at Burlington, Vermont, the 16th day of January, 2009

WILLIAM SORRELL
ATTORNEY GENERAL

By: _____
Wendy S. Beinner, A.A.G.
Vermont Department of Mental Health
1 Church Street, P.O. Box 70
Burlington, Vermont 05402-0070
(802) 657-4316

cc: Robert Hoffman, Secretary, Agency of Human Services
Michael Hartman, Commissioner, Department of Mental Health
Terry Rowe, Executive Director, Vermont State Hospital