

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Suite 216, The Public Ledger Building
150 S. Independence Mall, West
Philadelphia, PA 19106-3499

l: 9/16/08
CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Northeast Consortium/ Division of Survey & Certification

September 11, 2008

Ms. Nancy Agee,
Chief Operating Officer/Executive Vice President
Carilion Medical Center
1906 Belleview Avenue
Roanoke, VA 24033

CMS Certification Number: 49-0024

Dear Ms. Agee:

REMOVAL OF DEEMED STATUS-PLEASE READ CAREFULLY

Section 1865 of the Social Security Act and implementing regulations (42 CFR §488.5) provide that a hospital accredited by the Joint Commission (JC) will be deemed to meet all the Medicare Conditions of Participation with the exception of those relating to utilization review and the special staff requirements and special medical record requirements applicable to psychiatric hospitals. Section 1864 of the above Act, as amended by Public Law 92-603, authorizes the Secretary of Health & Human Services to conduct, on a selective sampling basis or in response to substantial allegations of non-compliance, surveys of JC accredited hospitals participating in Medicare as a means of validating the JC survey process (see also 42 CFR §488.7(a)). If, in the course of such a survey, a hospital is found not to meet one or more of the Medicare Conditions of Participation, the hospital will no longer be deemed to meet any Medicare conditions. Also, we are required to keep the hospital under Medicare State agency survey jurisdiction until it is in compliance with all Medicare Conditions of Participation.

Based on the State of Virginia (state survey agency) report of deficiencies found during the complaint investigation survey of your hospital on August 20, 2008, it has been found that Carilion Medical Center is not in compliance with the following Medicare Condition of Participation:

42 CFR § 482.13 Patient Rights

A complete listing of all cited deficiencies is enclosed (CMS-2567, Statement of Deficiencies and Plan of Correction). In accordance with the federal regulation at 42 CFR §488.7(d), we have determined that Carilion Medical Center will no longer be "deemed" to meet the Medicare Conditions of Participation and will be subject to the federal requirements applied to non-accredited hospitals. This document will be available to the public upon request, after thirty (30) days have elapsed allowing your facility the opportunity to respond to the cited deficiencies. Therefore, you may wish to file a plan of correction for the deficiencies cited with this office, and a send a copy to State of Virginia, as this will become a part of the public record.

The complaint investigation completed on August 20, 2008, did not cover all of the Conditions of Participation applicable to the hospital. We will schedule a complete Medicare survey of the hospital to evaluate its compliance with all Medicare Conditions of Participation (42 CFR §488.7(d)). After the completion of that survey you will be required to submit an acceptable plan for correction of all of the deficiencies identified during the complete Medicare survey and the complaint investigation. You are advised that failure to comply with all of the Conditions of Participation will result in termination of the hospital's participation in the Medicare program.

The finding that Carilion Medical Center is not in compliance with the Conditions of Participation does not affect your hospital's JC accreditation, its Medicare payments, or its current status as a participating provider of hospital services in the Medicare program. When the plan of correction has been implemented, and it has been found that all the Medicare Conditions of Participation for hospitals are met, we will discontinue the state agency jurisdiction. A copy of this letter is being forwarded to JC and the State of Virginia.

Under the Centers for Medicare & Medicaid Services (CMS) regulations 42 CFR 498.3 (d) (9), this notice of findings is an administrative action, not an initial determination by the Secretary, and therefore formal reconsideration and hearing procedures do not apply.

If you have any questions, please contact Maya Gripper at (215) 861-4265 or me at (215) 861-4277.

Sincerely,



Robin Thomas-Naarden
Principal State Representative
Certification and Enforcement Branch

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

PRINTED: 09/11/2008
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 490024	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED C 08/20/2008
NAME OF PROVIDER OR SUPPLIER CARILION MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 1906 BELLEVIEW AVENUE ROANOKE, VA 24033		
(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	<p>INITIAL COMMENTS</p> <p>On Monday August 18, 2008 a Medical Facility Inspector, Virginia Department of Health, Office of Licensure and Certification conducted an unannounced complaint investigation (# VA00014713). The following Conditions of Participation were reviewed.</p> <p>482.13 Patient Rights. 482.21 Quality Assurance. 482.55 Emergency Services.</p> <p>The facility was found not in compliance with the following Condition and Standard of 42 CFR 482, Medicare/Medicaid Conditions of Participations for hospitals and the complaint was substantiated.</p> <p>482.13 Condition level. Patient Rights 482.13(c)(2) Standard Level. Patient has right to receive care in safe setting.</p> <p>The findings of this investigation were based on:</p> <ol style="list-style-type: none"> 1. Observations 2. Staff interviews 3. Medical Record review. 4. Policy review 5. Review of Quality Assurance program 6. Review of facility Root Cause Analysis 	A 000			
A 115	<p>482.13 PATIENT RIGHTS</p> <p>A hospital must protect and promote the rights of each patient.</p> <p>This CONDITION is not met as evidenced by: Based on interviews, medical record review and</p>	A 115			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

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 115	Continued From page 1 the process of complaint investigation, it was determined that the hospital failed to protect and promote the rights of each patient. While being retained in the hospital's Emergency Department Annex, a six bed locked unit, a psychiatric patient, Patient #1, committed suicide. The facility failed to remove all safety hazards from the rooms in the Emergency Department Annex which was frequently used to retain psychiatric patients awaiting placement in psychiatric facilities. The facility staff failed to provide sufficient supervision of the patient after being informed that she had made a suicidal statement. Refer to A0144 for details.	A 115	
A 144	482.13(c)(2) PATIENT RIGHTS: CARE IN SAFE SETTING The patient has the right to receive care in a safe setting. This STANDARD is not met as evidenced by: Based on medical record review, observations and facility staff interviews it was determined that the facility failed to take adequate measures to ensure the safety of one patient, Patient #1, and potentially other patients in the Emergency Department Annex. Patient #1 committed suicide using the cord from medical equipment in the room to hang herself from the ceiling light. The findings include: 1. One of the hospital's Vice Presidents (VP) was interviewed on August 18, 2008. In this interview the VP acknowledged that there had been a	A 144	

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A 144	Continued From page 2 patient suicide in the Emergency Department (ED) on 7/25/08. The VP described how the event occurred and what the hospital had done to prevent future events. After the patient suicide occurred the hospital began their root cause analysis (RCA). The VP stated that the hospital was experiencing great difficulty finding beds for patients coming through the ED and falling under the category of mental health issues. She further stated that because of the lack of sufficient psychiatric beds available, that it is starting to put a great demand on the ED and forcing them to manage the patients until Emergency Outreach Services are able to assess and find appropriate psychiatric beds for the patients in the community. The VP said that due to this increasing demand that the ED had started putting their acute psychiatric patients in a side section of the ED called the ED Annex (EDA). The VP explained how the EDA has six treatment rooms and is locked so that only staff can enter and exit as needed. The EDA was still being used for patients other than psychiatric if the ED census and volume was high. On this particular day the EDA was full with six psychiatric patients waiting to be placed in other appropriate facilities in the area. The VP further explained how the hospital had stripped these six rooms in the EDA of all potentially harmful items but left the Otoscope and Ophthalmic equipment attached to the walls. The patient had asked staff if she could have some privacy and staff allowed her to draw the curtain closed. The patient then took the chord from this equipment, wrapped it over the overhead light and hung herself. As a result of hospital's RCA the staff immediately stripped these devices from the wall and instituted a policy for conducting 15 minute safety checks on identified psychiatric patients.	A 144		

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A 144	<p>Continued From page 3</p> <p>2. On Monday August 18, 2008 the VP took the MFI to the ED for a tour and introduced MFI to the Practice Administrator for ED (PAED). During the tour MFI observed the EDA as being a very small area with a patient restroom, a nurse station and a hallway. There was no exit out with out a key. On this day the EDA was also full with six psychiatric patients awaiting placement. There was one nursing staff and three security staff on the unit. The PAED explained that there are never less than two staff members on the floor and often more. The PAED showed the MFI where the suicide occurred. The suicide occurred in EDA room #1 which is five to six feet across from the nurse station. The VP explained that after the curtain was drawn at the patient's request for privacy, how the patient had taken the medical piece of equipment with an attached chord and draped it over the arm of the ceiling light and hung herself by the chord. The medical equipment was a Welch Allyn Ophthalmoscope and Otoscope with a long attached chord and they had been mounted to the walls in each treatment room. The VP showed the MFI an example of this equipment going into the ED just prior to touring EDA. As the VP had explained during interview and indicated during tour, these pieces of equipment had all been removed from the EDA after the suicide occurred.</p> <p>3. Review of patient #1's medical record revealed that the patient was a 44 year old female with multiple visits to the ED in the past. Over the course of the last four years, the VP stated that the patient had been seen 46 times for similar complaints of migraine headaches, leg or back pain. On this ED visit, the patient presented to the ED on 7/24/08 at 1742PM with complaint of</p>	A 144	

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A 144	Continued From page 4 leg pain. The medical record revealed a thorough medical work up to determine medical clearance. Documentation showed that the patient frequently requested medication for pain while in the ED. At 2200PM a nurse's note stated that she was called into the room by a young gentleman who stated the "patient wanted to leave and go and slit her wrist." The ED physician was notified of this and at 2208PM an order for an Emergency Outreach Service (EOS) consult was ordered. EOS is a part of the local Mental Health system (now called Community Service Boards) and routinely goes to ED's in the area for assessing psychiatric patients and to determine if appropriate beds are available for placement. At 2346PM EOS had not arrived yet and the physician placed a medical hold on the patient. The VP explained that local Magistrates have allowed this medical hold status to legally hold the patient until EOS can see the patient. In this case EOS arrived at 0030AM on 7/25/08. EOS staff found the patient to have a substantial likelihood of serious harm to self and met the criteria for involuntary admission to a psychiatric facility when bed available. According to interviews with VP and PAED the EOS staff was unable to secure a psychiatric bed placement in the surrounding community. This necessitated the ED to manage the patient until one would be available. The patient was managed in the main part of the ED until a bed became available in the EDA area for psychiatric patients and patient #1 was moved there between 0200AM and 0300AM. The patient's vital signs were taken routinely in the EDA and documentation shows vital signs stable and patient sleeping through the night. At 0659 a nurse's note showed next shift assuming care of the patient. At 0749 it is documented the patient requested pain medication. At 0752AM the chart documented patient #1 being offered	A 144	

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A 144 Continued From page 5

Ultram 50 mg for pain. Patient #1 refused, stating "that is not what I want. It does not help." When the nurse informed patient #1 that was what the doctor had ordered the patient threw cup of water at the wall. At 0804AM patient documentation showed refusal of breakfast tray. At 0917AM, the last entry prior to patient being found hanging by chord, stated that the patient was sleeping and a security officer was at the bedside. The next medical record documentation is at 1023AM where patient is found in room with no pulse. Efforts to resuscitate the patient were unsuccessful and patient #1 was pronounced dead at 1037AM. Roanoke City Police were called and at 1128AM the Medical Examiner was at bed side.

4. On August 19, 2008 the VP, the PAED and the Nurse Manager of ED (NMED) were interviewed. They were asked if the patient was placed on 15 minute checks for suicide precaution. All responded that the ED did not have a policy for placing suicidal patients on 15 minute checks at the time, but this was a change implemented as a result of the RCA. The NMED and PAED were asked about average daily volume of patients in the ED and what the volume was on the day of the event. The PAED supplied data showing the average number of patients over the last 45 days was 203, and the patient volume on 7/25/08 (the day of the Suicide) was 187. MFI then asked for a master staffing matrix for the ED and an assignment sheet for 7/25/08. Data supported that the ED was staffed according to the hospital's policies.

5. On Wednesday August 20, 2008 the hospital VP over Facility and Guest Services (which also includes hospital police and security) was

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A 144	Continued From page 6 interviewed. During this interview he stated that "in the last years our psychiatric cases have increased greatly. We are now stationing a security guard in the area for the last two years."	A 144		