THE SECRETARY OF VETERANS AFFAIRS
WASHINGTON

June 24, 2011

The Honorable William E. Reukauf
Associate Special Counsel
U.S. Office of Special Counsel
1730 M. Street, NW, Suite 218
Washington, DC 20036-4505

RE: OSC File No. DI-11-0967

Dear Mr. Reukauf:

I am responding to your letter regarding allegations by a registered respiratory therapist, previously employed at the Department of Veterans Affairs (VA) Overton Brooks Medical Center, Shreveport, Louisiana (hereafter, the medical center), that employees at the medical center inappropriately reissued home-use medical equipment in the inpatient arena without conducting maintenance and safety checks. You asked me to determine if the alleged misconduct constituted a violation of law, rule, or regulation. In addition, you asked me to determine if there was gross mismanagement or a substantial and specific danger to public health at the medical center.

I asked the Under Secretary for Health to review this matter and take any actions deemed necessary under 5 U.S.C. Section 1213(d)(5). He, in turn, directed the Office of the Medical Inspector (OMI) to investigate the disclosures and report their findings. The OMI review is contained in the enclosed Final Report and is submitted for your review. The OMI found no evidence that the medical center had violated any law, rule, or regulation, nor did they find any evidence of gross mismanagement. However, the OMI did make three recommendations for the medical center to address. Subsequently, the medical center implemented corrective actions on each recommendation.

Sincerely,

Eric K. Shinseki

Enclosure

OFFICE OF THE MEDICAL INSPECTOR

Revised Report to the

Office of Special Counsel

OSC File Number DI-11-0967

Department of Veterans Affairs

Overton Brooks Medical Center

Shreveport, Louisiana

Veterans Health Administration
Washington, DC

Report Date: November 6, 2012

2011-D-343

Executive Summary

The Under Secretary for Health requested that the Office of the Medical Inspector (OMI) investigate a complaint lodged with the Office of Special Counsel (OSC) by a registered respiratory therapist, (b)(6) (hereafter, the complainant), previously employed at the Department of Veterans Affairs (VA) Overton Brooks Medical Center, Shreveport, Louisiana (hereafter, the Medical Center). The complainant alleged that employees at the Medical Center inappropriately reissued used medical equipment for use in the Medical Center without conducting maintenance and safety checks. The OMI conducted a telephone interview with the complainant on March 4, 2011, and a site visit to the Medical Center on March 8-9, 2011.

Conclusions

The OMI found no evidence that the Medical Center violated any law, rule, or regulation, nor did we find any evidence of gross mismanagement or substantial and specific danger to public health and safety. However, the OMI did reach the following conclusions regarding the allegations:

1. The OMI substantiates the allegation that work orders to perform maintenance and safety equipment checks on home-use continuous positive airway pressure (CPAP) machines converted to inpatient use were not submitted to the Biomedical Engineering Department (Biomed) by the Respiratory Therapy Department (RT Department) prior to the use of these machines on the Medical Center inpatient units. However, we found that in June 2010, the Medical Center initiated submission of the required work orders on home-use CPAP machines prior to their placement in inpatient areas for multiple patient use.
2. The OMI also substantiates that the Medical Center failed to perform maintenance and safety checks on these machines prior to inpatient use as required by the facility's policies. However, we found that in June 2010, the Medical Center began complying with the requirement to perform the required maintenance and safety checks on the CPAP machines prior to their inpatient use.
3. The OMI does not substantiate the allegation that, as of January 2011, the Biomed maintenance and safety checks on these machines had not been performed. We found that all of the CPAP machines converted from home use to inpatient use that were in service on June 25, 2010, had the necessary Biomed maintenance and safety checks by January 2011.
4. The OMI found that the Medical Center's procedures in place at the time of the site visit satisfactorily address the concerns raised by the allegations.

Recommendations

The Medical Center should:

1. Conduct an audit of all RT Department CPAP machines to ensure that work orders have been submitted, and that the required maintenance and safety checks have been performed.
2. Monitor compliance with the new Respiratory Therapy Policy and Procedure 2.6, *Donated CPAPs and BiPAPs,* March 8, 2011.
3. Monitor the timeliness of Biomed work order submissions for CPAP machines converted from home use to inpatient use.

Office of the Medical Inspector Revised Report
to the Office of Special Counsel

I. Summary of Allegations

The Under Secretary for Health requested that the Office of the Medical Inspector (OMI) investigate a complaint lodged with the Office of Special Counsel (OSC) by a registered respiratory therapist (RRT), (b)(6) [redacted], hereafter the complainant, previously employed at the Department of Veterans Affairs (VA) Overton Brooks Medical Center, Shreveport, Louisiana (hereafter, the Medical Center). The complainant alleged that employees at the Medical Center inappropriately reissued used medical equipment for use in the Medical Center without conducting maintenance and safety checks.

II. Facility Profile

The Medical Center is a full-service health care facility providing comprehensive primary and specialty care in medicine, surgery, psychiatry, physical medicine and rehabilitation, neurology, oncology, dentistry, and geriatrics. The Medical Center operates 119 acute inpatient hospital beds and 3 community based outpatient clinics, and has community contracts for residential rehabilitation beds. The Medical Center serves Veterans and their families in 12 Louisiana parishes, 11 counties in Southern Arkansas and 9 counties in East Texas. The Medical Center is part of Veterans Integrated Service Network (VISN)16, the South Central VA Health Care Network.

III. Background

The OSC complainant expressed concern about the Medical Center's handling of continuous positive airway pressure (CPAP) machines.[1] CPAP machines assist sleep apnea patients with breathing during sleep. The machines provide positive airway pressure, which keeps airways open and reduces the effects of sleep apnea, via tubing from the machine to a tight-fitting face mask. The CPAP machines are used by patients at home or as inpatients at the Medical Center.

IV. Conduct of the Investigation

The OMI investigative team consisted of the Deputy Medical Inspector for National Assessments, (b)(6) [redacted]., and a Clinical Program Manager, (b)(6) [redacted] FNP. On March 4, 2011, the OMI interviewed the complainant by telephone. On March 8-9, the OMI conducted a site visit at the Medical Center, where they held an entrance conference with the Medical Center and VISN leadership: (b)(6) [redacted] Acting Medical Center Director; (b)(6) [redacted], R.N., Acting Associate Director; (b)(6) [redacted] R.N., Acting Nurse Executive; (b)(6) [redacted] M.D., Chief of Staff; (b)(6) [redacted], Acting Chief of Performance Improvement; and (b)(6) [redacted], M.D., VISN 16 Chief Medical Officer. The OMI team toured the Respiratory Therapy Department (RT Department), the CPAP Department, the utility area where CPAP

[1] For the purposes of this report, the term "CPAP machines" includes both machines that deliver continuous positive airway pressure during inhalation and exhalation and machines that deliver a greater pressure during inhalation and a lesser pressure during exhalation. The latter machines are called bilevel positive airway pressure (BiPAP) machines.

machines are cleaned, and the Biomedical Engineering Department (Biomed). On March 9, the OMI conducted 15 interviews and held an exit conference with Medical Center leadership: (b)(6) Acting Medical Center Director; (b)(6), R.N., Acting Associate Director; (b)(6) R.N., Acting Nurse Executive; (b)(6), M.D., Chief of Staff; (b)(6) Acting Chief of Performance Improvement; (b)(6), M.D., Chief of Pulmonary Medicine, and (b)(6) M.D., VISN 16 Chief Medical Officer. The OMI also reviewed work orders and medical records, as well as the policies and directives listed in Attachment A.

During the site visit, the OMI interviewed the following individuals: (b)(6), M.D., Chief, Pulmonary Medicine; (b)(6) Respiratory Therapy Technical Director; (b)(6) Respiratory Therapist; (b)(6) Respiratory Therapist; (b)(6) Respiratory Therapist; (b)(6) Respiratory Therapist; (b)(6), Respiratory Therapist; (b)(6) Respiratory Therapist; (b)(6) Respiratory Therapist; (b)(6) Respiratory Therapist (accompanied by (b)(6) Union Representative); (b)(6), Respiratory Therapist, Home CPAP Department; (b)(6) Respiratory Therapist, via telephone; (b)(6), Director, Biomed; (b)(6), Biomed; (b)(6) Biomed technician; and (b)(6) Property Management.

The OMI ***did substantiate*** allegations when the facts and findings supported that the alleged events or actions took place. The OMI ***did not substantiate*** allegations when the facts showed that the allegations were unfounded. The OMI ***could not substantiate*** allegations when there was no conclusive evidence to either sustain or refute the allegations.

V. Summary of Evidence Obtained from the Investigation, Conclusions and Recommendations

Allegation #1

The RT Department did not submit work orders to Biomed for equipment maintenance and safety checks when Veterans returned home-use CPAP machines, and those machines were converted to inpatient use in the Medical Center. Because of this practice, the required Biomed maintenance and safety equipment checks for these machines were not done.

Findings

The RT Department is under the supervision of the Chief of Pulmonary Medicine, (b)(6) M.D. CPAP machines ordered for home use are dispensed to Veterans from a subsection of the RT Department, the CPAP Department. The use and management of CPAP machines on inpatients in the Medical Center falls under the RT Department. The maintenance and safety checks of CPAP machines used in the Medical Center fall under the purview of Biomed according to Medical Center Policy, Management of the Environment of Care (August 2009, revised February 2011). Chapter 5 of the policy, *Medical Equipment Safety, Item 3*, stipulates that, "All medical equipment, regardless of ownership, brought into the facility for clinical use, must be inspected by Biomedical Engineering prior to initial use. This includes purchased, loaned, leased, clinical-trial, and staff-owned medical equipment."

The Medical Center has been accepting CPAP machines returned from home use for subsequent inpatient use since at least 2004, although the Medical Center had no standard operating procedures or written guidance describing the criteria used to accept donated CPAP machines for multiple patient, hospital use. Veterans or families who returned their machines did so to the CPAP Department. Often the machines were returned because the Veteran could not tolerate the tight-fitting mask during sleep or because the Veteran received an upgraded machine. The CPAP Department transferred these machines to a soiled utility room where an RRT from the RT Department removed and discarded any tubing and masks, and cleaned the machine exterior with the approved disinfectant. After the machine was clean, the RRT took it to the RT Department where it was entered into inpatient service. Prior to June 2010, used CPAP machines were placed in hospital use directly through the RT Department without the maintenance and safety checks required by the Medical Center's policy, Management of the Environment of Care Program.

Between 2004 and 2010, the Medical Center converted 22 CPAP machines originally issued to Veterans from home use to inpatient use. Attachment B shows the date each machine was dispensed to each Veteran, the date it was returned to the CPAP Department, the number of days the Veteran had the machine, the Medical Center estimate of the number of hours the machine was used, the reason for return, the date that the RT Department submitted a work order to Biomed for the initial maintenance and safety check, and the date that Biomed conducted that check.

In the spring of 2010, several employees, including the complainant, voiced a concern to the RT Department that the maintenance and safety inspections on used CPAP machines placed into in-patient use were not being performed. On June 25, 2010, the RT Department addressed this issue by submitting work orders to Biomed to perform the required maintenance and safety inspections.

Of the 22 machines converted from home use to inpatient service, 10 had been retired by June 25, 2010. On that date, the RT Department submitted work orders for the remaining 12 machines to be entered in the Biomed maintenance program, which included initial maintenance and safety checks. Biomed accomplished all of the requested work orders: 10 were done on August 16, and 2 on September 20. The time lapse between the dates when Veterans returned these 12 CPAP machines and the dates when the maintenance and safety checks were done ranged from 21 days to more than 5 years.

On March 8, 2011, the Medical Center issued *Respiratory Therapy Policy and Procedure 2.6, Donated CPAPs and BiPAPs,* which directs that donated machines may be accepted if the Veteran was non-compliant, there were fewer than 750 hours of use, the Veteran was a non-smoker, and the machine was in good working order with successful pressure checks. This policy also documents the procedure that the RT Department must follow to ensure these CPAP machines are properly entered into the Biomed system and that the first maintenance and safety checks are completed prior to inpatient use.

Conclusions

The OMI found no evidence that the Medical Center had violated any law, rule, or regulation related to allegation #1, nor did we find evidence of gross mismanagement or substantial and specific danger to public health and safety. The OMI reached the following conclusions regarding allegation #1:

1. The OMI substantiates the allegation that work orders to perform maintenance and safety equipment checks on home-use CPAP machines converted to inpatient use were not submitted by the RT Department to Biomed prior to the use of these machines on the inpatient units. However, we found that in June 2010, the Medical Center had initiated submission of the required work orders on home-use CPAP machines prior to their placement in inpatient areas for multiple patient use.
2. The OMI also substantiates that the Medical Center failed to perform the maintenance and safety checks on these machines prior to inpatient use as required by facility policy. However, we found that in June 2010, the Medical Center began complying with the requirement to perform maintenance and safety checks on the CPAP machines prior to their inpatient use.
3. The OMI found that the Medical Center's procedures in place at the time of the site visit satisfactorily addressed the concerns raised by allegation #1.

Recommendations

The Medical Center should:

1. Conduct an audit of all RT Department CPAP machines to ensure that work orders have been submitted, and that the required maintenance and safety checks have been performed.
2. Monitor compliance with the new Respiratory Therapy Policy and Procedure 2.6, *Donated CPAPs and BiPAPs,* March 8, 2011.
3. Monitor the timeliness of Biomed work order submissions for CPAP machines converted from home use to inpatient use.

Allegation #2

As of January 2011, the Biomed maintenance and safety checks on the home-use CPAP machines had not been performed.

Findings

The OMI found that of the 22 CPAP machines converted from home use to inpatient use, 10 had been retired from service prior to June 25, 2010; the remaining 12 machines had the required maintenance and safety checks prior to January 2011.

Conclusions

The OMI found no evidence that the Medical Center violated any law, rule, or regulation related to allegation #2, nor did we find evidence of gross mismanagement or substantial and specific

danger to public health and safety. The OMI reached the following conclusion regarding allegation #2:

4. The OMI does not substantiate the allegation that, as of January 2011, the Biomed maintenance and safety checks on these machines had not been performed. The CPAP machines converted from home use to inpatient use that were in service on June 25, 2010, had the necessary Biomed maintenance and safety checks by January 2011.

Recommendation

The OMI makes no recommendation regarding allegation #2.

Attachment A
Documents Reviewed

FDA, Office of Device Evaluation, April 1996, *Labeling reusable medical devices for reprocessing in health care facilities: FDA Reviewer Guidance.*

Overton Brooks VAMC, Respiratory Therapy Policy and Procedure 2.6, March 8, 2011, *Donated CPAPs and BiPAPs.*

Overton Brooks VAMC, Management of the Environment of Care Program, August 2009, *Section 6, Medical Equipment Management: Chapter 1, Medical Equipment Management Plan and Chapter 5, Medical Equipment Safety.*

VHA Directive 2009-004, February 9, 2009, *Use and reprocessing of reusable medical equipment (RME) in Veterans Health Administration facilities.*

VHA Directive 2009-031, June 26, 2009, *Improving safety in the use of reusable medical equipment through standardization of organizational structure and reprocessing requirements.*

Attachment B
Home CPAP Machines Reissued for Inpatient Hospital Use

CPAP	Date issued to Veteran for home use	Date returned to Medical Center CPAP Dept	Number of Days the Veteran had the CPAP	Estimated hours of use on the CPAP machine when returned	Reason for Return of CPAP	Date of work order request to Biomed	Date of first Biomed Inspection
1	05/27/03	06/21/05	756	1500	Deceased	06/25/10	08/16/10
2	11/19/03	11/18/05	730	135	Machine upgrade	06/25/10	08/16/10
3	02/12/04	12/08/04	300	unknown	Used little	06/25/10	08/16/10
4	02/23/04	04/19/05	421	4000	Machine upgrade	Machine retired prior to 06/25/10	
5	06/18/04	07/08/2005	385	< 1 hour	Machine upgrade	Machine retired prior to 06/25/10	
6	12/22/04	07/15/08	1301	234	Veteran incarcerated	06/25/10	08/16/10
7	02/14/05	05/16/05	91	10	Veteran did not tolerate	Machine retired prior to 06/25/10	
8	05/23/06	09/16/09	1212	60	Used little	06/25/10	08/16/10
9	08/09/06	08/01/08	723	500	Veteran did not tolerate	Machine retired prior to 06/25/10	
10	09/26/07	12/18/07	83	unknown	Deceased	Machine retired prior to 06/25/10	
11	10/18/07	07/28/09	649	1200	Machine upgrade	Machine retired prior to 06/25/10	
12	12/04/07	10/20/08	321	1500	No reason given	Machine retired prior to 06/25/10	
13	06/27/08	06/08/09	346	<1 hour	No reason given	Machine retired prior to 06/25/10	
14	07/02/08	09/12/09	437	460	Veteran did not tolerate	06/25/10	08/16/10
15	11/06/08	09/18/09	316	10	Veteran did not tolerate	06/25/10	08/16/10
16	01/07/09	01/29/09	22	unknown	No reason given	Machine retired prior to 06/25/10	
17	02/27/09	08/13/09	167	600	Veteran returned	06/25/10	08/16/10
18	04/24/09	08/12/09	110	264	Machine upgrade	Machine retired prior to 06/25/10	
19	07/01/09	09/24/09	85	2	Veteran did not tolerate	06/25/10	08/16/10
20	07/10/09	06/04/10	329	260	Veteran did not tolerate	06/25/10	08/16/10
21	10/22/09	04/28/10	188	2	Veteran did not tolerate	06/25/10	09/20/10
22	02/24/10	05/12/10	77	400	Machine upgrade	06/25/10	09/20/10