THE SECRETARY OF VETERANS AFFAIRS
WASHINGTON

November 15, 2011

The Honorable Carolyn Lerner
Special Counsel
U.S. Office of Special Counsel
1730 M Street, NW, Suite 300
Washington, DC 20036-4505

Re: OSC File No. DI-11-0967

Dear Ms. Lerner:

The Office of Special Counsel requested the Department of Veterans Affairs (VA) provide additional information clarifying whether there was a violation of rule, law, regulation, or a substantial and specific danger to public health and safety based on the allegations made by a former registered respiratory therapist at the Overton Brooks VA Medical Center in Shreveport, Louisiana (hereafter, the Medical Center). The complainant alleged that the Medical Center failed to perform required maintenance and safety checks of continuous positive airway pressure (CPAP) machines transferred from home-use by a single outpatient to hospital use by multiple patients. VA submitted the original report in response to the allegations dated May 12, 2011, to you on June 24, 2011.

During the investigation, the Office of the Medical Inspector (OMI) identified an additional concern regarding the reuse of the CPAP machines. The OMI found that biologic filters were likely not used in the home-use CPAP machines creating a potential risk in converting home-use CPAP machines for inpatient use.

The enclosed supplemental findings respond to your request for additional information, and also provide information regarding the concern about biologic filters that was discovered during the investigation. The Medical Center's corrective actions are also addressed. In addition, VA will continue to monitor home-use CPAP machines converted for hospital use and will apprise your office of any further concerns.

Sincerely,

Eric K. Shinseki

Enclosure

Supplemental Findings to OSC Report DI-11-0967
Overton Brooks Veterans Affairs Medical Center
Shreveport, Louisiana
September 19, 2011

2011-D-616

Background

The Office of the Medical Inspector (OMI) investigated for the Office of Special Counsel (OSC) a complaint by a registered respiratory therapist (RRT), previously employed at the Department of Veterans Affairs (VA) Overton Brooks Medical Center in Shreveport, Louisiana (hereafter, the Medical Center). The complainant alleged that the Medical Center did not perform required maintenance and safety checks of continuous positive airway pressure (CPAP) machines transferred from home use by a single outpatient to hospital use by multiple patients. VA submitted the original report in response to those allegations dated May 12, 2011, to OSC on June 24, 2011. During the investigation of that complaint, the OMI also looked into another aspect of the CPAP conversion practice. The OMI found that biologic filters were likely not used in the home-use CPAP machines creating a potential risk in converting home-use CPAP machines for inpatient use.

The supplemental findings clarify whether there has been any violation of rule, law or regulation or a substantial and specific danger to public health and safety based on the original allegations made by the former RRT. Additionally, these findings provide information regarding the use of biologic filters in the CPAP machines.

Clarification to the Original Report

Violation of Law, Rule or Regulation

The investigation found no violation of any statutory laws and no violation of rules or regulations as set forth in the Code of Federal Regulations. However, we did find that a number of the Veterans Health Administration (VHA) and Medical Center policies were violated. VHA Directive 2009-004 and VHA Directive 2009-031 require facilities to develop and follow standard operating procedures to properly maintain reusable medical equipment. Directive 2009-004 states "[i]t is VHA policy that systematic and local standard processes are developed in compliance with manufacturer's instruction, infection prevention and control principles, and effectively communicated and deployed to staff wherever procedures using Reusable Medical Equipment are performed." The Medical Center had a policy entitled Management of the Environment of Care Program which required that all medical equipment must be inspected prior to use. While the Medical Center had developed a policy it failed to follow that policy in regards to conducting the safety and maintenance checks which the policy required.

Substantial and Specific Danger to Public Health and Safety

We also found that there was not a substantial and specific danger to public health and safety due to the Medical Center's failure to conduct the safety and maintenance checks. The biomedical safety and maintenance checks on medical equipment serve two functions: 1) to assure that the equipment is operating correctly and safely and 2) to enroll the equipment into the facility's ongoing medical maintenance program so that future medical maintenance is scheduled appropriately for that piece of equipment.

The CPAP machines which were converted to inpatient use were originally dispensed to Veterans for home-use. Because the machines were designed to be used by patients at home, the user manual describes required maintenance. The manual recommends periodic inspection of the electric cord for insulation breaks and periodic cleaning of the intake air filter. The air filter keeps large particulate matter from entering the machine, but does not filter biologic material.

The returned CPAP machines were suppose to be given an initial safety and maintenance check, which would have included turning the machine on to assure it activates properly, performing the tasks described in the user manual, and entering the machine into the Medical Center medical equipment database. Because the maintenance tasks are directed at the user level, all these tasks except entering the machine into the Medical Center biomedical maintenance data base are routinely performed by the respiratory therapy technician when and if the machine is used in the inpatient setting. So, even though the initial biomedical safety and maintenance checks were not performed by the Biomedical Department at the time the machines were transferred into inpatient use, the required medical safety and maintenance check was still being completed by the Medical Center respiratory therapy technicians while in inpatient use. Therefore, there was no substantial and specific danger to public health and safety based on the failure to enter the machines into the biomedical maintenance data base.

Additional Findings

During the investigation, the OMI identified an additional concern with the reuse of the CPAP machines. OMI found that biologic filters were likely not used in the home-use CPAP machines creating a potential risk in converting home-use CPAP machines for inpatient use. This concern, the OMI's conclusions and recommendations, as well as the facility's actions in response to the recommendations follow.

As reported in the OMI Report, OSC File Number DI-11-0967, May 12, 2011, the Medical Center has been accepting previously dispensed CPAP machines from Veterans since at least 2004. The CPAP Department accepted the returned machines and transferred them to a soiled utility room where an RRT discarded tubing and masks, and cleaned the machine's exterior with the approved disinfectant according to the manufacturer's instructions. After cleaning the machine, the RRT took it to the Respiratory Therapy Department, where it was entered into inpatient service.

The Medical Center initially reported to the OMI that 22 CPAP machines, originally issued to Veterans for single-patient home-use had been converted to multi-patient use within the Medical

Center between 2004 and 2010. After the OMI completed its initial report, the Medical Center added one additional CPAP machine to the number that had been converted to multi-patient use. The Medical Center also reported one more machine that was returned from home-use but was not converted to multi-patient use and therefore will not be included in these numbers. Attachment B shows the date the 23 machines were dispensed to each Veteran, the date the machine was returned to the CPAP Department, the number of days the Veteran had the machine, the Medical Center's estimate of the number of hours the machine was used, the reason for return, and identification of those machines returned by Veterans whose medical records had reference to an infectious disease around the time their CPAP use.

In following the manufacturer's recommendations the Medical Center routinely uses biologic filters on all inpatient-used CPAP machines, changing the filter between patients. However, Medical Center employees confirmed in interviews with the OMI that biologic filters are not distributed to home CPAP users since biologic filters are not required for single patient use. In all likelihood, the home-use CPAP machines converted to hospital use had been used without a biologic filter during the time they were in each Veteran's home.

The Medical Center reported that the CPAP machines were all Phillips Respironics models. The Respironics online information, *In-line Outlet Bacteria Filter,* states that bacterial filters are indicated when a machine is used by more than one person. In addition, the *Warning* section of the Respironics *User Manual* states,

> If the device is used by multiple persons (such as rental devices), a low-resistance main flow bacteria filter should be installed in-line between the device and the circuit tubing to prevent contamination.[1]

There was no manufacturer guidance regarding the use of biologic filters for machines that were originally single patient use and later converted to multiple patient use.

The OMI reviewed the medical records of 23 Veterans whose home-use CPAP machines had been subsequently placed into hospital use for multiple patients. At least four Veterans had a clinical history associated with a potentially contagious disease, such as hepatitis A, B, or C, herpes zoster, or methicillin resistant *Staphylococcus aureus*. On average, each Veteran used the CPAP machine for over a year without a biologic filter, for an estimated 586 hours of use as calculated by the Medical Center.

Conclusions

1. The Medical Center placed 23 CPAP machines, originally dispensed for single patient home use, into multi-patient service. In these 23 cases, it is likely that a biologic filter was not used by the Veteran in the home-use setting.
2. Multi-patient use of CPAP machines without changing the biologic filter between patients is not recommended, carries a warning issued by the manufacturer, and is not in compliance with the manufacture's user manual.

[1] The Philips Respironics *User Manual* defines a *Warning* as "indicating the possibility of injury to the user or the operator."

3. Converting home-use CPAP machines from use by a single patient, where the biologic filter is not required, to use by multiple patients, where filter use is required, carries a potential risk to subsequent users from biologic contamination. The extent of the potential risk has not been determined at this time.
4. In the absence of a risk assessment, the practice of deploying single-patient, home-use CPAP machines for multi-patient, in hospital use presents a potential but unknown risk.
5. Regarding these supplemental findings, the OMI finds no violation of law, rule or regulation, nor evidence of a specific or substantial threat to public health and safety.

Recommendations

The Medical Center should:

1. Remove the 23 CPAP machines, initially dispensed for single-patient use and converted to hospital use, until a risk assessment is completed,
2. Assess the risk to each Veteran who used a home-use CPAP machine as an inpatient, in consultation with the appropriate VHA program offices,
3. Consider abandoning the program which places single-patient, home-use CPAP machines into use by any other Veteran, or if the Medical Center decides to continue with this program, develop, implement, and monitor a policy for deploying single patient, home-use CPAP machines into hospital service that complies with the manufacturer's recommendations for multi-patient use.

VHA should:

1. Determine the extent of conversion of home-use CPAP machines to multipatient, hospital use across VHA.
2. Take appropriate action based on the comprehensive risk assessment.

Actions Taken by the Medical Center on Response to OMI's Recommendations

The Medical Center leadership consulted with the Veterans Integrated Service Network 16 Chief Medical Officer, the Acting Chief Medical Officer over Supply, Processing, and Distribution (SPD) in VA Central Office, the VA National Infectious Disease Program Director, and the VA SPD Field Advisory Group. This group determined that there was minimal risk to hospitalized patients who used the machines originally dispensed for single patient use. This minimal risk determination was based on the very low likelihood that a home CPAP machine could be contaminated by the initial user even though the biological filter was likely not used. The CPAP machine works by delivering air to the user through tubing several feet in length and a tight fitting mask. Exhaled, potentially contaminated air is expelled to the environment through valves in the mask and does not travel back through the long delivery tubing before leaving the CPAP system. So, even without the biological filter in place, the risk of contaminating the CPAP machine was felt to be very low, and therefore, the risk to subsequent users was also felt to be very low. Based on this low risk, the group assessing the risk did not recommend that patients who used these CPAP machines needed further medical evaluation. The Medical Center reported that all CPAP machines that had been initially dispensed for Home-use and were

subsequently used on inpatients have been withdrawn from the inpatient setting and they have abandoned this program.

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, Respiratory Therapy Policy and Procedure 5.1, approved August 18, 2004, revised February 1, 2010, *Respiratory Therapy Infection Control.*

Overton Brooks VAMC, Management of the Environment of Care Program, February 7, 2011, *Medical Equipment Management, Chapter 1, Medical Equipment Management Plan and Chapter 5, Medical Equipment Safety.*

REMStar Auto-A Flex User Manual, Philips Respironics. Retrieved on May 17, 2011from http://respironicsremstars.respironics.com/PDF/REMstarAutoUserManual.pdf.

VA Medical Center, Shreveport, Louisiana, Policy and Operations Manual No. 118-20, July 29, 2010, *Reprocessing of Reusable Medical Equipment by High Level Disinfection.*

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	Humidification provided with CPAP machine	Possible infectious disease from medical record
1	05/27/03	06/21/05	756	1500	no	Yes
2	11/19/03	11/18/05	730	135	no	
3	02/12/04	12/08/04	300	unknown	no	
4	02/23/04	04/19/05	421	4000	no	Yes
5	06/18/04	07/08/2005	385	< 1 hour	no	
6	12/22/04	07/15/08	1301	234	no	
7	02/14/05	05/16/05	91	10	no	
8	05/23/06	09/16/09	1212	60	no	
9	08/09/06	08/01/08	723	500	yes	Yes
10	09/26/07	12/18/07	83	unknown	no	
11	10/18/07	07/28/09	649	1200	no	
12	12/04/07	10/20/08	321	1500	unknown	
13	06/27/08	06/08/09	346	<1 hour	no	
14	07/02/08	09/12/09	437	460	no	
15	11/06/08	09/18/09	316	10	yes	
16	01/07/09	01/29/09	22	unknown	unknown	Yes
17	02/27/09	08/13/09	167	600	yes	
18	04/24/09	08/12/09	110	264	yes	
19	07/01/09	09/24/09	85	2	yes	
20	07/10/09	06/04/10	329	260	no	
21	10/22/09	04/28/10	188	2	yes	
22	02/24/10	05/12/10	77	400	yes	
23	11/12/09	6/18/10	219	400	unknown	