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**Analysis of Disclosures, Agency Investigation and Report, Whistleblower Comments, and
Comments of the Special Counsel**

OSC File No. DI-05-1801

Summary

Gary DiLorenzo, Respiratory Technician, disclosed to the Office of Special Counsel (OSC) that medical personnel at the Department of Veterans Affairs (VA), Miami VA Medical Center (VAMC), Miami, Florida, are endangering the health of respiratory patients by administering the medications albuterol sulfate and ipratropium bromide in diluted doses and at incorrect intervals of time in order to cut costs. He also alleged that management at the VAMC instructs medical personnel to falsify medical records in order to conceal this wrongdoing. According to the agency report, the VA Office of the Medical Inspector (OMI) investigated Mr. DiLorenzo's allegations and found them to be unsubstantiated. However, the investigation did uncover other problems in the VAMC's Respiratory Care Unit, including a shortage of staff and poor documentation of medical treatments.

The Whistleblower's Disclosures

Mr. DiLorenzo, who consented to the release of his name, has worked as a respiratory technician for six years. He worked at the Miami VAMC from March 2, 2005, until May 14, 2005, when he was terminated.

Mr. DiLorenzo alleged that management at the Miami VAMC instructs medical personnel to administer incorrect dosages of the medications albuterol sulfate¹ and ipratropium bromide² to patients with respiratory problems. Mr. DiLorenzo advised that albuterol sulfate comes in packages containing 2.5 milligrams (mg) of albuterol in 3.0 cubic centimeters (cc) of saline solution, and ipratropium bromide comes in packages containing 0.5 mg of ipratropium bromide in 3.0 cc of saline solution. According to Mr. DiLorenzo, management instructs the medical staff to mix the albuterol sulfate and ipratropium bromide packages together in order to administer them at the same time. However, Mr. DiLorenzo asserted that this procedure has the undesired effect of reducing the efficacy of each drug by approximately one-half, as it doubles the amount of saline solution. Thus, instead of receiving 2.5 mg of albuterol sulfate in 3.0 cc of

¹ Albuterol sulfate is a beta-agonist medication that is used to prevent and treat wheezing, shortness of breath, and troubled breathing caused by asthma, chronic bronchitis, emphysema, and other lung diseases. It works by relaxing and opening air passages in the lungs.

² Ipratropium bromide is a bronchodilator that is used to prevent wheezing, shortness of breath, and troubled breathing caused by asthma, chronic bronchitis, emphysema, and other lung diseases. It relaxes and opens the air passages to the lungs, making it easier to breathe.

saline solution, the patient now receives 2.5 mg of albuterol sulfate in 6.0 cc of saline solution, and a similar dilution occurs in the concentration of ipratropium bromide. Mr. DiLorenzo alleged that the problem is compounded by the fact that management instructs medical personnel to administer these drugs at incorrect intervals of time. He related that, at management's direction, medical personnel administer albuterol sulfate and ipratropium bromide to patients once every 12 hours, instead of the correct frequency of once every 4 to 6 hours.

According to Mr. DiLorenzo, the combined result of these two practices is that respiratory patients receive these drugs at one-fourth of the correct potency. He advised that albuterol sulfate and ipratropium bromide given at such reduced dosages provide minimal, if any, respiratory relief. He related that several patients to whom he administered reduced amounts of albuterol sulfate and ipratropium complained to him that they were unable to breathe and felt as though they were suffocating. Mr. DiLorenzo also maintained that, by administering these medications in diluted doses at extended intervals, the VAMC places respiratory patients at increased risk of death. He explained that, when a patient's breathing is impaired, the level of oxygen in their blood decreases, which, in turn, causes their heart rate to increase. Mr. DiLorenzo explained that an elevated heart rate can cause a patient to go into cardiac arrest.

Mr. DiLorenzo stated that he reported his concerns to his supervisors, James Vance and Dixie Marchant, however, they informed him that the VAMC was not able to administer these drugs at the proper doses and intervals due to the high cost of the drugs and inadequate staffing levels. Lastly, Mr. DiLorenzo alleged that management instructs medical personnel to falsely claim on a patient's medical chart that they gave the patient the correct dosage of medication at the correct intervals.

Department of Veterans Affairs Investigation and Report

The VA Office of the Medical Inspector (OMI) investigated Mr. DiLorenzo's allegations. According to the agency report, a team of investigators conducted a site visit on October 3-5, 2005. The investigative team consisted of OMI's Chief of the Clinical Investigation Division (a registered nurse), Chief of Pulmonary Critical Care and Occupational Medicine (a physician), and a Chief Respiratory Therapist. The investigative team toured two medical wards and the intensive care unit, observed the administration of two nebulizer treatments and one metered dose inhaler, observed the documentation of respiratory treatments, assessed the VAMC's respiratory equipment, and spoke with three respiratory patients.

The agency report states that the investigators interviewed the VAMC Director, Chief of Staff, Chief Nurse, Chief of Quality Management, Risk Manager, Patient Advocate, Chief of Human Resources, Compliance Officer, Chief of Respiratory Therapy, Chief Medical Resident, Chief of Pulmonary Care, Administrative Officer of the Medicine Service, and a Respiratory Therapy Evaluator. They also conducted four group interviews: the first, with three night-shift respiratory therapists; the second, with two day-shift respiratory therapists and two evening shift respiratory therapists; the third, with pharmacy personnel including the Chief of the Pharmacy Service; and the fourth, with five staff nurses. Lastly, the investigators reviewed 42 electronic records and the VAMC policy regarding the administration of respiratory treatments.

According to the agency report, Mr. DiLorenzo had previously expressed similar concerns to the Hotline Division of the VA Office of the Inspector General, on May 4, 2005. In response, the Office of Healthcare Inspections (OHI) conducted an investigation. The OHI found that the respiratory therapists were administering nebulizer treatments properly. However, the OHI also identified several areas of respiratory care that needed improvement. To correct these deficiencies, they recommended that the VAMC: 1) document respiratory treatments with greater consistency, 2) increase staffing levels in the Respiratory Care Unit, 3) improve recruitment and retention strategies for respiratory therapists, and 4) clarify the policy on the administration of medications via aerosol delivery devices.

The subsequent OMI investigation similarly failed to substantiate Mr. DiLorenzo's allegation that the VAMC staff administer nebulizer treatments improperly. The pharmacy staff explained that it is appropriate to mix albuterol sulfate and ipratropium bromide in a nebulizer in order to administer them simultaneously. In addition, the report states that this practice is consistent with the drug manufacturer's recommendations and the Veteran Health Administration's "Clinical Practice Guideline for the Management of Persons with Chronic Obstructive Pulmonary Disease or Asthma" (November 17, 1997). The agency report states that the dilution of these medications is irrelevant, as they are administered until the vial is empty and the pharmacologic effects of these drugs are dependent upon the amount of medication, and not their dilution. In fact, the report maintains that the drugs may actually be delivered more completely when the same amount of medication is diluted in a larger volume of solution, because the residual amount of the drug remaining in the nebulizer is then smaller.

To rebut Mr. DiLorenzo's claim that the VAMC diluted the medications to save money, the pharmacists responded that the medications are very inexpensive, and described their cost as mere "pennies." All of the respiratory therapists denied that they had ever been instructed to delay a patient's respiratory treatment to save money or for any other reason. They protested that they would never purposefully engage in this behavior as it would jeopardize their professional licenses and careers. In addition, the Chief of the Respiratory Care Unit denied ever instructing staff to falsify medical records, and the respiratory therapists corroborated the Chief's testimony. The investigation did not uncover evidence that this had ever occurred.

Although the investigators did not substantiate Mr. DiLorenzo's allegations that nebulizer treatments are being administered improperly, they did find that patients did not always receive all of their treatments as prescribed. The respiratory therapists admitted that they are not always able to administer all treatments, and when this occurs, they pass the missed treatment along to the next shift. They explained that "they do the best they can, given the staffing shortage of RTs and high volume of treatments ordered." Upon reviewing 42 patient records from the time period March 6, 2005 to May 13, 2005, the investigators found that many respiratory treatments were not given in a timely fashion, few patients received all of the treatments ordered, and the documentation was inconsistent regarding the reasons for missed treatments. The agency report attributes these lapses to several factors: 1) patients are often out of their rooms for tests or other reasons, 2) the attention of the respiratory therapist is sometimes diverted by an emergency situation, and 3) the staffing shortage in the Respiratory Care Unit.

The Chief of Pulmonary Medicine and the Chief Medical Resident concurred that the Respiratory Care Unit is understaffed. The report explains that the VAMC has difficulty recruiting and retaining respiratory therapists. At the time of the investigation, the Respiratory Care Unit had recently downsized by 3.6 full-time equivalent employees and had two vacancies.

The OMI investigators agreed with the recommendations of the earlier OHI investigation, that the VAMC should 1) ensure that respiratory therapists improve documentation of treatments, 2) fully staff the Respiratory Care Unit, and 3) improve recruitment and retention strategies for respiratory therapists. In response to the findings of the OHI and OMI investigations, the report states that the VAMC is currently preparing an action plan to implement the recommendations.

The Whistleblower's Comments

Mr. DiLorenzo commented on the agency report. He asserts that the agency investigated the wrong allegations. Mr. DiLorenzo states that he never complained about the respiratory therapists mixing albuterol sulfate and ipratropium bromide together in a nebulizer. Rather, his allegations actually concern the fact that the drugs are being administered in an improper dilution. He explains that albuterol sulfate comes in two different dosages: 2.5 mg in 0.5cc of saline solution and 2.5 mg in 3cc of saline solution. He maintains that the VAMC used the incorrect dosage for mixing this drug with ipratropium bromide – 2.5 mg in 3cc, rather than 2.5 mg in 0.5cc.

In fact, the agency did investigate the correct allegations, as they were presented in OSC's referral letter to the Secretary. In his original disclosure to this office, Mr. DiLorenzo did not mention the issue of the two dosage amounts of albuterol sulfate. Furthermore, the agency report explains that, in terms of the pharmacologic effects of the medications, the dilution of these medications does not matter, only the ultimate quantity of medication administered.

Conclusion

Based on the representations made in the agency report and Mr. DiLorenzo's comments, I have determined that the agency report contains all of the information required by statute and findings appear to be reasonable.