DEPARTMENT OF VETERANS AFFAIRS
Office of the General Counsel
Washington DC 20420

AUG 10 2010

In Reply Refer To:

William E. Reukauf
Acting Special Counsel
U.S. Office of Special Counsel
1730 M Street NW
Suite 300
Washington, D.C. 20036-4505
Attn: Catherine A. McMullen, Chief, Disclosure Unit

RE: OSC File No. DI-09-3272

Dear Mr. Reukauf:

This is in response to the August 3, 2010, e-mail request from Ms. Siobhan Smith of your staff for additional information to supplement the report on allegations of improper cleaning and sterilization of reusable medical instruments and failure of management officials to initiate actions to address the practice at the G. V. Sonny Montgomery Veterans Affairs Medical Center, Jackson, Mississippi (OSC File No. DI-09-3272). Specifically, we were asked to provide more information on how the Pre-Clinical Risk Assessment Advisory Board (Pre-CRAAB) assessment was conducted on February 5, 2010. On July 12, 2010, we provided you with copies of the minutes from the Pre-CRAAB meeting, and VHA Directive 2008-002 (January 18, 2008), Disclosure of Adverse Events to Patients.

The minutes identify the participating members. Two staff members from Veterans Integrated Service Network (VISN) 16 and eleven facility staff members were present by telephone during the Pre-CRAAB meeting. The facility Director presented information. Other members from the facility also answered questions and participated in the discussions. Some members did not say anything. The Acting Principal Deputy Under Secretary for Health (Acting PDUSH) made the decision that a Clinical Risk Assessment Advisory Board (CRAAB) did not need to be convened regarding the events at the Jackson VAMC, and that the Jackson VAMC did not need to conduct a large scale disclosure regarding this event.

The Veterans Health Administration (VHA) does not have a formal Standard Operating Procedures (SOP) for conducting a Pre-CRAAB assessment. However, VHA does have informal guidance which is sent to the VISN and facility to explain the Pre-CRAAB process. A copy of this guidance is attached.

Please let us know if we can be of further assistance.

Sincerely yours,

Walter A. Hall
Assistant General Counsel

Enclosure

The PreCRAAB*

The convening of the PreCRAAB is in response to an incident brief (IB) received from the field that may prompt a large scale disclosure to patients. The purpose of the PreCRAAB is to assess the need for a large scale disclosure to patient. In order to accomplish this, the PreCRAAB will:

1. determine the facts of the incident (specifically, what was done and what actions or steps that, in retrospect, should have been done but were not done).
2. determine the risk to the Veterans.

The PDUSH will then make a decision about disclosure or non-disclosure to veterans. If the facts are not sufficiently clear or complete or the risk to patients needs further deliberation, the PDUSH will forward the issue to the Clinical Risk Assessment Advisory Board (CRAAB) for deliberation and a recommendation about disclosure to veterans.

The PreCRAAB is usually attended by VISN and facility staff along with representatives from Operations (10N), the Medical Surgical Services Office, the Infectious Disease (ID) program office, the National Center for Patient Safety (NCPS), the Office of Public Health and Environmental Hazards (OPHEH), the Office of Quality and Safety (OQS) and Risk Management. Additional subject matter experts may be present as required by the PDUSH. The goal is to have a collaborative discussion and to up date what is known about the incident as the facts may have changed from what was known at the time of the initial IB.

The sequence of events is usually:

1. The IB is distributed to all attendees prior to the meeting. It is expected that each attendee will be familiar with the content of the IB.
2. At the meeting, a facility member (usually the COS or a clinic director) presents a brief high level overview of what was done and discusses any necessary actions or steps that, in retrospect, should have been done. There are usually clarifying questions asked of the facility members at this point.
3. A representative from NCPS (who has conducted fact finding or discussed the issue with members at the facility) will add any additional information about the incident under discussion. At this point everyone should be in agreement with what happened and what should have happened.
4. If there is an infectious disease issue (there usually is), then the National Director for Infectious Diseases or designee will give an opinion about the risk to Veterans.
5. A general discussion (as necessary)
6. A decision by the PDUSH: disclosure, no disclosure, refer to CRAAB

The Director of Risk Management will prepare minutes of each PreCRAAB and 10N will prepare written notification to the VISN and VAMC about the PDUSH decision.

At no time should the PreCRAAB process delay appropriate clinical or institutional disclosure as outlined in VHA Directive 2008-002, "Disclosure of Adverse Events to Patients".

*CRAAB = Clinical Risk Assessment Advisory Board