

Thomas O. Forslund, Director

Governor Matthew H. Mead

May 7, 2012

Ref: WB-2012-254

Sidney M. Wolfe, M.D., Director
Michael A. Carome, M.D., Deputy Director
Public Citizen's Health Research Group
1600 20 Street, NW
Washington, D.C. 20009

Dear Drs. Wolfe and Carome:

Thank you for the concern for the health of the residents of Wyoming expressed by Public Citizen's Health Research Group in your letter dated March 13, 2012. The Wyoming Department of Health (WDH) has worked closely with leadership at Sheridan Memorial Hospital (SMH), the Centers for Medicare and Medicaid Services, and the Centers for Disease Control and Prevention (CDC) to resolve the situation related to SMH's processes regarding reusable laryngeal mask airways (LMAs).

As you may know, the level of risk associated with potential infection due to an inadequately sterilized LMA is difficult to quantify. A PubMed search revealed no published case reports of infection via this exposure, although there have been studies documenting residual protein deposits on LMAs post-processing which indicate the theoretical possibility of transmission of infection. After discussing the specifics of the sterilization protocol described by the inspector in the site visit and inspection report, experts at CDC equated the level of risk to that associated with endoscopic reprocessing, of which there have been published reports of post-exposure infection.

Therefore, although the risk was uncertain, out of an abundance of caution and in consultation with CDC, as State Health Officer I recommended that SMH notify all potentially exposed patients who underwent surgery at SMH during the time the substandard LMA sterilization protocol was in effect of their potential risk of exposure and offer those individuals testing for bloodborne pathogens (Hepatitis B, Hepatitis C, HIV) according to the CDC-recommended protocol. WDH also offered to assist SMH with epidemiologic support regarding this incident or for future potential infection control or public health concerns, just as we would with any of our healthcare institutions or other partners in Wyoming.

SMH agreed with the above recommendations and notified all potentially exposed patients and offered testing per the CDC protocol. That process and subsequent follow up are being managed by the hospital. SMH CEO Mike McCafferty also informed me that they were performing an internal review and had established an institutional policy of single-use LMAs. The WDH Office of Healthcare Licensing and Surveys verified during a recent on-site survey that reusable LMAs were no longer being utilized and the facility was using disposables.

Dear Drs. Wolfe and Carome
Page 2

May 7, 2012
Ref. WB-2012-254

This incident afforded us the opportunity to strengthen the partnership between the Wyoming Department of Health and Sheridan Memorial Hospital in achieving our common goal of protecting and improving the health of Wyoming residents.

Thanks again for your vigilance in protecting the health of America.

Sincerely,

A handwritten signature in blue ink that reads "Wendy E. Braund" followed by a series of initials and abbreviations: "MD MPH MEd FACPM".

Wendy E. Braund, MD, MPH, MEd, FACPM
State Health Officer and Senior Administrator
Public Health Division

WB/mp

c: Thomas O. Forslund, Director, Wyoming Department of Health