

**State Board of Medical Examiners
Open Session Minutes
May 9, 2007**

A meeting of the New Jersey State Board of Medical Examiners was held on Wednesday, May 9, 2007 at the Richard J. Hughes Justice Complex, 25 Market Street, 4th Floor Conference Center, Trenton, New Jersey. The meeting was called to order by Dr. Paul, President.

PRESENT

Board Members Criss, Criscito, Cheema, Ciechanowski, DeGregorio, Jordan, Lambert, Lomazow Mendelowitz, Nussbaum, Paul, Reichman, Salas-Lopez, Scott. Stanley, Strand, and Walsh.

EXCUSED

Board Members Clemency-Kohler, Haddad, Weiss and Wheeler.

ALSO PRESENT

Assistant Attorney General Joyce, Senior Deputy Attorney General Dick, Deputy Attorneys General Ehrenkrantz, Gelber, Hafner, Jespersen, Levine, Puteska, and Warhaftig; Executive Director Roeder, and Medical Education Director Blanks.

**STATEMENT CONCERNING THE
ANNUAL NOTICE OF PUBLIC MEETINGS**

The requirements of the "Open Public Meetings Act" have been satisfied by notice of this meeting given in the annual notice adopted by the New Jersey State Board of Medical Examiners on October 11, 2006 which was transmitted to the ATLANTIC CITY PRESS, STAR LEDGER, CAMDEN COURIER POST, ASBURY PARK PRESS, BERGEN RECORD and the TRENTON TIMES, all on the 1st day of November 2006.

ANNOUNCEMENTS

Dr. Paul announced that the following have accepted her request to serve as the nominating committee: Mr. Weiss (Chairperson), Dr. Reichman and Mr. Walsh. Dr. Paul further explained that Board members should reach out to this committee with suggestions for officers. The nominating committee would propose a slate of officers at the June meeting. Elections would then take place at the July meeting, at which time nominations would also be open from the floor.

PRESENTATION: Anthony T. Monaco, Environmental Scientist 1 Consumer and Environmental Health Services New Jersey Department of Health and Senior Services made a presentation to the Board concerning the use of medical devices. He offered some background explaining that the single use of devices is an issue that has been around for a number of years. In particular as it relates to hemodialysis or dialyzer reuse. The practice is regarded as safe if performed according to recognized protocols and there have not been any reported outbreaks in New Jersey.

Single use medical devices started in the 1980s and the users did not really see any additional benefit in changing the label to require a single use. The reprocessing started and around 1990 licensure standards were established. In general terms, single use items shall be reused or reprocessed only if the manufacturer recommends reuse or reprocessing or if the hospital has scientific validation of the safety of the reuse or reprocessing of the item. The procedures used for preprocessing and reuse shall conform with the same recommendations and validation data. In order to reprocess, one needs to understand the characteristics of the device, e.g., what is it made of and the compatibility of the device with the sterilizing agents. Also, one needs to take into consideration the functionality of the device so that ultimately it will function as it was manufactured to do so. While this standard was the

beginning of appropriate reuse/reprocessing protocols, newer and more complete standards were promulgated in 2002. Under N.J.A.C. 17:43G-8.4(b), all reusable patient care items shall be reprocessed according to the manufacturer's written recommendation. This was applicable to the acute care facilities, while in the ambulatory care facilities, one could only reuse or reprocess if the manufacturer provided written instructions concerning the cleaning and sterilization were in place. Also, there was a change in the understanding from a reuse to a reconditioning notion. Additionally, the third party reprocessed devices could be reused if the third party's standard comport with FDA, is registered with it as a third party reprocessor and that every device had already been submitted to FDA with the validation studies that approved the reprocessing. There also must be a quality control program that assures that the protocols were followed in the process of reconditioning of the device. There are also protocols that must be put in place that address how the devices are collected and stored prior to shipment to the third party. This, in turn, also requires certain precautions relating to the inventory of new stock. Generally, one cannot distinguish between a new and reconditioned device and in some ways, it is not necessary because if the device has been properly reconditioned, it should be the same as if it were new.

MINUTES THE BOARD, UPON MOTION MADE AND SECONDED, VOTED TO APPROVE THE APRIL 11, 2007 OPEN BOARD MINUTES.

MINUTES THE BOARD, UPON MOTION MADE AND SECONDED, VOTED TO APPROVE THE APRIL 16, 2007 OPEN CREDENTIALS COMMITTEE MINUTES.

MINUTES THE BOARD, UPON MOTION MADE AND SECONDED, VOTED TO APPROVE THE MARCH 26, 2007 OPEN ATHLETIC TRAINERS ADVISORY COMMITTEE MINUTES.

NEW BUSINESS

1. PROPOSED AMENDMENT - N.J.A.C. 13:35-2B.4

Attached for the Board's consideration was a draft proposed amendment the Physician Assistant scope of practice regulation.

THE BOARD, UPON MOTION MADE AND SECONDED, VOTED TO PUBLISH THE PROPOSAL IN THE NEW JERSEY REGISTER FOR NOTICE AND COMMENT.

2. LEGISLATION

S 2489 Seeks to provide for religious accommodation regarding admission procedures at licensed health care facilities.

THE BOARD, UPON MOTION MADE AND SECONDED, VOTED TO TAKE NO POSITION ON THIS PROPOSAL AS IT BELIEVED THAT THIS WAS ALREADY OCCURRING AT MOST, IF NOT ALL, FACILITIES WITHIN THE STATE AND THEREFORE, THIS BILL WOULD NOT BE NECESSARY.

OLD BUSINESS

INFORMATIONAL

PUBLIC COMMENT

Respectfully submitted,

Sindy M. Paul, M.D., M.P.H., President

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