

Minutes to the Meeting of the North Carolina Board of Pharmacy
Durable Medical Equipment Committee
January 24, 2006

Chairman Wayne Link called the meeting to order at 10:00am in the Chapel Hill office. Present for the Committee were members Larry Lankford, Marcia Ladd, and Parker Chesson. Present for the staff were Anna Choi, Steve Hudson, Amy Cook, Melissa Cummings, Krystal Brashears and Jason Smith. Chairman Link confirmed that members of the Committee had no conflicts of interest with any matters coming before them on this date.

Executive Director David Work thanked Mr. Lankford for his ten years of service on the committee and recognized his effort with a plaque. Mr. Work then welcomed Mel Elliot to the seat being vacated by Mr. Lankford.

Mr. Hudson introduced field staff members Amy Cook, Melissa Cummings and Krystal Brashears to the Committee. Mrs. Cook and Ms. Cummings have been assigned to attend to DME matters in replacement of Mr. Smith, who has been reassigned to investigate retail pharmacy matters. Mrs. Cook and Ms. Cummings will work one-half of their time on DME matters.

Minutes of the June 14, 2005 meeting were distributed, considered, and approved by the Committee.

OLD BUSINESS

The Committee voted in a prior meeting, to not require that a backup supply of oxygen be provided when the oxygen would be used solely for in-line C & BiPAP nocturnal treatment. Mr. Link reported that on further consideration, he is now of the opinion that there is not a need to change the requirement. He explained that physicians may wish to have the backup oxygen available to patients during power outages, and it would be too confusing to permit holders to exempt only a part of the oxygen backup requirement.

Mrs. Choi updated the Committee on her conversations with the attorney for the Respiratory Care Board. Mr. Bill Shenton stated that some of the Respiratory Care Board members are concerned about CPAP & BiPAP machines being dispensed by non-Respiratory Care Board licensed individuals and that this matter would be discussed in an upcoming practice committee meeting.

Regarding the meeting between herself, Mr. Lankford and Mr. Work on June 20, 2005, Ms. Ladd reported that Mr. Work indicated that, if passed, proposed legislation would increase the original DME permit fees to \$500, and reduce annual renewals to \$200. Mr. Work also committed to having two full-time employees assigned to work exclusively on DME matters if the legislation passed. It was also noted that the legislation referred to by Mr. Work passed.

NEW BUSINESS

The Committee reviewed a letter from Zee Medical, Inc., in which the company requested clarification on the need for the company to obtain a permit from the Board. The device manufactured by Zee Medical is an automated external defibrillator (AED) for use by lay people in such locations as the workplace. Ms. Cummings gave the Committee an overview of how the

AED works, emphasizing that the equipment has safeguards against injury to patients. It was the consensus of the Committee to allow Zee Medical, Inc., to operate without obtaining a Board permit.

Mr. Elliott introduced the concept of the Committee mandating compliance with the Standards and Ethics required by credentialing agencies. Specific Standards from the Rehabilitation Engineering & Assistive Technology Society of North America and the Ethics statement of the National Registry of Rehabilitation Technology Suppliers were provided for the Committee's review. Mr. Elliot pointed out that many DME businesses do not comply with the Standards/Ethics, which creates an unfair trade environment for other businesses.

Mrs. Choi explained that there must be statutory support for a principle before it can be codified as a regulation and subsequently enforced by the Board. Currently, there is no statutory authority for the Board to require a permit holder to follow the Standards/Ethics of a credentialing agency.

The Committee asked Mrs. Choi to research the matter further and provide the findings at a future meeting.

DISCIPLINARY CONFERENCES

Jay Enterprises, Permit No.346 & First Choice Medical

Mrs. Choi reported that staff attempted to serve Notices of a prehearing conference on two businesses. The first, Jay Enterprises, 4410-A Friendship Drive, Matthews, NC, accepted service of the Notice; however, First Choice Medical, 501 East Franklin Street, Monroe, NC, did not accept the Notice. Mrs. Choi informed the Committee that she attempted to call the number listed with the Board for First Choice Medical, but her call was received by an answering machine which identified the number as "Jay Enterprises". Also, on January 20, 2006, Mrs. Choi attempted a second call to the number but found that the answering machine message indicated she had reached the voice mail for David Warren. Mr. Warren is the permit holder of First Choice Medical. Mrs. Choi advised the Committee that if they found cause for disciplinary action in the case, since First Choice Medical had not received notice of the hearing, only Jay Enterprises permit no. 346 could be sanctioned.

Board Investigator Jason Smith was called to testify about his knowledge in the matter at hand. Mr. Smith reported that on February 10, 2005, he attempted to conduct an inspection of a business located at, 501 East Franklin Street, Monroe, NC. Signage at the location identified the business as "Jay Enterprises". Mr. Smith found that the Board did not have a permit issued to the business at the location; however, he found devices and medical equipment offered for sale at the location. He also found evidence that the store had been selling DME from the unregistered location since at least November 2004. An employee at the store contacted PIC David Warren at the directive of Mr. Smith. Mr. Smith advised Mr. Warren that the business must obtain a permit from the Board in order to continue operation.

Mr. Warren submitted an application for a permit for the business shortly after Mr. Smith's visit; however, the permit was never obtained. Mr. Smith confirmed that the business was still operating in May 2005, but without a permit.

Mrs. Choi informed the Committee of a Cease & Desist letter that was issued to David Warren &

Jay Enterprises, 501 East Franklin Street, Monroe, NC, by Mr. Hudson on May 12, 2005. In response to the Cease & Desist letter, Mr. Warren submitted a letter to Mr. Hudson in which he claimed that a new DME business, First Choice Medical, had been opened at the location. Mr. Warren further disavowed any common ownership between Jay Enterprises and First Choice Medical. Shortly there after, Mr. Warren submitted an application for a permit under the name of First Choice Medical, 501 East Franklin Street, Monroe, NC; however, the permit was never obtained.

Mrs. Choi verified that First Choice Medical is not registered as a business with the office of the Secretary of State.

By consensus, the Committee found that Jay Enterprises permit no. 346, directly operated or otherwise facilitated the operation of an un-permitted device and medical equipment business for at least eight months. Based on those findings, the Committee will recommend to the Board that permit no. 346 receive an eight month suspension; such suspension stated for five years on conditions set forth in the proposed Consent Order found later in these minutes.

UNNAMED DME BUSINESS OPERATING FROM A MINI STORAGE BUILDING

Mr. Hudson and Ms. Cummings reported that a business is seeking to sale equipment from a mini-warehouse. Ms. Cummings provided photographs of the location of the proposed business and conveyed conversations she had with the owner. The owner proposes to use the sight as a location for a company representative to meet with patients regarding equipment that had previously been sent directly to the patient from an out-of-state business. The out-of-state business holds a permit issued by this Board.

After a lengthy discussion, the Committee agreed that a permit can not be denied to the business based solely on the issue of it being in a mini-warehouse.

UNNAMED DME BUSINESS MOVING TWICE WITHOUT NOTIFYING THE BOARD

Mr. Hudson and Mrs. Cook reported that an unnamed business holding a permit has felled to notify the Board of at least two address changes during the past year. Mrs. Cook attempted to visit the business in November 2005, and found that it is not at the most recent address known to staff. That location is now a vacant building and the phone is no longer in service.

The Committee agreed to recommend that the business's permit be Summarily Suspended at the time of the February Board meeting. In the interim, staff is to issue a Cease & Desist letter to the last known mailing address of the business, and make a renewed effort to find the owner.

OTHER NEW BUSINESS

Mr. Link advised the Committee that his tenure on the Committee would be expiring this year. The Committee directed staff to solicit candidates for a replacement for Mr. Link, conduct an election, and present the sealed ballots for counting by the Committee at the next meeting.

Mr. Hudson reminded the Committee that the current rules have been in place for ten years. The Committee agreed that the timing is appropriate to conduct an in-depth review of the rules to

determine if any changes or additions are needed. It was agreed that this endeavor will be started at the next meeting of the Committee.

NEXT MEETING

The Committee set the next meeting at 10:00am on March 29, 2006, in the Newton office.

Wayne Link, Chairperson

Larry Lankford

(Not Present)

L. Stan Haywood

Marcia Ladd

Parker Chesson

Mel Elliott