

**Minutes to the Meeting of the North Carolina Board of Pharmacy
Durable Medical Equipment Committee
January 23, 2007**

Chairman Marcia Ladd called the meeting to order at 10 a.m. at the Board of Pharmacy office. Present for the meeting were Karen Womack, Joey McLaughlin and Mel Elliott, committee members. Also present were staff Karen Matthew, Krystal Brashears, Rachel Paris and Wendy Watson and Board Counsel Clint Pinyan, Alex Elkan and Sarah Phillips.

Chairman Ladd read the ethics statement

Minutes of the October 10, 2006 meeting were approved by all.

Clint Pinyan along with Alex Elkan and Sarah Phillips from the firm of Brooks, Pierce, McLendon, Humphrey & Leonard, LLP, were introduced as new Board counsel.

Old Business:

Pinyan reported that two proposed rules approved by the Board of Pharmacy were rejected by the North Carolina Rules Review Committee (RRC). The rules that were rejected by the RRC included 21 NCAC 46.1608(a)(3)(A) and 21 NCAC 46.2613. He reported that the rules had been rejected primarily due to vagueness in the wording and that the rules would be rewritten addressing the RRC's concerns and re-submitted for approval.

Pinyan was asked by Chairman Ladd to clarify if there was allowing for DME businesses currently located at residential sites to be "grandfathered." Pinyan stated rules do not contain any provision for "grandfathering" in DME permittees and allowing them to remain in current residential locations. As of January 2008, after a grace period, the Board of Pharmacy will start enforcing compliance with 21 NCAC 46.2601(c), providing that DME permits will not be issued to applicants located on residential property, and 21 NCAC 46.2612 (a), providing that devices and medical equipment shall not be stored on residential property.

Several of the committee members asked if 21 NCAC 46.2609(b)(4) could be changed to include the words "face to face." Pinyan stated that the Board staff's position is that the current requirement that a rehabilitation supplier "deliver, fit and adjust the prescribed equipment" already, by its plain meaning, contemplates that in-person fitting and adjusting take place. Moreover, Pinyan stated a change in the definition would require Board of Pharmacy action and a revised rule would have to be submitted to the RCC for approval.

Chairman Ladd also requested if there was a list available of companies that might require a N.C. Division of Facility Services (DFS) permit but would be exempt from

Board of Pharmacy (BOP) permits. Pinyan stated he would research the issue and report to the members of the subcommittee.

New Business

Dan Ragan, NC Department of Agriculture, Food and Drug Protection Division (NCDA), appeared before the committee. He stated that his inspectors visit facilities that are registered with the US Food and Drug Administration (FDA) to dispense oxygen to consumers and also transfill oxygen tanks (not including pharmacies in North Carolina that handle DME items). He reported that, although his inspectors perform inspections, they have no power to enforce compliance with FDA rules. He stated that NCDA's only recourse is to ask the Attorney General's office to enforce regulations, but it is a slow process. Ragan asked if there was any way for the Board of Pharmacy to assist in enforcing DME compliance with the regulations.

Following some discussion, Mr. McLaughlin asked if Ragan referred such DME non-compliance to Board inspector and investigators. Karen Matthew pointed out that if Ragan contacted her or the Investigations/Inspections Department about regulatory non-compliance by DME companies, the complaint would be reviewed, assigned to an inspector and investigated, and referred for administrative disposition as appropriate.

There was discussion concerning if DME companies started utilizing electronic patient charts instead of paper records, if such computerized charts would satisfy rules and regulations (specifically 21 NCAC 46.2301 – 21 NCAC 46.2305). Pinyan stated as long as the computerized charts satisfied these rules and were readily retrievable for review by BOP inspectors, such records would be acceptable.

A question was raised about the National Board of Pharmacy (NABP) certification of DME providers. NABP was approved by the Centers for Medicare & Medicaid Services (CMS) to become an accrediting organization. Such certification targets only state-licensed pharmacies that provide a limited line of durable medical equipment.

The next item on the agenda was reading of a letter from Senator Elizabeth Dole to the N.C. Board of Pharmacy. Senator Dole's letter expressed concerned over Senate Bill 3814 introduced in 2006 regarding home oxygen patient protection. No action has yet been taken on the bill, according to Senator Dole.

Investigator Krystal Brashears reported she is utilizing a new inspection form and will be testing it with new permits when inspected. Brashears also stated she normally tries to inspect four or five DME providers per day when she can. Mel Elliott asked how many DME providers were permitted by the BOP. Wendy Watson estimated there were around 650 DME providers presently permitted by the BOP.

Pinyan stated at present the DME Committee members (not including BOP members) were not covered by the new State Government Ethics Act but that they might be potentially covered by the Ethics Act in the future.

Meeting dates were set for the Committee for the rest of 2007: Tuesday, April 24; Tuesday, July 24; and Tuesday, October 23.

Chairman Ladd then introduced another item of new business. She stated she attended the meeting of the Respiratory Care Board (RCB) on January 11, 2007. During that meeting, the RCB rescinded a position statement on DME provider staff training on Continuous Positive Airway Pressure devices for patients who use them in home environments. Chairman Ladd stated the Committee might consider reintroducing the statement again for consideration in the future.

Mel Elliott asked if the Board of Pharmacy could send a letter to other North Carolina agencies dealing with Medicaid reimbursements to DME providers. Pinyan advised that the Board of Pharmacy by law is prohibited from lobbying.

The meeting adjourned at 11:25 a.m.

NEXT MEETING

The committee set the next date for a meeting on Tuesday, April 24, 2007.

Marcia Ladd, Chairperson

Karen Womack

Joey McLaughlin

(Not Present)
Parker Chesson

Mel Elliott