

LOUISIANA BOARD OF WHOLESALE DRUG DISTRIBUTORS

Board Meeting

MINUTES

March 15, 2011

AGENDA ITEM 1 - Call to Order

The meeting was called to order by Robert Broadus, Chairman, at approximately 10:00 am. The meeting was held in Harvey, Louisiana at the Airgas facility located at 1264 First Avenue - hosted by Board Member Michael Davis.

AGENDA ITEM 2 - Roll Call

It was noted by Mr. Broadus that those members in attendance were Mr. Broadus, Randall Brooks, Hersh Paul, Wayne Gremillion, Michael Davis, and Kenneth Dugas. William Crates was absent. Also present from the Board's administrative office were John Liggio, Kimberly Barbier, and George Lovecchio. The Board members in attendance constituted a quorum. There were guests in attendance - Mr. Wade Holt of Airgas, Inc., Ocoee, Florida and Mr. Michael Tiller of Compressed Gas Association, Chantilly, Virginia.

AGENDA ITEM 3 - Call for Additional Agenda Items *[for discussion in Agenda Item 10.a]*

1. Mr. Davis - Tour of Airgas facility for educational information on the workings of a medical gas distributor.

Motion was made by Mr. Paul to add the presented item to the agenda, seconded by Mr. Gremillion, and passed by voice vote - FOR: Mr. Broadus, Mr. Brooks, Mr. Paul, Mr. Gremillion, Mr. Davis and Mr. Dugas; AGAINST: None; ABSTAINED: None; ABSENT: Mr. Crates; RECUSED: None.

Mr. Davis introduced the guests in attendances; Mr. Wade Holt of Airgas and Mr. Michael Tiller of Compressed Gas Association.

Mr. Liggio re-presented the Compressed Gas Association's previous inquiry to the Board regarding plumbers and their lack of authority to acquire medical gases for system testing. Mr. Tiller reiterate that the Board's use of the wording "procure and possess" in the Board's licensee newsletter is of their concern. General discussion was held. The Board will review this concern and consider replacing the wording with "acquire" and/or defining "possess" as for redistribution of product.

The Board members, administrative staff, and guests present accompanied Mr. Davis on a tour of the Airgas facility.

Upon return to the conference room, the Board continued with the open meeting.

AGENDA ITEM 4.a.i. – Disciplinary Matters/ Disciplinary Action

Mr. Gremillion, Compliance Officer, presented a consent agreement for review and approval as follows:

- i. Mr. Gremillion presented the Consent Agreement executed for Docket No. 2011001 for Owens & Minor Distribution, St. Rose LA, license no. 4218; violation – La. R.S. 37:3474.1(A)(8) and LAC 46:XCI.311, purchasing and receiving legend drugs or devices from an unlicensed supplier(s); \$3,000 fine and \$500 reimbursed costs. **Motion was made by Mr. Davis to approve and accept the consent agreement as executed and presented, seconded by Mr. Paul and passed by voice vote – FOR: Mr. Broadus, Mr. Brooks, Mr. Paul, Mr. Davis and Mr. Dugas; AGAINST: None; ABSTAINED: None; ABSENT: Mr. Crates; RECUSED: Mr. Gremillion.**

AGENDA ITEM 5 – Approval of Meeting Minutes/ December 14, 2010

The minutes of the December 14, 2010 Board meeting were presented. **Motion was made by Mr. Gremillion to dispense with full reading of the minutes and to accept and approve the minutes as presented, seconded by Mr. Paul, and passed by voice vote – FOR: Mr. Broadus, Mr. Brooks, Mr. Paul, Mr. Gremillion, Mr. Davis and Mr. Dugas; AGAINST: None; ABSTAINED: None; ABSENT: Mr. Crates; RECUSED: None.**

AGENDA ITEM 6.a – Financial Matters/ Financial Statements

Financial information was presented for December 2010, January and February 2011. General discussion was held. No formal action was taken on this matter.

Mr. Liggio proposed the future upgrade of computer software including the possible use of a server system and the development of a program for the inspector to use a notepad in completing inspection forms during facility inspections. No formal action was taken on this matter.

AGENDA ITEM 6.b – Financial Matters/ Annual Financial Attestation – Fiscal Year 2011

Mr. Liggio presented the attestation questionnaire required for the upcoming annual financial attestation for fiscal year 2011 to begin July 1. General discussion was held. **Motion was made by Mr. Davis to approve the attestation questionnaire as presented for submission to the CPA for performance of the attestation, seconded by Mr. Brooks, and passed by voice vote – FOR: Mr. Broadus, Mr. Brooks, Mr. Paul, Mr. Gremillion, Mr. Davis and Mr. Dugas; AGAINST: None; ABSTAINED: None; ABSENT: Mr. Crates; RECUSED: None.**

AGENDA ITEM 7 - Professional Contracts/ Legal Services

Mr. Liggio presented a proposed two-year (renewal) contract between the Board and Ms. Celia Cangelosi to continue legal services provided to the Board by Ms. Cangelosi. Ms. Cangelosi's current contract ends June 30, 2011. **Motion was made by Mr. Paul to accept the two-year contract as presented, seconded by Mr. Davis, and passed by voice vote - FOR: Mr. Broadus, Mr. Brooks, Mr. Paul, Mr. Gremillion, Mr. Davis and Mr. Dugas; AGAINST: None; ABSTAINED: None; ABSENT: Mr. Crates; RECUSED: None.**

Mr. Liggio discussed the prospect that additional Board personnel may be required in the near future which may require more office space for the Board's administrative office. The current office lease expires on October 31, 2012. Mr. Liggio and Mr. Lovecchio had viewed office space in the vicinity of the current office location that is significantly larger than the current office space and is being offered at a square footage cost that is substantially less than the current lease. The current landlord has also made an offer of additional office space at the current location. No formal action was taken on this matter.

AGENDA ITEM 8.a - Licensing Issues/ New Licenses Issued

A list of approximately 113 new licenses as issued by the Board office on behalf of the Board since the December 14, 2010 Board meeting was available for review. No formal action was taken on this matter.

Mr. Liggio voiced his concerns regarding being able to look closer at suspicious licensees who keep having no business dealings year after year; and new licensees whose personnel seem to know nothing at all about the wholesale drug distribution industry. Mr. Liggio informed the Board that the Board office will step up the intervals of inspection for the first year after a new license is issued to every couple of months so that these licensees can be watched more closely. No formal action was taken on this matter.

Mr. Lovecchio made mention of a television investigative program that was recently shown regarding counterfeit drugs within the United States that he found very interesting and recommended for all to view. The Board requested that Mr. Liggio contact the federal government - FDA and DEA - to get updated information regarding counterfeit and adulterated drug investigations and seizures.

AGENDA ITEM 8.b. - Licensing Issues/ Medical Gas Bulk Distribution (Tanker Size)

Mr. Liggio presented general information regarding wholesale drug distribution and "labeled" product as licensed by the Board. General discussion by the Board with Mr. Holt and Mr. Tiller was held regarding separation plants and bulk distribution. Mr.

Liggio noted that medical gases in separation plants and distributed via bulk tankers are not "labeled" product and do not fall within the parameters for licensure by the Board. Mr. Holt explained Airgas' situation with bulk (tanker) distribution of product to hospitals. General discussion was held regarding pedigree of medical gases. It was noted that pedigree cannot be truly passed on medical gases and that most states with pedigree requirements may exempt pedigree on medical gases. The Board noted that passing on the certification certificate on oxygen to the hospital and/or a FDA establishment registration for manufacturing should be enough. With regards to the yards or sites where bulk product tankers holding oxygen are stored are considered by the Board to be in transit. These yards/sites and separation plants cannot be licensed by the Board as they do not fall under Board regulation.

AGENDA ITEM 8.c. - Licensing Issues/ Sales to Patient/Consumer

Mr. Liggio presented information regarding a retail store selling AEDs to consumers. General discussion was held noting that retail stores sales could not be validated as wholesale distribution. No formal action was taken on this matter.

Mr. Liggio presented information regarding electrodes found during an inspection that carried the federal caution that the device was restricted to the sale to or on the order of a physician along with wording such as *or use by a therapist*. The vendor was contacted and inquiry made as to how such additional wording regarding use by a therapist was approved by the FDA for class II device labeling. The vendor seemed confused as to how such wording got on the label and promised to check into it. No formal action was taken regarding this matter.

AGENDA ITEM 9 - Statutes and Rules/ Rule Promulgation Update

Mr. Liggio presented promulgation tracking reports for rule amendments currently in promulgation for LAC 46:XCI.105.A.1 (June 2010) - General Provisions, Exemptions. General discussion was held. No formal action was taken on this matter.

AGENDA ITEM 10.a - General/ Additional Agenda Items (*added per Agenda Item 3*)

1. Tour of the Airgas facility

The tour was taken after agenda item 3 before agenda item 4. No formal action was taken on this matter.

AGENDA ITEM 10.b - General/ Product Classification of Licensees

Mr. Liggio and Mr. Brooks presented information regarding a company selling a federal class II drug in which information indicates that numerous DEA form 222 will be used in the passing of this product from the prescriber down to the administering party. It was suggested that this be a Board of Pharmacy matter. Information provided indicates that the Board of Pharmacy may be awaiting FDA ruling regarding the possible re-classification of the drug before they will review the matter. It was noted

that if such product was found at a licensed wholesale drug distributor facility and the licensee has a DEA registration there would be no issue. No formal action was taken on this matter.

AGENDA ITEM 10.c - General/ Other State Licensees - Waiver of Inspection

Mr. Liggio presented information regarding the state of Maryland not accepting licensure from several states, including Louisiana, that they have found to have licensing requirements not equal to their own for reciprocity therefore requiring applicants from these states to receive VAWD certification before Maryland licensure is issued. Information suggests that some of these excluded states may now not license facilities located in Maryland for wholesale distribution into their state. General discussion was held. Mr. Liggio noted that if after review the Board decided that Maryland's inspection requirements through VAWD were not equal to Louisiana's then it could require that a Board inspector be sent to Maryland to inspect new license applicants from Maryland and physically perform annual inspection of all licensees located in Maryland in order for these licenses to be issued or annually renewed. No formal action was taken on this matter.

AGENDA ITEM 10.d - General/ Website Updates - Licensee Lookup

Mr. Liggio presented proposed changes to the licensee lookup information provided on the Board's website; specifically, identifying regulatory contact telephone and fax numbers, distribution addresses, and business addresses of licensees. General discussion was held. **Motion was made by Mr. Gremillion to approve changes to the Board's website licensee lookup page as proposed, seconded by Mr. Davis and passed by voice vote - FOR: Mr. Broadus, Mr. Brooks, Mr. Paul, Mr. Gremillion, Mr. Davis and Mr. Dugas; AGAINST: None; ABSTAINED: None; ABSENT: Mr. Crates; RECUSED: None.**

AGENDA ITEM 10.e - General/ Policy - Board Member Reimbursement

The policy as approved at the December 14, 2010 board meeting was presented in final version for review. **Motion was made by Mr. Brooks to re-approve the policy as presented in final version, seconded by Mr. Dugas, and passed by voice vote - FOR: Mr. Broadus, Mr. Brooks, Mr. Paul, Mr. Gremillion, Mr. Davis and Mr. Dugas; AGAINST: None; ABSTAINED: None; ABSENT: Mr. Crates; RECUSED: None.**

AGENDA ITEM 10.f - General/ Board Recognition

Mr. Liggio presented a letter from the Louisiana Department of Civil Service in praise of the Board's Performance Planning and Review (PPR) record for review. No formal action was taken on this matter.

AGENDA ITEM 10.g - General/ Schedule Board Meeting Dates for 2011

The additional meeting dates for 2011 proposed at the December 14, 2010 board meeting were found unacceptable by some members. New proposed meeting dates

were presented. The next Board meeting is tentatively set for Wednesday, June 15, 2011 (annual meeting). Board meetings tentatively set for the remainder of 2011 are Thursday, September 15, 2011, and Thursday, December 15, 2011 (budget approval).

Mr. Liggio and Mr. Lovecchio presented information with regards to licensees licensed for distribution from a public storage warehouse. Mr. Liggio and Mr. Lovecchio have been working to inform these licensees that their invoices must reflect the licensed facility location address. So far all seem to be in compliance.

AGENDA ITEM 11 - Adjournment

There being no further business before the Board, **motion was made by Mr. Gremillion to adjourn the meeting, seconded by Mr. Davis, and passed by voice vote - FOR: Mr. Broadus, Mr. Brooks, Mr. Paul, Mr. Gremillion, Mr. Davis and Mr. Dugas; AGAINST: None; ABSTAINED: None; ABSENT: Mr. Crates; RECUSED: None.**

The meeting adjourned at approximately 1:47 pm.



Randall Brooks
Board Secretary/Treasurer



John Liggio
Executive Director

Approved and accepted by the full Board -

Date: Thursday, May 5, 2011