LOUISIANA BOARD OF WHOLESALE DRUG DISTRIBUTORS

Board Meeting MINUTES March 24, 2015

AGENDA ITEM 1 - Call to Order

The meeting was called to order by Robert Broadus, Chairman, at approximately 9:40 am. The meeting was held in Baton Rouge, Louisiana at the Administrative Office of the Board located at 12091 Bricksome Avenue, Suite B.

AGENDA ITEM 2 - Roll Call and Introduction of Guests

It was noted by Mr. Broadus that those members in attendance were Mr. Broadus, Michael Davis, Randall Brooks, Wayne Gremillion, Kenneth Dugas, Chad Gielen, and Jacob Dickson. No Board members were absent. The Board members in attendance constituted a quorum. Also present from the Board's administrative office were George Lovecchio and Kimberly Barbier. There were no guests in attendance.

AGENDA ITEM 3 – Call for Additional Agenda Items [for discussion in Agenda Item 10]

- 1. Guidelines/procedures for Licensees Regarding DSCS Compliance.
- 2. Medical Marijuana.

Motion was made by Mr. Dugas to add items as noted to the agenda for discussion later in the meeting under agenda item 10, seconded by Mr. Davis, and passed by voice vote – FOR: Mr. Broadus, Mr. Davis, Mr. Brooks, Mr. Gremillion, Mr. Dugas, Mr. Gielen, and Mr. Dickson; AGAINST: None; ABSTAINED: None; ABSENT: None; RECUSED: None.

AGENDA ITEM 4 - Approval of Meeting Minutes

The minutes of the January 27, 2015 Board meeting were presented. Motion was made by Mr. Brooks to dispense with full reading of the minutes and to accept and approve the minutes as presented, seconded by Mr. Gremillion, and passed by voice vote – FOR: Mr. Broadus, Mr. Davis, Mr. Brooks, Mr. Gremillion, Mr. Dugas, Mr. Gielen, and Mr. Dickson; AGAINST: None; ABSTAINED: None; ABSENT: None; RECUSED: None.

AGENDA ITEM 5 - Old Business

- a. Statutes and Regulations
- i. Drug Supply Chain Safety (DSCS) Act

Mr. Lovecchio reviewed changes requested by the Senate sponsor to the Board's proposed statute amendments; one grammar edit and removal of the proposed increase of the Board's per diem pay. General discussion was held regarding the legislative approval process so far. It was noted the PhARMA's review was favorable for the proposed changes. Motion was made by Mr. Dickson to accept the changes requested by the Senate sponsor to the proposed revision of statutes in La. R.S. 37:3461-3482,

seconded by Mr. Gielen, and passed by voice vote - FOR: Mr. Broadus, Mr. Davis, Mr. Brooks, Mr. Gremillion, Mr. Gielen, and Mr. Dickson; AGAINST: Mr. Dugas; ABSTAINED: None; ABSENT: None; RECUSED: None.

Mr. Lovecchio offered information regarding his presentation on supply chain awareness and integrity as he presented to the Board of Physical Therapy at a recent meeting. The presentation was well received. The Physical Therapy Board has placed a notice of the subject on their website and in their newsletter. The information has generated a number of calls regarding licensure for wholesale distribution. The director of the Medical Examiners Board had also requested a presentation on the subject.

b. NetShapers- LMS Database Host

Mr. Lovecchio presented the letter received from the Division of Administration approving the contract with NetShapers for development of the new license management system (LMS) database currently in use. General discussion was held. It was noted that the balance of the initial development fee and outstanding hosting/maintenance monthly fees have been paid. Mr. Lovecchio noted that the Board office has a manual provide by DHH Contract Management for requests for proposal procedures on file for reference in the event RFP is required for any future contracts of \$50,000 or more. Ms. Barbier explained that DHH Contract Management has been merged over to DOA's new Office of State Procurement & Contracts; and that DOA OSP has created a new web submission program, PROACT, for submission of contracts for approval. No formal action was taken on the agenda item.

c. Third Party Logistic Providers- AG Opinion Request

Mr. Lovecchio distributed copies of opinion 15-0007 received from the Department of Justice, Attorney General in response to the Board's request for opinion regarding continued licensure of third party logistic providers under the Board's current statutes and regulation and with regards to the new federal DSCS Act requirements. The opinion was reviewed. General discussion was held. No formal action was taken.

d. InVitro Diagnostics (IVD)

Mr. Lovecchio presented additional information he found regarding IVDs and counterfeiting of IVDs. General discussion was held. Mr. Lovecchio will continue to research and monitor the IVD issue for future reporting and possible Board action.

AGENDA ITEM 6- New Business

a. Policy/Procedure- Criminal History Records Checks, Amendments

Ms. Barbier presented amendments to the Board's current policy/procedure for criminal history records checks. General discussion was held regarding validation time of criminal history records results, and issuance of new licenses (location change applications) and license renewals while awaiting criminal history record check results. General discussion was held. Motion was made by Mr. Brooks to approve the

amendments to the policy/procedure for criminal history records checks, seconded by Mr. Dugas, and passed by voice vote- FOR: Mr. Broadus, Mr. Davis, Mr. Brooks, Mr. Gremillion, Mr. Dugas, Mr. Gielen, and Mr. Dickson; AGAINST: None; ABSTAINED: None; ABSENT: None; RECUSED: None. The policy/procedure will be sent to the attorney for review and comments/suggestions.

AGENDA ITEM 7 - Professional Service Contract

a. Inspection Services - Danny Andrus (Contract Renewal)

Mr. Lovecchio presented a renewal contract to the professional service contact for inspection services provided by Danny Andrus for facility inspections. The contract is a continuation of services for another year. General discussion was held. Motion was made by Mr. Gielen to approve the contract (renewal) for professional inspection services effective July 1, 2015 through June 30, 2016 between the Board and Danny Andrus, seconded by Mr. Davis, and passed by voice vote- FOR: Mr. Broadus, Mr. Davis, Mr. Brooks, Mr. Gremillion, Mr. Dugas, Mr. Gielen, and Mr. Dickson; AGAINST: None; ABSTAINED: None; ABSENT: None; RECUSED: None.

AGENDA ITEM 8 - Financial Matters

a. Financial Statements

Mr. Lovecchio presented financial information for the month of January 2015. General discussion was held.

Mr. Lovecchio presented information regarding an upcoming NABP meeting to be held in New Orleans LA in May 2015 that has a couple of sessions on DSCS issues. Mr. Lovecchio will circulate the meeting information for anyone on the Board interested in attending.

Mr. Lovecchio presented financial information for the month of February 2015 for review. General discussion was held. No formal action was taken on this agenda item.

AGENDA ITEM 9 - Licensing Matters

a. New Licenses Issued List

Ms. Barbier presented a list of approximately 59 new licenses as issued by the Board office on behalf of the Board since the January 27, 2015 Board meeting for review. General discussion was held. No formal action was taken on this matter.

AGENDA ITEM 10 - Additional Agenda Items Properly Brought Before the Board (approved in agenda item 3)

1. Guideline/procedures for licensees on DSCS compliance

Mr. Lovecchio presented information regarding some inquiries recently received from licensees requesting guidance in regards to the new DSCS requirements. Mr. Lovecchio suggested and the Board agreed that Mr. Lovecchio should work with the attorney to review the DSCS requirements and put together a written

MINUTES March 24, 2015

guideline/procedure that would be available for licensees in helping to understand the new federal requirements and help licensees with compliance of the new requirements.

2. Medical Marijuana

Mr. Lovecchio presented information regarding a proposed bill to be presented at the next legislative session regarding medical marijuana. General discussion was held. No formal action was taken on this agenda item.

AGENDA ITEM 11 - Board Issues

Confirmation of Next Board Meeting

The Board confirmed it will tentatively schedule the annual meeting for Tuesday, June 9, 2015. It was noted meetings for the remainder of 2015 are tentatively set for Tuesday, September 8 and Tuesday, December 8, 2015.

Mr. Lovecchio and Mr. Gremillion presented information they had received in December 2014 that simulation or practice use saline had been purchased from a wholesale distributor via website; it was noted the simulation/practice use product had been available on the distributor's website along with medical saline. The simulation/practice use saline was then administered by the clinic to some patients who got sick. The FDA had investigated the incident and had the clinic destroy the product. The Board office was informed of the situation but upon review of information provided by the Medical Examiners Board and FDA on the incident, took no action against the wholesale distributor. The distributor has since moved the simulation/practice use saline item to a different location on their website for training use items. General discussion was held. No formal action was taken on this item.

Mr. Brooks presented information regarding the Right to Try bill that had passed during the last legislative session. This Act allows for patients to request and be granted use of unapproved/experimental drugs for medical treatment. The Board should be aware that unapproved drugs may be distributed into Louisiana under this Act and wholesale distribution licensure may be required of these entities. No formal action was taken on this item.

AGENDA ITEM 12 - Adjournment

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

The meeting adjourned at approximately 12:05 pm.

orechia

Approved and accepted by the full Board -

Date: ____

Randall Brooks

Board Secretary Treasurer

George Lovecchio

Interim Executive Director