

# LOUISIANA BOARD OF DRUG AND DEVICE DISTRIBUTORS

## Board Meeting – Budgetary Review

### MINUTES

March 21, 2023

#### ATTENDANCE:

##### Members Present:

Michael Davis- Chairman, James Delatte- Vice-Chairman, Chad Gielen- Compliance Officer, Scott Irelan- Member, Nicholas Latino-Member, Cindy Luton- Member, and Trion Horgan- Secretary-Treasurer

##### Members Absent:

Darrick LeBeouf- Member

##### Office Staff Present:

George Lovecchio- Executive Director, and Kimberly Barbier- Executive Assistant

##### Contract Team Present:

John Becknell- Attorney- The Becknell Law Firm, and Victoria Bienvenu- Compliance Management Consultant

#### I. Call to Order

The meeting was called to order by Michael Davis, Board Chairman, on Tuesday, March 21, 2023 at approximately 10:00 am. The meeting was held at the Board's administrative office located at 12091 Bricksome Avenue, Suite B, Baton Rouge, Louisiana. Board office general precautionary protocols were implemented to ensure the health and safety of members, staff, and all those in attendance.

#### II. Roll Call and Introduction of Guests

Roll call was taken by Trion Horgan, Board Secretary/Treasurer, with the above noted results. Members in attendance constituted a quorum. There were no public guests in attendance.

#### III. Approval of Meeting Minutes

##### A. December 13, 2022

Mr. George Lovecchio, Executive Director, presented draft minutes of the December 13, 2022 meeting. Individual review of the presented minutes was held. **Motion was made by Mr. Horgan to dispense with full reading of the minutes and approve the minutes as presented, seconded by Ms. Luton, and passed by voice vote - FOR: Mr. Delatte, Mr. Horgan,**

**Mr. Gielen, Ms. Luton, Mr. Irelan, Mr. Latino, and Mr. Davis;  
AGAINST: None; ABSENT: Mr. LeBeouf; ABSTAINED: None;  
RECUSED: None.**

IV. Financial Matters

A. Financial Statements

1. December 2022

Mr. Lovecchio presented a financial transaction list and balance reports for the month of December 2022. General review and discussion were held.

2. January 2023

Mr. Lovecchio presented a financial transaction list and balance reports for the month of January 2023. General review and discussion were held.

3. February 2023

Mr. Lovecchio presented a financial transaction list and balance reports for the month of February 2023. General review and discussion were held.

a. FY2023 to Date Review

Mr. Lovecchio presented a profit/loss report on budget versus actuals for current fiscal year 2023 through the month of February 2023. Review of the report and general discussion was held.

No formal action was taken on this agenda item.

B. Update- Proposed FY2024 New Budget

Mr. Lovecchio presented an update to the budget worksheet presented at the December 2022 Board meeting for proposed fiscal year 2024 budget. Mr. Lovecchio noted that the amounts for each budgeted item as presented at the December 2022 meeting were correct as approved. There was an incorrect formula function on the presented *worksheet* that rendered erroneous overall totals that the Board may note. There was general review of the corrected worksheet. Mr. Lovecchio noted he had contacted Mr. Horgan, Secretary/Treasurer, about this issue and he will have the spreadsheet reviewed by the CPA for accuracy. No formal action was taken on this agenda item.

C. Annual Attestation Report- Fiscal Year 2022



Mr. Lovecchio presented a copy of the financial attestation report by the independent accountant for fiscal year 2022 ended June 30, 2022. Mr. Lovecchio gave a general review of the findings. The item regarding annual review of the Board's ethics policy by employees was discussed resulting in the decision to also have all Board Members review the Board's ethics policy and provide a signed verification annually to the administrative office.

V. Service Contracts

A. Review- Compliance Management- Current Year Amendment

Mr. Lovecchio presented an amendment to Ms. Victoria Bienvenu's current contract ending March 31, 2023 for compliance management consulting services. The amendment was for an increase of the maximum contract amount from \$48,500 to \$53,000. The amendment was submitted to and approved by DOA Office of State Procurement, Professional Contracts in February 2023. General discussion was held. No formal action was taken on this agenda item.

B. Contract- Renew Services- Facility Inspections- John Liggio

Mr. Lovecchio presented a new contract for renewal of services between the Board and Mr. John Liggio for facility inspection services (south). Mr. Lovecchio presented a proposed increase to the per inspection fees based on the set complexity ratings: low complexity fee from \$165 to \$190, moderate complexity fee from \$220 to \$245, and high complexity fee from \$275 to \$300 per inspection. General review of the proposed contract was held. **Motion was made by Mr. Gielen to approve the increase of the per inspection fees: low complexity to \$190, moderate complexity to \$245, and high complexity to \$300; and to approve the proposed contract with Mr. Liggio for facility inspection services for the term of April 1, 2023 through March 31, 2024, at a maximum contract amount of \$22,000, seconded by Mr. Delatte, and passed by voice vote - FOR: Mr. Delatte, Mr. Horgan, Mr. Gielen, Ms. Luton, Mr. Irelan, Mr. Latino, and Mr. Davis; AGAINST: None; ABSENT: Mr. LeBeouf; ABSTAINED: None; RECUSED: None.**

C. Contract- Renew Services- Compliance Management Consulting- Victoria Bienvenu

Mr. Lovecchio presented a new contract for renewal of services between the Board and Ms. Bienvenu for compliance management consulting. General review of the proposed contract was held. **Motion was made by Mr. Gielen to approve the proposed contract with Ms. Bienvenu for compliance management consulting services for the term of April 1, 2023 through March 31, 2024, at a maximum contract amount of \$60,000,**

**seconded by Mr. Horgan, and passed by voice vote - FOR: Mr. Delatte, Mr. Horgan, Mr. Gielen, Ms. Luton, Mr. Irelan, Mr. Latino, and Mr. Davis; AGAINST: None; ABSENT: Mr. LeBeouf; ABSTAINED: None; RECUSED: None.**

VI. New Business

A. Preview to 2023 Louisiana Legislative Session

1. The Legislative Process

Mr. John Becknell, contract attorney, presented general information regarding the process of the State Legislative sessions; how a bill is presented and approved.

2. Roles of Board Members and Staff

Mr. Becknell gave a review of the roles Board members and office staff have in the legislative process.

3. Review of Bills Filed to Date

Mr. Becknell reviewed a list of Bills already filed that could affect the Board. He has found none that would directly affect Board function.

No formal action was taken on this agenda item.

B. FDA Guidance- Suspect and Illegitimate Product

Mr. Becknell presented the Food and Drug Administration's federal industry guidance just released on defining suspect and illegitimate product for verification obligation under the Drug Supply Chain Security Act (DSCSA); the guidance is to be published by the FDA around the week of June 13, 2023. Mr. Becknell will be reviewing the guidance and the board's statutes and regulations for possible amendments and will make a report to the Board at a later meeting. Mr. Lovechio spoke generally about this item and expectations on future guidance from the FDA regarding the DSCSA to compare with the Board's statutes and regulations with regards to future amendments.

VII. Old Business

A. Compliance Management Update

Ms. Victoria Bienvenu, contract compliance management consultant, provided an update on the compliance management plan. Ms. Bienvenu presented on the subject of - product loss, thief, and suspicious order reports as received from licensees. Ms. Bienvenu presented general information on facility inspections, violation findings, and compliance



administration including inquiries made and further investigations of compliance issues. Ms. Bienvenu presented a cursory summary of inspections performed and a description of the compliance manager position. General discussion was held. No formal action was taken on this agenda item.

VIII. Board Matters

A. Board Email Addresses

The topic of Board email addresses for Board members was presented. The question was offered, *what are other Board's doing?* Mr. Becknell presented that it has not been found that other Louisiana regulatory Boards are issuing individual Board members a Board email address. Mr. Becknell discussed this issue in general and relative to public records laws. No formal action was taken on this agenda item.

B. Licensee Newsletter - Cancelled and Not Renewed License Lists

General discussion was held regarding possibly publishing of lists of Louisiana legend drug/device distributor licenses that had been voluntarily surrendered and cancelled during the year and those licenses not-renewed in the bi-annual licensee newsletter. This item will be further reviewed and discussed at a later Board meeting.

C. Online Public Records Request

General discussion was held regarding offering an online request portal for public records such as the ability to download spreadsheet lists of active licensees.

D. General Presentation

1. Inspection form Comparison to Board Rules; and Recommendations

Ms. Cindy Luton presented a summary of her review of the current inspection form compared to the Board's statutes and regulations. Her conclusion was favorable that the form is acceptable.

2. Licensing Fees- In State vs Comparison to Other States Fees

Ms. Luton presented a summary of her comparison of the Board's licensing fees versus other state's licensing fees and application process. Her general conclusion is that the Board's licensing fees are acceptable.

3. Suspicious Order Reports Research

Ms. Luton continued her presentation with a summary of her research on the terms, definitions, and laws on suspicious order reporting. General discussion was held.

4. Non-Reporting of Suspicious Opioid Sales Cases

Ms. Luton concluded her presentation with a summary on her research into legal cases relative to suspicious ordering- cases of not reporting suspicious opioid sales and settlements; DEA's terms, definitions, and laws regarding suspicious order reports.

No formal action was taken on this agenda item.

E. Expense Reporting

Mr. Lovecchio presented a review and clarification regarding reporting of monthly expenses by Board members of work performed (per diem) and travel and other expenses. General discussion was held. No formal action was held on this agenda item.

IX. Licensure Matters

A. New Licenses Issued

Ms. Barbier presented a listing of new licenses issued on behalf of the Board since the last Board meeting. Approximately 122 new legend drug/device distributor licenses have been issued between December 10, 2022 through March 15, 2023; 60 of those licenses issued were for initial/first time licensure. No formal action was taken on this agenda item.

X. Confirmation of Next Board Meeting

The next Board meeting is tentatively set for Tuesday, June 13, 2023. This meeting is the Board's annual meeting.

A. Call for Agenda Items for Next Meeting

Mr. Davis made a call for agenda items for the next meeting on June 13, 2023. Any proposed agenda items should be submitted no later than Friday, June 2, 2023.

XI. Adjournment

There being no further business before the Board. **Motion was made by Ms. Luton to adjourn the meeting, seconded by Mr. Delatte, and passed by voice vote - FOR: Mr. Delatte, Mr. Horgan, Mr. Gielen, Ms. Luton, Mr. Irelan, Mr. Latino, and Mr. Davis; AGAINST: None; ABSENT: Mr. LeBeouf; ABSTAINED: None; RECUSED: None.**

The meeting adjourned at approximately 12:15 pm.

Approved and accepted by the full Board - Date: 6/13/23

*James Delatte*

James Delatte  
Board Vice-Chairman

*George Lovechio*

George Lovechio  
Executive Director