LOUISIANA BOARD OF DRUG AND DEVICE DISTRIBUTORS

Board Meeting MINUTES September 20, 2022

ATTENDANCE:

Members Present:

Michael Davis, James Delatte, Chad Gielen, Trion Horgan, Jeffrey Irelan, Nicholas Latino, Darrick LeBeouf, Cathy Luton

Members Absent:

None

Guests Present:

Victoria Bienvenu-Contract Compliance, Jessica Matthews-The Accountant Exec

Guests Present (Remote):

Riya Cao-LSPediA

Staff Present:

Kimberly Barbier-Executive Assistant, John Becknell-Contract Attorney, George Lovecchio-Executive Director

I. Call to Order

The meeting was called to order by Michael Davis, Board Chairman, at approximately 10:41 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 have been implemented to ensure health and safety of members, staff, and all those in attendance.

II. Roll Call and Introduction of Guests

Roll call was taken by James Delatte, Vice-Chairman, with the above attendance results noted. Members in attendance constituted a quorum.

III. Approval of Minutes

A. June 20, 2022- Annual Meeting

Draft minutes for the June 20, 2022 meeting were presented for review and general discussion. Motion was made by Mr. Delatte to dispense with full reading of the minutes and approve the minutes as presented, seconded by Mr. Horgan, and passed by voice vote- FOR: Mr. Delatte, Mr. Horgan,

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

IV. Financial Matters

A. Financial Statements

1. May 2022

Financial transaction list and balance reports for the month of May 2022 were presented. General review and discussion of the financial statements was held. No formal action was taken on this agenda item.

2. June 2022

Financial transaction list and balance reports for the month of June 2022 were presented. General review and discussion of the financial statements was held. No formal action was taken on this agenda item.

a. Review Close of Fiscal Year 2022

A budget versus actual report was presented for the close of fiscal year 2022 ended June 30, 2022. General review and discussion of the report was held. No formal action was taken on this agenda item.

3. July 2022

Financial transaction list and balance reports for the month of July 2022 were presented. General review and discussion of the financial statements was held. No formal action was taken on this agenda item.

4. August 2022

Financial transaction list and balance reports for the month of August 2022 were presented. General review and discussion of the financial statements was held. No formal action was taken.

B. Budget Review- Current Fiscal Year 2023

A budget versus actual to date report was presented for the current fiscal year 2023 (July 1, 2022 - June 30, 2023) through the month of August 2022. General review and discussion of the report was held. No formal action was taken on this agenda item.

C. Annual Financial Report- Fiscal Year 2022

The statements of net position; revenues, expenses, and changes of net position; and cash flows sections of the Annual Financial Report (AFR) for fiscal year 2022 (July 1, 2021 through June 30, 2022) recently submitted to State were presented for review. General discussion was held. No formal action was taken on this agenda item.

D. Certificates of Deposit (CDs)

The current Board policy relative to bank accounts and certificates of deposit was presented for review. General discussion was held. Mr. Davis called for establishment of a committee to review the current Board policy for potential changes. Mr. Davis offered to work with the new incoming Secretary/Treasurer (Trion Horgan) along with Mr. Lovecchio forming the committee to review the current Board policy. A committee report of any proposed amendments to the policy will be presented at an upcoming Board meeting. Motion was made by Mr. LeBeouf to establish the committee comprised of Michael Davis, the new Secretary/Treasurer (Trion Horgan), and George Lovecchio to review the Board's current policy on bank accounts and certificates of deposit for possible amendments to the policy, seconded by Mr. Horgan, and passed by voice vote- FOR: Mr. Delatte, Mr. Horgan, Mr. Gielen, Mr. LeBeouf, Ms. Luton, Mr. Irelan, Mr. Latino, and Mr. Davis; AGAINST: None; ABSENT: None; ABSTAINED: None; RECUSED: None.

V. Service Contracts

A. Proposed

1. Accounting Services

A proposed contract for general accounting services with a new vendor was presented for review to approve. General discussion of the presented contract was held. It was noted that the contract is necessary due to the previous vendor who provided the services to the Board for many of the past years elected to not renew the services to the Board. Motion was made by Mr. Gielen to approve the contract for general accounting services between the Louisiana Board of Drug and Device Distributors and The Accountant Exec LLC for the one-year term of October 1, 2022 through September 30, 2023 at the rate of \$65 per hour not to exceed the maximum

contract amount of \$3,200, seconded by Mr. LeBeouf, and passed by voice vote- FOR: Mr. Delatte, Mr. Horgan, Mr. Gielen, Mr. LeBeouf, Ms. Luton, Mr. Irelan, Mr. Latino, and Mr. Davis; AGAINST: None; ABSENT: None; ABSTAINED: None; RECUSED: None.

VI. New Business

A. Workshop-Regulatory Academy on Law, Licensing & Leadership Information was presented for a regulatory law, licensing and leadership workshop for review and discussion. An invitation from another Louisiana state regulatory board offering an upcoming presentation of the workshop to be held in Baton Rouge in February 2023 was offered for consideration for members and staff to attend. Office staff was instructed by Mr. Davis to send out an inquiry to all members, staff, and relative contractors to see who would be interested in attending the Baton Rouge scheduled workshop.

Mr. Davis called for a break before beginning the next agenda item presentation. The members left regular session for a break at 11:50 am; members returned to regular session at 11:59. The meeting continued with agenda item VI.B.

B. Track and Trace Technology

Ms. Riya Cao with LSPediA in West Bloomfield Township MI joined the meeting remotely. Mr. Lovecchio presented a general review of a three-part training class he had attended that was offered by LSPediA relative to the implementation of DSCS Act requirements. Mr. Lovecchio introduced Ms. Cao. Ms. Cao presented an overview of some of the information covered in the training class- serialization by barcode; use of barcode scanners in the field; implementation schedules; authentication; and investigators. Ms. Cao complemented Mr. Lovecchio's interest and efforts in the fight against counterfeit and suspicious drugs. Ms. Cao was thanked by the members for her presentation. Ms. Cao exited the meeting. Mr. Davis called for the establishment of a committee to review providers of serialization scanners and tracking software for report to the Board at a later meeting. Mr. Gielen and Mr. Irelan offered to work with Mr. Lovecchio and Mr. Becknell forming the committee to review serialization scanners and tracking software providers. Motion was made by Mr. Gielen to establish a committee comprised of Chad Gielen, Scott Irelan, and George Lovecchio to work with John Becknell to review providers of serialization scanners and tracking software, seconded by Mr. LeBeouf, and passed by voice vote- FOR: Mr. Delatte, Mr. Horgan, Mr. Gielen, Mr. LeBeouf, Ms. Luton, Mr. Irelan, Mr. Latino, and Mr. Davis; AGAINST: None; ABSTAINED: None; RECUSED: None.

VII. Old Business

A. Committee Report- FDA National Standards for DSCS Act Review

Mr. Becknell provided a general summary of the Board's *National Standards Review Committee*'s work on their review of the FDA's proposed national standards relative to the DSCS Act and the composition and submission of a response back to FDA. A copy of the response letter composed and submitted by the committee on behalf of the Board was provided for individual review. General discussion was held. No formal action was taken on this agenda item.

B. Self-Evaluation Report (SER)

General discussion was held regarding the preliminary *Self-Evaluation Report* (SER) that had been prepared by a consulting firm engaged by the Board in late 2019. The SER is a response to the implementation of Act 693 of the 2018 Regular Session of the Louisiana Legislature. Mr. Becknell informed the members that the legislature had replaced the previous statutory requirement with a newer statute requiring relatively the same information. General discussion was held. No formal action was taken on this agenda item.

C. Compliance Plan Update

Mr. Lovecchio introduced Ms. Victoria Bienvenu, the contracted Compliance Consultant. Ms. Bienvenu was contracted and has been working on a compliance management plan. Ms. Bienvenu presented a general overview of the work currently being performed with regards to compliance management including review of suspicious order reports that are received from licensee entities, inspection administration, and enforcement/disciplinary compliance tracking. Mr. Gielen commended Ms. Bienvenu for all the work she had already done towards the future development of the compliance management program. Mr. Lovecchio presented a view of the compliance tracking segment in the Board's license

management system (LMS). No formal action was taken on this agenda item.

VIII. License Matters

A. New Licenses Issued

Mr. Lovecchio presented a listing of new licenses issued by the administrative office upon satisfactory completion of the license application process for review. General discussion was held. No formal action was taken on this agenda item.

B. Nursing Homes- Authorized Recipient

Mr. Lovecchio provided discussion regarding the "Authorized Receipient" article printed in the licensee newsletter published twice per year. The article provides licensees with a general list of those regulated entities that have authorization by statutes or regulations for the procurement and possession of legend drugs (including medical gases and oxygen) or devices. There had recently been inquiries regarding nursing home facilities authorization to purchase and store medical oxygen on site. After review of the State's licensure requirements for nursing home facilities under Louisiana Department of Health, published regulatory general provision for nursing (home) facilities provides that these facilities are authorized to have oxygen tanks readily accessible for emergency use. It was presented that *nursing home* licenses issued by the Louisiana Department of Health can be accepted by licensee distributors for the procurement and possession of medical oxygen only by nursing homes. The nursing home license will be added to the licensee newsletter article as an acceptable authorized recipient.

IX. Board Matters

A. Vacancies and Nominations

Formal introduction of recently appointed new board members was presented.

Cindy Luton, consumer representative, appointment effective September 9, 2022 through September 8, 2027;

Jeffrey Irelan, distributor representative, appointment effective September 16, 2022 through April 25, 2023; and

Nicholas Latino, distributor representative, appointment effective September 16, 2022 through September 15, 2027.

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Ms. Luton, Mr. Ireland, and Mr. Latino recited the Oath of Service and were welcomed by all.

Motion was made by Mr. Gielen to hold a special election to fill the vacated Secretary/Treasurer position, seconded by Mr. LeBeouf, and passed by voice vote- FOR: Mr. Delatte, Mr. Horgan, Mr. Gielen, Mr. LeBeouf, Ms. Luton, Mr. Irelan, Mr. Latino, and Mr. Davis; AGAINST: None; ABSENT: None; ABSTAINED: None; RECUSED: None.

A call for nominations for Secretary/Treasurer position was made. Mr. Delatte nominated Mr. Horgan for the position of Secretary-Treasurer; Mr. Horgan accepted the nomination. Nominations were closed.

Motion was made by Mr. Gielen to elect Trion Horgan to the position of Secretary/Treasurer of the Louisiana Board of Drug and Device Distributors, second by Mr. Latino, and passed by voice vote- FOR: Mr. Delatte, Mr. Horgan, Mr. Gielen, Mr. LeBeouf, Ms. Luton, Mr. Irelan, Mr. Latino, and Mr. Davis; AGAINST: None; ABSENT: None; ABSTAINED: None; RECUSED: None.

Motion was made by Mr. LeBeouf to add an agenda item for review, discussion, and potential approval of a Board policy and procedure for Americans with Disabilities Act (ADA) requirements for compliance with Act 103 of the 2022 Louisiana legislative regular session, seconded by Mr. Horgan, and passed by voice vote- FOR: Mr. Delatte, Mr. Horgan, Mr. Gielen, Mr. LeBeouf, Ms. Luton, Mr. Irelan, Mr. Latino, and Mr. Davis; AGAINST: None; ABSENT: None; ABSTAINED: None; RECUSED: None.

A proposed draft of policy and procedures for ADA requirements based on the sample version available from the Office of the ADA Coordinator was presented. Review and general discussion was held. Motion was made by Mr. LeBeouf to approve the policy and procedures for Americans with Disabilities Act (ADA) requirements in compliance with Act 103 of the 2022 Louisiana legislative regular session as presented, seconded by Mr. Horgan, and passed by voice vote- FOR: Mr. Delatte, Mr. Horgan, Mr. Gielen, Mr. LeBeouf, Ms. Luton, Mr. Irelan, Mr. Latino, and Mr. Davis; AGAINST: None; ABSENT: None; ABSTAINED: None; RECUSED: None.

Page 8

The next Board meeting had been tentatively scheduled for Tuesday, December 6, 2022; this is the annual budgetary meeting.

XI. Adjournment

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

The meeting adjourned at approximately 1:30 pm.

Approved and accepted by the full Board -

Date: 12/13/2c

Trion Horgan

Board Secretary Treasurer

George Lovecchio

Executive Director