

Public Session Meeting Minutes

Board Members Present by video or phone:

Eugene Antonell, Chair (EA)
Stanley Zoll (SZ)
Loleata Wigall, Secretary (LW)
Camille Catalano (CC)

Staff Present by video or phone:

Kristina Gasson, Board Counsel
Thomas Burke, Executive Director
Lisa Guglietta, DOL
Eboni Lewis, DOL

Members of the Public Present by video or phone:

Jessica Niedzwiecki
Peter Lee

Called To Order:

- The meeting was called to order at 10:06 a.m. by EA.

Board Business:

- Review of Minutes:
 - July 30, 2021
A MOTION was made by CC to approve the public session minutes of the July 30, 2021 board meeting as amended. LW seconded. The motion passed on a roll call vote: CC – “Yes”; EA – “Yes”; SZ – “Yes”; LW – “Yes”.
- Report from Executive Director, Thomas Burke
 - Mr. Burke introduced new Executive Director, Lisa Guglietta, and Associate Executive Director, Eboni Lewis. Mr. Burke shared that this would be his last meeting as Executive Director and proposed the Board meeting dates for 2022.
- Approval of 2022 Board Meeting dates
A MOTION was made by LW to approve the proposed meeting dates of 1/7/22, 4/15/22, 7/15/22 and 10/21/22. SZ seconded. The motion passed on a roll call vote: CC – “Yes”; EA – “Yes”; SZ – “Yes”; LW – “Yes”.
- Report from Legal Counsel Kristina Gasson
 - Ms. Gasson reported that in-person meetings are to resume in April of 2022, will keep the board updated on any changes.
 - Ms. Gasson reported that she will keep the board apprised on any new information in regard to the Department of Public Health move.
 - Ms. Gasson reported that she is monitoring the FDA implementation and more would be discussed about OTC Hearing Aids later in the meeting.

Apprenticeship Extension Requests

- **Jessica Niedzwiecki**- Ms. Niedzwiecki met with the Board to request a formal extension of her hearing instrument apprenticeship. This is her first formal request to the Board for an extension.
A MOTION was made by CC to grant an 18-month extension of Ms. Niedzwiecki’s

apprenticeship. LW seconded. The motion passed on a roll call vote: CC – “Yes”; EA – “Yes”; SZ – “Yes”; LW – “Yes”.

Discussion:

- **Over the Counter Hearing Aids Update**

Ms. Gasson reported that the FDA regulations were eliminating the medical evaluation for many users, which necessitates changes in the Board’s regulations. Ms. Gasson updated the Board that OTC devices were for mild to moderate hearing loss for patients 18 and older. The public is invited to provide comments to the FDA, and the new rules will go into effect in 10 months. During the discussion of the FDA regulations, the Board discussed advertisements for hearing devices that were already on the market that may violate the Board’s statutes or regulations. A motion was made by LW to delegate EA and CC to work with staff to document evidence of statute violations for opening a complaint by the Board. CC seconded the motion. The motion passed unanimously on a roll call vote. Ms. Gasson recommended the Board put this item on the next agenda for the 1/7/2022 meeting and the Board will send comments individually to staff.

- **Review of Board Regulations, 265 CMR 2.00 – 10.00**

Ms. Gasson noted that a review of the Board’s regulations may now commence at the next two meetings now that FDA guidance has been received. Ms. Gasson reported that there are new definitions and a need to differentiate between OTC and medical devices. There will be a need to discuss limitations on audiograms.

Open Session for Topics not reasonably anticipated 48 hours in advance of the meeting:

- Licensee Peter Lee attended the meeting by phone at 11:16 a.m. A new patient who was in poor health lost his hearing aid. The patient’s family obtained a new hearing aid that required programming. It was not initially programmed because the patient did not have a recent audiogram. The Board recommended Mr. Lee do an audiogram test on the patient himself and document the procedure.

At 11:31 a.m., a MOTION was made by LW to adjourn the open meeting. CC seconded. The motion passed on a roll call vote: CC – “Yes”; EA – “Yes”; SZ – “Yes”; LW – “Yes”.

Respectfully Submitted,

Lisa M. Guglietta
Executive Director

Documents used in Public Session:

- Agenda for November 5, 2021 Board meeting
- Minutes of July 30, 2021 Board meeting
- Apprenticeship Extension request from Jessica Niedzwiecki

- FDA News Release: FDA Issues Landmark Proposal to Improve Access to Hearing Aid Technology for Millions of Americans
- FDA: Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products
- 265 CMR 2.00-10.00.