Livingston HEARING AIDS

5303 50th Street • Lubbock, Texas 79414
p: (806) 799-8950 • f: (806) 799-8939

June 28, 2019

RE: HB48 and NM Speech-Language Pathology, Audiology and Hearing Aid Dispensing Practices Board rule drafting

To Whom It May Concern,

My name is Richard Davila, II. I have been fitting and dispensing hearing instruments since October of 1990. I am licensed to fit and dispense hearing instruments in New Mexico, Texas & Arizona with an application pending in Oklahoma. I have been Board Certified in Hearing Instrument Sciences since 1995. I completed the Audioprosthology (ACA) requirements in 2000. I am the President of Livingston Hearing Aid Center. Livingston is the largest independent retailer of hearing instruments in the United States with over 250 team members and 90+ locations in New Mexico, Arizona, Texas and Colorado.

I was appointed by Governor Rick Perry to serve on the Licensing Board in Texas from 2002-2008. I was appointed a second time by Governor Perry to serve on the Licensing Committee from 2012 to 2018, at which time I was reappointed to serve an additional six years by Governor Greg Abbott. My current appointment will expire in 2024. I helped rewrite the Licensing Law in Texas during the second sunset review in 1993. I testified before the Texas Senate Committee and Sunset Advisory Commission in 2005 and again in 2011, as an advocate for licensure and how it relates to consumer protection. I rewrote the practical licensing exam in Texas in 2007 and then participated in updating the verification section of same in 2013. I helped rewrite the New Mexico practical exam in 2011.

In March of 2019, Governor Grisham signed HB48, requiring the Speech-Language Pathology, Audiology and Hearing Aid Dispensing Practices Board to adopt ethics rules requiring audiologists and dispensers to educate hearing aid purchasers (at the time of the initial exam for possible sale and fitting of a hearing aid) about the latest hearing aid options that can provide a direct connection between ALD technology and hearing aids. This is great news for the hearing-impaired community in New Mexico.

I have reviewed the proposed language written by the Speech-Language Pathology, Audiology and Hearing Aid Dispensing Practices Board to comply with the new mandate detailed in HB48. Respectfully, I would like to offer my opinion on the importance of verifying that the client has been informed and a method by which it can be accomplished. I would like to advocate that the new mandate be acknowledged by consumers with their initials at the time of the initial exam for possible sale and fitting of a hearing aid. This has proven to be a very successful process in the past.

If you have served on the NM Speech-Language Pathology, Audiology and Hearing Aid Dispensing Practices Board for any length of time you have undoubtably recognized that the overwhelming majority of consumer complaints to State Boards (in Texas, Colorado, Arizona, and New Mexico) involve the return privilege. For this reason, many business owners, and some licensing acts require a separate acknowledgement of the return privilege in addition to the consumer's signature on a purchase agreement or bill of sale for hearing instruments. This is done to "verify" that the patient has been informed about this very important information. Hearing aids are used to treat disease or condition. Thus, they are devices under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. 321(h), and have been

regulated by the FDA since 1976. From 1977 to December 2016, the FDA required consumers to undergo a medical examination in order to procure a hearing aid, or the execution of a waiver that informs patients that they may be making a mistake by skipping a medical examination. This information was acknowledged in most cases by the consumer's additional/separate signature or initials on the purchase agreement or bill of sale for hearing instruments. This practice was implemented to "verify" that the patient had been informed about the FDA requirement (21 C.F.R 801.420(c)(3)). Similarly, in an effort to "verify" that consumers have been informed about the latest hearing aid options that can provide a direct connection between ALD technology and hearing aids (HB48) I strongly urge the Board to consider a similar acknowledgement.

With this in mind I would like to strongly recommend that the rule drafted be modified to include a provision to "verify" that the hearing aid buyer be informed of the new HB48 mandate. I would like to respectfully offer my support of the following language proposed by the Committee of Communication Access in New Mexico:

> "(a)...examination and recommendation was made as a hearing aid dispenser or fitter and not as a medical diagnosis or prescription; the receipt must also contain the following language: 'I have been informed of hearing aid options that can provide a direct connection between hearing aids and assistive listening systems that comply with the latest standards for accessible design adopted by the United States Department of Justice in accordance with the Federal Americans with Disabilities Act of 1990, as amended. I am aware that the hearing instrument(s) referenced above include(s) / exclude(s) (circle one) such technology _____ (Buyer's initials)'"

In conclusion, I believe that the mandate of HB48 is so substantial to the hearing-impaired community that patients/consumers should acknowledge that they have been informed separately with their initials. Thank you in advance for your time and attention to my comments. Please do not hesitate to contact me should you have any questions regarding my remarks contained herein.

Respectfully Submitted,

Richard Davila, II
President