

FLORIDA BOARD OF HEARING AID SPECIALISTS AND FLORIDA BOARD OF SPEECH-LANGUAGE PATHOLOGY AND AUDIOLOGY

GENERAL BOARD MEETING

MEETING MINUTES

November 2, 2022, at 2:00 P.M. ET



Leanne Polhill, H.A.S., Chair
Randy Ellsworth, H.A.S., Vice-Chair
Frederick Rahe, Au.D., Chair
Sergio Guerreiro, Au.D., Vice-Chair

Janet Hartman, Chief of General Operations
Ashleigh K. Irving, Executive Director
Danielle Terrell, Executive Director



Please note that the meeting minutes reflect the actual order that agenda items were discussed during the meeting and may differ from the agenda outline.

**I. CALL TO ORDER
A. ROLL CALL**

The meeting was called to order on Wednesday, November 2, 2022, at approximately 2:00 P.M. EST by Leanne E. Polhill, H.A.S., Chair of the Florida Board of Hearing Aid Specialists.

Roll Call was conducted by Ashleigh Irving, Executive Director of the Florida Board of Hearing Aid Specialists.

HAS BOARD MEMBERS

Leanne E. Polhill, H.A.S., Chair
Randy Ellsworth, H.A.S., Vice-Chair
Pamela Dechmerowski, H.A.S.
Dean Easterwood, H.A.S.
Thomas Hollern

SLPA BOARD MEMBERS

Frederick Rahe, Au.D., Chair
Sergio Guerreiro, Au.D., Vice-Chair
Dania Lopez Ramirez, MS CCC SLP/FSL
Sherry S. Jordan, Ed.S
Niva Falk, MS CCC SLP

HAS BOARD STAFF

Ashleigh K. Irving, Executive Director
Eric Pottschmidt, Program Operations Administrator

SLPA BOARD STAFF

Danielle Terrell, Executive Director
Carol Taylor, Program Operations Administrator

HAS BOARD COUNSEL

Dianne Guillemette, Assistant Attorney General

SLPA BOARD COUNSEL

Ronald "Tom" Jones, Assistant Attorney General

Opening remarks were read by Danielle Terrell, Executive Director of the Florida Board of Speech-Language Pathology and Audiology.

II. F.D.A. RULE ESTABLISHING OVER-THE-COUNTER (OTC) HEARING AIDS

(TS 00:06:35 Minutes) Ms. Polhill directed the Board members' attention to the meeting agenda, noting the inclusion of the 65-page FDA Final Rule establishing over-the-counter (OTC) hearing aids, along with some additional information pertaining to the rule such as the most recent letter to state officials issued by the FDA clarifying the rule language and specifically the use of the word "prescription" in the rule.

(TS 00:07:20 Minutes) Ms. Polhill noted the importance of the Florida Board of Speech-Language Pathology and Audiology and the Florida Board of Hearing Aid Specialists having the same understanding or knowledge of this rule as licensed professionals dispensing hearing aids in the State of Florida.

(TS 00:07:32 Minutes) Ms. Polhill stated that she was aware that there was conversation taking place regarding integrating the word "prescription" into the Florida Board of Hearing Aid Specialists (HAS) rule language regarding hearing aids, and that this was discussed during the last HAS Board meeting. Ms. Polhill then solicited input from the Board members present.



(TS 00:08:10 Minutes) Ms. Guillemette introduced herself as Board Counsel for the Florida Board of Hearing Aid Specialists as well as introducing Mr. Jones as Board Counsel for the Florida Board of Speech-Language Pathology and Audiology, and stated that her understanding of the rules and the rule changes was that until the Florida legislation is changed, it would not be appropriate for the Board to change their rule language as the Florida rules flow from the Florida Statutes.

(TS 00:08:57 Minutes) Ms. Guillemette noted that the FDA change is in the form of a rule, therefore a federal rule was competing with Florida Statutes, and she believed that the Florida rules would have to follow Florida Statutes under that context. Ms. Polhill then stated that it was her understanding that the federal rule would preempt state law and state rule, to which Ms. Guillemette responded that this was not the case. Ms. Guillemette clarified that federal law would preempt state law, but that federal rule does not preempt.

(TS 00:09:46 Minutes) Ms. Guillemette shared that Mr. Jones spoke with the Joint Administrative Procedures Committee (JAPC) which conducts the review of rule language to ensure it is consistent with Florida law. Ms. Guillemette stated that JAPC's response was that due to the foreseeable changes to the Florida law, the Florida rules could be changed in anticipation of the change to Florida law. Ms. Guillemette then stated that though she had not yet prepared a rule mark-up to include the word "prescription" in the HAS rule language, based on this new information from JAPC she could prepare this proposed rule language to be presented at the next HAS Board meeting.

(TS 00:11:00 Minutes) Mr. Jones added that the SLPA Board met during the previous month and voted to approve the changes to the appropriate rules with the addition of the word "prescription" where appropriate before "hearing aid" or "hearing aids". Ms. Polhill noted the importance of the two Boards having the same timing for making these changes, and Ms. Guillemette then suggested that she will coordinate with Mr. Jones to ensure that the rule language gets adopted and becomes effective on the same date.

(TS 00:12:09 Minutes) Dr. Rahe introduced himself and stated that the concern of the SLPA Board was that the FDA Reauthorization Act created a class of OTC hearing aids which were exempt from any state requirements for testing, and that this leaves Florida Statutes in conflict as they require that any person getting a hearing aid must have tests conducted. Dr. Rahe added that until the Florida Statute is changed, the Board's solution to this was to by rule define the use of the terms "prescription" and "OTC" in order to establish by rule that there is a class of hearing aids that don't require professional intervention, as well as prescription hearing aids that do.

(TS 00:14:58 Minutes) Ms. Terrell then stated that the Department is moving forward with statutory changes as it relates to narrowing the scope to only prescription hearing aids. Ms. Terrell added that an analysis of that has been conducted and that the Department has provided a packet for the legislative changes, however she was unsure of the exact step in the process they were at currently with the statutory changes.

(TS 00:16:36 Minutes) Ms. Irving noted that Ms. Jessica Holley, MQA Legislative Liaison, was present on the call and stated that she may have some additional information to offer regarding the current status of the statutory changes. Ms. Holley added that the information provided by Ms. Terrell and Ms. Irving was the extent of the information that she had available at present, but that the proposed language will be included in part of the main DOH bill.



(TS 00:18:46 Minutes) Ms. Terrell added that a statute takes much longer to take effect and to go through the legislative process than a rule and briefly summarized the legislative process for statutory proposals. Ms. Holley noted that should the proposed statutory language move all the way through the legislature process and be signed by the Governor, this would go into effect July 1, 2023.

(TS 00:20:53 Minutes) Dr. Rahe inquired regarding the process of adopting the rule changes and whether they would be voting at the present meeting as separate boards should they wish to approve the proposed language. Ms. Terrell replied that the SLPA Board voted at the October 2022 meeting to update the rule language with the inclusion of the word “prescription” preceding the words “hearing aid” or “hearing aids”, as well as voting to proceed with the rulemaking process and to open Rule 64B20-8.009, F.A.C., regarding the Thirty-Day Trial Period, for development. Ms. Guillemette added that the HAS Board would be voting at the next meeting [scheduled for January 27, 2023].

(TS 00:23:34 Minutes) Ms. Polhill requested to call a special meeting prior to the January 2023 meeting in order to vote on updating the rule language, to which Ms. Irving responded in agreement and that she would correspond with Ms. Guillemette to see when the proposed language would be available to review.

(TS 00:26:18 Minutes) Discussion took place between Dr. Guerreiro, Ms. Guillemette, Ms. Terrell, Ms. Polhill, Mr. Jones, and Dr. Rahe regarding the inclusion of the proposed rule language relating to prescriptive devices in the agenda materials.

(TS 00:30:01 Minutes) Ms. Polhill opened the floor for public comment on this agenda topic specifically. No comment from the public was made at this time.

(TS 00:30:56 Minutes) Ms. Dechmerowski inquired if a motion by the HAS Board was needed to open Chapter 64B6, F.A.C., for development. Ms. Guillemette confirmed that this could be done during the present meeting.

After discussion, the HAS Board took the following action:

Motion: by Ms. Dechmerowski to open Chapter 64B6, F.A.C., for development.
Second: by Mr. Easterwood.
Vote: passed unanimously.

(TS 00:31:53 Minutes) Ms. Guillemette noted that SERC questions were not needed at this point until the proposed language is available.

III. CHAPTER 64B6, F.A.C. AND CHAPTER 64B20, F.A.C.

(TS 00:32:05 Minutes) Dr. Rahe introduced this agenda item, explaining that the concern being addressed by many audiologists involving Rule 64B20-8.009, F.A.C., regarding the Thirty-Day Trial Period and Refund, was that the rule was written in 1994 and reflects the average price of a hearing aid was approximately \$500. Dr. Rahe noted that this concern was that it could be unfair to the professional by limiting the fees that the professional can charge for fitting and dispensing a hearing aid based on these monetary figures from 1994. Dr. Rahe stated that while this has been discussed by the SLPA Board, they have not yet adopted final recommended rule, but think it best to remove the “not to exceed \$150.00” and “\$200” from the rule language to essentially not value the worth of services by rule, but to let the marketplace determine the value.



(TS 00:34:45 Minutes) Ms. Guillemette stated that there was a statute for HAS which addressed this specifically by stating that it should not exceed 5% of the total purchase price of the prescription hearing aid alone, and that if this is left up to the market price, they may have pushback from JAPC. Ms. Guillemette suggested that they mimic the verbiage in the statute that it should not exceed 5% of the total purchase price of the prescription hearing aid alone rather than leaving it up to market price.

(TS 00:35:47 Minutes) Dr. Guerreiro addressed Ms. Guillemette, noting that in the statute it states that the professional may charge 5% of the cancellation fee not to exceed the 5% of the total charge of the hearing aid alone. Dr. Guerreiro added that to limit the amount of what professionals charge for their services of ear molds, fitting, verification, and follow-ups for the next five years, was in his opinion not right as a free trade and as practicing professionals, they put a value on their time. Dr. Guerreiro reemphasized the importance of the inclusion of the words “of the hearing aid alone” rather than leaving it at “the total purchase price”.

(TS 00:37:32 Minutes) Ms. Guillemette, Dr. Guerreiro, and Dr. Rahe held additional discussion regarding possible rule language development regarding the Thirty-Day Trial Period and Refund and the possibility of removing the phrase “at a minimum” from the proposed rule language to allow the rule to be in accordance with the statute.

(TS 00:47:25 Minutes) After discussion, the SLPA Board took the following action:

- Motion:** by Dr. Guerreiro to adopt the proposed language for Rule 64B20-8.009, F.A.C., with the removal of the phrase “at a minimum”.
- Second:** by Ms. Falk.
- Vote:** passed unanimously.

(TS 00:48:52 Minutes) Mr. Jones stated that the SERC Questions would need to be asked as the Board has voted on a rule change. Ms. Guillemette then noted that the SERC Questions would likely be needed as well for HAS due to the potential for the costs of the consumer to be increased. Dr. Rahe and Ms. Terrell agreed, however, that this rule change would not appear to affect regulatory costs. Ms. Guillemette encouraged the SLPA Board to provide a reason as to why this rule change will not affect regulatory costs for the record.

SERC Questions

Will the proposed rule amendments have adverse impact on small businesses, or will the proposed rule amendments be likely to directly or indirectly increase regulatory costs to any entity including government in excess of \$200,000 in the aggregate in Florida within one year after implementation of the rule?

- Motion:** by Dr. Guerreiro to vote “No.”
- Second:** by Ms. Lopez Ramirez.
- Vote:** passed unanimously.

Should a violation of this rule or any part of this rule be designated a minor violation?

- Motion:** by Dr. Guerreiro to vote “No.”
- Second:** by Ms. Falk.
- Vote:** passed unanimously.



Would a Sunset provision be applicable to this Rule?

- Motion:** by Dr. Guerreiro to vote “No.”
- Second:** by Ms. Lopez Ramirez.
- Vote:** passed unanimously.

(TS 00:55:56 Minutes) Ms. Terrell noted that as statutory language is proposed it must go through a process and can change, adding that some of what the Boards are discussing in statute must be stricken. Ms. Terrell stated that Ms. Holley may want to elaborate on this, but that they were currently proposing to strike from Chapter 484.0512(2), F.S.: “Such rule shall be effective on or before December 1, 1994. Should the board fail to adopt such rule, a licensee may not charge a cancellation fee which exceeds 5 percent of the total charge for a hearing aid alone.” Ms. Guillemette and Dr. Rahe clarified that as they have now adopted such a rule, therefore the sentence which has been proposed to be removed would no longer be necessary in statute.

(TS 00:58:30 Minutes) Ms. Guillemette explained the changes in the proposed rule language for Rule 64B6-6.001, F.A.C., to the Board, detailing that there were four portions of the rule that would have the word “prescription” added before any mention of “hearing aid” or “hearing aids” based on the proposed language to mirror the language just passed by SLPA.

(TS 00:59:13 Minutes) After discussion, the HAS Board took the following action:

- Motion:** by Mr. Ellsworth to adopt the proposed language for Rule 64B6-6.001, F.A.C., as discussed.
- Second:** by Ms. Dechmerowski.
- Vote:** passed unanimously.

SERC Questions

Will the proposed rule amendments have adverse impact on small businesses, or will the proposed rule amendments be likely to directly or indirectly increase regulatory costs to any entity including government in excess of \$200,000 in the aggregate in Florida within one year after implementation of the rule?

- Motion:** by Mr. Ellsworth to vote “No.”
- Second:** by Ms. Dechmerowski.
- Vote:** passed unanimously.

Should a violation of this rule or any part of this rule be designated a minor violation?

- Motion:** by Ms. Dechmerowski to vote “No.”
- Second:** by Mr. Ellsworth.
- Vote:** passed unanimously.



Would a Sunset provision be applicable to this Rule?

Motion: by Ms. Dechmerowski to vote “No.”
Second: by Mr. Ellsworth.
Vote: passed unanimously.

IV. PUBLIC COMMENTS

(TS 01:02:58 Minutes) Dr. Rahe called for public comment. Julia Andrews introduced herself as an audiologist in the state and noted that much of the national advisements given from many different avenues have stated that the FDA rule would preempt state statutes and rules, requesting clarification as it was mentioned earlier in the meeting that the FDA rule would only preempt rule and not statute. Ms. Guillemette replied that she has researched this, and a federal rule does not preempt a Florida Statute. Ms. Guillemette followed by stating that while we are bound to the federal rule, Florida rule cannot be changed until the Florida Statutes are changed.

(TS 01:05:00 Minutes) Dr. Rahe added that the clarification letter received from the FDA during the previous week stated that the FDAs rule would not preempt state laws which required professional intervention, hearing tests, and/or medical clearance for prescription hearing aids, and that the FDA rule would only preempt state laws or rules that would attempt to put such restrictions on OTC hearing aids. Dr. Rahe, Ms. Andrews, Ms. Guillemette, and Ms. Holley continued to have discussion regarding the legislative process for statute.

(TS 01:15:25 Minutes) Laura Pratesi provided a comment before the Board expressing her appreciation as a small private practice owner to the Board members for the amendment made to the rule language during the present meeting, citing that there are certain costs that are incurred by clinics that are nonrefundable.

V. ADJOURNMENT

(TS 01:16:53 Minutes) After discussion, the Board took the following action:

Motion: by Dr. Guerreiro to adjourn the meeting.
Second: by Dr. Rahe.
Vote: passed unanimously.