



Scott Walker, Governor
Dave Ross, Secretary

HEARING AND SPEECH EXAMINING BOARD
Room 121A, 1400 E. Washington Avenue, Madison
Contact: Brittany Lewin (608) 266-2112
APRIL 14, 2014

The following agenda describes the issues that the Board plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. Please consult the meeting minutes for a description of the actions of the Board.

AGENDA

1:00 P.M.

OPEN SESSION – CALL TO ORDER – ROLL CALL

A. Adoption of Agenda (1-4)

B. Approval of Minutes from January 13, 2014 (5-10)

C. Administrative Updates

- 1) Staff Updates
- 2) July 18 Board Member Training

E. Education and Examination Matters – Discussion and Consideration

- 1) Exam Process

F. Legislative and Administrative Rule Matters – Discussion and Consideration

- 1) Scope Statement amending HAS 6 and 7 Relating to Licensure and Renewal (11-14)
- 2) Illinois Legislation Regarding Definitions of Limits of Internet and Mail Order Hearing Instruments (15-28)

G. Practice Matters – Discussion and Consideration

- 1) TMJ Clinical Study and Patient Information (29-36)
- 2) Review of Letter Regarding Ear Candling

H. Items Added After Preparation of Agenda

- 1) Introductions, Announcements and Recognition
- 2) Presentations of Petition(s) for Summary Suspension
- 3) Presentation of Proposed Stipulation(s), Final Decision(s) and Order(s)
- 4) Presentation of Final Decisions
- 5) Disciplinary Matters
- 6) Executive Director Matters
- 7) Education and Examination Matters
- 8) Credentialing Matters
- 9) Class 1 Hearing(s)

- 10) Practice Matters
- 11) Legislation/Administrative Rule Matters
- 12) Liaison Report(s)
- 13) Informational Item(s)
- 14) Speaking Engagement(s), Travel or Public Relation Request(s)

I. Public Comments

CONVENE TO CLOSED SESSION to deliberate on cases following hearing (s. 19.85(1)(a), Stats.); to consider licensure or certification of individuals (s. 19.85(1)(b), Stats.); to consider closing disciplinary investigations with administrative warnings (ss. 19.85 (1)(b), and 440.205, Stats.); to consider individual histories or disciplinary data (s. 19.85 (1)(f), Stats.); and to confer with legal counsel (s. 19.85(1)(g), Stats.)

J. Presentation and Deliberation on Proposed Stipulations, Final Decisions and Orders by the Division of Legal Services and Compliance (DLSC)

- 1) 12 HAD 010, James J. Gillis **(37-42)**
 - o Case Advisor – Samuel Gubbels
- 2) 13 HAD 008, Lindsey Jacob **(43-48)**
 - o Case Advisor – Patricia Willis

K. Presentation and Deliberation on Proposed Administrative Warnings by the Division of Legal Services and Compliance (DLSC)

- 1) 13 HAD 002, A.G. **(49-50)**
 - o Case Advisor – Patricia Willis
- 2) 13 HAD 006, M.R.H. **(51-52)**
 - o Case Advisor – Patricia Willis

L. Presentation and Deliberation of Proposed Final Decision and Order and Consideration of Objections

- 1) 13 HAD 001/SPS-13-0047, Scott C. Chase **(53-64)**
 - o Case Advisor – Steven Klapperich

M. DLSC Matters

- 1) Case Status Report **(65-66)**
- 2) Case Closing(s)
 - a. 13 HAD 004 (R.S.D.) **(67-70)**
 - b. 13 HAD 013 (C.N. and S.S.) **(71-74)**

N. Deliberation of Items Received After Preparation of the Agenda

- 1) Disciplinary Matters
- 2) Education and Examination Matters
- 3) Credentialing Matters
- 4) Class 1 Hearings
- 5) Monitoring Matters
- 6) Professional Assistance Procedure (PAP) Matters
- 7) Petition(s) for Summary Suspensions
- 8) Petition(s) for Extension of Time
- 9) Proposed Stipulations, Final Decisions and Orders
- 10) Administrative Warnings
- 11) Proposed Decisions
- 12) Matters Relating to Costs
- 13) Motions
- 14) Petitions for Rehearing

- 15) Case Closings
- 16) Appearances from Requests Received or Renewed
- 17) License Ratification

O. Consulting with Legal Counsel

RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

Vote on Items Considered or Deliberated Upon in Closed Session, if Voting is Appropriate

ADJOURNMENT

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**HEARING AND SPEECH EXAMINING BOARD
MEETING MINUTES
JANUARY 13, 2013**

- PRESENT:** Samuel Gubbels, Doreen Jensen, Steven Klapperich, Scott Larson, Tom Krier, and Barbara Johnson
- Excused:** Thomas Sather, Patricia Willis,
- STAFF:** Brittany Lewin, Executive Director; Matthew Guidry Bureau Assistant; and other Department Staff

CALL TO ORDER

The Chair, called the meeting to order at 1:20 p.m. A quorum of six (6) was confirmed.

ADOPTION OF AGENDA

- MOTION:** Samuel Gubbels moved, seconded by Doreen Jensen, to adopt the agenda as amended. Motion carried unanimously.

APPROVAL OF MINUTES

- MOTION:** Doreen Jensen moved, seconded by Samuel Gubbels, to approve the minutes of October 14, 2013 as published. Motion carried unanimously.

ELECTION OF OFFICERS

CHAIR

NOMINATION: Steven k nominated Doreen Jensen for the Office of Chair. Nomination carried by unanimous consent.

Executive Director Brittany Lewin called for other nominations three (3) times.

Doreen Jensen was elected as Chair.

VICE CHAIR

NOMINATION: Steven Klapperich nominated Samuel Gubbels for the Office of Vice Chair. Nomination carried by unanimous consent.

Executive Director Brittany Lewin called for other nominations three (3) times.

Samuel Gubbels was elected as Vice Chair.

SECRETARY

NOMINATION: Steven K nominated Thomas Sather for the Office of Secretary. Nomination carried by unanimous consent.

Executive Director Brittany Lewin called for other nominations three (3) times.

Thomas Sather was elected as Secretary.

MOTION: Steven moved, seconded by Thomas Krier, acknowledging the following 2014 Officer Election Results. Motion carried unanimously.

2014 OFFICER ELECTION RESULTS	
Chair	Doreen Jensen
Vice Chair	Samuel Gubbels
Secretary	Thomas Sather

Doreen Jensen assumes the role of Chair of the meeting.

Samuel Gubbels assumes the role of Vice Chair of the meeting.

Thomas Sather assumes the role of Secretary of the meeting.

APPOINTMENT OF LIAISONS AND COMMITTEE MEMBERS

The Chair appoints the following members to:

2014 LIAISON APPOINTMENTS	
Credentialing Liaison(s)	Patricia Willis, Thomas Sather, Steven Klapperich, Doreen Jensen, Scott Larson, Barbara Johnson, Samuel Gubbels
DLSC Monitoring Liaison(s)	Doreen Jensen
DLSC PAP Liaison(s)	Samuel Gubbels
Website Liaison(s)	Thomas Krier, Samuel Gubbels, Doreen Jensen, Thomas Sather
Practice Question Liaison(s)	Steven Klapperich, Patricia Willis, Barbara Johnson
Continuing Education (CE) Liaison(s)	Patricia Willis, Thomas Sather, Thomas Krier, Barbara Johnson
Exam Liaison(s)	Steven Klapperich, Doreen Jensen
Legislative Liaison(s)	Samuel Gubbels

2014 SCREENING PANEL APPOINTMENTS	
January- December 2014	Steven Klapperich, Barbara Johnson, Patricia Willis, Thomas Sather, Scott Larson

MOTION: Steven Klapperich moved, seconded by Samuel Gubbels, to acknowledge the appointments of the chair. Motion carried unanimously.

MOTION: Steven Klapperich moved, seconded by Doreen Jensen, that the Board delegates authority to the Chair to sign documents on behalf of the Board. In order to carry out duties of the Board, the Chair has the ability to delegate this signature authority to the Board’s Executive Director for purposes of facilitating the completion of assignments during or between meetings. Motion carried unanimously.

MOTION: Samuel Gubbels moved, seconded by Doreen Jensen, to adopt the Roles and Authorities Delegated to the Monitoring Liaison and Department Monitor document. Motion carried unanimously.

MOTION: Scott Larson moved, seconded by Thomas Krier, in order to facilitate the completion of assignments between meetings, the Board delegates its authority by order of succession to the Chair, highest ranking officer, or longest serving member of the Board, to appoint liaisons to the Department where knowledge or experience in the profession is required to carry out the duties of the Board in accordance with the law. Motion carried unanimously.

MOTION: Barbara Johnson moved, seconded by Doreen Jensen, to delegate authority to the Credentialing Liaison(s) to address all issues related to credentialing matters except potential denial decisions should be referred to the full Board for final determination. Motion carried unanimously.

EDUCATION AND EXAMINATION MATTERS

MOTION: Steven Klapperich moved, seconded by Scott Larson, to request that DSPTS Staff report a current exam process and provide information regarding potential implementation of a new exam process for the April meeting, and to Request Office of Education and Exam to provide each Board member with a copy of the current written exam by January 17, 2014. Motion carried unanimously.

MOTION Samuel Gubbels, seconded by Steven Klapperich, to request DSPTS staff draft a Scope Statement relating to the written examination, and designate Doreen Jensen to advise DSPTS staff. Motion carried unanimously.

LEGISLATIVE AND ADMINISTRATIVE RULE MATTERS

MOTION Steven Klapperich, seconded by Samuel Gubbels, to request DSPTS staff draft a Scope Statement revising HAS 6 relating to Licensure of Speech – Language Pathologist, Audiologist, and Temporary Licenses. Motion carried unanimously.

MOTION: Samuel Gubbels moved, seconded by Steven Klapperich, to designate Doreen Jensen and Samuel Gubbels to draft a letter expressing the Boards concerns about the practice of ear candling for review at the April Meeting. Motion carried unanimously.

CLOSED SESSION

MOTION: Samuel Gubbels moved, seconded by Doreen Jensen, to convene to closed session to deliberate on cases following hearing (s. 19.85(1)(a), Stats.); consider licensure or certification of individuals (s. 19.85(1)(a), Stats.); to consider closing disciplinary investigation with administrative warning (s. 19.85(1)(b), Stats. and 440.205, Stats.); to consider individual histories or disciplinary data (s. 19.85 (1)(f), Stats.); and, to confer with legal counsel (s. 19.85(1)(g), Stats.). Doreen Jensen, Chair; read the motion. The vote of each member was ascertained by voice vote. Roll Call Vote: Steven Klapperich – yes; Scott Larson – yes; Barbara Johnson – yes; Samuel Gubbels – yes; Thomas Krier – yes; and Doreen Jensen – yes. Motion carried unanimously.

The Board convened to Closed Session at 3:45 p.m.

RECONVENE TO OPEN SESSION

MOTION: Doreen Jensen moved, seconded by Barbara Johnson, to reconvene to Open Session. Motion carried unanimously.

The Board reconvened into Open Session at 4:48 p.m.

VOTING ON ITEMS CONSIDERED OR DELIBERATED ON IN CLOSED SESSION

MOTION: Samuel Gubbels moved, seconded by Doreen Jensen, to affirm all motions made in closed session. Motion carried unanimously.

PROPOSED STIPULATIONS, FINAL DECISIONS AND ORDERS

Steven Klapperich recused himself on deliberations and voting on the matter of 12HAD010, James J. Gillis.

MOTION: Samuel Gubbels moved, seconded by Barbara Johnson, to reject the Findings of Fact, Conclusions of Law, Order and Stipulation in the matter of disciplinary proceedings against James J. Gillis, (12 HAD 010). Motion carried.

MOTION: Scott Larson moved, seconded by Thomas Krier, to designate Samuel Gubbels as a case advisor in the matter of 12HAD010, James J. Gillis. Motion carried unanimously.

EXAM SCORES

MOTION: Samuel Gubbels moved, seconded by Steven Klapperich, that the Board ratify the scores from the January 13, 2014 exams and give Doreen Jensen the authorization to grant the licenses. Motion carried.

ADJOURNMENT

MOTION: Steven Klapperich moved, seconded by Thomas Krier, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 4:49 p.m.

DRAFT

**State of Wisconsin
Department of Safety & Professional Services**

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Sharon Henes Administrative Rules Coordinator		2) Date When Request Submitted: <i>2 April 2014</i>	
		Items will be considered late if submitted after 4:30 p.m. and less than: <ul style="list-style-type: none"> ▪ 10 work days before the meeting for Medical Board ▪ 14 work days before the meeting for all others 	
3) Name of Board, Committee, Council, Sections: Hearing and Speech Examining Board			
4) Meeting Date: 14 HAS 2014	5) Attachments: <input type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Discussion and Consideration of Scope Statement amending HAS 6 and 7 relating to licensure and renewal	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by _____ (name) <input type="checkbox"/> No	9) Name of Case Advisor(s), if required:	
10) Describe the issue and action that should be addressed:			
11) Authorization			
<i>Sharon Henes</i>		<i>2 April 2014</i>	
Signature of person making this request		Date	
Supervisor (if required)		Date	
Bureau Director signature (indicates approval to add post agenda deadline item to agenda)		Date	
Directions for including supporting documents: 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Board Services Bureau Director. 3. If necessary, Provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.			

STATEMENT OF SCOPE

Hearing and Speech Examining Board

Rule No.: HAS 6 & 7

Relating to: Licensure of speech-language pathologists, audiologists and temporary licenses and requirements for renewal of credentials granted by the Hearing and Speech Examining Board.

Rule Type: Permanent

1. Finding/nature of emergency (Emergency Rule only):

N/A

2. Detailed description of the objective of the proposed rule:

The objective of the proposed rule is to update the rule to reflect the changes due to Wisconsin 09 Act 356 relating to the requirements for licensure of audiologists, including temporary licenses, and removal of the requirement to provide certification of calibrations of audiometric equipment in order to renew a license.

In addition, the objective is to streamline, clarify and update the chapters HAS 6 and 7.

3. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:

Wisconsin 09 Act 356 modified the requirements for licensure of audiologists and removed the requirement to provide certification of calibrations of audiometric equipment in order to renew a license. The rule needs to be updated to reflect these changes in the statute.

The code also contains outdated practices and procedures. This proposed rule would review and update chapters HAS 6 and 7 in the interest of clarifying and streamlining the process while maintaining the health, safety and welfare of the public.

4. Detailed explanation of statutory authority for the rule (including the statutory citation and language):

§ 15.08(5)(b) Each examining board shall promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains, and define and enforce professional conduct and unethical practices not inconsistent with the law relating to the particular trade or profession.

§ 459.12(1) The examining board may make rules not inconsistent with the laws of this state which are necessary to carry out the intent of this chapter.

§ 459.12(2) The examining board shall promulgate rules establishing the frequency of the calibrations, the standards for the calibrations and the standards for the certifications required by s. 459.085.

§459.24(6)(c) A temporary license granted under this subsection is valid for a period designated in rules promulgated by the examining board. The rules may designate a period that terminates if an applicant fails to take the next available examination under s. 459.26(2)(a) or (b) for reasons other than inaction by the examining board or hardship.

5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule:

150 hours

6. List with description of all entities that may be affected by the proposed rule:

Hearing instrument specialists, speech language pathologists, audiologists, and applicants.

7. Summary and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule:

None

8. Anticipated economic impact of implementing the rule (note if the rule is likely to have a significant economic impact on small businesses):

Minimal to none

Contact Person: Sharon Henes, Administrative Rules Coordinator, (608) 261-2377

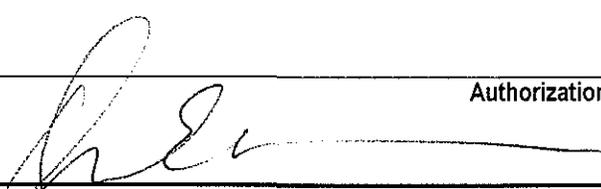
Authorized Signature

Date Submitted

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**State of Wisconsin
Department of Safety & Professional Services**

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: tDoreen Jensen		2) Date When Request Submitted: Items will be considered late if submitted after 4:30 p.m. and less than: • 10 work days before the meeting for Medical Board • 14 work days before the meeting for all others	
3) Name of Board, Committee, Council, Sections: Speech and Hearing Board			
4) Meeting Date: April 142014	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? <p style="text-align: center;">Illinois legislation regarding definitions limits of internet and mailorder hearing instruments</p>	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? <input type="checkbox"/> Yes by <input checked="" type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: <p style="text-align: center;">Discussion if board wishes to do so.</p>			
11) Authorization <div style="display: flex; justify-content: space-between;"> <div style="width: 60%;">  </div> <div style="width: 30%; text-align: right;"> <p style="font-size: 1.5em;">3-20-14</p> </div> </div>			
Signature of person making this request		Date	
Supervisor (if required)		Date	
Executive Director signature (indicates approval to add post agenda deadline item to agenda) Date			
Directions for including supporting documents: 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Board Services Bureau Director. 3. If necessary, Provide original documents needing Board Chairperson signature to the Executive Assistant prior to the start of a meeting.			

AN ACT concerning regulation.

**Be it enacted by the People of the State of Illinois,
represented in the General Assembly:**

Section 5. The Hearing Instrument Consumer Protection Act is amended by changing Sections 3 and 6 as follows:

(225 ILCS 50/3) (from Ch. 111, par. 7403)

(Section scheduled to be repealed on January 1, 2016)

Sec. 3. Definitions. As used in this Act, except as the context requires otherwise:

"Department" means the Department of Public Health.

"Director" means the Director of the Department of Public Health.

"License" means a license issued by the State under this Act to a hearing instrument dispenser.

"Licensed Audiologist" means a person licensed as an audiologist under the Illinois Speech-Language Pathology and Audiology Practice Act.

"National Board Certified Hearing Instrument Specialist" means a person who has had at least 2 years in practice as a licensed hearing instrument dispenser and has been certified after qualification by examination by the National Board for Certification in Hearing Instruments Sciences.

"Licensed physician" or "physician" means a physician

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licensed in Illinois to practice medicine in all of its branches.

"Trainee" means a person who is licensed to perform the functions of a hearing instrument dispenser in accordance with the Department rules and only under the direct supervision of a hearing instrument dispenser or audiologist who is licensed in the State.

"Board" means the Hearing Instrument Consumer Protection Board.

"Hearing instrument" or "hearing aid" means any wearable instrument or device designed for or offered for the purpose of aiding or compensating for impaired human hearing and that can provide more than 15 dB full on gain via a 2cc coupler at any single frequency from 200 through 6000 cycles per second, and any parts, attachments, or accessories, including ear molds.

"Hearing instrument" or "hearing aid" do not include batteries, cords, instrument or device designed, intended, or offered for the purpose of improving a person's hearing and any parts, attachments, or accessories, including earmold. Batteries, cords, and individual or group auditory training devices and any instrument or device used by a public utility in providing telephone or other communication services are excluded.

"Practice of fitting, dispensing, or servicing of hearing instruments" means the measurement of human hearing with an audiometer, calibrated to the current American National Standard Institute standards, for the purpose of making

selections, recommendations, adaptations, services, or sales of hearing instruments including the making of earmolds as a part of the hearing instrument.

"Sell" or "sale" means any transfer of title or of the right to use by lease, bailment, or any other contract, excluding wholesale transactions with distributors or dealers.

"Hearing instrument dispenser" means a person who is a hearing care professional that engages in the selling, practice of fitting, selecting, recommending, dispensing, or servicing of hearing instruments or the testing for means of hearing instrument selection or who advertises or displays a sign or represents himself or herself as a person who practices the testing, fitting, selecting, servicing, dispensing, or selling of hearing instruments.

"Fund" means the Hearing Instrument Dispenser Examining and Disciplinary Fund.

"Hearing Care Professional" means a person who is a licensed audiologist, a licensed hearing instrument dispenser, or a licensed physician.

(Source: P.A. 96-846, eff. 6-1-10.)

(225 ILCS 50/6) (from Ch. 111, par. 7406)

(Section scheduled to be repealed on January 1, 2016)

Sec. 6. Mail order and Internet sales. Nothing in this Act shall prohibit a corporation, partnership, trust, association, or other organization, maintaining an established business

address, from engaging in the business of selling or offering for sale hearing instruments at retail by mail or by Internet to persons 18 years of age or older who have not been examined by a licensed physician or tested by a licensed hearing instrument dispenser provided that:

(a) The organization is registered by the Department prior to engaging in business in this State and has paid the fee set forth in this Act.

(b) The organization files with the Department, prior to registration and annually thereafter, a Disclosure Statement containing the following:

(1) the name under which the organization is doing or intends to do business and the name of any affiliated company which the organization recommends or will recommend to persons as a supplier of goods or services or in connection with other business transactions of the organization;

(2) the organization's principal business address and the name and address of its agent in this State authorized to receive service of process;

(3) the business form of the organization, whether corporate, partnership, or otherwise and the state or other sovereign power under which the organization is organized;

(4) the names of the directors or persons performing similar functions and names and addresses of the chief executive officer, and the financial, accounting, sales,

and other principal executive officers, if the organization is a corporation, association, or other similar entity; of all general partners, if the organization is a partnership; and of the owner, if the organization is a sole proprietorship, together with a statement of the business background during the past 5 years for each such person;

(5) a statement as to whether the organization or any person identified in the disclosure statement:

(i) has during the 5 year period immediately preceding the date of the disclosure statement been convicted of a felony, pleaded nolo contendere to a felony charge, or been held liable in a civil action by final judgment, if such felony or civil action involved fraud, embezzlement, or misappropriation of property, and a description thereof; or

(ii) is subject to any currently effective injunctive or restrictive order as a result of a proceeding or pending action brought by any government agency or department, and a description thereof; or

(iii) is a defendant in any pending criminal or material civil action relating to fraud, embezzlement, misappropriation of property or violations of the antitrust or trade regulation laws of the United States or any state, and a description thereof; or

(iv) has during the 5 year period immediately

preceding the date of the disclosure statement had entered against such person or organization a final judgment in any material civil proceeding, and a description thereof; or

(v) has during the 5 year period immediately preceding the date of the disclosure statement been adjudicated a bankrupt or reorganized due to insolvency or was a principal executive officer or general partner of any company that has been adjudicated a bankrupt or reorganized due to insolvency during such 5 year period, and a description thereof;

(6) the length of time the organization and any predecessor of the organization has conducted a business dealing with hearing instrument goods or services;

(7) a financial statement of the organization as of the close of the most recent fiscal year of the organization. If the financial statement is filed later than 120 days following the close of the fiscal year of the organization it must be accompanied by a statement of the organization of any material changes in the financial condition of the organization;

(8) a general description of the business, including without limitation a description of the goods, training programs, supervision, advertising, promotion and other services provided by the organization;

(9) a statement of any compensation or other benefit given or promised to a public figure arising, in whole or in part, from (i) the use of the public figure in the name or symbol of the organization or (ii) the endorsement or recommendation of the organization by the public figure in advertisements;

(10) a statement setting forth such additional information and such comments and explanations relative to the information contained in the disclosure statement as the organization may desire to present.

(b-5) If a device being sold does not meet the definition of a hearing instrument or hearing device as stated in this Act, the organization shall include a disclaimer in all written or electronic promotions. The disclaimer shall include the following language:

"This is not a hearing instrument or hearing aid as defined in the Hearing Instrument Consumer Protection Act, but a personal amplifier and not intended to replace a properly fitted and calibrated hearing instrument."

(c) The organization files with the Department prior to registration and annually thereafter a statement that it complies with the Act, the rules issued pursuant to it, and the regulations of the Federal Food and Drug Administration and the Federal Trade Commission insofar as they are applicable.

(d) The organization files with the Department at the time of registration an irrevocable consent to service of process

authorizing the Department and any of its successors to be served any notice, process, or pleading in any action or proceeding against the organization arising out of or in connection with any violation of this Act. Such service shall have the effect of conferring personal jurisdiction over such organization in any court of competent jurisdiction.

(e) Before dispensing a hearing instrument to a resident of this State, the organization informs the prospective users that they ~~may~~ need the following for proper fitting of a hearing instrument:

(1) the results of an audiogram performed within the past 6 months by a licensed audiologist or a licensed hearing instrument dispenser; and

(2) an earmold impression obtained from the prospective user and taken by a licensed hearing instrument dispenser.

(f) The prospective user receives a medical evaluation or the organization affords the prospective user an opportunity to waive the medical evaluation requirement of Section 4 of this Act and the testing requirement of subsection (z) of Section 18, provided that the organization:

(1) informs the prospective user that the exercise of the waiver is not in the user's best health interest;

(2) does not in any way actively encourage the prospective user to waive the medical evaluation or test; and

(3) affords the prospective user the option to sign the following statement:

"I have been advised by (hearing instrument dispenser's name) that the Food and Drug Administration and the State of Illinois have determined that my best interest would be served if I had a medical evaluation by a licensed physician, preferably a physician who specialized in diseases of the ear, before purchasing a hearing instrument; or a test by a licensed audiologist or licensed hearing instrument dispenser utilizing established procedures and instrumentation in the fitting of hearing instruments. I do not wish either a medical evaluation or test before purchasing a hearing instrument."

(g) Where a sale, lease, or rental of hearing instruments is sold or contracted to be sold to a consumer by mail order, the consumer may void the contract or sale by notifying the seller within 45 business days following that day on which the hearing instruments were mailed by the seller to the consumer and by returning to the seller in its original condition any hearing instrument delivered to the consumer under the contract or sale. At the time the hearing instrument is mailed, the seller shall furnish the consumer with a fully completed receipt or copy of any contract pertaining to the sale that contains a "Notice of Cancellation" informing the consumer that he or she may cancel the sale at any time within 45 business

days and disclosing the date of the mailing and the name, address, and telephone number of the seller. In immediate proximity to the space reserved in the contract for the signature of the consumer, or on the front page of the receipt if a contract is not used, and in bold face type of a minimum size of 10 points, there shall be a statement in substantially the following form:

"You, the buyer, may cancel this transaction at any time prior to midnight of the 45th business day after the date of this transaction. See the attached notice of cancellation form for an explanation of this right."

Attached to the receipt or contract shall be a completed form in duplicate, captioned "NOTICE OF CANCELLATION" which shall be easily detachable and which shall contain in at least 10 point bold face type the following information and statements in the same language as that used in the contract:

"NOTICE OF CANCELLATION
enter date of transaction
.....
(DATE)

YOU MAY CANCEL THIS TRANSACTION, WITHOUT ANY PENALTY OR OBLIGATION, WITHIN 45 BUSINESS DAYS FROM THE ABOVE DATE.

IF YOU CANCEL, ANY PROPERTY TRADED IN, ANY PAYMENTS MADE BY YOU UNDER THE CONTRACT OR SALE LESS ANY NONREFUNDABLE RESTOCKING FEE, AND ANY NEGOTIABLE INSTRUMENT EXECUTED BY YOU WILL BE RETURNED WITHIN 10 BUSINESS DAYS FOLLOWING RECEIPT BY

THE SELLER OF YOUR CANCELLATION NOTICE AND ALL MERCHANDISE PERTAINING TO THIS TRANSACTION, AND ANY SECURITY INTEREST ARISING OUT OF THE TRANSACTION WILL BE CANCELLED.

IF YOU CANCEL, YOU MUST RETURN TO THE SELLER, IN SUBSTANTIALLY AS GOOD CONDITION AS WHEN RECEIVED, ANY GOODS DELIVERED TO YOU UNDER THIS CONTRACT OR SALE.

TO CANCEL THIS TRANSACTION, MAIL OR DELIVER A SIGNED AND DATED COPY OF THIS CANCELLATION NOTICE OR ANY OTHER WRITTEN NOTICE, OR SEND A TELEGRAM, TO (name of seller), AT (address of seller's place of business) AND (seller's telephone number) NO LATER THAN MIDNIGHT OF (date).

I HEREBY CANCEL THIS TRANSACTION.

(Date).....

.....

(Buyers Signature)"

The written "Notice of Cancellation" may be sent by the consumer to the seller to cancel the contract. The 45-day period does not commence until the consumer is furnished the Notice of Cancellation and the address and phone number at which such notice to the seller can be given.

If the conditions of this Section are met, the seller must return to the consumer the amount of any payment made or consideration given under the contract or for the merchandise less a nonrefundable restocking fee.

It is an unlawful practice for a seller to: (1) hold a

consumer responsible for any liability or obligation under any mail order transaction if the consumer claims not to have received the merchandise unless the merchandise was sent by certified mail or other delivery method by which the seller is provided with proof of delivery; (2) fail, before furnishing copies of the "Notice of Cancellation" to the consumer, to complete both copies by entering the name of the seller, the address of the seller's place of business, the seller's telephone number, the date of the mailing, and the date, not earlier than the 45th business day following the date of the mailing, by which the consumer may give notice of cancellation; (3) include in any contract or receipt any confession of judgment or any waiver of any of the rights to which the consumer is entitled under this Section including specifically his right to cancel the sale in accordance with the provisions of this Section; (4) misrepresent in any manner the consumer's right to cancel; (5) use any undue influence, coercion, or any other wilful act or representation to interfere with the consumer's exercise of his rights under this Section; (6) fail or refuse to honor any valid notice of cancellation and return of merchandise by a consumer and, within 10 business days after the receipt of such notice and merchandise pertaining to such transaction, to (i) refund payments made under the contract or sale, (ii) return any goods or property traded in, in substantially as good condition as when received by the person, (iii) cancel and return any negotiable instrument executed by

the consumer in connection with the contract or sale and take any action necessary or appropriate to terminate promptly any security interest created in the transaction; (7) negotiate, transfer, sell, or assign any note or other evidence of indebtedness to a finance company or other third party prior to the 50th business day following the day of the mailing; or (8) fail to provide the consumer of a hearing instrument with written information stating the name, address, and telephone number of the Department and informing the consumer that complaints regarding hearing instrument goods or services may be made to the Department.

(h) The organization employs only licensed hearing instrument dispensers in the dispensing of hearing instruments and files with the Department, by January 1 of each year, a list of all licensed hearing instrument dispensers employed by it.

(Source: P.A. 89-72, eff. 12-31-95.)

Section 99. Effective date. This Act takes effect upon becoming law.

**State of Wisconsin
Department of Safety & Professional Services**

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Karen Rude-Evans, Bureau Assistant, on behalf of Board Vice Chair Steve Klapperich		2) Date When Request Submitted: April 2, 2014 Items will be considered late if submitted after 4:30 p.m. on the deadline date: <ul style="list-style-type: none"> ▪ 8 business days before the meeting for paperless boards ▪ 14 business days before the meeting for all others 	
3) Name of Board, Committee, Council, Sections: Hearing and Speech Examining Board			
4) Meeting Date: April 14, 2014	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Practice Question: TMJ Clinical Study and Patient Information	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? <input type="checkbox"/> Yes (Fill out Board Appearance Request) <input checked="" type="checkbox"/> No	9) Name of Case Advisor(s), if required:	
10) Describe the issue and action that should be addressed: Informational item via Vice Chair Steve Klapperich regarding TMJ clinical study and patient information.			
11) Authorization			
Signature of person making this request		Date	
Supervisor (if required)		Date	
Executive Director signature (indicates approval to add post agenda deadline item to agenda) Date			
Directions for including supporting documents: 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director. 3. If necessary, Provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.			



Clinical Study Highlights

Registered at ClinicalTrials.gov: NCT00815776

- TMJ NextGeneration™ produced statistically significant reduction in pain from baseline within the first month, continuing throughout the study.
- Randomized controlled clinical trial (highest level of clinical evidence) demonstrated TMJ NextGeneration™ as effective as mouth splints.
- Excellent compliance for TMJ NextGeneration™ device, with patients wearing the device for an average of 18-21 hours/day during the clinical study.
- Bite Splint compliance with patients wearing the device was an average of only 7-8 hours/day
- A high level of patient satisfaction was observed, with 100% of subjects indicating excellent (71%) or good (29%) overall satisfaction with the device.

Roger N. Wixtrom, Ph.D, DABT

QUESTION #1: What is the TMJ NextGeneration™?

Response:

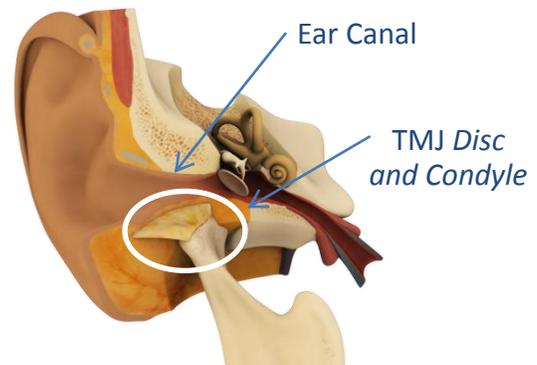
- The TMJ NextGeneration™ consists of a pair of prosthetic devices, with one device inserted in each of the ear canals, to reduce pain resulting from Temporomandibular Joint Disorder (TMJD)
- The devices conform to the shape of the ear canal when the jaw is in an open position
- The TMJ NextGeneration™ is hollow inside permitting full passage of sound



QUESTION #2: How does this device alleviate TMJD; what is the mechanism of action?

Response:

The two mechanisms believed to be responsible for the clinically proven effectiveness of the TMJ NextGeneration™ involve: 1) *“the ear insert supports the TMJ [Temporomandibular joint] and associated secondary musculature to reduce strain in the TMJ area”* (as cited in the device patent); and 2) the device provides *“cognitive awareness”* (consciously or subconsciously) to the wearer regarding para-functional habits (e.g., jaw clenching) that contribute to TMJD pain and dysfunction. Both the support and cognitive awareness mechanisms are the direct result of the proximity of the ear canal to the TMJ, and the change in the shape and volume of the ear canal as the jaw opens and closes. As can be seen in the figure, the ear canal (external auditory meatus) is located immediately posterior to the condyle and disc of the TMJ:



QUESTION #3: What was clinical study performed on the TMJ NextGeneration™?**Response:**

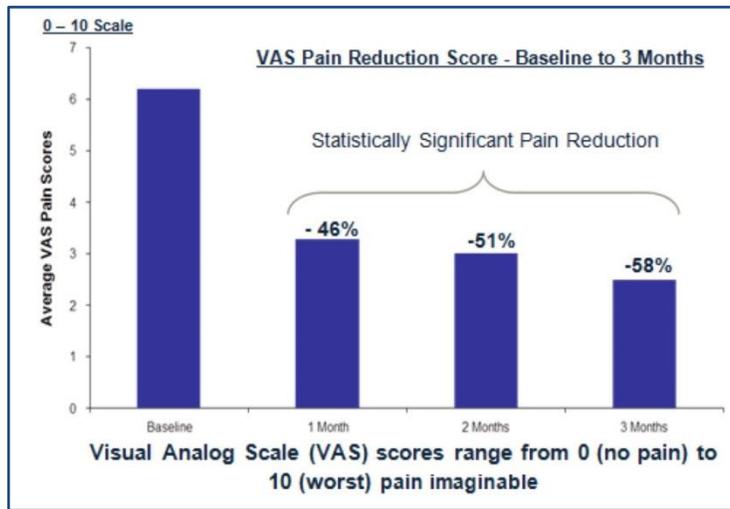
The clinical trial of the TMJ NextGeneration™ (formerly known as the CID) was a prospective, open-label, three-arm, randomized, and un-blinded clinical trial with a pre-treatment screening phase, baseline visit and three-month treatment phase. The objective of the trial was to characterize the safety profile and assess the effectiveness of the TMJ NextGeneration™ in treating subjects with Temporomandibular disorders. Two comparison treatment groups were incorporated into the study, one with patients wearing an intraoral stabilization splint, and the other with patients implementing a jaw exercise regimen. There were 60 patients in the TMJ NextGeneration™ group, 64 in the stabilization splint group, and 28 in the jaw exercise regimen group. Subjects enrolled in the study were those who met the inclusion criteria of having an RDC/TMJJD diagnoses that included at least one of the following: myofascial pain; arthralgia, or disc displacement with reduction; and a screening VAS pain score of >4. As mentioned previously, the distribution of these RDC/TMJJD diagnoses was very similar in all 3 treatment groups: I: Myofascial Pain (97-100%); II-a: Disc Displacement with Reduction (45-48%); and III-a: Arthralgia (55-61%). The instruments used to assess TMJD in this study included the Craniomandibular Index (CMI-RDC), the Symptom Severity Index (SSI), the VAS (Visual Analog Scale for pain), and the TMJ Scale™. Following a one-month baseline evaluation period, patients initiated treatment and were followed for 3 months, with follow-up visits and data collection occurring at 1, 2, and 3 months. The primary efficacy endpoint was non-inferiority of the TMJ NextGeneration™ to the stabilization splint in the reduction of the Craniomandibular Index (CMI) score from baseline to 3 months. The primary safety endpoint was to characterize the safety profile of the TMJ NextGeneration™ by collecting and reporting study-related adverse events. With respect to statistical methods, the null hypotheses for primary effectiveness was that the TMJ NextGeneration™ results in a reduction in CMI score of less than 80% of the reduction in score with the stabilization splint. The statistic used to test the null hypothesis of inferiority¹ was compared to the Student's t distribution with 2^{n-2} degrees of freedom, at a significance level of $\alpha = 0.05$.

¹ Laster, L.L. and M.F. Johnson. 2003. Non-inferiority trials: The 'at least as good as' criterion. *Statistics in Medicine* 22:187-200.

QUESTION #4: What were the patient’s outcomes from the clinical trial?

Response:

With respect to the primary efficacy endpoint, the TMJ NextGeneration™ demonstrated statistically significant non-inferiority to the stabilization splint in the reduction of the CMI score from baseline to 3 months (p=0.0096). Statistically significant reductions from baseline in TMJD pain, as assessed by in-office VAS (visual analog scale) scores, were also demonstrated for the TMJ NextGeneration™ device (see Figure below), with a 46% reduction at 1 month (p<0.0001), 51% reduction at 2 months (p<0.0001), and a 58% reduction at 3 months (p<0.0001). Such results supported the label claim for the TMJ NextGeneration™ as being “indicated as an aid in reducing Temporomandibular disorder (TMJD) pain.”



* n=60 Data on file, Ascentia Health, Inc. Rockford, IL

** Tavera A, et al: Approaching Temporomandibular Disorders From a New Direction: A Randomized Controlled Clinical Trial of the TMDes Ear System. *J Craniomandibular Practice* July 2012; Vol 30, No. 3, 172-181

Patient global satisfaction in the pivotal clinical trial was extremely high, with 100% of subjects in the TMJ NextGeneration™ group indicating excellent (71%) or good (29%) overall satisfaction with the device. In summary, in the pivotal clinical trial, the TMJ NextGeneration™ demonstrated comparable efficacy and safety to the stabilization

splint, a recognized standard of care and the most widely used current treatment for TMJD.²

Question #5: What has been the patient response to the TMJ NextGeneration™?

Response:

Patient global satisfaction in the pivotal clinical trial was extremely high, with 100% of subjects in the TMJ NextGeneration™ group indicating excellent (71%) or good (29%) overall satisfaction with the device. A sampling of patient testimonials can be viewed on our website: www.TMJNextGen.com

QUESTION #6: What are some potential complications with this treatment?

Response:

Given that the TMJ NextGeneration™ is comprised of a pair of small, hollow, ear inserts made of medical grade polymers that is custom-fit to each subject's ear canal, and is constructed from polymers and plastics that have been safely used in commercially available hearing aids for decades; no significant potential complications were expected.

The clinical trial of the TMJ NextGeneration™, which included as comparison groups patients treated with a stabilization splint or a jaw-exercise regimen, did, however, include evaluation of patients for a range of potential complications. There were no unanticipated adverse device effects or serious adverse events reported during the pivotal clinical trial. No study patients were found to have ear drainage, allergic reactions, swelling or changes to the mouth, ear or jaw at any of the follow-up visits. There were no reports of diminished hearing acuity in patients treated with the TMJ NextGeneration™.

² National Institute of Dental and Craniofacial Research (NIDCR). 2006. *TMJ Disorders*. NIH Publication No. 06-3487. Bethesda: National Institutes of Health. June.

No More Bite Splints...

Suffering from TMJ pain? We've got good news: At last, there's an effective alternative to uncomfortable and inconvenient bite splints. Introducing TMJ NextGeneration™ – a patented, FDA-cleared solution that is clinically proven to significantly decrease TMJ discomfort. Best of all, unlike bite splints, TMJ NextGeneration™'s custom-made ear canal inserts are comfortable, discreet and can provide you with relief all day long.

	TMJ NextGeneration™	Bite Splints
• Designed to be worn comfortably 24/7	✓	
• No interference with eating or talking	✓	
• Barely visible	✓	
• No nighttime discomfort	✓	
• No negative effect on your bite	✓	



TMJ NextGeneration™ looks and feels like high-end hearing aid inserts. They are discreet, easy-to-wear or remove and are very comfortable. Ask your healthcare provider about a prescription for TMJ NextGeneration™ today or visit tmjnextgen.com



Precautions:

It is not recommended that you wear the TMJ NextGeneration™ device while showering, swimming, or in a heated moist environment such as a steam bath or sauna.

It is recommended when participating in any contact sports that the TMJ NextGeneration™ devices be removed and stored in the pouch provided.

Significant weight gain or loss may affect the fit of the TMJ NextGeneration™ device within the ear and may require you to be refitted with new devices.

Warnings:

If you experience some initial discomfort, it may simply represent a brief adjustment period of the ear tissue as it adapts to the device. If, however, soreness, swelling, itchiness, drainage occurs in either one or both the ears, then you should remove the TMJ NextGeneration™ devices and call your healthcare provider to discuss your condition and schedule an appointment if necessary.

Safety and effectiveness of the TMJ NextGeneration™ device has not been established for people:

- Who have been diagnosed with rheumatoid arthritis, osteoarthritis, osteoarthrosis, or another connective tissue disorder
- Who have had direct trauma to the jaw; or
- Who have had prior TMJ surgery or ear surgery

When the Device Should Not Be Used (Contraindications)

You should not be fitted for a TMJ NextGeneration™ device if:

- You have active ear drainage, swelling, or redness
- You have an unresolved history of ear pain unrelated to TMJD; or
- Your ear canal anatomy does not allow for fit of the device (e.g., too narrow or prolapsed [fallen] canal, or previous mastoid surgery)

Risks and Benefits:

Patients wearing the TMJ NextGeneration™ device in a three month clinical study experienced a significant reduction in the pain and dysfunction associated with TMJD, to an extent at least as much as that experienced by patients wearing a stabilization splint (bite splint) or following a specified jaw exercise regimen. No unexpected or serious adverse events were reported and a comparable safety profile to the stabilization splint (bite splint) was observed. Patients in the study reported very high levels of satisfaction.

TMJ Health, LLC
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www.tmjnextgen.com
 38955 Hills Tech Drive • Farmington Hills, MI 48331
 023000 RevB 24JAN14

Say Goodbye to
 TMJ Pain.
 Say Hello to
 Comfort and Relief.



“Do I Have TMJ Disorder?”

The National Institute of Health estimates that TMJD (Temporomandibular Disorder) could afflict more than thirty-five million Americans. So, how do you know if you're one of them? People with TMJ disorders may exhibit a variety of symptoms including:

- Pain in the chewing muscles and/or jaw joint
- Radiating pain in the face, jaw or neck
- Jaw muscle stiffness
- Aching pain in and around the ears
- Difficulty chewing or discomfort while chewing
- Limited movement or locking of the jaw
- Painful clicking, popping or grating in the jaw joint when opening or closing the mouth

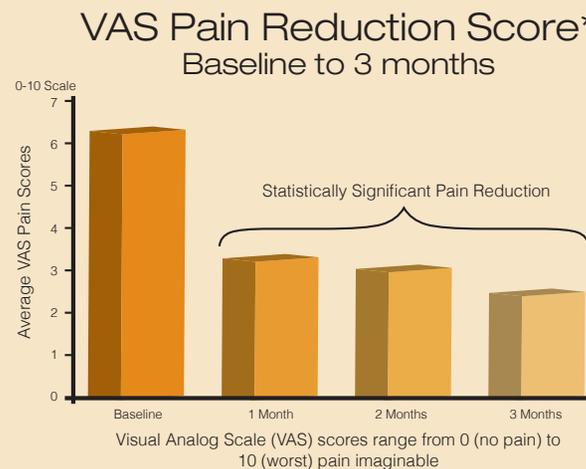


- Headache
- A change in the way the upper and lower teeth fit together

Be sure to tell your doctor if you're experiencing any of the symptoms listed above.

Don't Get Used to TMJ Pain, Get Relief with TMJ NextGeneration™

Want to decrease your TMJ pain significantly in as early as one month? In a randomized controlled study, TMJ NextGeneration™ was shown to significantly reduce the pain associated with TMJ Disorder.



* Tavera A, et al: Approaching Temporomandibular Disorders From a New Direction: A Randomized Controlled Clinical Trial of the TMDes Ear System. *J Craniomandibular Practice* July 2012; Vol 30, No. 3, 172-181

Relieving Your TMJ Discomfort is as Easy as 1, 2, 3.

Getting your custom-made TMJ NextGeneration™ ear canal inserts is a simple three-step process:



It's as easy as that.

Don't suffer from TMJ pain unnecessarily. Ask your healthcare provider about TMJ NextGeneration™ today or visit tmjnextgen.com