Mr. Ron Briel, Program Manager
Credentialing Review Program
DHHS Credentialing Review
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Lincoln, NE 68509-4986
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Re: Credentialing Review for the Nebraska Hearing Society

10-16-2023

Dear Mr. Briel,

This letter serves to present comments, clarification, and opposition to the proposed licensure law amendments for Nebraska Hearing Instrument Specialists (HIS) as outlined in the documents provided on the Department of Health and Human Services' (DHHS) website (https://dhhs.ne.gov/licensure/Pages/Credentialing-Review-(407)-Hearing-Care-Professionals.aspx) as titled 'Credentialing Review (407) Hearing Care Professionals'.

Thank you for the opportunity and for inviting professionals and the public to participate in the review process. By way of introduction, while I have not practiced audiology in Nebraska, I have served the audiology and HIS communities at the state and national levels for over four decades. I practiced audiology for 43 years. Part of that time was devoted to cochlear implant and middle ear implant research and working at an otology clinic. I owned and operated my private practice for 38 years. I served on numerous AAA and ADA committees (several of which involved audiology and HIS licensing laws), and am a past-president of the Academy of Doctors of Audiology. I served on the Oklahoma State Health Department's former 'Hearing Aid Dealers and Fitters Advisory Council for eight years, and was appointed to audiology ad hoc committees by the Oklahoma Board of Examiners in Speech-Language Pathology and Audiology; the work of which included revising and updating licensing laws. I have an appreciation for and a good understanding of business, public health and public health policy, licensing laws, state and federal statutes, and consumer protection. It is with this background that I respectfully offer additional information as well as my opinions and recommendations throughout this communication.

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Executive Summary

In reviewing HIS's request to amend the HIS Practice Act, I found much of what they are seeking to change as well-intentioned and worthwhile. Those in occupations and professions should strive to become better informed and be actively involved in life-long learning. However, significant portions of their amendments left me with the impression that some of the language was carefully crafted with an effort and intent to capture audiologist's scope of practice without earning a doctor of audiology degree and consequential audiology license. These procedures would come under the auspices of diagnosing and treating, for which HIS are not licensed. This would constitute 'holding oneself out to the public as an audiologist' (or a physician) and, consequently, practicing audiology (or medicine) without a license; or, the unlawful practice of audiology as well as being unethical. This would also violate consumer

protection laws. Legally, intent to do something wrong does not need to be intentional or purposeful to be unlawful. Consumers should be able to make health care decisions based on factual and accurate information.

It is incongruent and a conflict of laws for one branch of the government to create policies, rules, regulations, or statutes that contradict, conflict with, or interfere with another branch of the government's policies, rules, regulations, or statutes. To do so would not be in the public interest and would additionally and directly undermine the work done by the doctor of audiology schools, the National Council of State Boards of Examiners for Speech-Language Pathology and Audiology, and Nebraska's State Board of Audiology.

I believe that we can all agree that one of our goals is to be honest and truthful to the public and to ourselves. Good intentions do not necessarily make for good policy. Terms and phrases used incorrectly are misleading, can cause misunderstanding, can lead to public confusion, deception, fraud and/or harm. The public deserves to receive understandable, reliable, and truthful information, especially when it involves their health care.

Below are examples of inappropriate terminology I found throughout the proposed amendments:

- Case histories to include medical, otological, and pharmacological histories.
- … identifying possible otological conditions… which may indicate the need for a medical referral or which may have a bearing on needed rehabilitative measures, outcomes, or recommendations;
- Administering and interpreting tests of human hearing and middle ear function, including… such as tympanometry;
- Determining candidacy for … referral for cochlear implant evaluation or other clinical, rehabilitative, or medical interventions;
- Providing counseling and rehabilitative services
- Including 'All other acts of hearing assessment pertaining to hearing testing' (this could include a variety of diagnostic audiology procedures for which HIS are not licensed to conduct).
- Providing tinnitus management – assessment, selecting tinnitus maskers, therapy, counseling, administering and interpreting test of human hearing and middle ear function…
- Use of the term 'audioprosthologist'.
- Use of the term hearing center, or any variation or synonym (which constitutes holding oneself out to the public as an audiologist).
- Two-year degree in Hearing Instrument Sciences (there is no such science and no such degree).
- Practicum hours (are reserved for post-graduate clinical training hours, e.g., master's degree training in speech-language pathology).
- The hearing assessment…may also include tympanometry and acoustic reflex testing.
- Other speech test commonly used to assess human hearing acuity (This opens the door to conducting central auditory processing testing and other diagnostic audiologic tests.).
- Cerumen management.
- Counseling patients and others regarding aural rehabilitation.
- Use of the terms 'Board Certified' and 'Specialist' (The DHHS's attorney should review state laws to determine their statutory definitions; both terms of which are commonly utilized by professionals with advanced academic degrees, not by those in occupations who have received vocational training.).

According to Section 38-507 of the Nebraska Audiology and Speech-Language Pathology Practice Act, the:

- Practice of audiology means the application of evidence-based practice in clinical decision making for the prevention, assessment, habilitation, rehabilitation, and maintenance of persons with hearing, auditory function, and vestibular function impairments and related impairments, including (1) cerumen removal from the cartilaginous outer one-third portion of the external auditory canal when the presence of cerumen may affect the accuracy of hearing evaluations or impressions of the ear canal for amplification devices and (2) evaluation, selection, fitting, and dispensing of hearing instruments, external processors of implantable hearing instruments, and assistive technology devices as part of a comprehensive audiological rehabilitation program. Practice of audiology does not include the practice of medical diagnosis, medical treatment, or surgery. Aural rehabilitation is directed and conducted by audiologists as explained in Section 38-514.

Just as there are delineations in the health care hierarchy, there are delineations between what constitutes a profession vs. an occupation. Education at the bachelors, masters, or doctorate level is compulsory for a profession, but not for an occupation. Once we understand the structure of education, the hierarchy becomes more apparent in health care, work-roles, identities, licensing laws and their restrictions.

- Profession includes those individuals who enter a career requiring education and training at or beyond the baccalaureate degree. As audiologists and physicians, these licensed doctors are members of a profession. In healthcare, they are considered to have "scopes of practice".
- Occupation includes those individuals who enter a technical/vocational career requiring education and training with less than a baccalaureate degree. They are considered to have "work-roles", i.e., job duties and responsibilities and receive vocational training.

The audiology profession between 1945 until 1965 required an undergraduate bachelor's degree for clinical practice. Then, the entry level academic credential for audiology was upgraded to a master's degree followed by a clinical fellowship year. The inception of the Doctor of Audiology (Au.D.) degree began in 1988. Over time, audiologist's scope of practice rightfully progressed and advanced as they became better prepared for a contemporary doctoring practice. The HIS vocation has not undergone any discernable academic advances or upgrading of their occupation in over 100 years, yet, they seem determined to expand their vocational work roles and duties by encroaching on audiology's well-deserved scope of practice.

Audiologists prerequisite qualifications: They are required to earn a professional doctor of audiology degree from an accredited university (after having earned a baccalaureate degree) and pass a national examination in order receive a license to practice. The audiology programs go through the following processes in order to exist: University regional accreditation, Department of Communication Sciences and Disorders authorization, program accreditation from either the Council on Academic Accreditation or from the Accreditation Commission for Audiology Education, approval from the State Board of Education, and approval from the State Board of Regents.

HIS prerequisite qualifications: According to Title 172 Professional and Occupational; Chapter 75 Practice of Hearing Instrument Specialists, among other things, HIS are required to show completion of a 4-year course of study from an accredited high school, or equivalent. They receive supervised vocational on-the-job training and are required to pass a written and practical exam. Passing scores are considered at least 70 out of 100 in each subject examined. Section 38-1512 stipulates, in part, that, "The examination shall not be conducted in such a manner that college training is required in order to

pass." Section 38-1514 reads, in part, "The qualifying examination provided in Section 38-1512 shall be designed to demonstrate the applicant's adequate technical qualifications…".

There are certain well-established work-roles and scopes of practice in the health care hierarchy providing for a distinct, accepted, and understood "division of labor". For example, in nursing, there are nurse's aides (NA), licensed practical nurses (LPN), registered nurses (RN), nurse practitioners (NP), and doctors of nursing practice (DNP). Each has a well-defined position and specific level of education and training that prepares them for either occupational/vocational/technical work-roles for some; and for others, a professional scope of practice. It is recognized and easily understood that a nurse's aide is intentionally and purposely not prepared to perform the duties of a RN, NP, or a DNP.
Statutorily, the hierarchy, or division of labor, differentiates between occupations and professions and specifically defines and restricts what services are allowed to be provided, how they are provided, and by whom they are provided in order to meet the varying needs of and to protect the consumer. For example, otologic technicians and opticians are not allowed to incorporate ENT's and optometrist's scopes of practice into their respective work-roles. Similarly, neither are hearing aid dealers allowed to incorporate audiologist's scope of practice into the hearing aid dealer's work-roles beyond hearing aid dispensing. It is harmful to the public's best interest to expand any ancillary or support personnel's work-roles to include that of a healing arts doctoring profession's scope of practice.

HIS should rise to no higher level in the health care continuum than other health care employees who have jobs requiring a minimum of a high school diploma, on-the-job training, an apprenticeship, or a vocational/technical two-year associate of applied science degree. They are legislatively and statutorily mandated to be deliberately restricted and confined to narrowly defined work-roles. HIS have not earned the requisite academic degree nor do they possess the advanced training that goes along with the expanded scopes of practice responsibilities of allied health care professionals or doctors.

According to Nebraska's Uniform Credentialing Act, in part:

- Section 38-121. "Practices; credential required. (1) No individual shall engage in the following practices unless such individual has obtained a credential under the Uniform Credentialing Act (included are audiologists and HIS)". While audiologists engage similarly in the practice of hearing aid dispensing, HIS cannot engage in the full scope of practice of audiologists.
- Section 38-124 reads, in part, "The advertisement shall not include deceptive or misleading information and shall not include any affirmative communication or representation that misstates, falsely describes, or falsely represents the skills, training, expertise, education, board certification, or credential or credentials of the credential holder."
- Section 38-178 reads, in part, "Except as otherwise provided in sections 38-1,119 to 38-1,123, a credential to practice a profession may be denied, refused renewal, or have other disciplinary measures taken against it in accordance with section 38-185 or 38-186 on any of the following grounds:
  (5) Conviction of (a) a misdemeanor or felony under Nebraska law or federal law, or (b) a crime in any jurisdiction which, if committed within this state, would have constituted a misdemeanor or felony under Nebraska law and which has a rational connection with the fitness or capacity of the applicant or credential holder to practice the profession;
  (6) Practice of the profession (a) fraudulently, (b) beyond its authorized scope, (c) with gross incompetence or gross negligence, or (d) in a pattern of incompetent or negligent conduct;
  (10) Permitting, aiding, or abetting the practice of a profession or the performance of activities requiring a credential by a person not credentialed to do so;
  (13) Use of untruthful, deceptive, or misleading statements in advertisements, including failure to comply with section 38-124;

(14) Conviction of fraudulent or misleading advertising or conviction of a violation of the Uniform Deceptive Trade Practices Act;
(16) Violations of the Uniform Credentialing Act or the rules and regulations relating to the particular profession;
(17) Unlawful invasion of the field of practice of any profession regulated by the Uniform Credentialing Act which the credential holder is not credentialed to practice;

- Section 38-1,117 reads, in part, "False impersonation; fraud; aiding and abetting; use of false documents; penalty. Any person who
  (3) falsely holds himself or herself out to be a person credentialed by the department.

I urge DHHS to sit down with the audiology licensing board over all of these proposed changes, particularly since the proposed HIS amendments are infringing on audiologist's scope of practice. Simple resolutions to consider are:

1. Do not allow any changes in the HIS amendments to pass that would hold a HIS out to the public as practicing audiology without a license.
2. Explain to HIS that if they want to practice audiology, they should enroll in a doctor of audiology program, graduate, and apply for a license to practice audiology.

Detailed and Supplemental Information

June 9, 2023 and June 14, 2023 Letters of Intent to Ron Briel from Joseph Kohout for the Nebraska Hearing Society – Concerns:

- The purpose of the requested review is to enhance the authorized scope of practice for licensed Audiologists, Hearing Instrument Specialists, and Hearing Instrument Dispensers to better serve hearing impaired patients throughout Nebraska. (Audiologist's scope of practice is not enhanced by these proposed amendments.)
- The purpose of enhancing the authorized scope of practice for licensed Audiologists, Hearing Instrument Specialists, and Hearing Instrument Dispensers is to better serve hearing impaired patients throughout Nebraska.
- Hearing healthcare professionals are members of a distinct discipline.
  Dr. Engelmann: The importance and usage of correct terminology cannot be over-emphasized. Audiology is a profession, and HIS is an occupation, not a discipline. A discipline is commonly associated with a field of study like physics, chemistry, and mathematics. The phrase 'Hearing Health Care Professionals' (HHCP) started appearing in the National Academy of Sciences' (NAS) 2016 report related to over-the-counter hearing aids. The NAS report reads, in part, "For the purposes of this report the term "hearing health care professionals" is used broadly to encompass those who work in hearing healthcare (including audiologists, hearing instrument specialists, and otolaryngologists). The term is used throughout the report primarily for ease – that is, one collective term, rather than listing each group repeatedly throughout the report".

  Identification and recognition of separate occupations, i.e., HISs and professions, i.e., physicians and audiologists, are essential for consumer understanding and transparency. Neither expediency nor convenience should be accepted as a rationale to blur the lines between them. Referring to these groups in a generic "one size fits all" manner and as a collective of HHCPs will serve only to confuse and ultimately mislead consumers. Out of respect, their separate and very different identities should not be eliminated. The use of the misidentifying phrase 'hearing health care professionals' (HHCP) should cease.

Legislative Changes Sought as written in the Nebraska Hearing Society Application – Revised

38-1504. Current Law: Hearing instrument, defined.
Hearing instrument means any wearable instrument or device designed for or offered for the purpose of aiding or compensating for impaired human hearing and any parts, attachments, or accessories, including earmold, but excluding batteries and cords.
38-1504 Amended to read: *Hearing instrument means wearable amplification that is worn by a person with hearing loss and that has the ability to provide a fifteen-decibel gain or more at any given frequency, measured in a two-cubic-centimeter coupler.*
Dr. Engelmann: Unwarranted change – recommend deleting amendment. The FDA's definition is: 21 CFR 874.3300 Hearing aid. (a) Identification. A hearing aid is a wearable sound-amplifying device that is intended to compensate for impaired hearing. This generic type of device includes the air-conduction hearing aid and the bone-conduction hearing aid, but excludes the group hearing aid or group auditory trainer (874.3320), master hearing aid (874.3330), and tinnitus masker (874.3400).

38-1505. Current Law: Practice of fitting hearing instruments, defined.
Practice of fitting hearing instruments means the measurement of human hearing by means of an audiometer or by other means approved by the board solely for the purpose of making selections, adaptations, or sale of hearing instruments. The term also includes the making of impressions for earmolds. A dispenser, at the request of a physician or a member of related professions, may make audiograms for the professional's use in consultation with the hard-of-hearing.
38-1505 Amended to read: *Dispensing of hearing instruments means the following activities:*
(1) Eliciting patient case histories, including medical history, otological history, pharmacological history, amplification history, and patient attitudes and expectations;
(2) Administering otoscopy for the purpose of identifying possible otological conditions, including, but not limited to, any of the conditions related to warnings found in the regulations of the federal Food and Drug Administration, 21 C.F.R. 801.420, as such regulations existed on January 1, 2023, which may indicate the need for a medical referral or which may have a bearing on needed rehabilitative measures, outcomes, or recommendations;
(3) Administering and interpreting tests of human hearing and middle ear function, including appropriate objective and subjective methodology and measures, such as tympanometry;
(4) Determining candidacy for hearing instruments, hearing-assistive devices, or referral for cochlear implant evaluation or other clinical, rehabilitative, or medical interventions;
(5) Selecting or fitting appropriate hearing instruments and assistive devices, including appropriate technology, identifying electroacoustic targets, programming parameters, and choosing special applications, as indicated;
(6) Assessing hearing instrument efficacy utilizing appropriate fitting verification methodology and equipment, which may include real ear measures or speech mapping, and electroacoustic analysis equipment;
(7) Assessing hearing instrument benefits through appropriate validation measures, which may include communication assessment questionnaires or speech audiometry;
(8)(a) Taking ear impressions or electronic scans by any method used for the purpose of creating earmolds and (b) preparing earmolds for hearing instruments, assistive devices, telecommunications applications, ear protection, and other related applications;
(9) Designing and modifying earmolds and auditory equipment requisite to meet a patient's needs;
(10) Providing counseling and aural rehabilitative services in the use and care of hearing instruments and assistive devices and for effectively utilizing communication coping strategies and other approaches to foster optimal patient rehabilitation;

(11) Providing tinnitus management;
(12) Providing supervision and inservice training of those entering the dispensing profession;
(13) Provide post-fitting care and services and hearing instrument care and repair services; or
(14) All other acts of hearing assessment pertaining to hearing testing or the selling, renting, leasing, and delivery of hearing instruments.
Dr. Engelmann: Most of this entire proposed amendment is extremely objectionable and should be deleted. It would have the effect of enabling HIS to practice audiology and medicine unlawfully. I would advise to keep the Current Law.

38-1506. Current Law: Sell, sale, or dispense, defined.
Sell, sale, or dispense means any transfer of title or of the right to use by lease, bailment, or any other contract, excluding
(1) wholesale transactions with distributors or dispensers and
(2) distribution of hearing instruments by nonprofit service organizations at no cost to the recipient for the hearing instrument.
38-1506 Amended to read: *Hearing instrument specialist means a person who engages in the practice of dispensing of hearing instruments. Medical liaison means an otolaryngologist or a licensed physician if no otolaryngologist is available with whom a cooperative arrangement for consultation is established by a hearing instrument specialist. Providing tinnitus management means the assessment of tinnitus, recommendation and selection of tinnitus management devices, therapy, and counseling in accordance with section 22 of this act provided to a patient who exhibits symptoms of tinnitus during an evaluation of hearing loss conducted for the purpose of determining the appropriateness of hearing instruments or tinnitus devices and includes administering and interpreting tests of human hearing and middle ear function, including appropriate objective and subjective methodology and measures, such as tympanometry.*
Dr. Engelmann: This proposed amendment appears to have no relationship with the Current Law. Most of this entire proposed amendment is extremely objectionable and should be deleted. It would have the effect of enabling HIS to practice audiology and medicine unlawfully. I would advise to keep the Current Law.

38-1508. Current Law: Board membership; qualifications.
The board shall consist of five professional members and one public member appointed pursuant to section 38- 158. The members shall meet the requirements of sections 38-164 and 38-165. The professional members shall consist of three licensed hearing instrument specialists, one otolaryngologist, and one audiologist until one licensed hearing instrument specialist vacates his or her office or his or her term expires, whichever occurs first, at which time the professional members of the board shall consist of three licensed hearing instrument specialists, at least one of whom does not hold a license as an audiologist, one otolaryngologist, and one audiologist. At the expiration of the four-year terms of the members serving on December 1, 2008, successors shall be appointed for five-year terms.
38-1508 Amended to read: *The board shall consist of five professional members and one public member appointed pursuant to section 38-158. The members shall meet the requirements of sections 38-164 and 38-165. The professional members shall consist of three licensed hearing instrument specialists, at least one of whom does not hold a license as an audiologist, one otolaryngologist, and one audiologist. At the expiration of the four-year terms of the members serving on December 1, 2008, successors shall be appointed for five-year terms.*
Dr. Engelmann: This appears to be a legal question that is best suited for the DHHS's attorney.

38-1509. Current Law: Sale or fitting of hearing instruments; license required; exceptions.
(1) Except as otherwise provided in this section, no person shall engage in the sale of or practice of fitting hearing instruments or display a sign or in any other way advertise or represent himself or herself as a person who practices the fitting and sale or dispensing of hearing instruments unless he or she holds an unsuspended, unrevoked hearing instrument specialist license issued by the department as provided in the Hearing Instrument Specialists Practice Act. A hearing instrument specialist license shall confer upon the holder the right to select, fit, and sell hearing instruments. A person holding a license issued under the act prior to August 30, 2009, may continue to practice under such license until it expires under the terms of the license.
(2) A licensed audiologist who maintains a practice pursuant to
(a) licensure as an audiologist, or
(b) a privilege to practice audiology under the Audiology and Speech-Language Pathology Interstate Compact, in which hearing instruments are regularly dispensed, or who intends to maintain such a practice, shall be exempt from the requirement to be licensed as a hearing instrument specialist.
(3) Nothing in the act shall prohibit a corporation, partnership, limited liability company, trust, association, or other like organization maintaining an established business address from engaging in the business of selling or offering for sale hearing instruments at retail without a license if it employs only properly licensed natural persons in the direct sale and fitting of such products.
(4) Nothing in the act shall prohibit the holder of a hearing instrument specialist license from the fitting and sale of wearable instruments or devices designed for or offered for the purpose of conservation or protection of hearing.
38-1509 Amended to read: *(1)(a) Except as otherwise provided in this section, it shall be unlawful for any person to engage in the practice of dispensing of hearing instruments or display a sign or in any other way advertise or represent oneself as a person who practices dispensing of hearing instruments unless such person holds an unsuspended, unrevoked hearing instrument specialist license issued by the department as provided in the Hearing Instrument Specialists Practice Act. A person represents oneself to be a hearing instrument specialist if the person holds out to the public that the person engages in the practice of dispensing of hearing instruments, by any means, or by any service or function performed, directly or indirectly, or by using the term audioprosthologist, hearing center, hearing instrument center, hearing instrument office, hearing instrument specialist, hearing office, or any variation or synonym which expresses, employs, or implies these terms or functions.*
(b) A hearing instrument specialist license shall confer upon the holder the right to engage in the scope of practice of dispensing of hearing instruments.
(2) A licensed audiologist shall be exempt from the requirement to be licensed as a hearing instrument specialist if the audiologist maintains a practice in which hearing instruments are regularly dispensed, or intends to maintain such a practice, pursuant to:
(a) Licensure as an audiologist; or
(b) A privilege to practice audiology under the Audiology and Speech-Language Pathology Interstate Compact.
(3) A hearing instrument specialist or audiologist may order the use of devices pursuant to 21 C.F.R. 801.109, as such regulation existed on January 1, 2023.
(4)(a) Nothing in the Hearing Instrument Specialists Practice Act shall prohibit a corporation, partnership, limited liability company, trust, association, or other like organization maintaining an established business address from engaging in the business of selling or offering for sale hearing instruments at retail without a license if it employs only properly licensed natural persons in the direct sale and fitting of such products.
(b) Each such organization shall file annually with the department, on a form provided by the department, a list of the licensed hearing instrument specialists employed by the organization and a

statement, on a form provided by the department, that the organization agrees to comply with the rules and regulations adopted and promulgated pursuant to section 38-126.
Dr. Engelmann: It is objectionable to use the term audioprosthologist, hearing center, hearing instrument center, hearing office, or any variation or synonym which expresses, employs, or implies these terms or functions. The term "audioprosthologist" is clearly a derivative of the term "audiologist", which is a legally protected term. Unless otherwise authorized by the State Laws of Nebraska, Audioprosthologist is recognized by many states' attorneys general, as well as many audiology and speech-language pathology licensing boards as deceptive to the public. Consequently, use of the term in those states by non-audiologists is illegal. Hearing Center, Hearing Clinic, etc. constitutes holding oneself out to the public as an audiologist.

38-1510. Current Law: Applicability of act.
(1) The Hearing Instrument Specialists Practice Act is not intended to prevent any person from engaging in the practice of measuring human hearing for the purpose of selection of hearing instruments if such person or organization employing such person does not sell hearing instruments or the accessories thereto.
(2) The act shall not apply to a person who is a physician licensed to practice in this state, except that such physician shall not delegate the authority to fit and dispense hearing instruments unless the person to whom the authority is delegated is licensed as a hearing instrument specialist under the act.
38-1510 Amended to read: *(1) The Hearing Instrument Specialists Practice Act is not intended to prevent any person from engaging in the practice of measuring human hearing for the purpose of selection of hearing instruments if such person or organization employing such person does not sell hearing instruments or the accessories thereto.*
(2) The Hearing Instrument Specialists Practice Act does not apply to a person who is a physician licensed to practice in this state, except that such physician shall not delegate the authority to fit and dispense hearing instruments unless the person to whom the authority is delegated is licensed as a hearing instrument specialist under the act.
(3) The Hearing Instrument Specialists Practice Act does not change the scope of practice of a licensed audiologist.
Dr. Engelmann: Item #3 is a good addition.

38-1511. Current Law: Sale; conditions.
(1) Any person who practices the fitting and sale of hearing instruments shall deliver to each person supplied with a hearing instrument a receipt which shall contain the licensee's signature and show his or her business address and the number of his or her certificate, together with specifications as to the make and model of the hearing instrument furnished, and clearly stating the full terms of sale. If a hearing instrument which is not new is sold, the receipt and the container thereof shall be clearly marked as used or reconditioned, whichever is applicable, with terms of guarantee, if any.
(2) Such receipt shall bear in no smaller type than the largest used in the body copy portion the following: The purchaser has been advised at the outset of his or her relationship with the hearing instrument specialist that any examination or representation made by a licensed hearing instrument specialist in connection with the fitting and selling of this hearing instrument is not an examination, diagnosis, or prescription by a person licensed to practice medicine in this state and therefore must not be regarded as medical opinion or advice.
38-1511 Amended to read:
(1) A licensed hearing instrument specialist shall enter into a written contract for each sale of a hearing instrument which states the terms of the sale.
(2) A licensee shall, at the time of delivery of the hearing instrument, provide the patient with a receipt containing the signature, regular business address, and license number of the licensee; the brand,

model, manufacturer or manufacturer's identification code, and serial number of the hearing instrument; and the amount charged for the hearing instrument. The receipt shall also specify whether the hearing instrument is new, used, or rebuilt, as provided in 21 C.F.R. 801.420, as such regulation existed on January 1, 2023; the length of time and other terms of the guarantee; and by whom the hearing instrument is guaranteed.
(3) No hearing instrument may be sold to any person unless both the packaging containing the hearing instrument and the itemized receipt are in compliance with all applicable laws and regulations.
(4) Upon delivery, the licensed hearing instrument specialist shall confirm the physical and operational performance of the hearing instrument. If a patient purchases a hearing instrument from a licensee outside of the licensee's regular place of business and the regular place of business is beyond a reasonable distance, as determined by the board, the licensee shall provide the patient the address of an affiliate location with which the licensee is associated that is within a reasonable distance, at which a licensed hearing instrument specialist or audiologist is available for fitting services.
(5) Any seller offering for sale or selling a hearing instrument in this state or to a resident of this state shall make available in this state an in person fitting of the hearing instrument by a licensed hearing instrument specialist in this state prior to the sale.
Dr. Engelmann: This amendment is a reasonable request.

Sec. 27. *(1) A licensed hearing instrument specialist shall keep and maintain in the licensee's office or place of business the following records: (a) Results of tests and other records as they pertain to hearing assessments conducted by the licensee and the dispensing of hearing instruments by the licensee; (b) A copy of the written contract and, if executed, signed medical evaluation waiver; and (c) Copies of such other records as the department, with the recommendation of the board, reasonably requires. (2) Such records shall be kept and maintained by the licensee for a period of seven years.*
Dr. Engelmann: Unable to locate the Current Law. This amendment is a reasonable request.

Sec. 28. *A licensed hearing instrument specialist who is certified by the National Board for Certification in Hearing Instrument Sciences or has an advanced credential recognized or offered by the International Hearing Society may work for a company or organization as a trainer and provide specialized training in the practical application of hearing instrument sciences.*
Dr. Engelmann: Unable to locate the Current Law.

38-1512. Current Law: License; examination; conditions.
(1) Any person may obtain a hearing instrument specialist license under the Hearing Instrument Specialists Practice Act by successfully passing a qualifying examination if the applicant:
(a) Is at least twenty-one years of age; and
(b) Has an education equivalent to a four-year course in an accredited high school.
(2) The qualifying examination shall consist of written and practical tests. The examination shall not be conducted in such a manner that college training is required in order to pass. Nothing in this examination shall imply that the applicant is required to possess the degree of medical competence normally expected of physicians.
(3) The department shall give examinations approved by the board. A minimum of two examinations shall be offered each calendar year.
38-1512 Amended to read:
(1) Any person may obtain a hearing instrument specialist license under the Hearing Instrument Specialists Practice Act by successfully passing a qualifying examination pursuant to section 38-1514 if the applicant provides verification acceptable to the department, upon recommendation of the board, that such person:
(a) Is at least twenty-one years of age; and

(b) Has an education equivalent to a four-year course in an accredited high school; and
(c)(i) Has completed the minimum number of practicum hours prescribed by the board;
(ii) Has a two-year degree in hearing instrument sciences, or an equivalent as determined by the board, from an accredited institution approved by the board;
(iii) Has a master's or doctoral degree in audiology from an accredited institution approved by the board;
(iv) Has held a current, unsuspended, and unrevoked license to dispense hearing instruments from another jurisdiction for at least twelve of the last eighteen months prior to taking the examination;
(v) Is certified by the National Board for Certification in Hearing Instrument Sciences at the time of taking the examination; or
(vi) Holds an advanced credential offered by the International Hearing Society at the time of taking the examination.
(2) The department, with the recommendation of the board, may determine whether completion of a licensure program from outside of the United States qualifies a person to take the examination in this state.
(3) The department, upon recommendation of the board, may waive either or both components of the examination pursuant to section 38-1514 for licensure as a hearing instrument specialist if the person has passed the same examination as provided in section 6(2) of this act or a substantially equivalent examination as determined by the board.
(4) The department, with the recommendation of the board, shall determine whether a person has met the requirements to be eligible to take the examination.
Dr. Engelmann: I object to the use of the term 'practicum' in 1(C)(I). It's appropriate use connotes clinical training at the post-graduate level, e.g., practicum hours during a master's degree program in speech-language pathology. A more appropriate term or phrase associated with vocational training would be "on-the-job training hours". 1 (C) (ii and iii) are irrelevant. Licensing laws establish 'minimum standards' to receive a license. In this case, a high school diploma, or equivalent, is the minimum educational standard. An associates, bachelors, masters, or doctorate degree exceed the minimum standard and do not need to be added to the HIS licensing laws. 1(C) (v & vi) are irrelevant and do not need to be added to the HIS licensing laws. The credentials mentioned here are only acquired by someone who has already received a license.

38-1514. Current Law: Qualifying examination; contents; purpose.
The qualifying examination provided in section 38-1512 shall be designed to demonstrate the applicant's adequate technical qualifications by:
(1) Tests of knowledge in the following areas as they pertain to the fitting and sale of hearing instruments:
(a) Basic physics of sound;
(b) The anatomy and physiology of the ear; and
(c) The function of hearing instruments; and
(2) Practical tests of proficiency in the following techniques as they pertain to the fitting of hearing instruments:
(a) Pure tone audiometry, including air conduction testing and bone conduction testing;
(b) Live voice or recorded voice speech audiometry;
(c) Masking when indicated;
(d) Recording and evaluation of audiograms and speech audiometry to determine proper selection and adaptation of a hearing instrument; and
(e) Taking earmold impressions.

38-1514 Amended to read:
(1) The examination required by section 38-1512 for licensure as a hearing instrument specialist shall be comprised of two separate components:
(a) A practical examination approved by the board that requires the examinee to demonstrate competence in dispensing of hearing instruments, which may be an examination developed and maintained by the International Hearing Society; and
(b) A written or computer-based, psychometrically valid, competency examination approved by the board that tests the examinee for knowledge fundamental to the dispensing of hearing instruments, which may be an examination developed and maintained by the International Hearing Society.
(2)(a) If an examinee fails more than one portion of the practical examination, the examinee shall retake the entire practical examination upon payment of the examination fee.
(b) If an examinee fails only one portion of the practical examination, the examinee may retake that portion of the examination without payment of a fee.
(c) If an examinee fails the jurisprudence examination or competency examination, the examinee shall retake the entire examination upon payment of the examination fee.
(d) If an examinee fails either the practical or competency component of the examination and fails two subsequent reexaminations, the examinee shall be disqualified from retaking the examination a fourth time until the examinee meets with the board, presents an acceptable written training plan to the board for passing the components of the examination, and successfully completes that plan.
Dr. Engelmann: #1(a) – States are sovereign and should not be statutorily encumbered by or beholden to a membership organization. It would be in the state's interest to delete "International Hearing Society".

Sec. 17 *(1) A licensed hearing instrument specialist shall not engage in dispensing of hearing instruments with respect to a patient without first having conducted a face-to-face hearing assessment for the patient. A hearing assessment conducted in accordance with this subsection shall be valid for six months. Such hearing assessment shall include at least the following procedures, and any additional or modified procedures appropriate to technological developments as determined by the board:*
(a) Completion of a patient history questionnaire;
(b) Otoscopic examination;
(c) Testing to determine the type and degree of hearing loss which includes pure-tone air conduction testing at two hundred fifty hertz, five hundred hertz, one thousand hertz, two thousand hertz, four thousand hertz, and eight thousand hertz and bone conduction testing at five hundred hertz, one thousand hertz, two thousand hertz, and four thousand hertz;
(d) Effective masking when indicated;
(e) Appropriate testing to determine speech reception thresholds, word recognition scores, most comfortable listening levels, uncomfortable loudness levels, frequency-specific loudness discomfort levels, ability to understand speech in noise, and the selection of the best fitting arrangement for maximum hearing instrument benefit when indicated; and
(f) Other speech tests commonly used to assess human hearing acuity.
(2) The hearing assessment required pursuant to subsection (1) of this section may also include tympanometry and acoustic reflex testing.
(3) Each component of a hearing instrument shall be adapted to the needs of the patient. A licensed hearing instrument specialist shall conduct a final fitting to ensure physical fit and operational comfort of the hearing instrument and shall perform a hearing test in an environment with ambient noise sound levels of less than fifty-five A-weighted decibels.
Dr. Engelmann: Unable to locate the Current Law. I object to these statements: *Such hearing assessment shall include at least the following procedures, and any additional or modified procedures appropriate to technological developments as determined by the board; (f) Other speech tests*

commonly used to assess human hearing acuity; (2) The hearing assessment required pursuant to subsection (1) of this section may also include tympanometry and acoustic reflex testing. **These connote unlawful practice of audiology.**

Sec. 18 *A licensed hearing instrument specialist shall demonstrate the benefit of a hearing instrument fitting by using objective measures, such as aided and unaided sound field testing, real-ear measurements, speech mapping, or electroacoustic analysis, or any other method approved by the board.*
Dr. Engelmann: Unable to locate the Current Law.

Sec. 19 *A licensed hearing instrument specialist shall determine a patient's benefit with the hearing instrument fitting using validation measures, such as speech audiometry and validated communication assessment questionnaires, or any other method approved by the board*
Dr. Engelmann: Unable to locate the Current Law.

Sec. 20 *(1) A licensed hearing instrument specialist shall use the following equipment as part of any hearing testing conducted for the purpose of dispensing of hearing instruments:*
(a) An audiometer that has been calibrated within the twelve months preceding the test and that meets the specifications set forth under this section; and
(b) A speech audiometer or a master hearing instrument in order to perform speech tests as required in subdivision (1)(e) of section 17 of this act.
(2) A licensed hearing instrument specialist shall provide for the calibration of the equipment utilized for hearing assessments required under section 17 of this act and in the dispensing of hearing instruments at least annually in conformance with current standards of the American National Standards Institute or such other quality control standards established by the board. A licensee shall ensure that audiometric equipment has been evaluated electrically and acoustically annually, that the equipment has been adjusted or repaired if necessary, and that conformity with such standards was determined at that time. A licensee shall maintain calibration records for ten years and shall make the records available for inspection by the department at any time. A licensee shall also use routine procedures for the daily inspection of audiometric equipment, or prior to use if used less often than on a daily basis, to generally determine that the equipment is in normal working order.
(3) A licensed hearing instrument specialist shall provide the following care of the equipment used in the licensee's practice of dispensing of hearing instruments:
(a) Hearing instruments, assistive listening devices, and electronic equipment must be maintained according to the manufacturer's specifications;
(b) Instrumental technology must be maintained in proper working order and be properly calibrated according to accepted standards; and (c) Proper infection control and sanitation procedures must be utilized.
Dr. Engelmann: Unable to locate the Current Law. This is a reasonable addition.

Sec. 21. *Prior to engaging in cerumen management, a licensed hearing instrument specialist shall provide the board with evidence of*
(a) completion of an approved cerumen management course,
(b) professional liability insurance, and
(c) an arrangement with a medical liaison. The licensee shall annually thereafter provide evidence to the board of professional liability insurance and an arrangement with a medical liaison.
(2) Prior to engaging in cerumen management, a licensed hearing instrument specialist shall have an arrangement with a medical liaison. A licensee shall refer a patient to a medical liaison if the patient exhibits contraindications to cerumen removal requiring medical consultation or medical intervention.

If a licensee engaged in routine cerumen management discovers any trauma, including, but not limited to, continuous uncontrolled bleeding, lacerations, or other traumatic injuries, the licensee shall, as soon as practicable, refer the patient to the medical liaison.
(3)(a) Prior to entering into an arrangement with a medical liaison, a licensed hearing instrument specialist shall complete a cerumen management course approved by the board and provide the board with evidence of such completion and 12 competence. In order to be approved by the board, the course shall be approved by the International Hearing Society or another organization approved by the board and shall:
(i) Be conducted by an individual with an audiology certification or an equivalent credential or by a physician, an osteopathic physician, or a physician assistant licensed pursuant to the Uniform Credentialing Act;
(ii) Include a minimum total of four hours of instruction and supervised practice;
(iii) Include in person practice of cerumen management techniques; and
(iv) Include an infectious control component; and
(v) Result in a certificate of completion and attestation of competence
(b) The board may, only after consultation with the Board of Medicine and Surgery, adopt rules and regulations as provided in section 38-126 to provide requirements for the initial cerumen management course.
(4) The licensee shall maintain documentation evidencing the satisfactory completion of the training.
(5) A licensee shall carry appropriate professional liability insurance before performing cerumen removal.
(6) A licensee shall perform cerumen management using the customary removal techniques that are commensurate with the licensee's training and experience. Performance of cerumen management is limited to the patient's cartilaginous outer one-third portion of the external auditory canal.
(7) A licensed hearing instrument specialist engaged in cerumen management shall comply with the following requirements:
(a) The indications for cerumen management for a licensed hearing instrument specialist shall include:
(i) Enabling audiometric testing;
(ii) Making ear impressions;
(iii) Fitting ear protection or prosthetic devices; and
(iv) Monitoring continuous use of hearing aids;
(b) The licensed hearing instrument specialist shall refer a patient to the medical liaison, an otolaryngologist, or a licensed physician for medical consultation or medical intervention if the patient exhibits any of the following contraindications to cerumen removal:
(i) An age younger than eighteen years of age;
(ii) A perforated tympanic membrane;
(iii) A history of pain, active drainage, or bleeding from the ear;
(iv) Evidence of congenital or traumatic deformity of the ear;
(v) Any previous ear surgery;
(vi) Tympanostomy tubes, such that irrigation should not be used;
(vii) A bleeding disorder;
(viii) Actual or suspected foreign body in the ear;
(ix) Stenosis or bony exostosis of the ear canal;
(x) A tympanic membrane that the licensed hearing instrument specialist is unable to see; or
(xi) Any other contraindication to cerumen removal that requires medical consultation or medical intervention;
(c) If the patient, while undergoing cerumen management that did not present contraindications, complains of significant pain, exhibits uncontrolled bleeding or a laceration of the external auditory canal, or notices the acute onset of dizziness or vertigo or sudden hearing loss, the licensed hearing

instrument specialist shall immediately stop the procedure and refer the patient to the medical liaison, an otolaryngologist, or a licensed physician;
(8) The licensed hearing instrument specialist shall maintain the following proper infection control practices:
(i) Universal health precautions;
(ii) Decontamination;
(iii) Cleaning, disinfection, and sterilization of multiple use equipment; and
(iv) Universal precautions for prevention and the transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens, as defined by occupational safety and health standards promulgated pursuant to 29 C.F.R. 1910, as such regulations existed on January 1, 2023;
(9) The licensed hearing instrument specialist who performs cerumen management shall maintain a case history for every patient and informed consent signed by the patient as part of the patient's records; and
(10) The licensed hearing instrument specialist is prohibited from requiring patients to sign any form that eliminates liability if the patient is harmed.
Dr. Engelmann: Unable to locate the Current Law. This entire section should be deleted as HIS should not provide cerumen management. This procedure is contained within an audiologist's scope of practice. For HISs to conduct this procedure would be practicing audiology without a license. This could be very dangerous and a significant health risk for patients, especially for those patients with comorbidities and taking certain medications.

Sec. 22. *Prior to providing tinnitus management, a licensed hearing instrument specialist shall obtain the training, knowledge, and skills necessary to perform tinnitus management in accordance with federal regulations, if any, and rules and regulations adopted and promulgated under the Uniform Credentialing Act, if any.*
Dr. Engelmann: Unable to locate the Current Law. This entire section should be deleted as it constitutes practicing audiology without a license.

The Nebraska DHHS (https://dhhs.ne.gov/licensure/pages/hearing-instrument-specialist.aspx) defines the following:

- **Hearing Instrument Specialists sell and fit hearing instruments. To fit hearing instruments, they measure human hearing using an audiometer or another means approved by the board. They also make impressions for earmolds. A Hearing Instrument Specialist, at the request of a physician or a member of related professions, may make audiograms for the professional's use in consultation with the hard-of-hearing.**

The FDA has entirely separate classification categories for tinnitus treatment devices, prescriptive HAs, and now OTC HAs. Accordingly, one is not related to the other. It is essential that tinnitus patients are diagnosed and treated by an audiologist and/or a physician. HISs doing tinnitus management constitutes practicing audiology without a license and violates federal law.

The FDA makes a clear distinction between hearing aids and Tinnitus Maskers [under the 21 CFR (Code of Federal Regulations Title 21)]. ***The regulatory definition of a hearing aid and wireless air-conduction hearing aid is codified as follows*** **["Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products"(https://www.fda.gov/media/75418/download)]:**

21 CFR 874.3300 Hearing aid. ***(a) Identification. A hearing aid is a wearable sound-amplifying device that is intended to compensate for impaired hearing. This generic type of device includes the***

air-conduction hearing aid and the bone-conduction hearing aid, but excludes the group hearing aid or group auditory trainer (874.3320), master hearing aid (874.3330), and tinnitus masker (874.3400).

21 CFR 874.3305 Wireless air-conduction hearing aid. *(a) Identification. A wireless air-conduction hearing aid is a wearable sound-amplifying device, intended to compensate for impaired hearing that incorporates wireless technology in its programming or use.*

21 CFR 874.3400 Tinnitus masker. *The regulatory definition of a tinnitus masker is codified as follows* **["Title 21 - Food & Drugs; Chapter 1 - FDA Dept. of Health & Human Services; Subchapter H - Medical Devices; Part 874 ENT Devices; Subpart D - Prosthetic Devices; Sec. 874.3400 Tinnitus Masker" (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=874.3400)]:**
(a) Identification. A tinnitus masker is an electronic device intended to generate noise of sufficient intensity and bandwidth to mask ringing in the ears or internal head noises. Because the device is able to mask internal noises, it is also used as an aid in hearing external noises and speech.

There is no problem wanting and taking steps to improve and expand ones' knowledge base. What is a problem is when HISs acquire this information and then goes back to work and start conducting diagnostic audiologic testing, diagnosing, and treating a tinnitus patient(s). Learning about this topic and receiving CEUs for the class does not, in any way, supersede state and federal laws.

For a more detailed discussion regarding many of the above issues, concerns, and objections, please refer to: ***Engelmann, Larry, M.S., Au.D., "Branding the Lie or Branding the Truth: The Need to Differentiate Audiologists from Hearing Aid Dealers", In Audiology Today, Part 1, July/Aug 2018, pps. 34-44; Part 2, Sept/Oct 2018, pps. 50-63; and Nov/Dec 2018 Letter to the Editor, pps. 12-14.***