

## **Audiology Practice Accreditation Standards**

January 2020

**Purpose**: ADA is committed to the advancement of audiology practice excellence, high ethical standards, professional autonomy and sound business practices in the provision of quality, evidence-based, audiologic care to encourage practice facilities to deliver care in a consistent and standardized process.

**Methods**: Evidence-based best clinical and business practices are essential to the delivery of exceptional audiology patient care. ADA Audiology Practice Accreditation Standards were assembled by consensus, using research as the basis for decision-making.

ADA Audiology Practice Accreditation Standards when incorporated into the clinic will demonstrate a commitment to ethical, legal, clinical, operational, and relational excellence.

### **Section 1: Rights and Needs of the Patient**

- 1.1 Commitment to Patient-centered Care: The practice through its audiologists and support staff shall integrate a patient-centered approach in the provision of services, and all aspects of hearing and balance health care delivery.
  - **1.1.1** Audiologists and support staff shall provide patients with timely, transparent, and complete information about the benefits, risks, and side effects regarding the proposed care and services.
  - **1.1.2** Audiologists and support staff shall seek out patient perspectives, goals, and values, and they shall provide information and services that are responsive to individual patient preferences, respect patient autonomy, and empower patients to make informed decisions.
  - **1.1.3** Audiologists and support staff shall foster an inclusive environment that maximizes participation from patients, family members and/or communication partners throughout the delivery of care.
  - **1.1.4** Audiologists and support staff shall use effective written and oral communications to foster patient comprehension, inquiry, and to reinforce an informed and shared decision-making process.
  - 1.1.5 The practice shall adopt and publish a formal statement outlining its commitment to high ethical, clinical, and operational standards, including its adherence to federal, state, and local laws.
  - 1.1.6 The practice shall demonstrate adherence to Americans with Disabilities Act (ADA)<sup>1</sup> requirements for the provision of sign language interpreters, as requested by the patient, to facilitate successful communication.
- **Patient Safety:** Patients shall be treated in a manner that promotes health, well-being, and safety, and is free from violence, neglect, exploitation, verbal, mental, physical, and sexual abuse.
  - 1.2.1 The practice environment shall support and foster the health, safety, well-being, and comfort of patients and the public.
  - **1.2.2** The practice shall publish and maintain a zero-tolerance policy for violence, neglect, exploitation, verbal, mental, physical, and sexual abuse.
  - 1.2.3 The practice shall adopt processes and procedures for patients to report patient safety issues, and to address patient grievances and concerns.
  - **1.2.4** Audiologists and support staff shall be able to identify and implement proper hygiene and infection control procedures.<sup>2</sup>
  - 1.2.5 The practice shall adopt, implement, and maintain an emergency action plan (EAP) to address medical emergencies, fire, and other foreseen emergencies that may occur at the practice location.<sup>3</sup>

- **1.3 Protection from Discrimination and Harassment**: The practice shall maintain an environment free from discrimination and harassment.
  - **1.3.1** The practice shall develop, publish, and enforce written anti-discrimination and anti-harassment policies that meet or exceed federal, state, and local laws.<sup>4</sup>
  - 1.3.2 The practice shall establish and maintain mechanisms and procedures for addressing patient complaints regarding discrimination and/or harassment in the practice.
- **1.4 Access to Medical Records:** The practice shall provide access for patients to inspect, review, receive, and/or transfer their medical records, in accordance with federal, state, and local laws.<sup>5,6</sup>
  - 1.4.1 Upon request of the patient, the practice shall deliver medical records, including billing records, case management, insurance claims processing information, and other records containing protected health information (PHI) in a format that is consistent with federal, state, and local laws.
  - 1.4.2 The practice shall adopt, publish, and disseminate the procedures by which patients may access their medical records, even if there should be a change of practice ownership or practice closure, so that patients have a clear understanding of the process, timeline, and fees.
- **1.5 Commitment to Transparency Regarding Fees, Costs, and Coverage of Care:** The practice shall operate in a manner that promotes transparency in the cost and coverage of audiologic and vestibular services to empower patients to make informed decisions regarding their care.
  - 1.5.1 The practice shall provide a written bill listing services and corresponding fees to each patient, which clearly outlines the goods and services necessary for the provision of high quality audiologic care regardless of being a bundled or itemized/unbundled model.
  - 1.5.2 The practice shall establish, maintain, execute, and document communication protocols and activities to inform patients about financial information necessary to their treatment decision-making process, including but not limited to, the status of their insurance claims, the need for insurance waivers, notices of non-coverage (including Medicare Advance Beneficiary Notices), required out-of-pocket costs, and alternative financing options.
  - 1.5.3 The practice shall adopt and enforce a conflict of interest (COI) policy that guarantees and protects the independent judgment of providers for any advice or treatment offered to patients.
    - 1.5.3.1 Conflicts of interest include but are not limited to loans, incentives, minimum purchase agreements, stock ownership, and/or the acceptance of gifts or items of value which exceed "nominal value" as defined by the U.S. Department of Health and Human Services Office of Inspector General (OIG).7
    - **1.5.3.2** The COI policy shall require that a conflict of interest, which may compromise the practice's or provider's primary duty to the patient will either be resolved in the best interest of the patient or will be disclosed to the patient.
  - 1.5.4 The practice and its providers adhere to truth in advertising laws, and ethically present their education and credentials to patients, as consistent with professional organizational guidelines. 8.9.10.11

#### **Section 2: Clinical Services**

- **2.1 Commitment to Preventive Care within the Community**. The practice shall engage in concerted education, outreach, hearing conservation, and falls risk prevention activities.
  - **2.1.1** The practice shall promote a variety of hearing healthcare initiatives to educate and increase public awareness for the prevention of audiologic and vestibular disorders.
  - **2.1.2** The practice shall educate colleagues in other health disciplines to promote timely referral for audiologic and vestibular issues.
  - **2.1.3** The practice shall provide a range of information to individuals regarding factors that may cause temporary or permanent damage to the auditory/vestibular system.
  - 2.1.4 The practice shall offer hearing screening tools for the determination of hearing health status. (e.g. questionnaires, screening programs, web-based screen, etc.).
  - **2.1.5** The practice shall provide a range of information and/or screening tools to educate individuals on factors which may increase falls risk.
- **2.2 Process of Diagnosis.** The practice shall use and document systematic, evidence-based protocols throughout the diagnostic process.
  - 2.2.1 The practice shall utilize a detailed case history process (not limited to the cochlear and vestibular systems) to document patients' symptoms, medical, and pharmacological history to formulate the test battery in support of a comprehensive assessment of each patient's auditory and/or vestibular system.
  - 2.2.2 The practice shall seek, critically evaluate, and provide diagnostic protocols, which comprehensively asses the differential diagnosis of the auditory and/or vestibular systems including audiologic assessments, vestibular assessments, and other services as required.
- **2.3 Process of Treatment.** The practice shall develop specific and measurable goals outlined within patient treatment plans, which recognize and support the unique needs of each patient.
  - 2.3.1 Communication needs assessment: The practice shall complete a communication needs assessment, which includes a battery of both objective and subjective measures intended to assess residual auditory function beyond what can be determined by pure-tone and monosyllabic word-recognition-in-quiet testing.<sup>12,13</sup>
  - 2.3.2 Non-auditory assessment: The practice shall investigate associated non-auditory function as a part of the development of the treatment plan (such as, cognitive, visual, dexterity screenings, discussion of support system, environmental characteristics, etc.).<sup>12,13,14</sup>
  - 2.3.3 The practice shall offer a wide range of technological and aural rehabilitation training options to demonstrate a range of cost options and provide accessibility to patients from all socioeconomic populations.
- **2.4 Treatment with Amplification**. The practice shall adhere to rigorous and consistent measures of quality control in the dispensing of amplification products.
  - 2.4.1 The practice conducts an electroacoustic analysis to correlate and confirm device function with current ANSI standards of tolerances prior to dispensing a new, repaired, and/or reconditioned products.<sup>15</sup>
  - **2.4.2** The practice shall use the most reliable evidence-based method for gain verification to measure audibility of soft and average speech input signals across the speech spectrum,

- as well as to determine maximum output levels to avoid exceeding a patient's loudness discomfort level (LDL) i.e. Real-Ear measures, Real Ear to Coupler Differences.<sup>16</sup>
- 2.4.3 The practice shall use alternative conformity assessments, such as sound field measures for functional gain, aided speech in noise testing, and questionnaires. Alternative assessments may be used if and when the technology or patient characteristics do not allow for real-ear protocols (deep insertion devices, implantable technology, etc.).<sup>17</sup>
- 2.4.4 The practice shall have an established process of technology orientation and counseling support to ensure appropriate information has been provided and the patient and/or caregiver no longer requires further post-fitting care.
- 2.4.5 The practice shall perform outcome measures to ensure intervention has made a difference and provides benefit to the patient. The test battery shall include assessment of objective benefit, subjective benefit, satisfaction, and pattern of usage.<sup>17</sup>
- **2.5 Other Services.** If additional clinical services are provided by the practice, the practice shall establish a plan of pre- and post-treatment measures to evaluate the effectiveness of services.
  - **2.5.1** Treatment services may include, but are not limited to: Vestibular rehabilitation, tinnitus, aural rehabilitation, counseling, (central) auditory processing disorder (CAPD), and implantable technology.
- 2.6 Referral Capabilities. The practice shall have access to an established professional network to support timely referral when the patient's needs fall outside of practice services. The referral network may include outside audiology practices, primary care providers, and specialty providers such as otologists, neurologists, physical therapists, psychologists and other related specialties, when needed.
  - **2.6.1** The practice shall use appropriate interprofessional and intra-professional communications when collaborative care is needed.

## **Section 3: Instrumentation, Equipment & Facilities**

- **3.1 Recognition of Impact and Importance of Instrumentation and Equipment on Standard of Care.** The practice shall house and maintain instruments and equipment to assure safety and efficacy in treatment, as dictated by the services provided.
  - **3.1.1** Infection control equipment is mandatory for the provision of care, and includes the following:

| Infection Control Equipment & Supplies | Requirements  | Additional Considerations |
|--|---|---------------------------|
| Disposable Equipment                   | Disposable ear specula, eartips, earmold impression syringe tips, insert receivers, REM/PMM probe tubes, earphone covers, gloves, and/or other one-time-use equipment; Must meet OSHA and CDC guidelines. 18,19 |                           |
| Personal Protective<br>Equipment       | Safety eye goggles,<br>glasses, face masks,<br>gloves, smocks, and/or<br>other personal protective<br>apparel and equipment;<br>Must meet OSHA and CDC<br>guidelines. <sup>18,19</sup>                          |                           |
| Cleaning and Disinfecting<br>Products  | Cleaning supplies and applicators; sterilization/antiseptic/antimicrobial/disinfectant agents, soaps, and cleansers; Must meet OSHA and CDC guidelines. 18,19   |                           |
| Waste Capture and Storage              | Paper towels, wipes,<br>storage containers, and/<br>or waste receptacles;<br>Must meet OSHA and CDC<br>guidelines. <sup>18,19</sup>   |                           |

**3.1.2** Audiologic diagnostic equipment includes the following (note: all required equipment is dependent upon services provided):

| Audiologic Diagnostic<br>Equipment                  | Requirements  | Additional Considerations   |
|---|---|---|
| Otoscopic Equipment                                 | Must meet U.S. Food<br>and Drug Administration<br>requirements outlined in 21<br>CFR 874.4770 <sup>20</sup>   |   |
| Sound-treated Enclosure                             | Must meet ANSI standards <sup>21</sup>  |   |
| Audiometer  | Minimum 1.5 channel, capable of Air-conduction and Bone-conduction audiometry, live and recorded speech (recorded material available e.g. recorded word lists, Quick SIN), and both inserts, and headphones are available. Must meet U.S. Food and Drug Administration requirements outlined in 21 CFR 874.1050 <sup>20</sup> | Include considerations for special populations (e.g. high-frequency audiometer and headphones, visual reinforcement audiometry etc.)  |
| Acoustic Immittance<br>Instrumentation              | Tympanometry, Acoustic<br>Reflex Thresholds, Acoustic<br>Reflex Decay and Eustachian<br>Tube Function testing. Must<br>meet U.S. Food and Drug<br>Administration requirements<br>outlined in 21 CFR 874.1090 <sup>20</sup>  | Include considerations for<br>special populations (e.g.<br>high-frequency probe tone,<br>wide-band, reflectance)  |
| Diagnostic Otoacoustic<br>Emissions Instrumentation | Must meet U.S. Food<br>and Drug Administration<br>requirements outlined in 21<br>CFR 874.1050 <sup>20</sup>   | Include considerations for<br>special populations (e.g.<br>auditory brainstem response<br>(ABR) instrumentation,<br>(central) auditory processing<br>disorder (CAPD) test<br>materials) |

## 3.1.3 Audiologic treatment and management equipment includes the following (note: all required equipment is dependent on services provided):

| Audiologic<br>Treatment and<br>Management<br>Equipment                                  | Requirements   | Additional<br>Considerations   |
|---|--|--|
| Amplification and programming instrumentation and software appropriate to patient needs | All tools, software, and equipment needed for dispensing, modifying, and maintaining hearing devices (daily wear and extended wear).   | Hearing aids, implantable devices, sound generators, alternative amplification devices, and hearing assistive technologies |
| Hearing instrument electroacoustic test box   | Calibrated annually, or as required by state law.  |  |
| Real ear<br>measurement<br>instrumentation  | Calibrated annually, or as required by state law. Must meet U.S. Food and Drug Administration requirements outlined in 21 CFR 874.3310 for "Calibrator, Hearing Aid/Earphone & Analysis Systems" <sup>20</sup>   |  |
| Audiometer<br>with soundfield<br>equipment  | Calibrated annually, or as required by state law.  Must meet U.S. Food and Drug Administration requirements outlined in 21 CFR 874.1050 <sup>20</sup>  |  |
| Cerumen<br>management tools<br>and instrumentation                                      | Curettes, alligator forceps, suction tools and equipment, magnification and illumination instrumentation, and lavage equipment and instrumentation. Must meet U.S. Food and Drug Administration requirements outlined in 21 CFR 874.4420 <sup>20</sup> |  |
| Telehealth<br>equipment and<br>interfaces, consistent<br>with patient needs             | *Secure and dependable internet<br>connection. Hardware including computers,<br>tablets, telephones, cameras and other<br>equipment, and associated software<br>specific to telehealth   | Compliant with federal and state laws and insurance requirements   |

# 3.1.4 Vestibular Diagnostic equipment includes the following (note: all required equipment is dependent upon services provided):

| Vestibular Diagnostic<br>Equipment   | Requirements   | Additional Considerations |
|--|--|---------------------------|
| Otoscopic equipment  |  |                           |
| Video nystagmograph with<br>goggles and TV/Projector for<br>stimulus   | Calibrated annually or<br>as required by state law.<br>Must meet Food and<br>Drug Administration<br>requirements outlined in 21<br>CFR 882.1460 <sup>22</sup>  |                           |
| Caloric irrigator/stimulator   | Must meet Food and<br>Drug Administration<br>requirements outlined in 21<br>CFR 874.1800 <sup>20</sup>   |                           |
| Plinth Table/Exam table  | Must meet Food and<br>Drug Administration<br>requirements outlined in 21<br>CFR 890.3520 <sup>23</sup>   |                           |
| Advanced diagnostic equipment, potentially including the following: Rotary chair, video head impulse test (VHIT) equipment, vestibular evoked myogenic potential equipment, auditory brainstem response instrumentation, computerized dynamic posturography equipment, dynamic visual acuity test equipment, vestibular autorotational test equipment.  Subjective Visual Vertical equipment | Advanced diagnostic equipment must meet applicable Food and Drug Administration requirements outlined in 21 CFR 882.1460, 21 CFR 882.1900, 21 CFR 882.1890, 21 CFR 874.1820, and other sections of the Code of Federal Regulations as applicable. <sup>20,22</sup> |                           |
| Electrophysiology Equipment  | Must meet Food and<br>Drug Administration<br>requirements outlined in 21<br>CFR 890.1175 <sup>23</sup>   |                           |

**3.1.5** Vestibular Treatment and Management includes the following (note: all required equipment is dependent upon services provided):

| Vestibular Rehabilitative<br>Equipment | Requirements  | Additional Considerations |
|--|---|---------------------------|
| Plinth Table/Exam Table                | Must meet Food and Drug<br>Administration requirements<br>outlined in 21 CFR 890.3520 <sup>23</sup> |                           |
| Video goggles                          | Recording capability  |                           |

- **3.2 Facilities Management.** The practice shall use and maintain facilities that promote patient safety, security, access and mobility.
  - 3.2.1 The practice shall provide waiting, treatment, and office areas which adhere to Americans with Disabilities Act (ADA) regulations.<sup>1</sup>
  - 3.2.2 The practice shall house, manage, and store patient records in a manner that complies with Health Insurance Portability and Accountability Act (HIPAA) regulations.<sup>5</sup>
  - **3.2.3** The practice facilities shall be clean, well-maintained, well-lit, and free from hazards.
  - **3.2.4** The practice facilities shall meet or exceed zoning, fire, and occupancy requirements as determined by local, state, and federal law.

### **Section 4: Practice Administration**

- **4.1 Mission and Vision**. The practice shall develop a mission statement or formal statement of purpose that clearly outlines its purpose, services offered, and how and by whom services are rendered.
  - **4.1.1** The practice shall develop a written statement of its commitment to operate in a manner that ensures the rights of its patients.
  - **4.1.2** Practice staff members shall be able to describe the mission and core philosophies of the practice.
  - **4.1.3** The practice mission statement and supporting information shall be readily accessible to staff and patients.
- **4.2 Human Resources.** The practice shall establish and maintain standards for the recruitment, administration, management, training, and separation of employees. For the purpose of this document, the term "staff" may include students, independent contractors, volunteers, owners, and full-time and part-time employees.
  - 4.2.1 The practice's employment policies shall be regularly evaluated against federal, state, and local laws, and meet or exceed those requirements. All staff, including students and observers, shall sign a confidentiality agreement to protect patients' Personal Health Information (PHI) and non-disclosure of said information outside of the office.
  - **4.2.2** The practice shall provide each staff member with a current job description for their role in the practice.
  - **4.2.3** The practice shall ensure that all staff has the appropriate credentials, licensure, and documentation for employment and the delivery of assigned services.
    - **4.2.3.1** The practice shall collect and record all required documentation for immigration, licensure, credentialing, insurance, education/training, and such documentation shall be kept in a manner and format which complies with federal, state, and local laws.
    - 4.2.4 The practice shall provide staff with an employee handbook containing information concerning employment policies, expected practice etiquette, related guidelines, and a process by which to ask questions or seek clarification on matters that are not clear.
    - **4.2.4.1** The practice employee handbook shall minimally include information regarding roles, responsibilities, employment evaluations, anti-discrimination, benefits, training, conflict-resolution, sick and vacation policies, hiring, discipline, dismissal policies, emergency/evacuation planning and training, infection control policies, general conduct, and OSHA safety standards.
    - **4.2.4.2** The practice employee handbook shall include an organizational chart, job descriptions, and other information that clearly delineate the responsibilities of all personnel.
- **4.3 Policies & Procedures.** The practice shall provide written guidelines, processes and procedures to staff covering office and business management procedures, and clinical and safety protocols for staff and patients.
  - **4.3.1** The practice shall establish and document a clinical protocol for all diagnostic, rehabilitative, and preventive services as described in Standards 2.2, 2.3, 2.4 and 2.5.
  - **4.3.2** The practice shall implement a regular process and format for staff coaching, and feedback, which includes both verbal and written communications.
  - 4.3.3 The practice shall establish and hold regular meetings to discuss practice operations, and modifications to or questions regarding established practice requirements, processes, procedures, and patient management.

- **4.4 Accounting and Financial Management.** The practice shall establish and adhere to legal and ethical procedures for fiscal management
  - **4.4.1** The practice shall rely upon a system of checks and balances to ensure compliance with generally acceptable accounting procedures for cash management, banking, billing and receipting of patients' transactions.
  - **4.4.2** The practice has a system to manage insurance claims and other forms of payments, along with a policy for accounts receivable collections.
  - 4.4.3 The practice has a system for documentation and payment of salaries and other payroll benefits to staff, which ensures accuracy, and compliance with required federal, state, and local tax laws.
  - **4.4.4** The practice shall have policies that ensure payments are made in a timely fashion, and a system for payment of accounts payable.
  - 4.4.5 The practice shall have the ability to produce financial statements and a policy of regularly providing profit and loss, balance sheet, cash flow, and other reports to owners and designated managers at minimum on a quarterly schedule.
  - **4.4.6** The practice shall prepare and implement a budget on an annual basis.
  - **4.4.7** The practice shall establish and maintain systems and mechanisms to deter or prevent theft, fraud, or waste.
- **4.5 Insurance Contracting & Reimbursement.** The practice shall establish and maintain policies, procedures, and documentation that demonstrate conformity with current accepted coding practices, and compliance with federal, state, and local laws including HIPAA, Stark, anti-kickback, false claims, truth-in-advertising, and other laws related to the commercial delivery of health care services. <sup>57,8,24,25</sup>
  - **4.5.1** The practice shall have contracts in place and on file for every third-party payer for which they are contracted.
  - 4.5.2 All applicable CPT, ICD and HCPCS codes utilized for each patient shall be listed on the itemized bill of services.<sup>26,27</sup>
  - 4.5.3 Third party waivers shall be given to the patient when applicable to apprise and educate the patient of their financial obligations and those of their payer(s).
  - 4.5.4 For Medicare Part B patients, Advanced Beneficiary Notices (ABNs) should be given prior to service delivery for mandatory or voluntary use. Mandatory use is when the provider questions whether they will meet the Medicare definition of medical necessity. Voluntary use can be offered, but is not required, for those services that are statutorily excluded.
  - **4.5.5** For Medicare Part C patients, a pre-authorization for non-covered services should be given by each specific Medicare Advantage plan and should be obtained from that payer.
  - **4.5.6** Services provided by students must be supervised 100% of the time for diagnostic services billed to Medicare Part B and for other payers who require supervision by the supervisor.
  - 4.5.7 For commercial insurance, waivers shall be given when the patient chooses to upgrade their technology from a basic (covered) item or service to a more sophisticated (non-covered) item or service, with the approval by the payer. Providers may offer their own waiver if permitted by the payer.
  - **4.5.8** For Third Party Administrators, waivers may not be applicable and need to be verified by the payer; when signing the contract, you have agreed to all fixed terms of the contract.

- **4.6 Patient sales contracts and purchase agreements.** State licensure laws often offer requirements of what is to be included in the purchase agreement when devices are purchased. Practices must demonstrate adherence to these requirements.
  - 4.6.1 At a minimum sales agreements must include the name and address of the practice, the name and license number of the provider, name of patient, the date of the purchase agreement, the terms of the purchase agreement that includes the length of time for the device's evaluation and adjustment period, the amounts due and when, the process for return for credit and the amount of funds to be retained by the practice when the device(s) are returned in good condition, the terms if they are not returned in good condition, the serial number of the devices and for which ear and the time and coverage of the warranty period.
- **4.7 Marketing and Communication Plan.** The practice shall create and implement a marketing and communications plan that is consistent with its vision, mission, and best business and clinical practices.
  - **4.7.1** The practice shall advertise and promote services in a manner that is complies with legal requirements and professional code(s) of ethics for audiology.<sup>8,9,10,11</sup>
  - 4.7.2 Marketing strategies employed by the practice may include research, traditional media, interactive media, community outreach, physician/provider outreach, patient recall, public relations, and other methods as needed to support practice objectives.
  - **4.7.3** The practice shall create and adopt a crisis communications plan.
- **4.8 Records Management and Retention.** The practice shall establish and maintain a records retention policy that assures electronic, paper and multi-media data and records are maintained in a manner that protects them from theft, harm, or destruction, and that is compliant with federal, state, and local laws.
  - **4.8.1** The practice shall record and implement a records retention schedule that addresses the following types of records: Patient, financial, equipment/instrument ownership and calibration, corporate and insurance contracts, corporate filings, tax, safety, vendor, and employment records as required to comply with state, federal, and law.<sup>29,30</sup>
- **4.9 Vendor Management.** The practice shall establish and follow policies and for engaging and maintaining relationships with product and service providers, creditors and industry partners.
  - **4.9.1** The practice shall establish a process for evaluating and selecting vendors.
  - **4.9.2** The practice shall maintain contracts with vendors whenever feasible.
  - 4.9.3 The practice shall have Business Associate Agreements (BA) in place with vendors who will have access to patient personal health information (PHI) as defined under HIPAA.<sup>5</sup>

### **Section 5: Quality Assurance and Performance Improvement**

- **Training & Education: Audiologists.** The practice shall demonstrate a commitment to training and education for audiologists as a means of quality assurance and exceptional performance.
  - **5.1.1** The practice shall assure that audiologists providing direct patient care acquire and maintain a license in the appropriate state and/or federal jurisdiction to legally provide clinical services on behalf of the practice. Liability insurance must be maintained on an annual basis for all providers.
  - **5.1.2** The practice shall assure that its practicing audiologists obtain a minimum of 15 hours of continuing education credit annually, or the state licensure requirement, whichever is greater.
- **Training & Education: Support Staff.** The practice shall demonstrate a commitment to training and education for support staff as a means of quality assurance and exceptional performance.
  - 5.2.1 At a minimum, support staff and facility-employed hearing instrument specialists, audiologist's assistants, and other clinical staff must acquire and maintain a license (if one is required) in the state(s) where the practice is located, or where services will be provided.
    - **5.2.1.1** The practice shall document that required training requirements have been met for the maintenance of state licensure for clinical support staff (if licensure is required).
  - **5.2.2** Patient care coordinators and front office staff engaging in hearing aid services shall be trained to adhere to federal and state regulations.
- **Training Plan.** The practice shall establish a training plan for each audiologist and clinical support staff member and shall provide support for continuing education.
  - **5.3.1** All staff shall be provided opportunities for training that will encourage them to follow and observe best practices.
    - **5.3.1.1** Support may be provided through financial, time (for onsite or offsite training), review and analyzation of case studies conducted by the staff, and/or other applicable activities and resources, that are directed to acquire, maintain, and advance the necessary skills in the provision of licensed audiologic services and support services.
- Written clinical protocols. All provided clinical services shall have a corresponding, written protocol attesting to the evidence based best practice for all specific services or procedures. Protocols shall be developed for both routine and rare events. [Examples may include, but are not limited to sudden hearing loss, ototoxicity baseline and monitoring, falls risk, and tinnitus mental health referrals for those experiencing depression.]
- **Clinical Decision Trees (Algorithms).** Practices shall develop (or adopt) step-by-step clinical algorithms to determine whether and when to perform procedures to solve a clinical problem.
  - 5.5.1 Clinical decision-making algorithms shall be based on documented evidence-based best practices, professional judgment, and individual patient characteristics. The assessment procedure may vary from these algorithms based on patient needs, cooperation, and the assessment setting. Algorithms should be used to determine, identify, quantify, describe, and/or assess.<sup>17,31,32</sup>
  - **5.5.2** Clinical decision-making algorithms shall be evaluated annually with clinical documentation of the review.
  - **5.5.3** Clinical decision-making algorithms should be examined against several factors.

- **5.5.3.1** Algorithms shall address the developmental age, or special populations for which the algorithm is appropriate.
- **5.5.3.2** Algorithms shall address the referrals received for which algorithm is appropriate as well as referrals outside the practice, which are appropriate for this algorithm.
- **5.5.3.3** Algorithms shall address expected outcomes the audiologist plans to develop or prepare for patient as a result of completing the assessment.
- **5.5.3.4** Algorithms shall address the clinical process, including the decision-making and interpretation regarding diagnostic and rehabilitative implications of information, observations, and results occur throughout this process.
- **5.5.3.5** Algorithms shall be accompanied by references.
- **5.5.3.6** Algorithms shall be reviewed at regular intervals to incorporate new evidence.
- **Coordinated feedback.** The practice shall implement mechanisms for formal and informal feedback from patients and staff.
  - **5.6.1** Patient surveys shall be used to assess patient satisfaction with clinical services, operations, and outcomes.
    - **5.6.1.1** Patient feedback should be obtained at regular intervals, and at least annually.
    - **5.6.1.2** The practice may use written, verbal, or online survey tools to obtain feedback.
  - **5.6.2** Staff surveys shall be used to assess staff satisfaction with clinical services, operations, and outcomes.
    - **5.6.2.1** Staff feedback should be obtained at regular intervals, and at least annually.
    - **5.6.2.2** The practice may use written, verbal, or online survey tools to obtain feedback.
  - 5.6.3 Staff meetings shall be held regularly to assess clinical operations to ensure the delivery of cohesive, evidence-based services. Staff meetings should provide an opportunity to discuss and address quality improvement efforts, specific concerns or negative outcomes, risk management, and innovations in all systems.
    - **5.6.3.1** For those facilities who do not employ any staff, it is understood that self-reflection activities will be conducted in lieu of staff meetings.
- **Practice**, **Provider and Patient metrics**. The practice shall establish and use metrics to evaluate business and clinical outcomes, improve performance, and to identify risks, strengths, weaknesses, opportunities and threats.
  - **5.7.1** The practice shall develop and apply the Key Performance Indicators (KPI), to each area of the practice.
  - 5.7.2 The practice shall publish the KPIs to be monitored, and document the rationale, the chain of responsibility, and the intervals for measuring and reporting.
  - 5.7.3 The practice shall inform and train staff regarding each metric/KPI for which they will have responsibility to develop, impact, monitor, or report.
  - **5.7.4** The practice shall provide documentation that KPIs have been recorded, monitored, and utilized in decision-making processes.

- **Equipment Calibration and Maintenance**. The practice shall establish and implement a calibration and maintenance schedule for equipment and instruments, which meets or exceeds both legal and recommended industry standards.
  - **5.8.1** Calibration and maintenance records shall be maintained by the practice in conjunction with the practice's record retention policy.
  - **5.8.2** Maintenance and calibration records shall be publicly available upon request.

#### REFERENCES:

- 1. Americans with Disabilities Act (ADA) Federal Government website. Accessed on April 27, 2018 at the following link: <a href="https://www.ada.gov/">https://www.ada.gov/</a>.
- 2. Bankaitis, A U, and Robert J. Kemp. *Infection Control in the Audiology Clinic*. United States: Auban, 2005. Print.
- 3. United States Department of Labor Occupational Safety and Health Administration. Evacuations Plans and Procedures e-tool website. Accessed on May 15, 2018 at the following location: <a href="https://www.osha.gov/SLTC/etools/evacuation/checklists/eap.html">https://www.osha.gov/SLTC/etools/evacuation/checklists/eap.html</a>.
- 4. U.S. Equal Employment Opportunity Commission. Discrimination Laws and Statutes website. Accessed on May 15, 2018 at the following location: <a href="https://www.eeoc.gov/laws/statutes/">Https://www.eeoc.gov/laws/statutes/</a>.
- 5. U.S. Department of Health and Human Services. HIPAA requirements. Accessed on May 10, 2018 at the following location: <a href="https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html">https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html</a>.
- 6. Findlaw website for state laws related to medical records. Accessed on May 10, 2018 at the following location: <a href="https://statelaws.findlaw.com/health-care-laws/medical-records.html">https://statelaws.findlaw.com/health-care-laws/medical-records.html</a>.
- 7. Office of the Inspector General. Statement on nominal value. Accessed on May 12, 2018 at the following location: <a href="https://oig.hhs.gov/fraud/docs/alertsandbulletins/OIG-Policy-Statement-Gifts-of-Nominal-Value.pdf">https://oig.hhs.gov/fraud/docs/alertsandbulletins/OIG-Policy-Statement-Gifts-of-Nominal-Value.pdf</a>.
- 8. Federal Trade Commission website. Truth in Advertising laws. Accessed on May 15, 2018 at the following location: <a href="https://www.ftc.gov/news-events/media-resources/truth-advertising">https://www.ftc.gov/news-events/media-resources/truth-advertising</a>.
- 9. USA.gov State Consumer Protection website. Accessed on May 16, 2018 at the following location: <a href="https://www.usa.gov/state-consumer">https://www.usa.gov/state-consumer</a>.
- 10. Academy of Doctors of Audiology Code of Ethics. Accessed on May 10, 2018 at the following location: <a href="http://www.audiologist.org/academy-documents/code-of-ethics">http://www.audiologist.org/academy-documents/code-of-ethics</a>.
- 11. American Academy of Audiology Code of Ethics. Accessed on May 10, 2018 at the following location: <a href="https://www.audiology.org/sites/default/files/about/membership/documents/Code%200f%20Ethics%20with%20procedures-REV%202018\_0216.pdf">https://www.audiology.org/sites/default/files/about/membership/documents/Code%200f%20Ethics%20with%20procedures-REV%202018\_0216.pdf</a>.
- 12. Committee on Accessible and Affordable Hearing Health Care for Adults; Board on Health Sciences Policy; Health and Medicine Division; National Academies of Sciences, Engineering, and Medicine; Blazer DG, Domnitz S, Liverman CT, editors. Hearing Health Care for Adults: Priorities for Improving Access and Affordability. Washington (DC): National Academies Press (US); 2016 Sep 6. Available from: https://www.ncbi.nlm.nih.gov/books/NBK367633/ doi: 10.17226/23446
- 13. ASHA. Hearing aids for adults. 2016f. [April 25, 2016]. <a href="http://www.asha.org/Practice-Portal/">http://www.asha.org/Practice-Portal/</a> Professional-Issues/Hearing-Aids-for-Adults.
- 14. Valente M. Guideline for audiologic management of the adult patient. 2006. [February 22, 2016]. http://www.audiologyonline.com/articles/guideline-for-audiologic-management-adult-966.
- 15. Ravn G, Preves D. Hearing Aid–Related Standards and Test Systems. *Seminars in Hearing*. 2015;36(1):29-48. doi:10.1055/s-0034-1396925.
- 16. Lindsey E. Jorgensen, Verification and validation of hearing aids: Opportunity not an obstacle, Journal of Otology, Volume 11, Issue 2, 2016, Pages 57-62, ISSN 1672-2930, <a href="https://doi.org/10.1016/j.joto.2016.05.001">https://doi.org/10.1016/j.joto.2016.05.001</a>. (<a href="https://www.sciencedirect.com/science/article/pii/S1672293016300228">https://www.sciencedirect.com/science/article/pii/S1672293016300228</a>)
- 17. American Academy of Audiology Guidelines and Standards website. Accessed on May 7, 2018 at the following location: <a href="https://www.audiology.org/publications/guidelines-and-standards">https://www.audiology.org/publications/guidelines-and-standards</a>.

- 18. U.S. Department of Labor. Occupational Safety and Health Administration. Healthcare. Infectious Diseases. Accessed on May 14, 2018 at the following location: <a href="https://www.osha.gov/SLTC/">https://www.osha.gov/SLTC/</a> healthcarefacilities/infectious\_diseases.html,
- 19. United States Centers for Disease Control and Prevention. Guidelines for Infection Control. Accessed on May 15, 2018 at the following location: <a href="https://www.cdc.gov/infectioncontrol/guidelines/index.html">https://www.cdc.gov/infectioncontrol/guidelines/index.html</a>
- 20. U.S. Food and Drug Administration. Code of Federal Regulations Title 21 Section 874. Accessed on May 16, 2018 at the following location: <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=874">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=874</a>.
- 21. ANSI-S3.1-1991, Maximum permissible ambient noise levels for audiometric test rooms. <a href="https://www.ansi.org/">https://www.ansi.org/</a>
- 22. U.S. Food and Drug Administration. Code of Federal Regulations Title 21 Section 882. Accessed on May 16, 2018 at the following location: <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=882">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=882</a>.
- 23. U.S. Food and Drug Administration. Code of Federal Regulations Title 21 Section 890. Accessed on May 16, 2018 at the following location: <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=890">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=890</a>.
- 24. Centers for Medicare and Medicaid Services (CMS) <a href="https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index.html">https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index.html</a>. Physician Self-Referral website. Accessed on May 14, 2018.
- 25. Office of Inspector General, U.S. Department of Health and Human Services. Fraud and Abuse Laws website. Accessed on May 15, 2018 at the following location: <a href="https://oig.hhs.gov/compliance/physician-education/01laws.asp">https://oig.hhs.gov/compliance/physician-education/01laws.asp</a>.
- 26. Centers for Medicare and Medicaid Services (CMS) coding and Education website. Accessed on May 15, 2018 at the following location: <a href="https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/MLN-Publications-Items/ICN900943.html">https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/MLN-Publications-Items/ICN900943.html</a>.
- 27. Sjoblad S, Abel D. How to Implement Itemization in an Audiology Practice. *Seminars in Hearing*. 2016;37(2):137-147. doi:10.1055/s-0036-1579704.
- 28. Internal Revenue Service (IRS) website. Accessed on May 10, 2018 at the following location: <a href="https://www.irs.gov/businesses/small-businesses-self-employed/how-long-should-i-keep-records">https://www.irs.gov/businesses/small-businesses-self-employed/how-long-should-i-keep-records</a>.
- 29. Centers for Medicare and Medicaid Services (CMS) Medical Record Retention and Media Formats for Medical Records. Accessed on May 15, 2018 at the following link: <a href="https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1022.pdf">https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1022.pdf</a>.
- 30. The American Speech-Language Hearing Association. Practice Portal, Audiologists. Accessed on May 15, 2018 at the following link: <a href="https://www.asha.org/Practice-Portal/Audiologists/">https://www.asha.org/Practice-Portal/Audiologists/</a>.
- 31. The American Speech-Language Hearing Association. Joint Committee Clinical Practice Statements Algorithms. Accessed on May 15, 2018 at the following link: <a href="https://www.asha.org/policy/GL1999-00013/">https://www.asha.org/policy/GL1999-00013/</a>.