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Laws, Regulations and Professional Conduct for Hearing Aid Dispensing in New York

Barbara Kruger, Ph.D.

Limitations/Risks

Please review these bullets and make any revisions/additions as applicable for your course.

- The applicability and accuracy of the course content may vary by the clinical, geographical, and cultural context; you should evaluate the course accordingly.
- As healthcare is rapidly evolving, new findings may change the validity of the information presented in this course. Providers should always consult the latest research and guidelines from professional associations.
- The interventions discussed in this course may be limited in generalizability, requiring practitioners to consider specific individual and population factors.
- The course may not cover all possible risk factors, diagnostic methods, or treatment options, and complex cases may require additional considerations.
- Healthcare providers should apply cultural competence and sensitivity to ensure effective and respectful care based on their patients' diverse needs.
- Providers should always evaluate the limitations of diagnostic and screening tools, considering their potential for false results as well as any ethical implications.
- It is the responsibility of course participants to critically evaluate the evidence from multiple sources to guide professional practice.

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- **Presenter Disclosure:** Financial: Barbara Kruger received an honorarium for presenting this course. Non-financial: Barbara Kruger has no relevant non-financial relationships to disclose.
- **Content Disclosure:** This learning event does not focus exclusively on any specific product or service.
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Learner Outcomes

- After this course, participants will be able to state who must register as a hearing aid dispenser in NY and explain the renewal requirements including those for continuing education.
- After this course, participants will be able to explain the regulations pertaining to medical/ORL evaluation and clearance for the purchase of a prescription hearing aid in NY state, in light of current federal regulations.
- After this course, participants will be able to describe the requirements for giving candidates for hearing aids a copy of their audiogram/hearing test in NY State and summarize the educational materials and forms that should be provided to the consumer and what should be explained to the consumer about the prescription hearing aid(s) being purchased in NY state.

NY State & Federal Law, Regulations & Professional Conduct for Hearing Aid Dispensing – Updated 2025

Barbara Kruger, Ph.D.

Hearing Aid Dispensing Advisory Board –

Audiologist Member – *13 years through 5/1/2012*

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barbara@audiologist1.com

<https://dos.ny.gov/hearing-aid-business>

<https://dos.ny.gov/nys-hearing-aid-dispensing-advisory-board>

NOT <https://video.dos.ny.gov/licensing/hearingaid/hearingaid.html>

www.dos.ny.gov/licensing/hearingaid/hearaid.html

FDA & NYS Law & Regulations for Dispensers of Prescription Hearing Aids; and FDA Regulations for OTC Sellers

- Laws, Rules and Regulations –
 - Status:
 - **what changed re: FDA**
 - **What should still change re: FDA**
- Registration –
 - Licensing
 - Trainee registrations
- Renewal
- Training
- Business Practices –
- Records – to make changes based on FDA regs
- Training of the Consumer

FDA Final Regulations for OTC Hearing Aids & for Prescription Hearing Aids (PHA): Effective Oct. 17, 2022

- **NY State law must = Federal law;**  yet ???

Goal: increase access to amplification & stimulate the market

- **FDA Removed required Medical Evaluation** –
 - No Prior Medical Approval required => 18
- FDA FINAL regs
 - for OTCs - Federal only
 - For Prescription HAs – Federal and State
 - Final State Implications – **Still No Changes**

Business Practices for HAD – Medical “Prior” Evaluation Condition for Prescription HA (PHA) Sales

orig. 1977, Changes 2016, proposed 10/20/2021, final change 10/17/2022

- **FDA regulations in 1977:** required a prior medical evaluation
 - NYS DOS law & regs (798.8 and 192.11)
 - Dispenser shall advise the perspective hearing user to consult promptly with a physician (preferably an ENT)
 - Complied with old 1977 FDA regulations
- ***FDA 2022 regulations –***
 - do not require medical/ORL evaluation
 - There is no mention of a waiver
 - Now 8 (really 9) Red flags for medical referral signs
- ***NYS still original 8 Red flags or 8 medical referral signs***
- ***NYS - Still Requires medical /ORL eval or
May opt to sign waiver of Med/ORL evaluation***

OTCs and Prescription Hearing Aids: FDA final: When to See a Doctor

- **OTCs: 9 Red Flag Warnings** — (proposed 7; DOS 8)
 - Your ear has a birth defect or unusual shape
 - You saw blood, pus or fluid coming out of your ear in past 6 mos
 - Your ear feels painful or uncomfortable
 - You have a lot of ear wax, or something could be in your ear
 - You get really dizzy, or have a feeling of spinning or swaying (called vertigo)
 - Your hearing changed suddenly in past 6 mos
 - Your hearing changes: it gets worse & then better again
 - You have worse hearing in one ear
 - You hear ringing or buzzing in only one ear

FDA PHA **Reg Flags** –7+1 Medical Warning Signs conditions for HAD – advise about consulting a licensed physician, preferably an ENT

- Visible deformity of the ear, either congenital or traumatic
- Fluid, pus or blood coming out of the ear in the past 6 months
- Pain or discomfort in the ear
- History of excessive wax or suspicion that something is in the ear
- Dizziness, either recent or long-standing
- Sudden, quickly worsening, or fluctuating hearing loss within previous 6 months
- Hearing loss or ringing (tinnitus) only in one ear or a noticeable difference in hearing between ears

+

- Audiometric air-bone gap equal to or greater than 15 dB at 500 Hz, 1000 Hz, and 2000 Hz

NYS DOS LAW – 8 Medical Warning Signs conditions when HAD **must advise client** to consult a licensed physician, preferably an ENT

- Visible congenital or traumatic deformity of the ear,
- History of, or active drainage from the ear within previous 90 days
- History of sudden or rapidly progressive hearing loss within the previous 90 days
- Acute or chronic dizziness
- Unilateral hearing loss of sudden or recent onset within the previous 90 days
- Audiometric air-bone gap equal to or greater than 15 dB at 500 Hz, 1000 Hz, and 2000 Hz
- Visible evidence of bleeding, significant cerumen accumulation, or a foreign body in the ear canal
- Pain or discomfort in the ear

OTCs and Prescription Hearing Aids Where are we now?

- OTCs
 - FDA is the Law
 - No State laws for OTCs
 - Primarily Labelling
 - Self-perceived Mild to Moderate Hearing impairment
 - No Medical eval => 18
 - No Hearing eval => 18
 - Self-fitted or adjusted
- Prescription (PHA) HAs
 - FDA
 - No prior medical approval
 - State law governs HAD
 - Changes to be made to comply with FDA
 - Can be stricter or “more stringent” than FDA

Prescription Hearing Aids (PHAs) State can be stricter than FDA

- More stringent refers to a requirement of greater restrictiveness or one that is expected to afford to those who may be exposed to a risk of injury from a device a higher degree of protection than is afforded by a requirement applicable to the device under the Federal Food, Drug, and Cosmetic Act.
- How is this interpreted?

OTCs Hearing Aids: Where are we now?

- OTCs:
 - New Regulatory category –
 - Purchased **without** involvement of hearing healthcare professional *
 - Lots of Labeling outside and inside the devices
 - 21 CFR Part 800, 801, 808, and 874
- IEC/ISO: OTC = Direct to Consumer

OTCs & Prescription Hearing Aids (PHAs)

Where are we now?

- OTCs: WARNINGS Outside
 - OTCs – only for users who are 18 and older
 - If 18 or younger, you should go to a doctor, preferably an ear-nose-throat doctor
- PHAs:
 - Same age criteria as OTCs apply for PHAs

OTCs Hearing Aids: Where are we now?

- OTCs: Labelling and Warnings **Outside**
 - **Self Perceived** mild to moderate hearing loss
 - You have trouble hearing speech in noisy places
 - You find it hard to follow speech in groups
 - You have trouble hearing on the phone
 - Listening makes you tired
 - You need to turn up the volume on the TV or radio and other people complain it's too loud

OTCs Hearing Aids: Where are we now?

- OTCs: Labelling and Warnings **Outside**

Who may need hearing healthcare professional help

- You can't hear speech even if the room is quiet
- You don't hear loud sounds well, e.g.
 - you don't hear loud music, power tools engines or other very noisy things

OTCs Hearing Aids Where are we now?

- Allows lay user to **Select ... How OTCs are Fit**
 - **Customize:** Manipulate to meet hearing needs
 - Frequency bands
 - Volume (no gain limits)
 - **Self-Fit** – not clearly defined
 - Use Online tools, test, software -- 800.30(b)
 - Adjust How hear: independently control settings based on their input using self-fitting strategy

OTCs Hearing Aids: Where are we now?

- OTCs: Lots of Labeling **Outside** the box
 - Contact info, including instructional brochure
 - Succinct accurate statement of return policy
 - Marked as OTC
 - Battery information
 - Indication of Control Platform –
 - Is a mobile device or other non-included control platform required? it's type & how it connect to OTC

OTCs Hearing Aids Where are we now?

- OTCs: Labeling **Inside** the box Instructional brochure
 - Make an electronic version available for download –
 - Without site or customer registration or
 - Without requiring purchase of any product or service
 - Age and Red Flag Warnings

OTCs Hearing Aids: Where are we now?

- OTCs: Labeling **Inside** the box
 - The HA should not cause pain when inserting it
 - This is not hearing protection –
 - Remove if you experience overly loud sounds
 - Use right kind of hearing protection
 - Sound output should not be uncomfortable or painful
 - You **might need medical help** if gets stuck in your ear
 - If remain concerned, consult a professional

OTCs Hearing Aids: Where are we now?

- OTCs: Labeling **Inside** the box
 - What you might expect
 - It won't restore hearing
 - You may still have some difficulty hearing over noise
 - Many people find that training or counselling can help them get more out of their devices
 - If you have hearing loss in both ears – you might get more out of using hearing aid in both ears

OTCs Hearing Aids: Where are we now?

- OTCs: Tell FDA about injuries, malfunctions or adverse events
 - ~~<https://fda.gov/Safety/MedWatch>~~ Not now!
 - <https://fda.gov/MedWatch> ← NOW
 - Call 1-800-FDA-1088
 - A downloadable form to mail to the FDA

OTCs Hearing Aids: Where are we now?

- OTCs: Labeling **Inside** the box
 - Illustration with operating controls, user adjustment and battery compartment
 - Function of all controls for user adjustment
 - Description of & use accessories
 - Instructions for sizing & inserting eartip:
 - $\geq 10\text{mm}$ from TM
 - Tools, tests or software to control OTC including self selecting & self checking performance to customize to user's hearing needs

OTCs Hearing Aids Where are we now?

- OTCs: Labeling **Inside** the box
 - Maintenance and Care instructions
 - Battery Use and Expected Life: to replace or recharge
 - Possible physiological Side effects e.g. skin irritation
 - If wireless technology info about it's compatibility
 - Labelling
 - Serial number
 - Battery – meaning of + meaning positive terminal

OTCs Hearing Aids: Where are we now?

- OTCs: Technical Specifications
 - Output Limit Levels
 - Shall not exceed 111 dB SPL -- (proposed 115 dB SPL)
 - Output Limit with input–controlled compression
 - Shall not exceed ≤ 117 dB SPL (proposed 120 dB SPL)
 - Many more details for OTC specification and testing - no gain limits

OTCs Hearing Aids: Where are we now?

- OTCs: Technical Specifications
 - Output SPLs 90 (OSPL90)
 - Full-On Gain with 50 dB SPL pure-tone input, Volume at Full-ON
 - Total Harmonic distortion
 - Self Generated Noise Value
 - Time latency value
 - Upper and lower cutoff frequencies for bandwidth
 - Software labeling - lots More details

OTCs Hearing Aids Where are we now?

- OTCs: Effect on State Law
 - State or local government law is preempted
 - No State laws on sale or distribution etc.
- A licensed person may
 - service, market, sell, dispense and provide customer support for OTCs or
 - distribute OTCs
 - State laws about dispensing and servicing apply

Prescription Hearing Aids (PHA): non-OTC

Where are we now? **FDA Final Rule**

- 801 Labeling -
 - 801.420, 801.421, and 801.41 removed
- **Defines Prescription Hearing Aids**
 - added 801.422 part H
 - a hearing aid that is not OTC (800.30)
- Technical specifications: ANSI/ASA S3.22-2014 (R2020)
 - Warnings to HAD re: Outputs over 132 dB SPL

Prescription Hearing Aids (PHA): non-OTC Where are we now? **FDA clarifies Final Rule**

- Who may prescribe:
 - **No change in qualifications of who provides hearing healthcare with prescription HAs**
 - Including selection, fitting and dispensing
 - **Same licensed professionals as before**
- Medical evals - no additional professionals
 - **NOT require physician's involvement**
 - not require an examination of any kind

Prescription Hearing Aids (PHA): non-OTC

Where are we now? **FDA Final Rule**

- **Under 18: should** see MD, have recent medical eval that advises use of appropriate HA
 - MD identify & treat medical conditions
 - MD may refer to Audiologist: Test and HAE
- **People age 18 and over**
 - **No Medical EVAL REQUIRED by FDA**
 - No MD prior approval to dispense PHAs by FDA
 - No waiver for MD evaluation

Generally, **Medicare** requires a physician's order for audiology services in all settings.

- CMS exception to the physician order requirement at **42 CFR 410.32(a)(4)**
- Allows patients to directly access audiologists:
 - For dates of service on, or after, January 1, 2023,

Federal Good News: Medicare Part B Limited Audiology Access Provisions 2023

- **Audiology Services WITHOUT Physician order -- Medicare.gov**
 - **Once per year**
 - New AB modifier with one of 36 CPT codes
 - Non-acute hearing conditions (like hearing loss that occurs over many years)
 - Diagnostic services related to hearing loss that's treated with surgically implanted hearing devices
 - BUT NOT tests for disequilibrium or imbalance.

Prescription Hearing Aids: non-OTC

Where are we now in NYS?

- Governed by Department of New York State
 - Signed by Pataki 9/1998, Board formed 1999
 - Article 37A – General Business Law – effective 1/1/2001
 - **no change yet (except to change year to 2023)**
 - Rules & Regulations - 19NYCRR Part 192:
 - to change
 - **Must comply with Federal Regulations ****
- Purpose → **Consumer Protection**

Prescription Hearing Aids: non-OTC

Where are we now?

Re: FDA--What should change - NYS law !

- No prior approval by MD or ENT or WAIVER
 - 798.5 mandates prior MD approval,
 - 798.6 and 798.7 and 798.8 mandates
 - medical/ENT eval and allows waiver if =>18,
 - 6e Posting of 40 pt sign requiring medical eval
 - 6f waiver details
 - 798.7 and 798.b an 798.c mandates
 - referral criteria for dispensing and waiver based on religious beliefs is to be discouraged

Prescription Hearing Aids: non-OTC Where are we now?

Re: FDA-What should change - NYS Regs !

- 192.1 Prescription hearing aids
 - all reference to hearing aids must state Prescription HAs
- Update General Business Law & regs from 2016 *
 - 3 mandated Continuing Ed. Courses
 - 40 pt Sign posted to include:
 - Telecoil and ALD benefits – from 2019
 - Still mandated prior approval by MD/ENT or Waiver
 - Change: no longer Mandatory, but Advisory in 798.8 & 192.11, 192.12
 - from mandatory 8 Reg Flags (FDA 1977) to 9
 - to -- consider suggesting a medical evaluation

FDA Tries to Direct States to Comply – Sent Letter to States: Oct. 13, 2022

- The final rule also makes **several changes to Federal regulations** that apply to hearing aids, including:
 - Repeals the conditions for sale for hearing aids under 21 CFR § 801.421;
 - Defines
 - non-OTC hearing aids **as prescription devices**, subject to 21 CFR § 801.109, **rather than restricted devices** (see 87 FR at 50755, removing § 801.421); and
 - Provides **updated labeling requirements for such prescription hearing aids** (see id., adding new 21 CFR § 801.422).

FDA Tries clarify the final rule and to Direct States to Comply: Sent Letter to States: Oct. 13, 2022

- Does **not change the necessary qualifications of who may provide hearing healthcare with prescription hearing aids**, including the recommendation, selection, fitting, and dispensing of these devices;
- Does **not in any way require a physician's involvement prior to fitting these devices**; and
- Does not require an examination of any kind to obtain a prescription hearing aid.

NYS STILL Applies Old Rules

- WHY – Speculation
 - **can opt to be more stringent**
 - Risks of Opening the Law,
 - Could edit to use wording of FDA as it did to redefine Prescription Hearing Aids
- How to proceed
 - Work to correct # of HADAB members
 - Professional Orgs with Legislators

HAD Advisory Board (HADAB): in 2025 ... only 5 of 13 members

- 4 non-audiologist hearing aid dispensers (1) - 3 vacant
- 4 audiologist dispensers (2) - 2 vacant
- 2 otolaryngologists (1) - 1 vacant
- 3 knowledgeable lay public citizens (1) 2 vacant
 - At least 1 over 50 - (0) - 1 vacant
 - At least 1 shall be hearing aid user - (2) - 1 vacant
- Required to meet 4 times/year – gaps continues -- BIG ISSUE
 - NEVER sufficient to have quorum
 - but still meet and staff implements what they want
- First change in members: May 2012 ... and more since
- Now Need 8 -- 2 Audiologists who dispenses
3 non-audiology dispensers,
1 ORL and 2 public citizens

Prescription HA Dispensing: WHO needs a License or registration?

- Any individual
 - who is engaged in the act of “fitting, selecting,
renting, adapting, or servicing of **prescription**
hearing aids or any other instrument to
compensate for impaired hearing.”
- A separate business registration to operate a
business

Individual HA Dispenser

Non-audiologist HA Dispenser

- Any person ≥ 21 yrs
- 2 years of college
- Trainee program 1 yr
- Theory & Practical Exams
- Training program credit for course work completing
- If complete theory instruction with approved educational provider, trainee may be granted 3 mos less training time
- see Section 192.4 Education Part (k):

- An **Audiologist** dispenser
 - Either **first** licensed under the Education Law (Article 159)
 - **Practical Exam – only**
 - OR Two Options - **Au.D. student before Audiology license**,
 - 1. Wait, get Au.D., & Audiology Lic. then take **HAD practical exam**
 - **Can take 4-5+ years to get HAD Lic**
 - 2. Theory & Practical Exams –
 - Au.D student, with trainee certificate of registration, may be granted 3 mos less training time see Section 192.4 Education Part (k):

HAD Trainee Certificate: for non-AuDs

HAD trainee –

Dispenser Trainee

- Obtain trainee registration for 1 year
 - – Can only be extended ONCE
- Pass Theory & practical exam
- Get HAD License

HAD Trainee Certificate of Registration for Audiology students

- EACH year when working with Prescription hearing aids on people
 - **starting with 1st Clinical Placement/Externship**
 - Au.D. Student must be in a nationally accredited university program that leads toward NYS licensure in Audiology
- <https://dos.ny.gov/hearing-aid-business> download HAD application
- Process for Obtaining a Trainee Registration for an Audiology Student
 - Problems continue

Audiology AU.D. Students, MUST have HAD Trainee “temporary certificate of registration”

1. Complete HA Dispenser Application: each year
 - Select number 2 - “first-time applicant for temporary certificate Employer's Affidavit portion by University's supervisor, or designee.
 - Select number 3 - “applying for each additional each year
 - With Au.D., apply for Audiology license first then
 - Register to take and pass HAD practical exam,
 - HAD license
- Or 2 Complete number 4 on HAD application: 6 mos (or 3 mos)
 - submit six-month training certificate along with the required fee.
 - Supervising instructor may give **3-mos of credit for completion of theory hours** may giving by initial the bottom of the certificate --
 - Trainee must **pass both the written exam and practical exam** (ear mold and audiometric portions.)
- After 6 more mos, Complete Number 5 on HAD application
12-month training certificate & required fee for two-year license.

Terms of HAD registration and renewal: Section 792

- Renew **Every 2 years** ← individuals & businesses
- Sign affirming compliance with
 - **Continuing education** — Law 794 Rules and Regs 192.7
 - **mandated courses 1x/each 2 yr renewal cycle** ←
 - Annual equipment calibration and
 - Test room adequacy
- Fees — posted on website and varies with type of setting

DOS Continuing Education Requirements for non-Audiologist HAD Dispensers .. since 1/1/2019

- **20 hrs** relating to dispensing hearing aids
 - on hearing and hearing aids - Not business and sales
 - 3 mandated hours – 1x in **every 2 yr renewal cycle**
 - 1 hour on each of 3 mandated course –
 - **Infection Control**
 - **New York & Federal Law, Regulations and Professional Conduct**
 - 1 hour course “**must include the topic of telecoil (t-coil) and other assistive listening devices**”
- **Courses and instructors approved by DOS - face-to-face only**
 - **Or** Live-distance Learning
 - if CEU plan approved by DOS Div Licensing
 - If active presence is verified throughout the presentation – e.g., Q&A etc.
 - Must sign in/out participate & attest to presence

DOS Continuing Education Requirements for Dispensing Audiologists since 1/1/2019 **

- DOS Requires CE hours - **EVERY 2 Years**
- 4 hours on hearing aid dispensing - Not business and sales
 - 3 mandated hours: 1x per 2yr renewal cycle
 - 1 hour on each of 3 **mandated** course – in **every 2 yr renewal cycle**
 - **Infection Control**
 - **New York & Federal Law, Regulations and Professional Conduct**
 - 1 hour course “**must include the topic of telecoil (t-coil) and other assistive listening devices**”
 - 1 additional hour on hearing aids
- DOE Audiology license renewal
 - 10 hrs/yr 30 hours/3 years for Audiologists ***
 - dually certified clinicians: 50 hrs/3yrs 20+20+10 flexible Aud or SLP,

Renewal of licenses

- How often do you **renew HAD Reg/Lic**?
 - Every ___ years? 1, 2, 3,
- How often do you renew **Audiology Lic.**?
 - Every ___ years? ... 2, 3, 6
- How often **must** you take the **HAD mandated courses**?
 - The answer is --- every ___ years 1, 2, 3,
- How many **1 hour mandated CE** courses are required for the **DOS**:
 - DOS requires _____ courses every 2 years? 1, 2, 3,

Trainee Certificates –

- Audiology License from **another** State
 - there is essentially **no reciprocity**
 - With no recent Dispensing experience, Audiologists must become trainees
 - With recent Dispensing experience, file for practical exam to get HAD lic.

CE: Equivalency Credit Section 192.7 (S)

- Courses not prior approved by DOS and Offered outside of NYS
- To get credit for these courses:
 - Submit application – website
 - At least 30 days prior to expiration of registration
 - Documentation of satisfactory completion
 - Official description of course

Trainee Year –

- Registered HAD is responsible for all actions for trainee year
- 1st 3 mos - **Direct** supervision
- 2nd 3 mos - actions only with immediate consent, review & approval, & **availability of on-premises HAD**
- at 6 mos – after course - May take exam after 3 mos e.g. with extensive education like AuD students
- During last 6 mos – **still supervised for sales**

Curriculum - Minor Revisions 2016

in Sections 1,2,3,4,5,8,9

Curriculum	Theory	Practical
Acoustics: General Principles	5	10
Acoustics: Hearing and Speech	5	10
The Human Ear, Sect 8	5	10
Disorders of Hearing, Sect 9	5	10
Pure-tone Audiometry, Sec 1	20	40
Speech Audiometry, Sec 2	15	20
Hearing Analysis, Sect 3	45	90
Hearing Aids & Instruments, Sect 4	45	90
Infection Control, Sect 5	5	10
NYS & Fed Law, Regs & Professional Conduct	5	10
TOTAL	155	310

Education of Trainees:

GBL 796 192.4 Education & 192.5 Training Program

- Curriculum from DOS, Bureau of Educational Standards –
- Syllabus
 - Theory: 155 hours (124)
 - Practical: 310 hours
- DOS must approve **you** as an instructor
- One year of Responsibilities
 - supervision and training
- Exams

Practical exam Section 192.10

- gloves,
- wipes,
- liner on surface,
- clean and dirty containers for transport,
- describe faults of impression if any etc.

Only licensed Audiologists: take the practical exam only

- Earmold and counseling sections
- not audiometric testing section

Practical exam

- Bring an “ear” with you in a Live Model
- Look in ear before & after
 - Use different otoscope speculum for each ear
- Be sure to brace properly
 - secure hand against patient’s head when inserting anything in patient’s ear – oto-light, otoscope, impression syringe



Brace Properly



- Secure hand against individual's head



Practical Test for HAD trainees

- Audiometric Section
 - Demonstration of hearing testing
- Need to bring your own audiometer

Not only Microphones in Hearing Aids, Telecoils, Loops and Assistive Listening Devices for HAD

Standards – safety, data exchange, quality control
product regulation

Re: Measurements on Hearing Aids via Microphone and
Telecoil for phones, loops or other ALDs

Counseling

National and International Standards

Primary Deliverables

- ANSI Approved Documents

- American National Standards
- Nationally Adopted International Standards
- ✓ Technical Reports registered with ANSI

- ISO/IEC Deliverables

- ISO/IEC Standards
- Technical Reports
- Technical Specifications
- Publically Available Specifications
- International Workshop Agreements



- ANSI = American National Standards Institute
- ISO = International Standards Organization
.....for procedures
- IEC = International Electrotechnical Commission
... for measuring equipment

Standards for Hearing with Hearing aids and T-coils: ANSI & IEC

- **Referenced in HAD business law and under article 159 of Education Law**
 - Includes ANSI and IEC standards for
 - Audiometers S3.6, earphones, bone conductors S3.13, couplers, ear and head simulators 3.25, and S3.55- 1, -3, -5
 - Hearing aids specification S3.22, ear hooks, S3.37 & performance in noise S3.42 and IEC 60118-0
 - **Telecoils S3.22 and IEC 60118-0, -4 for loops,- evolving**
 - Assistive listening devices S3.47
 - Real Ear Measurement S3.46
 - And more

WHY the IEC 60118 standard is important?

- **Telecoils & Hearing Aids:**
 - **IEC 60118-0 for TC**
 - now includes R&D & QC
 - **IEC 60118-4 for loops**
 - **ANSI S3.22**
 - updated to 2014 (R 2020)
 - in Final FDA regs
 - **NOW S3.22 2025:** not in FDA
 - harmonized with IEC
- Ensures**
 - **loops anywhere are set to uniform standard strength & perform the same**
 - **EMI**
 - **won't interfere with speech understanding**

Standards: ANSI Harmonized with IEC

ANSI S3.22 & IEC 60118-0 – Differences that will remain

- HA1–HA4 Coupler configurations: ANSI S3.22 only
- SPLIV & SPLITS tests - in both* with differences
 - SPLIV - information only - no tolerances
 - SPLITS - tolerances
- Tolerances ANSI 3.22 only
(with informative explanation
of Uncertainty and Umax)

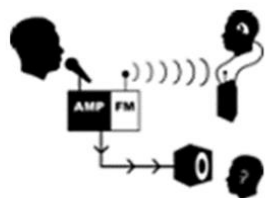
Optimize Hearing ---- with Hearing Aids

Primary Focus of Hearing Aid Fitting

- Performance of Hearing Aid Response
 - With **Microphone input**
 - On a person - REM
 - In a test box
- **BUT microphone response — limited**
 - Phone
 - Works at distance of nearer than 6'-15',
 - Dependent on noise and interference

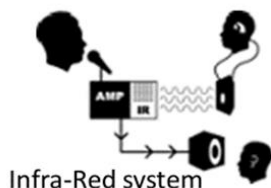
Improved Hearing Options When Hearing Aid Has A Telecoil (or FM Rec)

Public Assistive Listening Systems

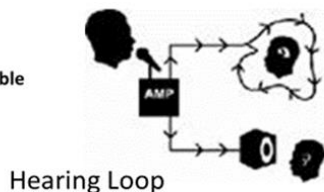


FM System

FM and Infra-red systems improve SNR but are **not directly** hearing aid compatible – Hearing loops are.

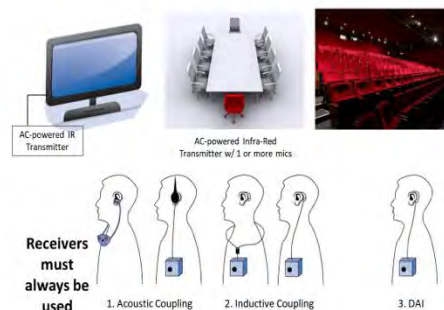


Infra-Red system

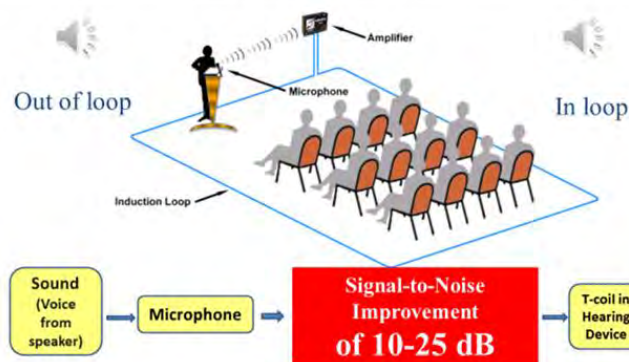


Hearing Loop

Infrared or FM



What is the benefit to the User?
Pure & Direct Sound



Pictures from Juliette Sterkens 2018

Evaluating the Telecoil

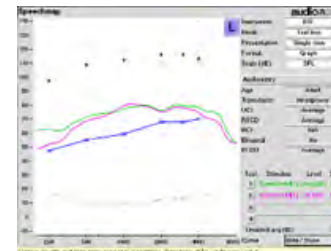
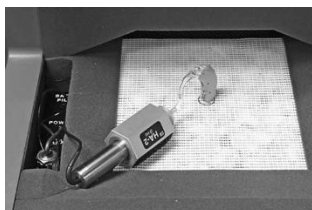
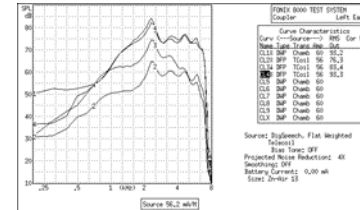
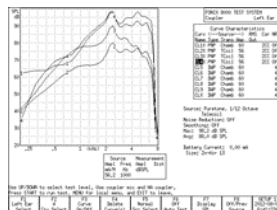
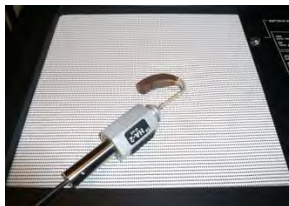
TFMS =Telephone Magnetic Field Simulator

Use TMFS or built in loop

- HA Test boxes
 - Frye and Audioscan or Verifit

Tcoil tests:

Pure tone or Digital
Speech (Frye) or
Speechmap Verifit



Measurements to optimize hearing for hearing aids with Telecoils and Loops: IEC & ANSI

Telephone: TC best Horizontal Loop: TC best Vertical

- **SPLITS or Telephone Simulator**

Telephone: TC best horizontal

- Single figure of merit.
- BTE HA case held near TMFS to optimize response of T-coil

- If T-coil is vertical,
SPLITS = SPLIV

- **SPLIV or Vertical Magnetic Field**

Loop: TC best Vertical

- single figure of merit - for loops
- T-coil response SPL in the vertical (or as worn position)

Or Telephone simulator =
Vertical magnetic field

Where are the loops ???

Loop Installation – uses IEC 60118-4 Simple Loop or Hire Installer

Perimeter loop Less costly (Left & far right)

Overspill (not necessarily bad)

Not appropriate in places with lots of metal

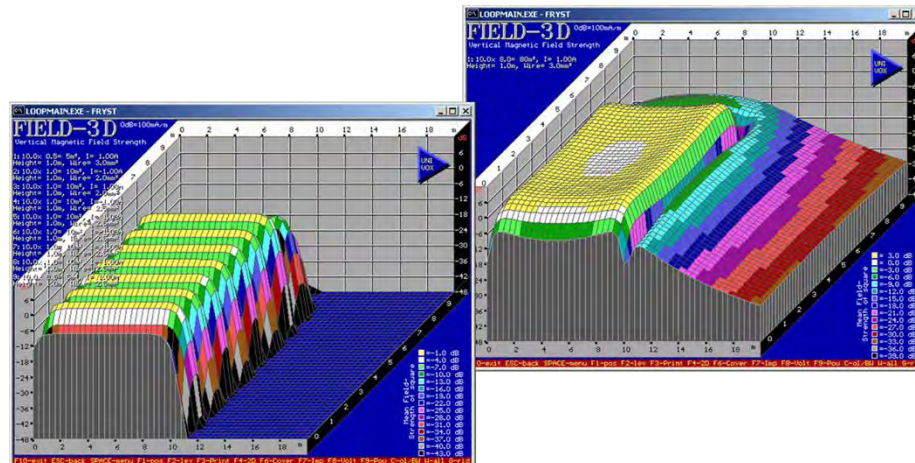
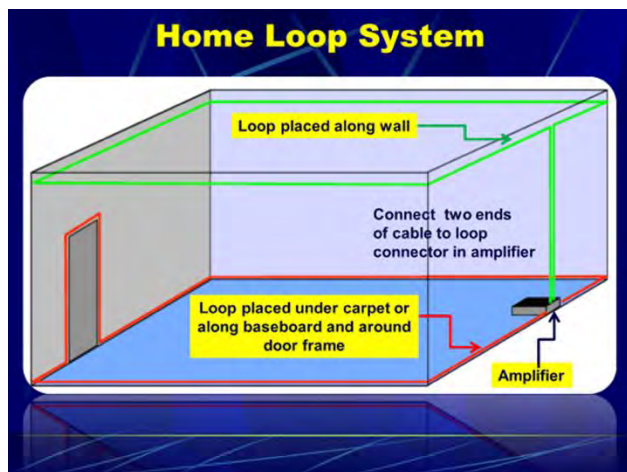
head position & t-coil position matter
Or where confidentiality is involved

Phased Array Loop (Picture in middle)
Much more engineering/ wiring – more costly

No overspill – good for confidentiality

Even magnetic field without head tilt issues – head position and t-coil position doesn't matter

No dead spots above the wires



Connectivity: Access includes hearing aids with telecoils for loop & phone use

- Counseling about Connectivity: Audibility, Clarity, and Access
- What devices, switches they have or can add
- What local venues are looped

Hearing Testing – by Audiologists *

- All hearing aid candidates
must be given a copy of their audiogram
 - Proper Labeling on audiogram:
 - If they sign a waiver, i.e., have not had a medical evaluation and/or medical approval
 - The copy of the audiogram must say:

“This is an audiological evaluation and
is not a medical examination.”
- No Changes at NYS level –
 - Federal - no medical approval for adults 18 & over
 - NYS not change this requirement - yet

Hearing Testing: by Non-A HAD *

- All hearing aid candidates must be given
a copy of their “test”
 - Proper Labeling on Non-Diagnostic Test:
 - If they sign a waiver, i.e., have not had a medical evaluation and/or medical approval
- The copy of the test must say:
- “This information is intended for the sole purpose of fitting or selecting a hearing aid and is not a medical examination or an audiological evaluation.”
- No Changes at NYS level –
 - Federal - no medical approval for adults 18 & over
 - NYS not change this requirement - yet

Required Business Practices for HAD

GBL – Section 798, Rules & Regs - 192.11-18

- Maintain Place of Business
- Report Address of each office
- Report changes within 30 days

Business Practices for HAD

- Display registration: Posting required
- Business registration:
 - At each & every business location
- Individual hearing aid dispenser registrations
 - At each & every business location

Business Practices for HAD

- For Businesses –
- Owner or manager or franchisee must be a Hearing Aid Dispenser
- HAD IS RESPONSIBLE for DISPENSING
ANY HEARING AID at that location

Business Practices for HAD

- Minimum criteria, procedures & Equipment
 - Personal history questionnaire
 - Disclosure Statement

Testing Rooms:

- Requirements of testing room & Equipment – ANSI regs, AAA, ASHA



Testing Rooms:



Current NYS Law Business Practices for HAD

*Conflict w FDA

- **Waiver of medical evaluation** - Conflict NYS & FDA
 - No action to encourage the use of a waiver
 - Inform prospective user of
“statement” advising medical evaluation
- Text of NYS WAIVER:

“at my request, (name of dispenser) has informed me that **I may waive medical evaluation of my hearing due to my personal or religious beliefs**, signed (name of prospective user or parent or guardian)”

This does not make any sense – but it's still in the law

Business Practices for HAD *

- It is unlawful to dispense a hearing aid unless
 - Otoscopic and general observation
 - **8 medical referral signs**
 - **FDA Rule suggest medical eval**
 - red flag signs within 6 mos
 - 9 for OTCs
 - 8 for Prescription hearing aids

Business Practices for HAD

May 2017
and current:

POST the NEW
40 Point Sign

Must change but
hasn't yet



Department
of State

Hearing Instrument Consumer Rights

Federal law requires a medical evaluation of your hearing loss by an otolaryngologist, or if none is available, by another licensed physician. You have the right to waive this requirement. If you waive this requirement, you must sign a statement of waiver of your rights.

State law requires you to be informed of the benefits of telecoil (or t-coil) technology for hearing devices and t-coil use in looped environments and with assistive listening devices.

Consumer Complaints

Contact the New York Department of State,
Division of Licensing Services,
Toll-Free at (877) 545-5864.

Business Practices for HAD

ANDREW M. CUOMO
GOVERNOR



Department
of State

ROSSANA ROSADO
SECRETARY OF STATE

NOTICE TO ALL HEARING AID DISPENSERS

The New York State Department of State (“Department”) has created a new sign for businesses to display which will both protect consumers and will ensure your business complies with existing law. The Department has reviewed current industry practices and found that information regarding T-Coils and other assistive listening devices are, in many cases, not being shared with the consumer. The Department has, therefore, also revised our consumer brochures to provide businesses with updated, printed educational materials to be provided to the consumer.

Please see the following links (duplication of these materials is permissible):

- **Sign for Hearing Aid Dispensing Businesses to Display** (copy enclosed)
(<http://www.dos.ny.gov/licensing/pdfs/TelecoilSign01.pdf>)
- **Consumer Guide for Purchasing Hearing Aids** (copy enclosed)
(http://www.dos.ny.gov/licensing/pdfs/hear_aid_guide062616.pdf)
- **A Consumer’s Guide to Hearing Aids** (online multi-page brochure)
(<http://www.dos.ny.gov/licensing/pdfs/Consumers%20Guide%20to%20Hearing%20Aids062416.pdf>)

Law Booklet for Article 37A of the GBL, Registration of Hearing Aid Dispensers:

<http://www.dos.ny.gov/licensing/lawbooks/HearDispatch.pdf>

ALBANY OFFICE: One Commerce Plaza, 99 Washington Avenue, P.O. Box 22001, Albany, NY 12201-2001 •
Customer Service: (518) 474-4429 • Website: www.dos.ny.gov • E-Mail: licensing@dos.ny.gov

REGIONAL OFFICES:

• BINGHAMTON • BUFFALO • HAUPPAUGE • NEW YORK CITY • SYRACUSE • UTICA

Business Practices for HAD *

- Hearing Aid Dispenser
 - No verbal or written statement or reference regarding a medical condition or diagnosis

Business Practices for HAD *

- Comply with Federal Law
- EXCEPTION
 - Replacement of identical hearing aid within one year

Testing procedures – FYI.....

Business Practices for HAD 192.12

- Pure tone AC thresholds – each ear
 - Mask if 40 dB diff between AC of either ear and BC of better BC
- Pure tone – BC of EACH ear
 - Mask if 15 or more difference BC of better ear and AC of poorer ear

Testing procedures – FYI.....

Business Practices for HAD 192.12

- SRT (or SAT) for each ear
- MCL for speech for each ear
- **Threshold of Discomfort (TD) or Uncomfortable (UCL) for speech for each ear**
- Speech Recognition scores
- **IF NOT TESTED –**
must indicate WHY in chart

Purchase Agreement or Receipt *

Business Practices for HAD: 798 11

- Date of consummation of sale
- Make, model and serial numbers of HAs
- Address of business(es) all sites)
- Office hours
- New or reconditioned
- Registrant's certification numbers of business and all HAD or trainees

Purchase Agreement or Receipt

Terms of Warranty Business Practices 798 11

Statement in 14 point:

- “The purchaser has been verbally advised at the outset of his or her relationship with the registered hearing aid dispenser that any examination or representation made by a hearing aid dispenser in connection with the business of dispensing this hearing aid, or hearing aids, 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.**”

Business Practices for HAD: Purchase Agreement -- written guarantee of 45 day money-back trial (GBL 798 12)

- Cancellation fee
- **For-profit:**
 - 10% of purchase fee
- **Not-for-profit:**
 - 5% of purchase fee **and**
 - \$200 for 1 aid, \$300 for 2
- 45 days of use of operational hearing aid.

Purchase Agreement or Receipt For-Profit Businesses: 798.11 *

- In immediate proximity to space for signature of buyer – **12 POINT**
- “IN ADDITION TO OTHER RIGHTS, THE BUYER HAS THE RIGHT TO CANCEL THIS PURCHASE FOR ANY REASON AT ANY TIME PRIOR TO TWELVE MIDNIGHT OF THE 45TH CALENDAR DAY (/ /) AFTER RECEIPT OF THE HEARING AID AND RETURN THE HEARING AID IN THE SAME CONDITION, ORDINARY WEAR AND TEAR EXCLUDED. BY LAW, THE SELLER IS ALLOWED TO RETAIN AN AMOUNT UP TO **TEN PERCENT** OF THE TOTAL PURCHASE PRICE OF THE CANCELLED HEARING AID INCLUDING BATTERIES AND CORDS OR ACCESSORIES THERETO, INCLUSIVE OF ALL FEES RELATED TO THE HEARING AID.”

Purchase Agreement or Receipt Not-For-Profit Businesses: 798.11 *

- In immediate proximity to space for signature of buyer
- “IN ADDITION TO OTHER RIGHTS, THE BUYER HAS THE RIGHT TO CANCEL THIS PURCHASE FOR ANY REASON AT ANY TIME PRIOR TO TWELVE MIDNIGHT OF THE 45TH CALENDAR DAY (/ /) AFTER RECEIPT OF THE HEARING AID AND RETURN THE HEARING AID IN THE SAME CONDITION, ORDINARY WEAR AND TEAR EXCLUDED. BY LAW, THE DISPENSER IS ALLOWED TO RETAIN AN AMOUNT UP TO **FIVE PERCENT** OF THE TOTAL PURCHASE PRICE OF THE CANCELLED HEARING AID INCLUDING BATTERIES AND CORDS OR ACCESSORIES THERETO, INCLUSIVE OF ALL FEES RELATED TO THE HEARING AID, PLUS A SERVICE FEE OF NOT MORE THAN TWO HUNDRED DOLLARS, UNLESS A SECOND HEARING AID WAS FITTED AND DISPENSED AT THE SAME TIME AS THE FIRST, THEN SUCH FEE SHALL NOT EXCEED THREE HUNDRED DOLLARS FOR BOTH HEARING AIDS.”

Special Provisions – **Non-for-profit sales** 802

- ORLs, or other physicians

No Otolaryngologist who has conducted a medical evaluation of hearing loss shall engage in the business of dispensing hearing aids **for profit**

Clarification of Section 802 *

- As such, physicians, who dispense hearing aids on a not-for-profit basis, **do not need to register** as hearing aid dispensers.
- The sections cited in the statute -- with which physicians must comply (791, 798 and 803) **do not refer to education, training or continuing education.**
- As such, physicians are **exempt from the training and continuing education** requirements as well.

Be Alert for HAD Legislation: in 2025

- **2017 & 2018-20 * 2022 NYS & FDA**
 - No corresponding legislation with matching numbers Senate and Assembly
 - 2021 – matching bill –failed
- **NOW !!! – 2025 Act when necessary**
 - Changes via amendment, or opening law

Federal & State Legislation to Watch 2025

- **Medicare Audiologist Access & Services Act** (MAASA) HR 1587
 - Change classification **Supplier to practitioner**
 - Would allow Audiologist to diagnose and treat
- Expanding Telehealth
 - NYS telehealth for Aud & SLP since 2016:
- DOS changes should match FDA Register final regs
 - for Prescription hearing aids

Conditions for **ONE Year Return** *

Business Practices for HAD

The purchaser shall have the right to rescind the transaction... if

- Consults ORL or MD **and**
- Certifies in writing that “in his or her professional judgment, at the time the dispensing occurred the purchaser had
 - either a hearing impairment for which a hearing aid provided no benefit **or**
 - had a condition which contraindicates the use of a hearing aid **AND**
 - Purchaser experienced no improvement in quality of hearing
- **Full and complete refund in 10 days**

RECORDS

- What records are you required to keep?



RECORDS *

Business Practices for HAD: 798 14, 192.15

Maintain a Copy in office for 6 years of:

- Tests, Fitting, and selection,
- Sales,
- Rental or adaptation or servicing
- Purchase agreement
- Waiver

*RECORDS **

Business Practices for HAD: 798 14, 192.15

- Customer's file:
 - Written guarantee
 - Invoice/ Purchase agreement for HA, mold
 - Correspondence to/from customer
 - Copy of statement given to customer if exercise right to return HA in 45 days

Repair and Service & Charges

Business Practices 192.14 – Records too

- **Must accept** any hearing aid, or accessory, you sold or rented for a period of 5 years
- **Reasonable fees for repair..? clarified**
 - if >\$50:
 - Need customer approval & Itemized receipt
 - If Cost for estimated charge: can retain fee
 - Flat rate & 30 day guarantee
 - Do not need itemized receipt

Repair and Service & Charges Records too

- **Loaner:**
 - can charge fee
 - Customer does not have to accept loaner with a fee in order to repair the instrument

RECORDS

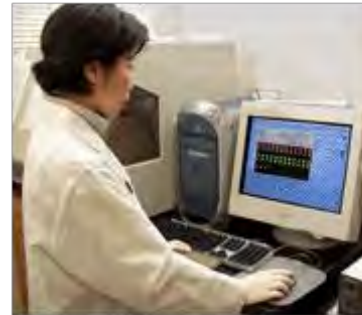
Business Practices for HAD: 798 14, 192.15-6

- Files for
 - Invoices on batteries and record of rebates
 - Requests for Home Visits
 - **Advertisements** 192.16
 - claims about inventions or scientific principle for Hearing Aids or molds: **true** and **filed**,
 - Testimonials – signed with address
 - Can't list ORL or Audiologists
unless they provide services there

Records for Advertisements

- Documentation of Claims

Research



Education



Clinical Study



Community Outreach



Technology



Advertisements *

Business Practices for HAD: 798 1

- CATALOG SALES -- No Sale of Hearing Aids by “Direct Mail” - - is allowed within NYS
 - applies to NYS businesses
- Telemarketing must comply with federal and state Law
 - No sale of a hearing aid by telephone or telemarketing
 - Need Specific statements from consumer initiating telephone contact

General Business Law – as amended November 12, 2012

- Requires all telemarketers doing business in New York to register with the Department of State.
 - will allow more enforcement authority for violations of the law.
- **Prohibits** all telemarketers doing business in New York from delivering prerecorded messages by telephone call to customers without express consent from the recipient and
- **Requires** a mechanism that allows the consumer to automatically add the telephone number called to that caller's do-not-call list.

Canvassing *

Business Practices for HAD

798 17

- NO Canvassing from house-to-house
- Commentary on canvassing – era specific
 - There are no controls on internet market or sales.

Consumers 192.18

- Convey general information...
- on advantages and disadvantages of
 - monaural and binaural hearing aid,
 - consumer protection,
 - telephone switch
- Avoid hard sell, giveaways

Training of consumers

- This is expected to take 45-60 minutes



Training of consumers

- Use a check list of the following items covered
 - Have consumer sign the list
 - I have been counseled about...



I, _____, acknowledge that:

- ☐ I received a copy of my audiogram in a timely fashion after the audiologic evaluation.
A copy of the audiogram was either given to me, or sent to me, after the hearing test, with the report that was sent to my physician(s)
- ☐ I was counseled about my hearing loss.
- ☐ I underwent a hearing aid evaluation, which resulted in the recommendation and selection of the appropriate type(s) of hearing aid(s) for me.
- ☐ I completed a questionnaire to determine my hearing abilities and listening needs as part of the audiologic evaluation and/or hearing aid evaluation.
- ☐ I had a 45-day (or more) trial period with the selected hearing aids.
- ☐ I was given a book about hearing and hearing aids entitled:
A Consumer Handbook on Hearing Loss & Hearing Aids – A Bridge to Healing. Ed. Richard Carmen, clinical audiologist.
- ☐ I was counseled about the care and maintenance of the hearing aids and all its features or controls in compliance with NYS Law and good hearing health care.
- d) training of consumers in regulation – estimated to take 45 min to 1 hour
 - § basic care and use of the hearing aid
 - § communication strategies to adjust to a new hearing aid
 - § information on support groups
 - § storage of the hearing aid when not being used
 - § protection of the hearing aid from perspiration and moisture
 - § installation of a battery frequency of necessity to purchase batteries
 - § use of the telecoil-switch
 - § telephone usage
 - § reasonable longevity of the hearing aid
 - § information about purchasing insurance to cover loss and damage
 - § review of the 45 day return policy
 - § review of complaint policy
- ☐ I was given cleaning tools for my hearing aid.
- ☐ I was given batteries for the trial period of my hearing aid.
- ☐ The outcome of the hearing aid fitting and the performance of my hearing aids were measured, verified, and validated using techniques appropriate for my hearing loss and the selected hearing aids. Some of these techniques include real-ear probe microphone measurements, electroacoustic performance, speech recognition ability, questionnaires to evaluate benefit or satisfaction with amplification, etc.
- ☐ I was counseled about the use of auditory and visual cues to improve understanding, and listening strategies to optimize my benefit from the hearing aid(s).
- ☐ I was advised about available additional maintenance methods and devices to extend the life of my hearing aids and about assistive listening devices to expand upon the benefits derived from my hearing aid(s).
- ☐ I completed a questionnaire to assess the benefits my new hearing aid(s).

Signature

Date

Training of consumers 192.18

- basic care and use of the hearing aid
- communication strategies to adjust to a new hearing aid
- information on support groups
- storage of the hearing aid when not being used

Training of consumers – cont'd

- protection of the hearing aid from perspiration and moisture
- installation of a battery
- Frequency/necessity to replace/purchase batteries
- use of the telecoil-switch
- telephone usage



Training of consumers – cont'd

- reasonable longevity of the hearing aid
- information about purchasing insurance to cover loss and damage
- review of the 45 day return policy

Consumers 192.18

- review of complaint policy
- In educational and HIPAA information
- DOS Consumer Brochure

Consumer Guide For Purchasing Hearing Aids: Changed – 10 pages w QR code - AND

The Sales Contract

As a New York State consumer, you have legal rights when purchasing a hearing aid. Be sure to get a purchase agreement or sales contract containing all the terms of the transaction in writing. Read it carefully. It should include the following items: the state registration numbers of both the dispensing audiologist or hearing aid dispenser and his or her office; office location, telephone number and hours of operation; date of purchase; manufacturer, model and serial number; total price, payment terms, refund provisions, adjustment services, and warranty information.

Satisfaction Guarantee

New York State requires that audiologists and hearing aid dispensers grant a 45-day satisfaction guarantee. If you purchased a hearing aid in New York, you have the right to cancel the transaction for any reason prior to midnight of the 45th calendar day from the date of purchase and return the hearing aid in the same condition (ordinary wear and tear excluded by law). The seller is allowed to retain an amount up to ten percent of the total price of the canceled hearing aid, including all fitting fees, batteries and accessories.

State Agencies

New York Department of State (DOS)

• Division of Licensing Services (DLS)

The New York State Department of State licenses and regulates the dispensing of hearing aids by audiologists, hearing aid dispensers and other hearing care professionals.

Questions regarding any aspect of hearing aid dispensing may be directed to the number below.

The Department's website contains the current law and regulations pertinent to hearing aid dispensing, as well as frequently asked questions.

Hearing Aid Dispenser Information:
(518) 474-4429

Complaint Hotline (toll-free; voice/TTY):
(877) 545-5864

• Division of Consumer Protection (DCP)

Consumers with questions about hearing aid sales, contract negotiations and warranty specifics or any consumer-related issue may contact the Consumer Assistance Hotline.

Consumer Assistance Hotline:
(518) 474-8583 or (800) 697-1220

Website: <https://dos.ny.gov>

New York State Education Department (NYSED)

• Office of the Professions (OP)

The New York State Education Department licenses and regulates audiologists to practice in New York State.

Audiologist Information: (518) 474-3817, ext. 100

Complaints: (800) 442-8106

Website: www.op.nysed.gov

New York State Department of Health (DOH)

• Office of Professional Medical Conduct (OPMC)

The New York State Department of Health licenses and regulates physicians.

Complaints/Inquiries: (518) 402-0836 or (800) 663-6114

The New York State Department of Health strives to protect and promote the health of New Yorkers through prevention, science and the assurance of quality health care delivery.

Public Health Duty Officer Helpline (toll-free):
(866) 881-2809

Website: www.health.ny.gov



Department of State
Licensing Services

Kathy Hochul
Governor

07/24

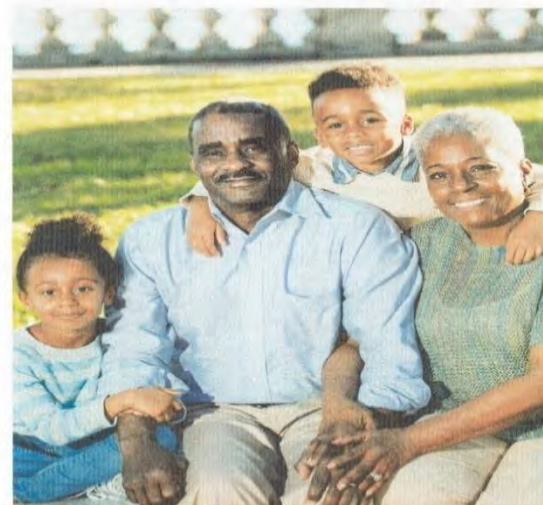
Walter T. Mosley
Secretary of State



Department of State
Licensing Services

Consumer Guide for Purchasing Prescription Hearing Aids

in New York State



Consumer Guide For Purchasing Hearing Aids: Changed to 10 pages with QR code AND

You don't hear well and you've decided to do something about it.

You have many unanswered questions:

- Do you need a hearing aid?
- Where do you go to get your hearing evaluated?
- What kind of hearing aid should you buy?
- Will a hearing aid restore normal hearing?

Where Do You Begin?

You may consider purchasing an over-the-counter (OTC) hearing aid, or a hearing aid prescribed by a hearing health professional. To understand the differences between OTC and prescription devices, please see Consumer Education Guide: Understanding Hearing Aid Options.



<https://dos.ny.gov/system/files/documents/2024/05/hearingaidguide.pdf>

If you decide to purchase a prescription hearing aid, you should consider the information contained within this brochure.



You may visit a licensed physician, preferably one specializing in diseases of the ear, for a medical evaluation before purchasing a hearing aid. This will ensure that medically treatable conditions that may affect your hearing are identified and treated before a hearing aid is purchased.

Once you have determined that your hearing difficulties are not medically or surgically correctable, you should have your hearing tested by a registered audiologist or registered hearing aid dispenser. New York State requires that all dispensing audiologists and hearing aid dispensers be registered with the Department of State and that they display their business and individual dispenser registrations prominently at their place of business.

Selecting a Hearing Aid Dispenser

Only audiologists, hearing aid dispensers, otolaryngologists and otologists are permitted to fit and sell hearing aids in New York State. The same level of service should be expected from all.

Selecting a hearing care professional is extremely important because you are choosing a person with whom you will have a long-term relationship. Because of the importance of hearing in one's everyday life, you will want the relationship to be trusting and comfortable.

What You Should Tell the Dispenser

Communication with your audiologist or hearing aid dispenser should be a two-way street. Express your needs and concerns clearly so that they can address them to your satisfaction.

The Hearing Test and Evaluation

The audiologist or hearing aid dispenser will conduct a series of tests to determine the type and extent of your hearing loss. These tests are painless and assess your ability to hear tones, as well as to understand speech. The results of your hearing examination are recorded on an "audiogram" and should be explained to you. New York State law requires that you receive a copy of your audiogram, whether or not you purchase a hearing aid.

Binaural Hearing (using both ears)

If you have hearing loss in both ears, you should consider a binaural fitting (two hearing aids). The advantages to wearing two aids may include improved listening in noisy environments, improved speech understanding and the ability to determine both distance and direction of sounds.

Hearing Aid Selection

Your individual hearing loss and needs will be considered in selecting the right aids and options for you. Be willing to consider all styles of hearing aids, as there may be specific reasons why certain types would be best for you. Be aware that there is no "best" hearing aid for everyone.

Telecoils (T-Coils) and Assistive Listening Technology

State law requires hearing care professionals to inform you of the benefits of telecoil technology, looped environments and assistive listening devices. Before making a purchasing decision, you should be given the option of obtaining a hearing aid or aids that contain a telecoil (or T-coil).

Telecoils are tiny circuits imbedded in hearing aids to enable the user to receive an audio signal wirelessly in environments that have installed hearing loops or utilize other assistive listening systems. Your dispensing professional is required to explain how hearing assistive technology can help maximize your ability to understand speech coming from the television, in group settings or at a distance from the source, such as theaters, museums, banks, and other venues where audio signals and speech are present.

Keep Your Expectations Realistic

Hearing aids will not correct hearing in the way that glasses correct vision, nor will hearing aids restore normal hearing. The secret to success is having realistic expectations. You should know that hearing aids won't allow you to hear as you once did, and that it is difficult for hearing aids to provide optimal hearing in background noise.

Sanitation – Infection Control*

- Test rooms



Sanitation – Infection Control *

- Entry area Grinding/Lab area



Infection Control Program and Plan (Procedure Manual)

- Definitions
- **Clean**: What and when
- **Disinfect**: What and when
- **Sterilization**: What and when

Health and Safety Deficiencies

Failure to.... *

- remove gross contaminants prior to disinfection or sterilization
- use EPA approved hospital grade disinfectant
- properly store disinfected or sterilized items
- properly store, maintain or monitor disinfection or sterilization of surfaces and implements

Specific procedures & schedules for cleaning, disinfecting and sterilizing

- Hearing aid and mold must be wiped off **prior** to handling by office staff
- Phones, BC oscillator headbands **1x/wk**
 - **EXCEPT – Disinfect prior to re-use,**
if evidence of drainage or sore
- Clean & Disinfect hearing aid cleaning tools and listening stethoscopes –
prior to use

Specific procedures & schedules for cleaning, disinfecting and sterilizing

- Disinfect reception countertops and table tops
 - 1x/day
 - EXCEPT – Disinfect prior to re-use,
if evidence of drainage or sore
- Disinfect reception arm rests used by clients in test rooms – 1x/week
 - EXCEPT – Disinfect prior to re-use,
if evidence of drainage or sore

Health and Safety Deficiencies Failure to.... Continued *

- maintain Material Safety Data Sheets (MSDS) for required solutions in proper metal file accessible to employees
- observe proper procedures or **schedules for disinfection or sterilization of surfaces and implements**
- observe proper procedures with respect to blood, body fluids and client contact
- observe proper hygienic practices

AROUND THE EAR

KN95 –

straps tend to break

nose shaper tends to come off

staples and glue work

Can use elastic band with buttons to keep loop off ear



AM Alliable Medical 630 S. Jefferson St, Ste. A, Placentia CA 92670 800-339-0238 or Amazon
MB100 Medium or Large, made in Korea

Good fit good contact all around the face,

Nose clip (internal) bends easily to contour to the nose

Comfortable easy to breathe and

Earloop clip secures the fit on faces of all sizes



aerX KF94>95 PPE-R/02.075 version

NIOSH 42 CPR 94 performance classification and N95 performance standard

comfortable and Good (can be too big for some)

Earloop clip secures the fit on faces



Cords above & below the ear: avoids the ear-- Good for hearing aid users.

BNX A96 Particulate Filtering Protective Mask SKU: BN-A96-5PP

BNX.com

BNX Covering, LLC 16727 Park Row, Houston TX 77084

Fits well and it breathable.

Fits nose well; two head bands stretch and one goes on top of the head; the other at the nape of the neck



ONE OF THE BEST!!

PROTEKX N95 Respirators

Foldable with adjustable straps:

showing internal Premium Grade

Silicone seal

NIOSH TC-84A-8131



In Office, closed space health care offices etc.
Double mask and glove &
if near the patient/person Add a face shield and or goggles



Add the commonly used Typical face mask
Single use 3 layer Flat mask with ear loops ---NOT N95, NOT NIOSH

USE ONLY AS SECOND MASK
OR perhaps as a single IF IN THE PARK WITH A FRIEND who is vaccinated



As second mask

The **Tie-On Surgical** Mask by 3M is an N95 Mask Model 1818
 3M health Care, St Paul MN 55144-1000



DON'T USE (unless no other options exist)

Cloth masks, even with 3 layers, --> no vented cloth masks please!
 No Scarves, etc.

Also DON'T USE

N95 vented masks - unless you double mask and then ?? They protect
 the wearer, the surgeon, but not the others nearby.

They have tight over-the-head straps and the fit on the face is tight!



PROTEKX N95 Respirator NIOSH TC-84A-8131
Made and distributed by Ever Win Int'l Corp. City of Industry, CA
Available from: LPM Supply Inc., 28 N. Saginaw St., Ste. 801, Pontiac, MI 48342

<https://dos.ny.gov/hearing-aid-business>

Any individual engaged in the dispensing of hearing aids must register. The General Business Law (Article 37-A, Section 789[8]) defines a hearing aid dispenser as any person 21 years of age or older or an audiologist licensed under the Education Law (Article 159) who is engaged in the act of "fitting, selecting, renting, adapting, or servicing of hearing aids or any other instrument to compensate for impaired hearing." Explicitly included are testing and fitting procedures. Testing is only for purposes of fitting and is not an audiological or medical exam. *It is the responsibility of licensees to understand the Hearing Aid Dispenser License Law. Registration Requirements Fees and terms of registration*

<https://dos.ny.gov/hearing-aid-business>

Forms:

- Hearing Aid Dispenser Application – Individual Hearing Aid Business Application
- Notice of Employment Status (Hearing Aid Dispenser)
- Credit Card Authorization Form Duplicate License/Registration Request Change Notice (*Required when changing a name or address*)
- Special Testing Arrangements Request

<https://dos.ny.gov/hearing-aid-business>

Course Applications:

- [Hearing Aid Dispenser Qualifying Course Approval Application](#)
- [Hearing Aid Dispenser Qualifying Course Approval Renewal Application](#)
- [Hearing Aid Dispenser Continuing Education Course Approval Application](#)
- [Hearing Aid Dispenser Continuing Education Course Approval Renewal Application](#)
- [Hearing Aid Dispenser Continuing Education Equivalency Application](#)
- [Hearing Aid Dispenser Instructor Application](#)
- [Technical Hearing Aid Dispenser Instructor Application](#)

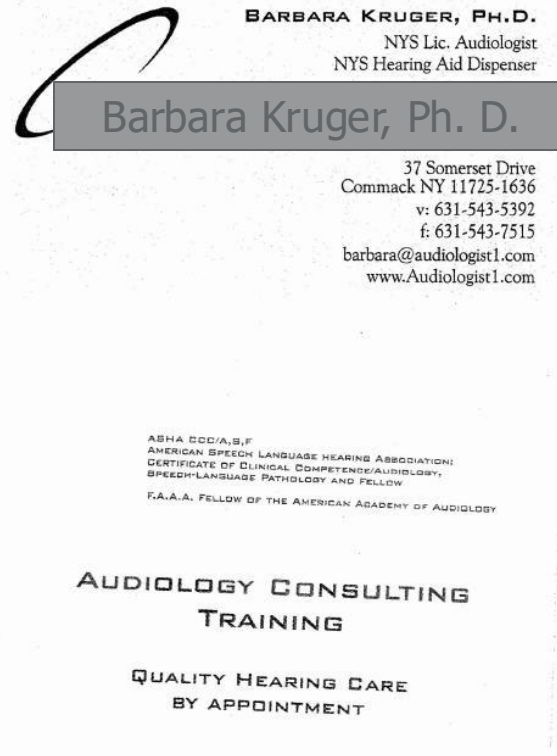
<https://dos.ny.gov/hearing-aid-business>

Examination Information and Schedule

•Written Exam:

- [January - June 25](#)
- [Hearing Aid Continuing Education Course Providers](#)
- [NYS Hearing Aid Dispensing Advisory Board](#)
- [Process for Obtaining a Trainee Registration for an Audiology Student](#)
- [Consumer Guide for Purchasing Hearing Aids](#) (pdf)
- [A Consumer's Guide to Hearing Aids](#) (pdf)
- [Frequently Asked Questions](#)

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The End - Questions?

- Any Questions?

