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

Presenter: Barbara Kruger, PhD

Welcome everyone to our classroom. Thank you so much for being with us today here at continue.com We're so delighted to have you with us today and we have a wonderful update from Dr. Barbara Kruger. She's going to update on the laws, regulations, and professional conduct for hearing aid dispensing in the state of New York. Dr.

Kruger, can you please advance the next slide? Here are the limitations and risks for this presentation. And Dr. Kruger, can you please advance as well as the presenter disclosure there.

And last time, Dr. Kruger, and these are the learning outcomes for today's presentation.

It's my pleasure to welcome back Dr. Barbara Kruger. And like I said, today's an update for the New York State and federal law and regs for the hearing aid dispensing for this year, 2025. If you'd like to learn more about Dr. Kruger, you can read her course bio on the registration page.

Over to you, Dr. Kruger. Okay, thank you very much. This purpose of this page is not just to remind you of the title, but to look at the website links for that you might need if you're needing to get information from the Department of State website.

We're going to go over the laws, the rules and regulations, what's current federal in federal law versus what's true in New York State law. We will talk about registration, the licensing process, a trainee registration process, renewal of your license, the training process for training a dispenser, and business practices for operating your business, and any records that you need to keep, and the training of the consumer that is your, of course, professional responsibility. The FDA regs, which changed as of October of '22, were supposed to create changes so that the New York State was supposed to equal the federal state law, but there are some changes that have still not been made. The primary thing is that the federal law removed the requirement for a medical prior evaluation or any evaluation at all. and the FDA regulations or laws now changed for over-the-counter hearing aids, and only federal law

applies for over-the-counter hearing aids.

There are no state law for new over-the-counter hearing aids. And all the other, all the remaining types of hearing aids that are not over-the-counter hearing aids are prescription hearing aids, and the federal and state laws still don't equal each other. The state needs to make some changes. The original medical prior approval regulation started with the first hearing aid dispensing regulations that were in 1977, and that's where they included the evaluation, prior evaluation, and medical approval for the purchase of hearing aids. The FDA in 2022 removed that regulation and there is no mention of a waiver either.

There are eight flags for medical referral in situations that are indicated and you might suggest that to your patients, but it is no longer a requirement federally. However, in New York State, The eight medical referral signs remain, and the medical prior approval does remain. And the use of a waiver is what is indicated if the patient does not have a medical evaluation. The over-the-counter regulation, the over-the-counter hearing aids have nine red flags. for when you should see a physician or a doctor specializing in the ear, nose, and throat.

Birth defect, blood and puffs coming out of the ear, pain, earwax, dizziness, sudden changes in hearing. And they introduce one for the over-the-counter hearing aids that's fluctuating hearing loss. And you have worse hearing in one ear compared to the other and some ringing or tinnitus. Those are the indicators for over-the-counter hearing aids. The fluctuating hearing loss somehow is incorporated in here.

So for prescription hearing aids, the FDA has 7 plus 1, and the 7 is subsumed in what we just discussed, and includes the airbone gap at 5/1 in 2000. New York state law incorporates those as a set of eight for the prescription hearing aids. Over-the-counter hearing aids, only federal law applies. The primary changes as of October of '22 were labeling changes and a description of what is supposed to

be a self-perceived mild to moderate hearing impairment. That means almost anybody with any hearing loss because most of the time they only fess up to having a I can hear okay, mild to moderate hearing loss.

So they might just purchase an over-the-counter hearing aid with a very severe to profound hearing loss. Those devices can be self fitted or adjusted by the consumer. Prescription hearing aids are every other type of hearing aid that is not over-the-counter. Federal law requires no medical prior approval, but the state law still governs in New York State for hearing aid dispensing. And they've made very few changes, seeming to have taken the, I'm allowed to make it stricter, more stringent than the FDA.

And this was the wording. So they are making it stricter than the FDA regulations, still requiring the medical prior approval. Over-the-counter hearing aids are a new regulatory category since October of '22, and they're purchased without the involvement of healthcare professional. There's a labeling to that effect, and the over-the-counter hearing aids that we know of in the United States are really in the rest of the world considered direct-to-consumer. Over-the-counter hearing aids have labeling on the outside They are for people 18 years and older.

If you're younger, you must go to an ear, nose, and throat doctor prior to getting fit or referred to an audiologist. Prescription hearing aids, same age rules apply as the over-the-counter. You must be over 18 to have a prescription hearing aid and not see a physician. According to the federal law in New York State, you still have to see a physician unless you waive it, that option. For what they describe as this self-perceived mild to moderate hearing loss is that they might have trouble hearing speech in noisy places and might find it hard to follow speech in groups.

Trouble hearing on the telephone. They get tired from listening. It's a strain. And they might be turning up the TV volume more than people around might want.

And they might find the labeling on the box should say that they may need the help of a hearing healthcare professional, especially if they can't hear speech or understand speech if the room is quiet and that they have difficulty hearing loud sounds like loud music and power tools. Over the calendar, hearing aids are fit either by the, they're fit by the consumer. They're fit to customize the device collecting perhaps frequency bands and volume adjustments, or self-pit entirely with tests that would be software provided with online tools, and they then can adjust the device with whatever fitting strategy is used by that manufacturer. Over-the-counter hearing aids have lots of labeling outside, There should be an indication that there's an instructional brochure, that there is a return policy, that it's marked as an over counter device, information about how either a battery is used or there's a recharging capability for the device, and indications about the control platform that might work with other devices that couple with the device, the hearing aid. to other devices they may use for telephone and computer.

Inside the box for over-the-counter hearing aids, there needs to be an instructional brochure or a link to a website where they can obtain and print or download their instructional brochure. and at no additional cost. And indications about the age for which over-the-counter hearing aids are used, over 18, 18 and over, and the red flags. Inside the box, it should also indicate that a hearing aid shouldn't cause pain and it is not hearing protection. So if it's too loud and it's uncomfortable, you need to take it out of your ear.

It's not going to protect your hearing and you need to reconsider adjusting it or giving it get giving it back. And a hearing aid should not be painful. And if it gets stuck in your ear, you should see a physician. The labeling inside the box does indicate that hearing devices will not restore hearing and that they may still have difficulty hearing over noise. And that sometimes training or counseling from professionals may actually help them use their devices.

And if they have hearing loss in both ears, it would be wise to use hearing aids in both ears. Now, there has been some changes, as you know, there are lots of changes at websites now due to changes in our government. But the FDA originally indicated that there were injuries. If you had injuries or malfunctions or any adverse experiences trying over-the-counter hearing aids, you were supposed to report it to the FDA. line that's crossed out is no longer available, and it is now fda.gov/medwatch.

You can also call that phone number, and you can download a form that you would then mail to the FDA to report any incidents that were adverse. Labeling inside the box, again, illustrations of the device, and the controls and how to manipulate those controls, any description of accessories that work with the device, the hearing and device, and instructions on how to select tips that make sure you're not putting anything closer than 10 millimeters from the eardrum. There are any tools or testing software need to be accessible and and or obtainable from instructions inside the box. It gives you maintenance instructions, how to care for the device, how to charge the device, how to replace batteries or use a charger, how to be aware of any physiological side effects like irritation in your ear and how to connect it to other technology. And of course, it should have a serial number and so forth.

It tells you also that the output from the hearing aid should not exceed 111 dB SPL. If it's an output compression device, and if it's an input compression hearing device, it should not exceed 117 dB SPL. And many more details for specifications, for standards for the hearing aid performance, how it would perform with a 90 dB SPL input, what the output would be, and what the full-on gain with 50 dB input would be. They're at full-on gain. What harmonic distortion there might be if there's any noise the device makes itself, any latency that changes in the signal, and the bandwidth through which you can hear the lowest and the highest pitches and any software that's involved in using the device.

The state law is preempted by the federal law, so there are no state laws. And any licensed professional in New York State who can, in fact, dispense over-the-counter hearing aids. But the state

laws about dispensing pertain to the handling of those over-the-counter devices.

What is a prescription hearing aid? That's everything that is not an over-the-counter hearing aid, very specific. At least it's not called restricted anymore. And the technical specifications for a hearing aid, that is a prescription hearing aid, is defined by ANSI S3.22-2014, which has been reaffirmed in 2020 and actually has been reaffirmed in 2025, but the 2025 version is not incorporated yet into the FDA rules and regs. The output SPL for a prescription hearing aid needs to be labeled with a warning if it's over 132 dB SPL.

There is no change as far as the FDA is concerned in the professionals who would be prescribing and fitting prescription hearing aids. The medical prior evaluation is not required federally, but it is required in New York State.

If you're under 18, For prescription hearing aids, you do need to see a physician federally and of course in New York State. And then that physician may evaluate your hearing, refer you to an audiologist who may test and then eventually do the hearing aid evaluation and fitting. For people 18 and over, no medical evaluation is required by the FDA, no prior approval, and no waiver is even mentioned in the document. We all know that Medicare requires a physician's order for audiology services in all clinical settings. But as of January of '23, we are now allowed to get direct contact with the patient and test their hearing once a year, as long as they meet certain criteria for the kind of hearing loss.

And that is if you use an AB modifier with one of the 36 CPT codes for non-acute hearing conditions, somebody who has hearing loss has occurred over many years, you can evaluate them once a year without a physician's order. And the diagnostic services that you might provide for somebody who has a surgically implanted hearing device, you can test them once a year. But it's not for testing people with regard to balance or disequilibrium. The hearing aid laws in New York State are governed under Article 37A of the General Business Law. That is the same.

They should have made some more changes to it, but maybe if you get your energy up, you can fight to make the laws change. The rules and regulations are in that section mentioned here. and they were developed originally for consumer protection. And they were signed into law in September of 98. A board was formed and the rules and regulations were developed and it went into effect 2001.

The thing is, these are the specific areas where there should be changes. It shouldn't say it mandates medical prior approval. The medical evaluation and allowing a waiver should be changed. Most importantly, the posted sign is wrong. It lies and that part needs to change.

And we'll talk more in detail when we get to that slide. And then information about the waiver needs to change.

There have been changes since the law started, and there were changes in 2016 that changed the mandated courses. The mandated courses actually started to be reinforced in 2009, but in 2016, they changed to be three one-hour courses. And the posted sign then needed to change because it incorporated since 2019 the requirement that you explain and make sure the consumer understands the telecoil and assisted listening device benefits with hearing aids. And the sign says that it mandates that the federal law mandates a prior approval or a waiver, and it no longer mandates that it should be changed to say that it is suggesting a medical evaluation.

What actually happened is the FDA really tried to get the states to do it right and to reflect the federal law. They sent letters clearly indicating that there were changes and that the federal law no longer called the hearing aids restricted devices. They changed them to prescription devices. They updated labeling and they did not change the necessary qualifications of the person providing the hearing health care. and most importantly, does not in any way require a physician's involvement prior to fitting the devices.

But that New York state, for two reasons. One, there's a fear of opening the law and the physicians opting to jump in and be able to do for profit. dispensing, which they do under other guises now. And there's also a hearing aid advisory board, HAB, that is relatively non-functional and they're just not doing what they should be doing to change the law, to reflect federal law, or at least change that sign, which is wrong. Here's that advisory board.

It's supposed to have 13 members. It only has five. They can never have a quorum. They can never make a decision and tell the rest of these staff in the Department of State what they want and make the changes. So basically not much is going to get done unless some people get on the board.

They now need at least two audiologists to dispense. They only have two. They need three non-audiologist dispensers. Right now, there's three vacancies. They have only one ENT and they need two public citizens, so they need eight people in order to get something done.

Who needs to have a hearing aid dispensing license? This hasn't changed. It's anybody who touches a hearing aid in any way, whether they're servicing it or renting it or programming it and touching a patient. So those are the people who need an individual license. And if you own or operate a franchise of a business, you have to have a business registration.

A non-audiologist dispenser is different from an audiologist dispenser. A non-audiologist dispenser is somebody who is 21 years old or greater, two years of college, one year of training, and they have passed a theoretical and practical exam. An audiologist dispenser is somebody who first becomes an audiologist, gets their audiology license, then applies to take the hearing aid dispensing license, and they are then allowed to take the practical exam. All people, whether they are non-audiologist dispensers or, or AUD students, when they are in training, have to have a trainee registration. So the audiology student gets a trainee license and then they have an option.

They can wait until they get their audiology license and then register to take the practical exam and get their license, which will take them four and a half to five and a half years. If instead, somewhere in their second or third year as an AUD student, they decide to take the theoretical and practical exam, they can get their hearing aid dispensing license before they go into their clinical externship year and be very useful in their practice. The dispenser who is a trainee needs to have that trainee registration, and during that year, they need to take their training and pass the theoretical and practical exam and then get their license. And the AUD student needs to have a trainee certificate in every year they're an AUD student, starting with the first clinical placement. And you go to the website and you download the hearing aid dispensing application and follow the instructions.

In the first time you are registering to get your hearing aid trainee registration, you go take that application, download it, you fill out and select number two for the first time applicant for the temporary certificate. And you have your university supervisor sign for you. and the second year you and all subsequent years that you choose to continue to do that certificate process, you use number three. And if you decide to take this theoretical and practical exam during your training, you take the same application and fill out number four. And the trainee dispenser would have to do the same thing.

If they're a non audiologist dispenser, they would Pass both a written and practical exam. It should be a lot easier for an AED student. And after six more months of after you've passed those exams, you would be able to apply to fill out number five and get your hearing aid dispensing license. So that hearing aid dispensing license needs to be renewed every two years. And in order to renew your license, you need to have taken the three mandated courses.

There's one hour course for each of the courses taken every two years, and you attest to the fact that your equipment is calibrated and the room you're testing in is adequate, and you pay your money. If you're a non-otologist dispenser, You have 20 hours of dispensing hearing aid courses and the hearing

aids, you need to take the courses on hearing and hearing aids, not business sales techniques. There are three courses, one hour on infection control, one on New York State and federal law, regulations and professional conduct, and one hour on telecoils and assisted devices. Now, a non- audiologist dispenser must take their continuing education face to face with one exception, and that is if it is a live distance learning where the person signs in, attests to being present throughout the seminar and signs out and then fills out all the paperwork. That's the only exception.

after COVID because during COVID they were allowed to use Zoom.

The audiology students and audiologists, licensed audiologists, dispensing audiologists need to every two years have four hours in hearing aid dispensing. Three hours on the mandated courses, one hour each, and one additional hour on hearing aids. The other remaining hours are on all things other that relate to audiology, cognitive function, speech and language, all the things that are in the field that pertain balance issues.

The Department of Education is the department that reviews all of our coursework, with the exception of the fact that the Department of State checks that you've taken the three mandated courses. And if you are dually licensed, you have your audiology license renews every three years. But if you're also licensed as a speech language pathologist, you can take 20 hours in audiology, 20 hours in speech and language related issues, and attend in another area. So your license, you renew your hearing aid license every two years. You renew your audiology license every three years.

And you must take the hearing aid mandated courses every two years. And there are how many one hour mandated courses? There are three.

If you come from another state and you can apply for your license in audiology in the state, but there's no reciprocity state to state. And if you have not had recent hearing aid dispensing experience, you

would have to become a trainee for a year. If on the other hand, you've had recent dispensing experience, you would then after you get your license, file for the hearing aid dispensing license and take file to take the practical exam, sign up to take the court, the exam, and then you pass that, you get your dispensing license. Courses that are approved in New York State are no issue with continuing education. If you've taken a course out of state and it wasn't prior approved, by the Department of State, it should get approval by submitting out all the information about the course prior to renewal, sufficiently 30 days in advance of renewing.

And if you've taken a continuing ed medical course, for instance, in New York State, you'll never get a approval for it unless it was prior approved by the Department of State. But most of our courses go through the Department of Education, so you may have less of an issue. A trainee in their training year, you have to be training your trainee under direct supervision for the first three months. And in the second three months, you must be available on premises to answer any questions. And for the remaining six months after that, after They may take the exam after six months, but after they have taken the exam and after that six months, the last six months of their one-year training is supervised for sales.

They cannot conduct sales on their own.

These, this is the list of topics theoretical and in the number of hours that the have to be trained in the theory of Acoustics all the way through the rules and regs and the number of practical hours, practicum hours, 310 compared to 2000 plus that the AUD student has. The theoretical hours are really only 124 because they're allowed to to miss 10%, they could be sick. But if you take on the training of a non-audiologist dispenser, you're responsible to get your state instructor approval prior to doing it. And you need then to be responsible for training, supervising, and getting them through their exams. What is in the practical exam?

All people who become hearing aid dispensers in New York State have to have taken a practical exam. The practical exam, best to use gloves and wipes and put out a clean liner on the surface of the table that you're working on. Bring your tools in separate containers, clean and dirty containers, describing any faults in the impression you make. You're making an earmold impression on one ear of a person. You come with you and you're counseling them while it is setting up, but you do not have an audiometric testing session.

So you bring your best friend for whom you've done many ear mold impressions in that ear and you make sure you have used an otoscope speculum properly, looking in the ear before and after, but make sure you brace your hand against the head of the patient while doing that or you'll fail the exam. Make sure you brace properly so that you don't damage or hurt the patient.

There are practical tests for the hearing aid dispensing trainee. The practical test is not just an earmold impression. So if the AUD student decides to take it, you need to carry a portable audiometer and prove that you can do hearing testing, which I'm sure you can. So you bring your own portable audiometer and demonstrate that you can do air-bone speech and masking.

Now I'm talking a little bit about the telecoils and loops from the standpoint of standards and the measurements and why we do them. There's a whole nother course, but standards in the United States are developed by the American National Standards Institute. Standards throughout the world are in two categories. They're for procedures developed through the International Standards Organization or the measuring equipment, the earphones, the audiometers, the couplers, it's developed through the International Electrotechnical Commission. These are the standards that you must comply with and your office must comply with.

ANSI S322 covers telecoils in the United States and IEC 6118-0 covers it in internationally and -4 is for loops.

This is kind of saying the same thing, but if a loop has been set up based on the standard 6118-4, the loop anywhere set up by that standard will have uniform standard strength and perform the same, and it won't allow electromagnetic interference to affect speech understanding. As I pointed out before, S322 in the FDA regs is 2014. It was reaffirmed in 2020 to be the same as what was in 2014, but there are changes in the 2025, and that has not been Added to the FDA regs, everything drags, and now who knows what's going on federally. Hopefully they still have the FDA persons handling hearing aids. The attempt is always to try to harmonize.

That means make the standards here for the US the same as in the rest of the world. But it's not always the same. and they have decided so far to maintain some differences between S322 and 6118. There are slight differences in the couplers that only exist within 33222. And the splivin splits tests, they are a bit different.

The splits test, which is for the telephone Simulator has tolerances, but only in S322, and the SPLIV test does not.

The primary focus of hearing aid fitting is, of course, that you should be able to hear with the microphone working in the hearing aid. So microphone is important and that's what we assess when we do real ear microphone technology or in a test box. But a microphone only works over a short distance and in quiet or relatively low noise environments. So there are people with different hearing losses who will require more than a microphone and they might need an FM system or an infrared system or a loop to be able to improve their signal to noise ratio. And you have to be sure you are coupling the devices properly.

The consumer knows how to optimize their situation with the proper devices.

And most importantly, you need to make sure the response with the microphone for performance, for hearing is the same as or as close as possible to the performance with the telecoil so that they can hear well.

The SPLS test is used as the telephone simulator. A telephone is heard best when the telecoil is in a horizontal position and a loop is best when the telecoil is in a vertical position. So when you are testing within a telephone simulator in a test box, you're adjusting the position of the hearing aid to maximize its response or optimize its response and then letting the consumer know which position is optimal for their hearing aid. For this vertical position, when you're testing for the telecoil being in a vertical position, you're always using the vertical magnetic field regardless of what position the telecoil is in. So that there, you're getting the signal to be the same when their head is vertical so that when they're in a sound field, they can actually hear without having to adjust the position of their head.

And if an a loop has been set up according to 6118-4, and it's a phased array loop. There's no interference in electromagnetic field or head position. If you have a simple loop that you just set up in your office or in a place that didn't pay the money to get a phased array loop, it is possible the position of the head could affect the ability to hear with the telecoil. You're responsible for explaining all that simply to your consumer so they know how to use the devices and switch from one mode to the other and know where to find a looped environment. Hearing testing now becomes a key issue.

And we used to say keep one copy of your audiogram available that says it's an audiological evaluation, not a medical medical examination. But now, since the federal law says you don't have to have a medical evaluation, and New York State says you do, you have to make some decisions about the, and the consumer has to make some decisions as to when they choose to have that medical evaluation and how often you need to use an audiogram. that says it's an audiologic evaluation and not a medical examination, being in that instance they would not have had, they've opted not to have the

medical evaluation.

And they would opt then to use a waiver.

Where a non audiologist hearing a dispenser, the copy of their test needs to say it's the testing was for the sole purpose of fitting or selecting a hearing aid and is not a medical examination or an audiological evaluation. No changes in New York State, so still encouraged. And you must send to an ENT or a physician to get the evaluation. If the patient opts for the waiver and doesn't want to go, then you have to use that other form. Business practices.

Simple. You maintain a place of business, you have to keep that address, and the department state aware of that address. If you move, they have to be notified within 30 days. Everybody in that office has to have an individual dispensing registration, and it has to be posted at each and every business location. And if the owner of the business has to have a business registration, In each and every location.

And the, if it's the owner is a franchise owner rather than a direct owner or manager, they still have to have the New York State license and they are responsible for any hearing aid dispensed at that location. When you are testing and working with your consumer, you need to have a medical questionnaire, or at least a history questionnaire about their hearing in different situation, difficulty, and any disclosure statements. You need to make sure you're testing in a proper sound treated room. Double walled is best, single walled is possible, is for the hearing testing, not for hearing aid fitting. And you can test in a very quiet room, especially if they have more of a hearing loss.

But you're not supposed to cue the patient, of course. In New York State, the waiver is not supposed to be encouraged, but and the use of a waiver indicates that they are waiving medical evaluation for personal and religious beliefs. Makes no sense still in New York State, but they have done what they

have done. They at least have to change that sign. The medical referral signs are the ones we discussed.

There are nine for over-the-counter hearing aids. and there are eight for prescription hearing aids. This is the sign that has to change. This is just gets me angry. It says here that the federal law requires medical evaluation of your hearing loss by an otolaryngologist or if none is available, another licensed physician.

That is a lie. It should say suggests it does not require. It can say New York state requires it if that's what they insist on, but it does not say the federal law requires it. And it makes me angry that this is required to hang. We are required to hang this in our offices.

You need to make sure you have the sign posted. You need to be have available the consumer guide for purchasing hearing aids and the consumer guide to hearing aids in general.

A dispenser is not allowed to discuss a medical condition or write anything about a medical condition or diagnosis. An audiologist, on the other hand, can. They just can't diagnose. If you have a patient who's lost a hearing aid, you can replace the identical hearing aid within one year. That is the same.

Obviously, you need to do air and bone testing and you know how to do that. If there's an air bone gap in the mid frequencies of 15, you need to referral and you need to know when to mask. You need to make sure you do speech testing, most comfortable loudness testing, and threshold discomfort testing, at least if not for each frequency. And speech recognition scores. If you haven't tested any of them, you must document everything in your chart because it may come to a point where you need to prove that you have done everything And for the consumer, your purchase order agreement has to have the date of sale, make and model number and serial number, your business address, your office hours, whether the instrument is new or reconditioned, and the certificate numbers for each of your licenses for the

trainees as well, for all the dispensers in that office and the business office.

and I miss one? No.

So on the purchase order agreement, it needs to state, and this is still acceptable, that it is not an examination diagnosis, a prescription by a person licensed to practice medicine in the state, and therefore not regarded as medical opinion. can't object to that. And it tells you where it's supposed to be and what size font. If you're a part of a for profit business and you have a 45 day trial period with any devices in New York State of the prescription hearing aid type, you are allowed to retain 10% of the purchase fee if in fact the consumer decides they haven't benefited from the hearing aid that you've selected for them in that 45 day period of operational use. The hearing aid, even if it goes out for repair or adjustment or refit or whatever, it has to be 45 days of actual use with the hearing aid that's been fitted.

So you adjust the date on your purchase order agreement. You have plenty of time to return the hearing aid to the manufacturer for so not to worry. And if you're an off the profit business, you can retain five percent of the purchase fee and get 200 for one hearing aid and 300 for two. And again, that needs to be in this font and listed near the same place where the person signs. So it's clear they understand that they have a trial period and that you will retain some of the money, not for profit, 10 and for profit, enough for profit, five percent and for profit, 10%.

It's the other way around. And ENTs are not supposed to be dispensing hearing aids for profit if they've done a medical evaluation of the individual's hearing loss. They found wiggle room and that's what they're not supposed to do according to the law.

If they have are not for profit and they then do not need to register as a dispenser, they are not required to have any continuing education or training at all with regard to dispensing hearing aids. They are only

just supposed to stay in their lane and diagnose and the hearing laws.

Our regulations are always up for grabs. There are organizations, Physicians of all types, trying to dispense hearing aids for profit. And there have been attempts at legislation. There's only been one year where there's been a matching bill in, in both the Senate and the assembly. so they, we just pay attention and, and work with the mishla, New York State speech language hearing Association, because they are your primary lobbying group for hearing in New York state.

There should be and still has not gotten to come to pass the MASA or the Medicare audiologist access and services act. and that is where the, we, it will change us from being a practitioner, would change us to being a practitioner from a technician. Right now, we are licensed at, audiologists are considered technicians under ENT codes in the Medicare system. If this would allow audiologists to diagnose and treat and actually do the rehabilitation, we do all the time and bill for it. And the, the, there is now one state, and it's Arkansas, that has that law on the books.

We can work in our state to try to do that. Let's just work hard with Nishla to do it. And, and we need to expand telehealth. became very important during COVID and remains important. And Department of State should try to match the federal regulations for prescription hearing aids.

There is still the condition for a return of a hearing aid for one year. If somebody decides they haven't gotten any benefit, it's always best to give them the complete refund and then make sure you've documented everything in your chart and you are in fact going to then refile and get your money back from the Department of State. The conditions that they can return it under are really the following. They have to get somebody who's a professional, a physician or to an ENT or another physician who would write in their judgment that the purchaser either had a hearing impairment for which they had no benefit from the hearing aid they had, or it was they had a condition which contraindicated the use of a hearing aid and they got no benefit. So document, document, document.

Make sure you indicate everything you've done and every bit of benefit with Real Ear and other techniques to questionnaires. Make sure you know that you, you know, the person that you're treating is, is being helped. And these are the records you need to keep, tests, sales, any rental agreements, purchase agreements, any waivers, any written guarantees, any correspondence to and from that consumer, a copy of a statement if they decided to return the hearing aid in 45 days. You must accept any hearing aid that's up to five years old for repair, and you can charge a fee for the repair. And there is an estimated charge for it.

There isn't any way you can get that estimate. You can just tell them at a time and give them a receipt.

A consumer does not have to accept a loaner if you're charging them a fee, but you can charge them a fee. It depends on the circumstances and how you do your business.

Files need to be kept for any batteries, sales, purchase prices of the devices, anything regarding advertisements to document that whatever you've claimed in an ad is true and you've kept record of it, whether it is a testimonial or that you can't say that any or an audiologist works out of your office if they don't on a regular basis. It's not a one day show and tell and sell.

Your records for advertisements need to be kept in a file and documented clearly as to what is true and that you claim. There are no direct sales in New York State. If a manufacturer of a hearing aid is in New York State, they cannot direct mail to New York State, but they can direct mail from any other state or over the internet. So, but telemarketing must comply with federal and state law. So no hearing aid is allowed to be sold by telephone or by telemarketing unless the consumer has initiated the telephone contact.

And telemarketers are supposed to file as doing business in New York State. They're not permitted to do pre-recorded messages to the consumer, and the consumer can put themselves on a do not call list. No door-to-door sales with regard to hearing aids. And your responsibility is to train the consumer. If what are the advantages of monaural and binaural hearing for them?

is the consumer protections that are offered. How do they work with a telephone? Is not oversell. You're supposed to be training the consumer at least 45 to 60 minutes out of more fitting process. It is wise that you keep a checklist of all the things you've counseled the consumer about and how well they have done with the devices you have given them and the rehabilitation you have trained them with.

It's wise to have a form that shows that they've received a copy of their audiogram, that they've been counseled, they've been informed about support groups, they know how to use a telephone, they know about a 45-day trial period and so forth. They've gotten instructions on how to maintain the batteries, care for the hearing aid, clean, use cleaning tools and so forth and have it signed so that you can document. And when somebody tries to return a hearing aid and say they had not had benefit, that's malone.

You need to train the consumer for the best care and use of the hearing aids and what can communication strategies help that will help them and what they can expect. the limits that they can expect the device to do. No hearing aid is a miracle cure. And in what kind of support you offer in your office or that might be available in local area for that consumer. And how to care and maintain the hearing aid, make sure they can replace and purchase batteries or know how to recharge the device and use the telephone or other assisted devices.

Again, they need to know the hearing aid is expected to last about five years, but they need to know that they can purchase additional loss and damage insurance or maintenance repair warranties. And that, again, they understand the 45-day trial period, that they can return it.

you have to have a HIPAA policy and have a consumer brochure. Department of State, the consumer brochure available. You have a complaint policy in your office. This is the purchase agreement for hearing aids. And this is the I'm going to stop.

Until the stop phone stops ringing. Okay. I'm starting again with this slide. This is the Consumer Guide for Purchasing Hearing Aids. This is the new brochure.

They've now made it in color and you'll see it even has a QR code. So if you should have this available in your office, it's downloadable, obviously, with the QR code. and sanitation and infection control becomes an issue because the state law doesn't really reflect anything practical. You need to maintain clean test rooms and entry areas, and you need to make sure you are cleaning, disinfecting, and sterilizing. You need to remove any gross contaminants before you actually start the cleaning.

process, then you are disinfecting and under sterilizing, and you store your equipment so that it remains clean. And you keep records. Your hearing aids need to be wiped off prior to use so that your staff isn't handling them. They put in a cup or an envelope or something so they're not handling the dirty hearing aid. And the bone oscillators or other transducers need to be cleaned more than once a week.

They need to be cleaned between consumers and you need to disinfect, clean and disinfect any of those tools, listening stethoscopes that you might be using on the hearing aid. If you don't transfer from one consumer to the next, the countertops need to be cleaned at more than once per day. And so too the arm rests in both the test room and in the waiting room. And any toys should be cleanable, not cloth. You need to maintain safety data sheets, the material safety data sheets.

They need to be kept in a file and you need the schedule of your sterilization listed there and your staff needs to be trained regularly in that practice. We live through COVID. We could be living through the

bird flu or God knows what will hit us next. There are times still that a mask is appropriate. You may have a cold.

Somebody in their family who comes in with them may have a cold. You may not want it. So you wear a mask and you just are aware of the fact that they are no longer able to liberate you. And there are certain masks that are appropriate and certain ones that are not. If you are in fact, you don't want one that has air leaking, so you don't use an N95 vented mask.

And if you have somebody who sneezes and sprays a shield, A face shield will help. You are required to know the general business law and understand it because it is your responsibility as a professional. The hearing aid business application is on the website at this address and lots of other documents are available in terms of continuing education that you might need to look up. This is available on the website and it is important for you professionally to make sure your alphabet soup is understood by the consumer. I will also now give you my cell phone number because there are multiple numbers that will be available to reach me.

and these are two of them, but 516-509-7596 is my cell phone and the one that's used most often. And we are done. You have any questions?

Thank you so much, Barbara.