eAudiology: Ethical Considerations in Audiology Practice

Presenters: Melissa Ferrello, AuD, Victor Bray, PhD, Alison M. Grimes, AuD, Devon Weist, AuD

At the conclusion of each session block attendees will be provided access to a session survey. CEUs will be awarded upon completion of the survey. Most session blocks are one hour and may contain two learning modules or three research podiums. Finally, if you would like to ask presenters questions, please use the Q and A tab. Again, thank you for attending AAA 2021 Virtual and now please enjoy the session.

Welcome to AAA 2021 Virtual. To earn CEUs at AAA 2021 Virtual, attendees must view the entire session block, which may include multiple presentations. At the conclusion of each session block attendees will be provided access to a session survey. CEUs will be awarded upon completion of the survey. Most session blocks are one hour and may contain two hello, I'm Melissa Ferrello, Chair of the AAA Ethical Practices Committee.

Thank you for joining us for this year's Ethics featured session.

We have some interesting topics planned for you tonight. Since we couldn't be together this year, we wanted to make it engaging and interactive as well as give you the Tier one nature of this presentation. So the topics really are a collection from across a wide range. For our standard disclaimers, the content of this presentation does not reflect or represent the views of the presenter's employer or professional affiliations. The presentation does not constitute legal advice.

Please consult with your attorney if you have questions regarding legal practice and or professional behavior in your area. The content of this presentation does not comprise an exhaustive representation of all professional or legal viewpoints. And with that I'll hand it off to former committee member and current AAA Board member Devin Wiest.

All right, so thank you Melissa for passing it over. I'm going to begin our talk here with some ethical considerations in regards to to students, universities, our off site practicums, and basically how those

dynamic work, how those dynamics work, especially how those dynamics work in the midst of the pandemic and beyond. So as Melissa mentioned, my name is Devin Wiest. Just a couple of my disclosures. I am a clinical instructor and the director of the Hearing Clinic at the University of South Florida Communication Sciences and Disorders Department.

And then in addition, I am currently a member at large on the American Academy of Audiology Executive Board. So to dig right in here, when we think about the framework for ethics and students, we need to think about who the stakeholders are when we talk about this. And obviously the first one that comes to mind is our students. But our students interact with a lot of people as they move through their audiology education. So first and foremost would be the university in and of itself, the faculty members that work there, the staff that work there.

But then in addition, going beyond the university, we know that our students don't just stay at a university for four years as they learn audiology, they also interact quite a bit with the audiology community as a whole. So the preceptors that they work with, not just preceptors, but also, you know, anytime they're at conferences or they're engaging with any of the manufacturers, so there really is a network for how our students are learning and all of the skills and tools that they're developing in regards to ethics that goes beyond just them themselves in their individual learning process. And then obviously how they interact with their patients that they're going to serve at, they're going to serve in regards to when they're a student, but then also beyond.

So when we talk about students and ethics, a lot of times we hear these two terms come up, professionalism and ethics. And they often are used interchangeably. But in reality, are they really one in the same? And if you look at the definitions that are on the screen here, you'll see that when we talk about professionalism, we really look at the skills, the competence and the conduct that is displayed by an individual of a certain profession. So another way to think about professionalism would really be the

set of values or beliefs that someone has.

Ethics, on the other hand, when we look at the definition of ethics, we look at this is the guidelines for individuals, and it's really more of a do's or don'ts. How should we be acting? So when we think about these two terms together, really ethics is basically a component of professionalism. And you'll see up here in the corner, it says the name Duane. Claudia Duane is actually a social worker.

And there's a lot of information in the professions of social work and nursing. And they have looked at how professionalism works and ethics work in terms of how we interact with students, how supervisors or preceptors are working with students, and how they're modeling ethical behavior. And to touch a little bit more on that, obviously we as a profession are dictated by the AAA Code of ethics. And as you all are probably familiar with, there are eight principles within the Code of Ethics. And those range from, you know, information on how we should conduct ourselves in terms of working with our patients, keeping confidentiality, their medical records, that we provide, you know, honest and dignified services in regards to not just services, but also the products that are in the best interest for our patients, that we treat all of the patients, that we come in contact with, respect and dignity and then specifically, as you can see here, I'm going to talk a little bit about principle two, because really, when we look at the code of ethics, that's how we practice in regards to a profession, how we interact with our patients, how we interact with colleagues, other healthcare providers.

But when we're thinking about students, how does this come into play with students? Obviously, we want our students to model and follow the code of ethics. But when we get into the supervisory role, how is the supervisory role? How does that come into play when we talk about ethics? And really, you could argue that every principle that we just talked about comes into play because we want to model best practices.

But specifically, when you look at Principle 2, Principle 2 talks about how we, if we are doing, if we are in a supervisory role, we're making sure that those that we're supervising, we are assuming full responsibility, and we're making sure that they are not practicing services, they're not qualified to do so. When we think about ethics right now, and, you know, we're all living in the midst of a pandemic that's been going on for the past year, how does that come into play in regards to, you know, audiology as a whole, but not just audiology as a whole, but how students are involved? And basically, there are a lot of considerations that maybe we thought about prior to the pandemic, but have really become at the forefront currently. And we talk about safety and survival, you know, the safety of our patients, the safety of those of us who are working with the patients, whether it's ourselves as audiologists or the students that are with us. When we talk about survival, we think about there's a lot of considerations for.

There was a time when, you know, healthcare shut down and then we reopened. So businesses are really thinking about how that impacted them financially and do they have enough supplies to continue to see the patients that they serve safely? And on top of that, if you're a clinic that is working with students, where do students fit into all of this? Can clinics accommodate them? Should universities feel liable to have students in a clinic when there's all these risks that are happening?

What if a student happens to contract Covid who all needs to know about that, and where do they fit in? So really, while these things that I'm mentioning may not be true ethical dilemmas, they really do set the stage for how ethics impacts everything that we do in audiology and audiology training. So some policies that are around and have been around in regards to students, universities and clinics all working together, one of the things that is dictated is something called ferpa. And if you're not familiar with that, that's the Family Educational Rights and Privacy Act. And basically that's a federal law that applies to all educational institutions that receive funds under any program administered by the Secretary of Education.

And it's really about a student's educational rights and what can be disclosed and not disclosed. And part of that disclosure deals with a student's medical records. So when students are working in off site clinics, the relationship and how the relationship works is universities have something called an affiliation or a memorandum of agreement. And that agreement agreement really protects the student, it protects the university, and equally it protects the clinic and the preceptors that are working with that student. Well, does any.

Did anything change during the pandemic? Well, if you think about it, we now have greater risks when we're working with patients and we have a very infectious disease that is at the forefront of all of our minds. So if a student were to get this, were to contract Covid, how does that work and how does that apply? And, and yes, in previous times under ferpa, a lot of times things couldn't be disclosed. But in the midst of a national pandemic, open communication essentially always needs to happen so that we're keeping our patients safe, we're keeping the students safe, we're keeping that clinic safe.

The other thing that also happened is there was a time when students were not necessarily seeing patients directly. You know, universities had shut down, obviously, clinics were not doing direct care. But. But as that started to change and we got further into the pandemic and states started to reopen again, universities really looked at, okay, well, we have an ethical obligation to keep our students safe. And we understand that when they are in a healthcare profession where they're training to be a healthcare professional, where you have to directly see patients, how does that look?

And basically universities were saying, we need students to understand that there is risk involved in going back into clinic. But in order to train you properly, you as a health future healthcare provider need to go out and you need to start seeing patients again. And there were waivers that students were signing and are continuing to sign that are saying, you know, we understand that there's a risk, we're monitoring it, that clinic is monitoring it. But as a healthcare provider, you do need to understand that

you have to interact with patients.

So when we think about COVID obviously it has changed everything. It's changed how we think about working with patients, it's changed how we set up our clinics. And ethically, who is this obligation to. If we have to suddenly wear additional supplies that we didn't have to wear before, there's costs involved with that. So making sure that a clinic has enough of that so that they can keep their patients safe, that they're working with.

If clinics are limiting the number of people that are actually in the clinic, if you introduce students into that mix, well, that's an extra person. So. So how does that look? Are patients going to be okay with that, knowing that they're not only going to see an audiologist, but they're going to see a student? If there are limited appointments?

If clinics are not back to full strength because they are trying to social distance and limit the amount of individuals in the clinic at one time, if the clinic is not seeing a normal caseload, should there be a student placed at that clinic at that time? Maybe not so much. If a clinic is also starting to develop. We know that telehealth has really taken off in audiology, especially during this pandemic. But what are the capabilities of that and what does that look like?

If a student is also involved, is there training so that everyone is using that adequately? And then also in terms of all of this, what is the university's obligation? So these are all things that the clinic is considering and they're trying to make good decisions about. Ethically, is it okay for me to take a student at this time, knowing I have all these things to think about? But then, from a university standpoint, what is student safety?

Can we ensure that our students are safe when they're going out into clinics? Can we also ensure that if there are limited appointments or if telehealth is happening all the time, are the students getting those

learning competencies that they still need to meet in order to graduate and be licensed? So as we move forward, some things that have been happening and will continue to happen is there has been some change in terms of what placements were available, and some placements that previously were utilized may not be taking students at this time. So if that's the case, then what is the university doing to make sure that students are still graduating at the level that they need to, and they're getting all the competencies that they should? And what's been so great about this is universities, just like clinics, have become really creative in implementing alternative learning plans.

So virtual clinics are a thing that are now occurring at universities, you know, across the nation. And what I mean by virtual clinic is developing case scenarios. We know we have lots of cases. We all know we see a ton of patients, but is there something that we can do virtually with students if they can't be directly involved with the case? Can they work through it?

Can they talk about how they would counsel that patient? Can they model that? Simulations are something that has really become a part of audiology education. There are simulations where students can practice doing audiograms online. They can practice masking skills.

There are now, just like Kemar, there's now something called Carl, which is basically a mannequin that has lifelike ears. So students can take impressions, they can do probe mic measures, they can do wax removal. So they're still getting to do those really essential skills, but they're not doing them directly on a person. They're doing them through virtual activities. We talked about telehealth.

Telehealth is something that, you know, is going to continue to be a part of our profession. Are we training students appropriately and making sure that they understand that that is important. But when is it appropriate to offer telehealth and when is it not appropriate to offer telehealth? And then another consideration is tele supervision. So do we have to be sitting next to that student while they're seeing patients 100% of the time, or can we be doing things virtually to supervise?

And that's obviously going to depend on the type of patient we're seeing, the type of services that we're doing. It's also going to depend on our payer sources. We know that with cms, with Medicaid and Medicare, there are some very strict guidelines on how supervision occurs. But is telesupervision something that we can look to for the future so that, you know, we don't always have to be 100% in the room at any time. But above all of that is if we're going to start to do these new models, we still need to ensure at the end of the day that patient centered care is still happening.

And are simulations as the same as the real as the real thing? Probably they're not. But is it something that can complement the real thing, or is it something that maybe students can start to do and then they can move up to actually seeing patients? So maybe their first year they're learning more in simulation type activities to build up to actually directly seeing patients? And is it still possible to make connections if we're not seeing people directly?

And the case may be yes and no. There might be times where it's completely appropriate, but there might be other times where we know that patient care needs to happen when we're directly in the room.

So this could probably be a whole topic in and of itself. But in terms of modeling ethical behavior, there's a lot of things to consider with this. And this has been a big forefront, not just in audiology, but in healthcare in general and in training future healthcare providers. What are the ethical responsibilities outside of typical, what I say, audiology student hours? So what I mean by that is what happens after students go home from the university or after they go home from their clinical practicum site?

You know, these are individuals who are working with patients who are immunocompromised or they're around a lot of people at all, at all times in their clinics. So our students understanding that as a future healthcare provider, just because you take those scrubs off at the end of the day or you take off your audiology badge, are you still practicing good, you know, good procedures for what we know we need

to do to stay safe during a pandemic? Social distancing, avoiding groups wearing masks in public, and really understanding that those choices have consequences. And they may not be the best consequences because in, in terms of a student, yes, we know that if they're engaging in risky behaviors like this, they could potentially, you know, they could potentially harm their patients. They could spread Covid to their patients.

We know that. But beyond that, they could, you know, take this infectious disease into a clinical clinic and they could, you know, spread this to their, their preceptor, which then if their preceptor is not in a big clinic where maybe someone can cover, it's a private, small, private practice, maybe that shuts down the clinic completely. If they unfortunately spread it to their classmates, their classmates then become out of commission and aren't able to see patients and aren't able to continue to more move forward in their education, or if they spread it to faculty members, faculty members aren't able to then educate students. Maybe classes have to stop or, you know, in person labs discontinued during that time. So there really are, there really are a lot of things that can be impacted by not following best practices.

And ethically, is that okay? You know, students sign up, and we all sign up when we become audiologists to understand that we're healthcare providers and there are risks that are associated with that. But at the same time, we want to make sure that we can mitigate those risks. And then finally, and this is not finally, this is a big topic here, but in terms of thinking about vaccination ethics, there's a lot of information, not just in audiology, but in the American Medical association, looking at other healthcare professions, looking at big hospitals, is it ethical as a healthcare provider to not get vaccinated? And it's not my job to say yes or no.

It's just thinking about this. This is a big topic of conversation. This vaccine was approved under the emergency use authorization, we all know that. But if people are choosing not to do this, how does that

impact clinics? How does that impact hospitals?

How does that impact the future of our profession? And really what has started to happen in all of this is it's not just looking at, you know, what is a clinic's or a institution's beliefs, but then also what is an individual's beliefs and how do those two collide and where do we go with that? And really we have an ethical obligation as healthcare providers in terms of beneficence and non maleficence to do no harm to our patients. So if we are not gonna partake in being provided the vaccine or having the opportunity to get the vaccine and taking that, then what does that look like? Are we putting patients at risk?

Are we putting our clinics at risk? Are we putting undue burden on fellow audiologists or fellow students who are trying to learn and maybe can't? Because we have shut down, we've shut down that clinic or we've shut down that learning experience. So there's really a lot of information to think about in terms of what are the ethics involved with being vaccinated too?

So in terms of just kind of wrapping that up, I know that was a brief overview of some of the things to consider. But when we think about future debt directions and takeaways, I talked about telesupervision, where we might go with that. Right now it seems that telesupervision, there are some guidelines and there are some policies in place in different states when supervision is happening with audiology assistance. But how does that apply to students? And is that something that could potentially apply to students?

And that's going to depend on state licensing laws. So really if that is something that's a consideration, working with the university's clinical education coordinator so that everyone stays on the same page for that and understanding how that might work and again, what patients that's appropriate for or what payer sources might, might permit us to be able to do, like that simulation based clinical learning, it really has implications for the future. You know, we have universities all over the country and yes, it was something that, that became apparent during a pandemic. But beyond the pandemic, we know that

weather can wreak havoc on schedules. So is this something that, you know, if a, if a particular area is shut down due to inclement weather, could, could learning still happen?

And I think the answer is definitely yes. You know, if there, if patients have canceled and there are no show or no shows, if a preceptor is out on medical leave, are there still ways that students can get learning? And I think the answer is definitely yes, that we can still do this. But I think ethically we need to remember this is not a substitute for the real thing. We obviously know that audiology is about directly seeing our patients and directly diagnosing and treating them.

But can we think a little bit outside of the box for the future and maybe help complement some of those things that we do directly if we're not able to do that at all times? And really, the biggest thing in terms of all of this is, you know, the pandemic has been hard on everyone and it's been hard on audiology as a whole. But if we think about training students and making sure that they are still getting the competencies that they need to meet to be able to be licensed or if they choose to go through certification to be certified, then really what we need to think about is we need to think about open communication between the students, between the clinics that the students are out in with those preceptors they're working with, and the university to make sure that we can delve into new ways to do things and make sure that we still are furthering our profession. And the last two things I want to leave you with here are these are just two scenarios to potentially consider in terms of how you might handle when it comes to ethics of students and kind of working through the pandemic. And the first one here you will see this is the case of weekend jam sessions.

And the scenario for this is there's a student that's working with you this semester, and the student's a huge fan of music and tells you that they've attended over 200 live concerts. It just so happens that the following week they show you pictures of attending an in person concert. But at that concert, there were no masks worn. Social distancing didn't happen. It was a very large group setting.

The first patient that's on the schedule for that day happens to be a patient who needs hearing aid services. They are 85 years old and they are immunocompromised because they just finished their last round of chemotherapy. So if you think of this from an ethical standpoint, is this an ethical concern. Is this okay if a student is vaccinated, if the audiologist is vaccinated, if the patient is vaccinated? Where does work versus personal time stop and start?

Should the preceptor discuss directly with the student or should they go to the university? Is this the university's responsibility? So think about that and when we get to the question and answer session we can talk more about that and then an additional one here a different scenario. This is the case of supervision in pajama bottoms. So your child tests positive for Covid and you're therefore required to a mandatory quarantine period.

Your practice will need to reschedule the next 10 days worth of patients. However, you think I have an excellent fourth year extern who can certainly see most of our patients independently, given how our practice is using Microsoft Teams for meetings and even for patient appointments. Because it is a hipaa, it does have a HIPAA compliant telehealth feature. You think maybe I should work out a plan where I can sit at home and I can be present in all the appointments via this teleconsulting feature? So again, is this an ethical concern?

Does it depend on the appointment type? Does it depend on licensing laws? Does it depend on if this is a CMS patient where clear supervision guidelines exist is on site versus insight super supervision. The same thing. Should patients be notified and allow them to decide if it's okay, if they're okay with this.

So some things to consider in terms of ethics and students. And at this point I'm going to turn it over to Alison Grimes for the next part of our presentation.

Great. Thanks, Devon. I can see already that your slides are so much more cleverly put together than mine are. I just don't have the artistic focus that you have. So I'd like to bring up a couple of tricky issues in daily practice.

I'm Alison Grimes. I'm the Director of Audiology and Newborn Hearing at UCLA Health in Los Angeles. There are things that we should do and there are things that we should avoid doing. We should always stay within our own scope of practice, legally and ethically. We have a scope of practice for a reason and it defines what we are licensed and possibly certified to do.

Of course, within all of that, we want to do first no harm. So we keep that in mind. We need to meet the needs of the patients before meeting our own personal needs. And we want to put the preferences of the patient and the family first insofar as possible. Sometimes that's not possible, but they are consumers of our services.

And we need to rise to their expectations and meet their needs. Unfortunately, we also need to follow their insurance authorization. So sometimes that limits in ways that we would, that we would prefer to not be limited, but we can be limited by the insurance authorization. And we need to be sure that we bill compliantly, meaning billing for services rendered, of course, and not billing for services not rendered. And through all of this, we are, as Devon so carefully and well pointed up in her presentation, we need to model this behavior for our students.

Our students are watching us in the clinic. They're seeing how we, how we run through our test battery. They're observing how we counsel the patient and family. And we do need to always model that ethical behavior for the students themselves. So I tried to come up with a couple of ethics issues that occur within the clinic on a fairly regular basis.

What about the issue of single versus multiple hearing aid manufacturers? Let's say that there's a situation, and this is not uncommon, of course, where an audiologist is employed by the manufacturer or is employed indirectly by a manufacturer through a dispensing practice outlet. That audiologist may have an arrangement or an expectation with a manufacturer that they will sell X number of products every month. So there is an incentive to choose that particular product knowing that they have that arrangement set up. And these arrangements are often set up in exchange or in return for better pricing or possibly other benefits that can accrue to the practice.

Is this a quid pro quo? I'm not an attorney, I'm an audiologist. But it certainly has a little bit of a feel of this for that kind of arrangement. This sets up an expectation for which products will be dispensed. And it certainly is possible that the employer of the audiologist, who may or may not be an audiologist, him or herself, the employer may even not permit purchasing or dispensing non company products.

In my mind, that sets up a conflict with the necessity to first do no harm. So even if there's not an appropriate product in the product line, is there an expectation that the audiologist in this circumstance will find a product in that product line? Or is it our ethical responsibility to refer the patient to an office who can better, better meet their needs? So let's think of a couple of examples. What if your Your employer is ABC Hearing Aid Co.

And they don't have a bone conduction hearing device, but your patient has atresia? Or your patient has a surgical ear and cannot wear a typical hearing aid, but you don't have that particular option on your Menu of items that you can dispense what if a patient comes in with a cochlear implant processor on one side and wants to purchase the hearing aid that is compatible with a cochlear implant on the other side? What if your employer doesn't have that particular hearing aid available for purchase or available for sale within that office? That sets up an ethical dilemma. What if the patient needs a CROs device?

What if a patient needs a headbanger hearing aid? For want of a better term, what if a patient needs a hearing aid with very high gain and high output for a severe to profound hearing loss and there is no such item available in the list of products that the manufacturer owned practice has available and there are a number of other examples I'm sure we could all come up with. So this really goes back to first do no harm. The patient's needs must be met before the audiologist's needs need to be met. So it may be important, or it may be necessary to refer the patient to another office by simply saying you need a product that does exist, but I can't provide that to you within this office and perhaps I can send you to another office that might have that device available, but I can't do it here in my own practice.

In some practices it may be possible to get a special dispensation to purchase outside of the product line for a particular patient need. It is important through all of this to educate your patient about what his or her options are in the entire environment of audiology products. Whether or not you are able to provide that to him. It's important to educate the patient about what solutions might be available somewhere in the audiology world, knowing that your patient may choose to go elsewhere. And I think it's important also to work with your employer to help your employer understand that they're is occasionally a necessity to go outside the standard product line.

Dispensing a device that is not optimally suited for the patient is not only a potential ethics violation, but it's also a potential violation of your state licensing law. And certainly it's not holding practice to the highest standard. How do you know what how do you know that a hearing aid is appropriate for a specific patient? Patient comes in and through the if you are working in a practice where products are limited to only a particular manufacturer, it's very important that it can be demonstrated that the hearing aid is appropriate for a specific patient. And this is not even just in manufacturer own practices, but it's in all of our practices.

So we Know that we have two ways that really ensure that we have fitted appropriate hearing aids for a specific patient. One is to verify the hearing aid fitting after it's fitted, and one is to validate. The second is to validate that hearing aid fitting over a longer period of time. And in dispensing hearing aids, we need to assure that the hearing aids are selected and fitting for the particular needs of the particular patient. And we don't know that this is the case unless we verify the hearing aid fitting using probe microphone measures to objectively assure that we have provided appropriate audibility for that patient's hearing loss.

And then also to validate that we look over a slightly longer term to ensure that the hearing aid fitting is meeting the needs of the specific patient insofar as possible, so we validate longer term that benefit is achieved. What if we don't verify the hearing aid fitting and we all know that this happens? We don't really know what we're dispensing in that case. If we don't verify it, we think we know what we're dispensing. But until we actually objectively verify the fitting, we don't know what we're dispensing.

In California, and I would suspect in most states, the Licensure Practice act specifically indicates that hearing aids are selected and fitted for the specific needs of the purchaser. And in fact, on the contract that we are legally obligated to use in California, that language is written on the contract. So we are signing that we are specifically selecting and fitting for the specific needs of the purchaser. If we don't verify, we don't in fact know this to be true.

So when, if you work for an employer that doesn't have verification equipment, for instance, or doesn't have, doesn't utilize a protocol for verification and validation, or perhaps only has a limited product selection that is available to be used with the patients that you see. You could appeal to your employer to purchase outside the standard menu of products for a particular patient. You could inform your patient that you unfortunately cannot help her or him with the particular products that you have available, but you know that there are other products available elsewhere that might be more

appropriate. You could fit a company approved but less than optimal device. If you do that, do you disclose that to the patient?

And in that case, how would you be able to sign the California contract that says that you are fitting hearing aids that are specifically designed and fitted for the specific needs of the patient? So that's a bit of a conundrum that we should keep in mind. Okay, let's talk about something else. How about cognitive screening? Is that in our scope of practice?

Is that permitted by your state license? And importantly, what do you do with the information once you've done a cognitive screen? So I think once again, it is important to know not only what our scope of practice indicates through the academy, but what is permitted under your state license. And a second and related question to consider is are you the audiologist, competent to select a correct test, to administer it, to interpret it? And really importantly, are you competent to counsel patients on results and implications?

Are you competent and knowledgeable to make appropriate referrals or treatment decisions based on the outcome of the cognitive screening? One could ask, if the outcome of the cognitive screening test doesn't change your evaluation and treatment plan, should you even do it? So is there value in doing a screening if it's not going to change your diagnosis and your treatment plan? And what do you do with the information once you have achieved it? If you do a screening, do you make a diagnosis of cognitive decline?

Is this in your scope of practice? And I would doubt it. It certainly is important to consult with the patient's primary care provider and consider carefully how you might share this information with the patient themselves and with their family members.

Okay, one more possible topic, one of my favorites. That's a joke. Insurance authorization versus best practice. What do you do when you are authorized for a lesser code and you know you need to do more testing? Or what do you do if you're authorized for a higher level code but you really can reasonably do only a lower level of testing?

So let's think about an example. You get an authorization for 92557, air, bone and speech. And this is a patient that you see every year. And this patient has a typical noise induced age related hearing loss, doesn't report any concerns or any new signs or symptom and you see him every year and his hearing has been quite stable over the last three or four years. So you do air conduction thresholds and lo and behold they haven't changed for the last three or four years.

But your authorization is for a 92557 air, bone and speech. So do you do all of the testing? Do you do a lesser, lesser testing and bill for the full code or do you go back and try and get a different authorization? So certainly billing for airbone and speech and only doing air conduction testing is not compliant billing. And we run into both an ethical and a potential legal issue by billing for a higher level code and doing a lower level service.

This is also, once again, something to consider as we model our behavior for our students. If they watch us bill for a higher code and do lesser testing, that's a model that we don't want to exhibit as being professional.

So what about if the authorization is only for pure tone air conduction testing, but there are signs for conductive hearing loss? Do you need to get a new authorization? Perhaps. Do you need to do additional testing and just not bill for it? Perhaps that is the easier way around.

So there are certainly issues in billing for services not rendered, and these are serious compliance and ethics issues. And we need to be cautious about the choices that we make as we see our patients with

insurance authorizations. Which of these scenarios threaten your license? Potentially any or all of the above. So, of course, we know that ultimately we need to put the needs of the patient first.

No matter if we're doing diagnostic testing, if we're doing a cognitive screening test, if we're dispensing hearing aids, we want to always keep the needs of the patient paramount. And remember that first we want to do things that aren't harmful. And as important as our, as our scope of, as our ethics practice guidelines are for the Academy, it's also very important that we know what our license permits us to do and doesn't permit us to do. And also very important to know what the current professional guidelines are that the Academy espouses. Okay, and for the next discussion, I'll be handing this off to Victor.

Victor Bray.

Thank you, Allison. My name is Victor Bray and I too am a member of the AAA Ethical Practices Committee. I'm on faculty at Salus University, Osborne College of Audiology. And I don't have any financial disclosures that would impact this presentation. I've been here at the university for a little over a decade, following a decade and a half in industry and another decade and a half working clinically.

And I hope to bring information from all three of these areas into this presentation. From the beginning, let me say that the topic of ethical considerations in over the counter hearing aids is somewhat speculative and that the EPC has not yet seen any ethics complaints in this area. And my hope is that by talking to you on this topic today, maybe we can head off some of the complaints that could emerge in the future.

The specific topic of today's presentation is ethical considerations and over the counter hearing aids. Today's perception for some is shown on the slide where many of us see the world of ear conduction amplification systems as relatively Black and white. On the left side in the circle, there are amplification products for the amelioration of hearing aid for hearing loss. These are hearing aids. They're class one

or class two.

They are medical devices with controlled distribution through licensed providers. In contrast, on the right side in the circle, there are amplification products that are personal sound amplification products or PSAPs. These air conduction devices are not medical devices, are not sold through a control distribution system and cannot be marketed as for the treatment of hearing loss. Yet it is obvious from the product design and the product marketing that the intended use of PSAPs is as an OTC hearing aid. But black and white hearing AIDS are not PSAPs and PSAPs are not hearing aids.

But I want you to think of the topic of today's presentation really is ethical considerations in direct to consumer hearing aids. Some see today's and tomorrow's world of devices much differently than the previous slide, where the world of air conduction amplification systems now only has shades of gray. In between hearing aids and PSAPs. In the middle circle, I've created a category of OTC hearing aids which may not be either.

These are symbolized in the big box of direct to consumer hearing aids because that is how they will be delivered. The OTC Hearing Aid act was signed in 2017 to enable adults with a percentage received mild to moderate hearing loss to access OTC hearing aids without having being seen by a hearing care professional. The legislation requires the FDA to establish a new category within three years, which was 2020 and is now past due and is expected in 2021. The FDA rules once proposed, hopefully this year, must be finalized within 180 days after the close of the comment period, which projects out to devices being on the market in 2022. So in one respect you really should expect those markets, those devices coming soon.

Thus the impetus for this presentation. But within another respect, some of these amplification devices are already leaking out and are being marketed as OTC hearing aids today. On the left side, we should be aware that Class 1 and Class 2 hearing aids are being sold as direct to consumer today. And so I've

enclosed them also in the big DTC box on the slide. Some of these hearing aids are being sold DTC with audiological guidance, some without.

If you don't believe me, just go to Amazon and search for hearing aids. There are literally hundreds of hearing aids advertised as hearing aids delivered right to your door. Features include digital signal processing, noise reduction or cancellation, directional microphones, rechargeable batteries and wireless capability and Prices range from $100 to $1,000 a unit. What I think you should expect in the very near future is that some of today's hearing aids will be rebranded, relabeled and marketed tomorrow as over the counter hearing aids. Thus the overlapping circles of hearing aids as medical devices and as OTC hearing aids.

In addition, some of today's PSAP devices will be rebranded, relabeled and marketed as over the counter hearing aids. Thus the overlapping circles of PSAPs and OTC hearing aids. And within these shades of gray we may be seeing the early stages where all air conduction amplification devices will somehow be made available direct to consumer. Thus all three circles are within the DTC box. Now in this discussion on over the counter hearing aids I can refer you to the Academy documents, go to the Academy website and search on OTC hearing aids and there is a multitude of information now what is a concern?

As an audiologist you provide professional services. Depending on your work environment. Sometimes your professional services are bundled into a variety package price for an amplification system. In other environments your professional services are unbundled from the prices of products. What differentiates you from others in this emerging landscape is your professional services, not your ability to have exclusive access to some particular product category.

It should be a major concern to you. If you currently have a bundled evaluation plus dispensing plus product package and are not considering a change, you may want to reevaluate your practice to an a la

carte services package of evaluation and dispensing separate from product because that is the way patients who are tomorrow's consumers will evaluate spending their dollars. So what are some ethical considerations? Most of us are operating in the environment of the previous slide. There are hearing aids and there are PSAPs.

Some of us, maybe many of us, are seeing our environment changing into what's shown in this slide. How do you respond in an ethical manner? Do you start playing in the product distribution margins where you start edging towards over the counter and direct to consumer using a product oriented approach? Or do you start emphasizing your professional ability to evaluate and comment on any device someone brings to your clinic that is a service oriented approach?

The AAA Code of Ethics has eight principles and within each principle there are from two to six sub points. Today I'd like to look at three of the principles and their primary sub point. Let's start with Principle 1 and 1A of the Code of Ethics and focus on the statement that members shall provide professional services and that Individuals should not limit the delivery of services, services that is unjustifiable with respect to need for potential benefit. So what's a concern? The focus is clearly on your professional services.

What are these services? Your unique ability to provide a holistic diagnostic diagnosis and evaluation and treatment of hearing and balance disorders. Let me also say frankly, we have no unique ability in the dispensing of hearing aids. And non audiologists have proven that their fitting and dispensing outcomes are on par with ours. The focus needs to be on the patient discovering any abnormal function of the auditory system and thus relating it to its impact on the patient's function in life.

In short, it's often not about impaired hearing, it's about impaired communication ability. So what are some ethical considerations? If a patient comes to see you having moved from another town, would you see them and evaluate their device? I think all of us would say yes. What if you see the patient and

they came to see you with a hearing aid from another clinic in town for a second opinion or because they were dissatisfied with the device?

Again, most of us, but maybe not all of us would say yes. Well, what if a patient comes to see you with a hearing aid that's from a deceased family member, Would you see them and evaluate their device? Many, but not all of us would say yes. But what will you say when the patient comes to see you with an over the counter device or a direct to consumer hearing aid that they want you to adjust or even fit? If you've not seen this yet, it will be coming.

Will you see them? I know audiologists who are drawing a line and saying no, I won't work with them if they have amplification products that were obtained through what I believe is an improper distribution system. I can understand that position, but I also see that the code of ethics is that we should provide professional services with compassion and respect and not limit our services based on unjustifiable or irrelevant conditions. Is the way that our patient obtained an amplification device relevant or is it just or unjust to deny patient care because they obtain devices through a method that we don't personally support?

Let's continue with Principle 4 and 4A of the Code of Ethics and focus on the statement that we provide services and products that are in the best interest of the patient and we do not exploit patients. So what's a concern? The focus is on the best interest of the patients, not on our interest as audiologists. This is a fundamental tenet of being a doctoring profession in healthcare. As Dr.

Schrupp and Garner wrote in chapter one of the Green Book on Ethics and Audiology. As healthcare providers, audiologists must ensure that they keep the interest of the patient paramount in working with patients. In the past, the communication strategy path for devices typically involved hearing aids once you wanted them and then cochlear implants when your hearing aids no longer met your needs. But in working with patients in the future. The communication strategy plan for devices may involve starting

with a PSAP today for hearing help with normal hearing except maybe in noise, moving on to an OTC hearing aid come 2022 for perceived mild to moderate loss, then on to hearing aids once the OTC hearing aid is no longer sufficient, and then the cochlear implants as soon as the patient fits the eligibility criteria.

In this scenario, you may be providing a lifetime of services, but never ever be the actual provider of the amplification device. In all of these cases. PSAP to OTC to hearing aid to cochlear implant you are being tasked with providing guidance as to whether or not the devices are in the best interest of the patient, and they often will be, and not to use the clinical encounters as an opportunity to turn product sales through your clinic. So what are some ethical things to consider if you decide to work with a patient who brings in a PSAP device to overcome their hearing loss, which is actually a threshold loss on the audiogram? Are you bound to honor the FDA labeling requirements and not fit a PSAP to a hearing loss?

For example, the fitting of a PSAP device for a hearing loss would be off label use and in contraindication of the product labeling for use only for normal hearing. How would you resolve this ethical dilemma if you agree to work with patients who bring you over the counter and direct to consumer amplification products or decide to carry these devices in your clinic? What are your obligations and restrictions based upon state laws? For example, does your state law allow you to provide services that are only face to face? Could you go beyond this and provide remote care such as teleaudiology even if you might not be able to provide some of the services mandated by your state law?

Will you expand to provide services by phone contact only or go to written contact only or even Internet contact only? Where do you draw the line based on ethics and provided services and products that are in the best interest of those served? Do you have to be face to face to provide professional services?

Let's wrap up this discussion with Principle 5 and 5A of the Code of Ethics and focus on the statement that we provide accurate information about services and products that a reasonable person would want to know. So what's a concern? The focus today is on whether or not you can provide a professional assessment of any air conduction amplification device regardless of where it's obtained without having an audiological evaluation. After all, PSAPs and over the counter hearing aids are for use based upon patient perception of having normal hearing or hearing loss, not on our opinion or measurement of hearing loss. So what are some ethical considerations?

So you agree to work with direct to consumer amplification products, specifically PSAP devices that are not for hearing loss or OTC hearing aids which are labeled for self perceived mild or moderate loss. Can you provide these products without an audiological evaluation? For example, if a patient has a hidden pathology and chooses to purchase the OTC hearing aid at CVS or Amazon, is it caveat mtor where the principle is if the buyer alone is responsible for checking the quality and suitable of goods before a purchase is made by inference and maybe by statute, they would also be self responsible for the status of their auditory system, including any pathology hidden from them. But what if they purchased that OTC hearing aid from you? As a licensed and degreed professional, what would be your responsibility as a professional, a doctor in the healthcare system?

Would you need to ensure that there was no pathology that needed intervention beyond amplification? If you sell the OTC in a manner that CVS and Amazon will do, you carry the extra burden to protect the patient from themselves? Does the patient's safety become your responsibility once you start working with the patient? If you agree to work with any amplification products and follow best practices, you can calculate an aided Speech Intelligibility index value. If you do real ear measurements and you can tell a patient what percentage of SII is achieved with their walk in device, you can also compare that to a fitting from your own that would match maybe more closely a validated prescriptive target such as NAL NL2.

But to do that you need a target and to do that you need an audiogram. Can you provide an evidence based consultation on product performance to needs as appropriate or inappropriate without performing an audiological evaluation as part of your consultation, even though evaluation is not part of a legal requirement to purchase the device? I and others don't know the future of how the over the Counter Hearing Aid act will impact the distribution model of consumer access to amplification devices as opposed to the long standing distribution model of patient access to medical device hearing aids. But I will certainly bet dollars to doughnuts that five years out from now, clinical practices will and must be different. What may have been a time in audiology where clinic revenues were driven by device sales will have to change over to a new time where audiology provides and charges for professional services because products will be bought elsewhere.

This change is no different than Walmart coming into town and replacing the small town downtown mom and pop businesses, or Costco's and Sam Club replacing shopping centers, or Netflix replacing Blockbuster and then pivoting from DVD by mail to streaming of the movies. Internet delivery of medical devices now such as corrective vision wear, contact eyeglasses, pharmaceuticals for a variety of concerns, cardiovascular tools such as pulse oximeters and portable ECG monitors or frankly, Amazon replacing everything. Into this new world. We will need to work together to use our ethical guidelines to forge ahead. I want to thank you for your time today and I hope I've stimulated some thoughts in the ethical practice of audiology for your professional future.

Thank you. And I'd like to hand this back to Melissa. Thank you. And I want to thank Victor, Allison and Devin for doing their research and presenting these topics today. I want to also thank everyone for their time and listening to our presentation.

And with that, we'll take questions.