

I am compiling a list of state statutes that address a mandatory trial period on hearing aid sales. I am having difficulty finding specific statutes relating to the following 8 states. If any of you know of the specific regulation that pertains to these states, I would be grateful for the information.

STATE	COMMENTS
AZ	Here in AZ there is no legal requirement for a dispenser or dispensing audiologist to provide a mandatory trial period.
CA	<p>I have to take strong issue the proposition that trial periods only result in high return rates. I have routinely offered a 60-day trial period. My record will show that my return rates are well below the industry average and my record is long for I have been dispensing as an audiologist for 30 years. I think that the successful use of a trial period has a lot to do with how it is presented.</p> <p>I avoid counseling that the trail period is only a right to return and end the process of fitting, but rather I present the trail period as an opportunity within the 60 day time frame to try another approach with amplification if what we have tried is failing to meet the patient's expectations. It is true that their expectations have a lot to do with my proper counseling, but the patient must feel satisfied or we end up with another patient sharing their horror stories with their friends and neighbors that no amount of good advertisement easily overcomes.</p> <p>I do frame the process of fitting a hearing aid in the terms of "OUR" expectations, (the patient, their family and my expectations). The trial is a means of insuring that "OUR" expectations will be met. After all I can say...we have the right to return an instrument to the manufacturer if a particular hearing aid does not meet our expectations. "WE" have the right is an important difference from they have the right. We have the right to return the instrument and do something different.</p> <p>I always try to make the fitting a "we" process. Though ultimately the patient knows that they can get a full refund, the point of the trial period in my practice is that it is a TOOL to insure a proper fitting. It is rare for me to have to change to a different model and/or circuitry, but patients are put at ease in a process that can be scary and strange to them. No only are my patients put at ease, but my referral base is also put at ease.</p> <p>When fitting a hearing aid there are choices and variables that do influence the fitting outcome. There are choices the patient makes and that I can make can influence the outcome in a negative way. For example; The patient may insist on a cosmetic feature that may lead to a poor fitting (maybe despite my counseling to try something else) or I may use an instrument whose claims of benefit from the manufacturer are not revealed in the real world of the fitting on a patient.</p> <p>If one presents the trial as an aspect of expected failure I guess it would be negative, but there is one aspect of negativity that anyone who dispenses hearing aids does not need and that is a hearing aid sitting in a drawer and <b>IS A WONDERFUL TOOL TO OBTAIN PATIENT CONFIDENCE AND OVERCOME THE EFFECTS OF THE HORROR STORIES!</b></p> <p>Larry T. McPherson, Au.D. Lancaster Audiology Services Lancaster, California</p>
CA	It is true that issues related to success and outcomes are dependent on more than the hearing aid performance. But if there is truly a difference in discrimination then the aided HINT is an excellent tool to measure the difference. I would recommend a front back testing

	<p>situation and take a comparison. Probably noise front and then noise back. If you have DIR MICS then it will be even more powerful. Using this technique I have adjusted hearing aids on policemen to pass the HINT. The problem is that you should be able to tune both hearing aids (with similar gain and output) to appear to do the same thing. The thought that hearing aids are so different is not necessarily true from the amplifier only side. It is the features chosen and how and when they are applied (i.e. DIR Mics, Phase Cancellation, Compression) that makes the difference. How much compression is too little or too much? What is the output per channel? Certainly, other issues outside of the fitting can ultimately be in control the outcome, but if the response is not meeting the needs then just changing hearing aids is not always the answer, most likely changing prescriptions is fruitful. In fact, there is very little reason for a return.</p> <p>The current industry return standards are unnecessary. We are coming to an age where our services must be strategic and correct. I also learn something new all the time. I hope this helps someone learn this quicker than it took me. This is a wonderful question that we all should answer on each and every patient. Is our selection correct and what evidence do we have to prove it? Thanks Dennis</p> <p>Dennis A. Colucci, Au.D., M.A., FAAA  Auditory Disorders and Balance Laboratory  Saddleback Valley Medical Center  23961 Calle De La Magdalena  Suite 355  Laguna Hills, Ca 92653  949 830-5770  949 830-2324 (fax)</p>
CA	<p>Great question Cindy: The difference in many cases is how you set the compression and output. If audibility is reached with both hearing aid types and one outperforms the other there is no reason except the choices of compression kneepoints and output. Also, I have a tendency to shut of some of the high priced automatic stuff for noise etc. if it is in the primary channel because it also misleads the fitting. So, if you are doing real ear testing and the responses are the same then the differences are the type of compression used and the setting selected. I suspect that the linear device had much less compression and possibly better headroom for a great dynamic. Some ears actually work great without all the fancy stuff and others require it for a variety of reasons. Good Luck I hope this explanation helped. D</p> <p>Dennis A. Colucci, Au.D., M.A., FAAA  Auditory Disorders and Balance Laboratory  23961 Calle de la Magdalena, Suite 355  Laguna Hills, Ca 92653</p>
CO	<p>Colleagues,</p> <p>In line with the discussion on 30-day return policies, it would be valuable to know what it costs manufacturers to offer this policy. Have any studies been done by the manufacturers looking at how much the 30 or 60 or 90 day credit return policy adds to the cost of any hearing aid?</p> <p>I would assume it is much higher for a custom product than a BTE? Certainly companies have looked at this cost, which must be built into the cost of every hearing aid. Can any of the manufacturers answer this question? I believe it was Starkey who first designed this policy, do they have any cost figures?</p> <p>Linda Van Dyke</p>
CO	<p>I found that regulation in the Colorado code (see <a href="http://www.ago.state.co.us/consprot/consumerlaws/CCPA2005.pdf">http://www.ago.state.co.us/consprot/consumerlaws/CCPA2005.pdf</a>)</p>

	<p>So, you all can see the reasons for compiling this stuff. I was surprised that no such compilation exists in any of the national offices, trade journals, or other source.</p> <p>YIKES!</p> <p>Mike</p> <p>Michael J. Metz, Ph.D.          Director of Audiology          Ear Professionals International Corporation          17870 Castleton St., Suite 320          Industry, CA 91748          Voice: (877) 606-3742          Fax: (626) 913-6454          e-mail: <a href="mailto:mmetz@epichearing.com">mmetz@epichearing.com</a></p>
CO	<p>I believe this is where the Federal regulation comes from:          The 30-day trial is addressed under the Consumer and Commercial Affairs, Consumer Protection Act, 6-1-105.5 Hearing aid dealers - deceptive trade practices. (2)(e)(III). This is where it is stated that the seller must provide a written contract or receipt with the statement that the "buyer has the right to cancel this purchase for any reason at any time prior to 12 midnight of the 30th calendar day after receipt of the hearing aid by giving or mailing the seller written notice of cancellation." This Act goes on to state that this statement is to be in all capital letters of no less than ten-point bold-faced type.</p> <p>In the State of Colorado, the 30-day trial, and any extension of it, is addressed in the Audiology Registration Rules &amp; Regulations.</p> <p>Jenny Weber, AuD          Associate Professor          University of Northern Colorado          970-351-2012          970-351-1601 fax</p>
CT	<p>Richard writes: In my opinion, it is a hold over from the days of door to door sales of hearing aids and for our profession to continue to lobby for it (as per the information provided by Barry from 1993) is contrary to what I feel is proper.</p> <p>My recollection is that a thirty-day trial from the manufacturers was started when Starkey was trying to assure dispensers that in-the-ear aids could work. It was a way of getting us to try a new technology. I am really, really glad we still have it for that reason. There is no way I see that "evidence" is going to keep up with technology on the market, unless new technology cannot be sold until there is "evidence." While the psychological issues of a "trial" is a problems to be handled with a new patient/HA user, I am really glad I have one for the 92-year-old-on-a-limited-budget I have trying a Synro who has a Senso of equal power. She is hearing better. Yet, I have had a few Syncro returns ("no better.") Otherwise, it is like when I first worked before we dispensed and before there were trials and we did not recommend amplification to borderline or many difficult candidates. And some people used a really wide border... What about no loss below 3000 Hz? Severe unit SNHL with 70% dicrim? High power digital on longtime analog user? 30 dB HF HL? I sure these readers can think of lots of other examples. Pauline</p>
FL	<p>FDA:          I found the notebook from the original FDA testimony in response to the 11/10/93 Federal Register request for responses to Rulemaking: Medical Devices; Hearing Aid Requirements. The testimony was provided by:</p> <p>Susan Whichard, President, ADA</p>

	<p>Lucille Beck, Pres, AAA Sharon Lesner, Pres ARA Jeri Logemann, Pres ASHA Peggy Von Almen, Pres EAA</p> <p>In the response, the following was stated to FDA: "Specific changes in label and labeling requirements are recommended to protect consumers, including a mandatory trial period of at least 30 days..."</p> <p>Further, under Recommended Components of Hearing Aid Fitting/Verification/Orientation, the testimony stated, "30-day environmental/field trial."</p> <p>FTC: In addition, if you look at the FTC website, they offer the following advice to consumers looking to buy a hearing aid:</p> <p>"Can I get a trial period? Many states recommend or require that consumers get at least a free 30-day purchase price- if you return the hearing aid during that time. In fact, many manufacturers will make adjustments during the trial period, and allow returns within 60 to 90 days of purchase at no charge to the dispenser."</p>
IL	<p>Don't forget that when you talk about returns that the manufacturers also consider an exchange a return. That needs to be considered when setting percent goals for "returns"... the number must include all returns, not just returns for credit. Far too many don't consider an exchange a return, but in reality an exchange is a return.</p>
IL	<p>Richard: I too think (?) your memory is correct and that the mandate for a trial period was dropped and made voluntary... I am not 100% sure and my old memory could be failing. :) However, most continued to offer the "trial period" either because their state required it (keeping in mind State law can be more restrictive than Federal law) or because the precedence was set and some felt it helped sales. That's partially why it's important to know your state's regulation. It used to be my responsibility to investigate state laws and modify our hearing aid contracts when we entered a new state. It was not possible to have one contract that met all state's requirements... and to keep things on one page!</p> <p>Kathy Foltner, Au.D. Practice Management Consultant</p>
IL	<p>Just an FYI - when I was in private practice we choose to increase our "adjustment period" from 30 days to 60 days. As a result, our return rate dropped from 10-15% to 5-7% increasing our net profit. Also, our sales increased as it eliminate some of the risk for our patients. We promoted it as increased value for the patient and our confidence in our services and products... in essence to fulfill our Mission to "exceed customer expectations". To me, as important as the time, the 30, 45, or 60 days, is our words. Although required language in some states, "trial" connotes possible failure and return whereas "adjustment" connotes one must get used to or adjust to their new amplification. Adjustment period is a better term if one can use it on their contract and still be in compliance with their state law.</p> <p>What we'll never know is how the sales of hearing aids would be today if there never was a trial period. Certainly, we all pay for the national return rate in the products we buy and many of us need to do a better job with our returns and exchanges.</p> <p>Kathy Foltner, Au.D. Practice Management Consultant</p>
IL	<p>Gary - depending upon your state's and each state's licensure laws, being an audiologist does</p>

	<p>not necessarily exempt us from the hearing aid dealer regulations. To assume "this does not apply to us" is not a wise decision. In some states hearing aid dealers are licensed separately from audiologists, but in other states they are together or at least intertwined. If you sell hearing aids, even if you are licensed as an audiologist, you should confirm what regulations do and do not apply to you. State laws do not have to match Federal law. State law can be more restrictive than Federal Law, but not less restrictive.</p> <p>Kathy Foltner, Au.D. Practice Management Consultant</p>
MD	<p>I agree that a longer than 30 day trial period is a good idea and one that I use. It is in our best interest to give the patient an impression that this is an adjustment period and not just a trial, suggesting that it is a whim that they would keep the aids. It also puts patients under pressure as 30 days is not very long especially given the complexity and flexibility of the digital aid.</p> <p>Are there audiologists out there that do NOT give a return option?</p> <p>Leslie B. Papel, Au.D. Hearing Services 1838 Greene Tree Road Suite 370 Baltimore, Maryland 21208</p>
ME	<p>In Maine we have a similar issue with the wording of our dispensing law.</p> <p>"If any service, fitting or repair is performed, a new 30-day trial period commences as of the date of this service."</p> <p>As far as I know a problem hasn't happened here but I've always had trouble with this wording. Is an adjustment to the compression ratio or changing the vent considered "service"? Has that changed the "fitting"? Are they now entitled to a new 30-day trial? You can't expect manufacturers (or us) to accept returns forever.</p> <p>Cindy Hyman</p>
MO	<p>While I do agree that there are both positives and negatives, I thought I would point out some of the positives.</p> <p>I have a patient who really wants to hear better, but his discrim in his non-aided ear is zilch. We tried a very good digital hearing aid, but it did not work. Did I consider this a failure? Absolutely not. He wanted to try, and a trial was the only way to know for sure if it would have worked or not. Another patient came in with ancient bicros aids. I fitted him with high-end digital aids to help his discrim, but they did not improve his discrim. We returned those and tried some programmable analog hearing aids. His discrim improved significantly.</p> <p>In my 4 short years as an audiologist, I don't see what experience could have predicted that outcome.</p> <p>I am one of those people with a "funny" eyeglass prescription. I trust that my eye Dr. knows what he is doing, but I never know how MY brain and MY eyes are going to react to a certain prescription. I feel much better knowing I have a trial period (did not keep the soft contacts.)</p> <p>Cindy Modrosic Missouri</p>
NY	<p>The trial period has both its positives and negatives. At worst, this mandate by law reinforces the notion that hearing aid sales are still considered something that is under</p>

	<p>suspicion and still needs regulation. And audiologists continue to be linked to the underlying reasons for the laws, and that is because of untrustworthy hearing aid dispensers.</p> <p>It also reinforces a subtle message that we're not sure about the likelihood of a successful fitting. Having said all of this, I do allow the patients the amount of time that the manufacturer allows for returns and this is partly a business decision based on what the competition is doing, but I stress that whatever decision the patient and I have made with regard to the instrument selected will most likely be the right decision as long as we do the necessary follow-up and be patient with the re-adaptation process necessary for the brain.</p> <p>Counseling is always king.</p> <p>Bonnie Rubin, Au.D. Board Certified Audiologist</p>
NY	But everyone is covered by the federal requirement for 30 days, right? Angela Loavenbruck
NY	<p>I guess the current discussion is directed at those fortunate individuals who by the absence of state law have the choice of whether to offer a patient a trial period. Those of us in New York, as in many states, have no choice but to implement a state mandated, general business law directive. The specifics of the trial period must be disclosed in writing, and thus must be discussed during the "hearing aid evaluation" before a patient agrees to order a hearing aid. How you approach the "right of return" will determine the patient's trust in you and their perception of your abilities. I find that almost every patient who sits across from me is aware of the trial period and is waiting for me to bring it up for discussion. By having done so I have shown that I am up-front and honest. I provide an historical reason for the existence of the trial period, i.e., past abuses from those who are opportunistic. So I say that the trial period and the "right of return" is discussed because it has to be discussed, by law, and not because I am casting any doubt on what can be achieved. And if you lay out realistic expectations you can be consistent with your stated achievement goals. The patient realizes that the trial period is a state mandated formality, not a doubt on what you as a professional, in it for the long haul, can achieve. Confidence in you is established and you enter into the hearing aid fitting process together. For those of us who dispense under a state mandated trial period, it is a way of life that is an unyielding directive. But despite that, the patient's confidence in us is ultimately what will move our profession forward in such a way that no one else can duplicate.</p> <p>Neal A. Sloane, Ph.D. Great Neck, New York</p>
NY	<p>The trial period has both its positives and negatives. At worst, this mandate by law reinforces the notion that hearing aid sales are still considered something that is under suspicion and still needs regulation. And audiologists continue to be linked to the underlying reasons for the laws, and that is because of untrustworthy hearing aid dispensers.</p> <p>It also reinforces a subtle message that we're not sure about the likelihood of a successful fitting. Having said all of this, I do allow the patients the amount of time that the manufacturer allows for returns and this is partly a business decision based on what the competition is doing, but I stress that whatever decision the patient and I have made with regard to the instrument selected will most likely be the right decision as long as we do the necessary follow-up and be patient with the re-adaptation process necessary for the brain.</p> <p>Counseling is always king.</p> <p>Bonnie Rubin, Au.D. Board Certified Audiologist</p>
NY	Personally, I hate the "trial period" and never refer to it as such but rather as the adjustment

	<p>period. I much prefer my old practice of standing behind the product. My preferred programs is that I will remake or exchange the instrument for up to one year if the patient cannot adjust to the hearing aid rather than to refund the price. The hearing loss does not go away if they return the hearing aid but they are left with the perception that there is something inherently wrong with the aids when it is most likely the failure to follow directions, incorrect programming, or (heaven forbid), the wrong hearing aid in the first place. I get quite a few people who come in now and say "I tried digital before and they didn't work!" as if an analog with work the miracle that can't be brought about with proper fitting and counseling with a digital.</p> <p>The 30 day trial period is a hold over from when hearing aids were sold door to door with the expectation that either the salesman had no intention of being back in their neighborhood in the next 30 days (or ever) or the idea that the longer they have it the more likely they are to keep it. Audiologists and dispensers who don't know what they are doing and are therefore unsure if what they are doing will work are still using it rather routinely. Some people continue to sell the trial period rather than the benefits and responsibilities of using hearing aids.</p> <p>The direct cost of 30 day trials are born by the people that keep their hearing aids in that both manufacturers, dispensers, and audiologists must make up the loss somehow. So it is patently unfair to successful hearing aid users from a monetary standpoint and unfair to the unsuccessful users in that they still have hearing problem that has not been resolved.</p> <p>Bonnie Rubin &lt;<a href="mailto:hearingcenter@optonline.net">hearingcenter@optonline.net</a>&gt; wrote: The trial period has both its positives and negatives. At worst, this mandate by law reinforces the notion that hearing aid sales are still considered something that is under suspicion and still needs regulation. And audiologists continue to be linked to the underlying reasons for the laws, and that is because of untrustworthy hearing aid dispensers.</p> <p>It also reinforces a subtle message that we're not sure about the likelihood of a successful fitting. Having said all of this, I do allow the patients the amount of time that the manufacturer allows for returns and this is partly a business decision based on what the competition is doing, but I stress that whatever decision the patient and I have made with regard to the instrument selected will most likely be the right decision as long as we do the necessary follow-up and be patient with the re-adaptation process necessary for the brain.</p> <p>Counseling is always king.</p> <p>Bonnie Rubin, Au.D. Board Certified Audiologist</p>
PR	In Puerto Rico there is no mandatory trial period.
TN	<p>I think that in some cases it MAY be somewhat clear that patient mindset is affecting their acceptance/success with a specific device. For example a person with a moderate to severe loss rejecting an aid claiming it did not help. However, in many cases it will be difficult to be sure that the person is returning the aid because of a "poor mindset" rather than returning the aid because it does not provide enough benefit (given the cost, their degree of loss e.g. more mild to moderate loss) for them in their specific situation. A trial period for these people is really mandatory. Additionally, while rate of returns is clearly an important measure of business success it does not seem to me to be an appropriate measure of hearing aid fitting success.</p> <p>Ben</p>
TX	For the record, Texas - where I am located - has a mandatory 30-day trial period. As you can tell, I do not support the concept of the 30-day trial period and would hope that everyone on the national level becomes cognizant of the fact that not everyone in the profession supports the 30-day trial period.

	<p>To date, I am not aware of anyone else in this forum coming out against the 30-day trial period but I am doing just that. In my opinion, it is a hold over from the days of door-to-door sales of hearing aids and for our profession to continue to lobby for it (as per the information provided by Barry from 1993) is contrary to what I feel is proper. In fact, as far as I am aware only 1 of the esteemed individuals to represent our profession in the FDA testimony in 1993 actually dispensed hearing aids from a private practice office. Certainly, Jerri Logemann never did as she is an SLP and, therefore, should not be providing testimony in support of something she knows nothing about.</p> <p>I am well aware of the fact that many states require a trial period. I am well aware of the fact that many patients expect a trial period and many expect a "free" 30 day trial period as this is what the dealers offer. Some might say that this is good marketing but I say it is poor judgment. I believe that audiologists should not be trying to meet the standards set up by and for dealers.</p> <p>Most of the time, before laws are passed or changed there is an opportunity for input to the state and federal legislatures. We have the opportunity to make our views known and I, for one, feel we should lobby against the mandatory trial period in any future legislation whether it is a sunset provision or a brand new law.</p> <p>I realize that this is Don Quixotesque but I have been called worse things than Don Quixote as this issue is a lot like chasing windmills when so many of my colleagues are willing to accept the status quo instead of looking for better alternatives to better patient care.</p> <p>So we grew up as a profession with a 30-day trial period. We also have gone through a period when audiologists could not dispense hearing aids without being kicked out of the only professional organization at the time. We should be looking forward rather than holding on to the past. I believe there are valid reasons to change or eliminate the mandatory 30-day trial period and I haven't heard a single valid one why we should keep it. Patients can and should be protected in other ways.</p>
TX	<p>One other point, if memory serves me, this testimony was collected but was never acted upon by the FDA as the FDA continued and continues to stall in updating the requirements for hearing aids. So this information is part of the tons of information stacked in Washington, which no one is using. I, for one, would encourage all of our national spokespeople to stop with the 30-day trial as it is counter productive, costly, and a disservice to consumers, manufacturers, and professionals.</p>
TX	<p>Nice job on the research. I interpret this as meaning that there is no federal Requirement for a 30-day trial but a recommendation. The 30-day trial is vested in state law, then.</p>
TX	<p>I can't be too specific about the individual cases you cite; however, there are good methods for predicting the likelihood of hearing aid success if you are looking at SR as the meter for improved performance. This meter, however, has oodles and oodles of research documenting that this is a poor choice for hearing aid selection and fitting. I feel it can be used as a qualitative tool but one must take into account all of the other variables inherent in that patient the acoustical signal reaching the ear and the neural signal reaching the brain as well as all the non-auditory issues. In the patients you described, a simple PB-Pi function would have told you up front if SR could be improved with amplification. Then it becomes an issue of proper programming, earmold and shell adjustments, counseling, and involving the patient in their own care. I agree with Dennis that programming issues are critical; however, I prefer not to sell someone a hearing aid that has all kinds of horns and whistles, which must be turned off. Rather than turning them off, I would choose something that costs them less and doesn't have the extra features they don't need.</p> <p>As far as having just 4 years of fitting experience, don't worry about that. I have over 27 years of fitting experience and I learn something new everyday.</p>
TX	<p>I am not aware that the FTC ever made any regulations about a required 30-day trial period</p>



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