

Regulations for Internet Sales of Hearing Aids (as of 2013¹)

The introduction of hearing aid sales via the Internet has raised many concerns and questions as to the legality of these types of models. Of critical importance is adherence to the current U.S. Food and Drug Administration (FDA) regulations as well as state requirements for the sale and dispensing of hearing aids.

Some states may specifically or generally prohibit the sale of hearing instruments through the mail or online. Nine states (as of this writing) have placed specific restrictions on the sale of hearing aids via the Internet.

Without the involvement of hearing healthcare professionals in the fitting of amplification, patient safety may be in jeopardy. One area that is of concern is the medical evaluation waiver. Some sites merely require the purchaser to check a box to waive the medical evaluation. This measure can be potentially in conflict with the FDA requirement at 42 CFR § 801.421, which states that the hearing aid dispenser may afford the prospective user an opportunity to waive the medical evaluation *provided that the hearing aid dispenser:*

- (i) Informs the prospective user that the exercise of the waiver is not in the user's best health interest;
- (ii) Does not in any way actively encourage the prospective user to waive such a medical evaluation; and
- (iii) Affords the prospective user the opportunity to “sign” a detailed statement of waiver.

It is not clear at this time how a dispenser selling hearing aids over the Internet can demonstrate they meet (i) and (ii) above, nor whether the check box is viewed as equivalent to a written signature, indicating a purchaser's review and comprehension.²

The FDA has stated that it will investigate direct-to-consumer Internet sites to determine if the waiver is in compliance with relevant sections of the Code of Federal Regulations at Title 21. To report concerns regarding the sale of hearing aids and the FDA compliance, you can send an email to webcomplaints@ora.fda.gov.

¹ Information contained in this document was accurate at the time of its release in February 2013. For the most up-to-date information, check with state board of health and/or licensure boards.

² <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=801.421>