



REMINDER

Registration Requirements for Prescription Hearing Aid Fitters and Dealers

Any person or persons who are engaged in the business of selling prescription hearing aids or the practice of fitting and selling prescription hearing aids in the Commonwealth of Pennsylvania are not preempted by federal law from the registration requirements under the Pennsylvania Hearing Aid Sales Registration Law (35 P.S. § 6700-101 *et seq.*) and the accompanying regulations (28 Pa. Code § 25.201 *et seq.*). Therefore, such person or persons who are engaged in the business of selling hearing aids or the practice of fitting and selling prescription hearing aids in the Commonwealth of Pennsylvania must adhere to all the requirements set forth within the aforementioned statutes and regulations including but not limited to obtaining registration.

For any registrant to receive or maintain a certificate of registration as a fitter or dealer in the Commonwealth of Pennsylvania, the following necessary requirements must be fulfilled by a fitter or dealer regardless if the sale or lease of a hearing aid occurs in person, by telephone, internet or mail order:

1. Ensure business papers are filed with Pennsylvania Department of State, Bureau of Corporations
2. Submit application and obtain hearing dealer registration from the Pennsylvania Department of Health.
2. Maintain physical place of business located in Pennsylvania where aids are sold.
3. Maintain proper calibrated equipment and selection of hearing aids at the Pennsylvania location
4. Must employ at least one licensed or registered Pennsylvania hearing aid fitter, licensed audiologist, or licensed physician at all times and said Pennsylvania hearing aid professional must ensure requirements have been met for the fit and sale of a prescription hearing aid in Pennsylvania.
5. Tests and evaluations are to be provided and completed by a registered hearing aid fitter, licensed audiologist, or licensed physician prior to the fitting and selling of a hearing aid.
 - a. Certain tests are required for the sale of hearing aid. (See Laws & Regulations)
 - b. Some tests and evaluations are required to be performed in a quiet environment (55 dB or lower).
 - b. Some tests and evaluations require a face-to-face examination.

6. Provide and explain User Instructional Brochure. *See* 28 Pa. Code § 25.213.
 - a. Provide prospective hearing aid user or authorized representative with a copy of the User Instructional Brochure for the hearing aid that has been or may be selected for the prospective user.
 - b. Review the content of the User Instructional Brochure with the prospective hearing aid user or authorized representative.
 - c. Give the prospective hearing aid user or authorized representative an opportunity to read the User Instructional Brochure.
7. Obtain medical referral or if appropriate, obtain a medical waiver.
 - a. If any of the conditions are found to exist (visible congenital or traumatic deformity of the ear; active drainage from the ear within the previous 90 days or history of this symptom; sudden or rapidly progressive hearing loss within the previous 90 days or history of this symptom; acute or chronic dizziness; unilateral hearing loss of sudden or recent onset within the previous 90 days; visible evidence of cerumen accumulation or a foreign body in the ear canal; significant air-bone gap, when generally acceptable standards have been established; or pain in the ear within the previous 90 days) either from observation by the registrant or on the basis of information furnished by the prospective hearing aid user as outlined in 35 P.S. § 6700-402 and 28 Pa. Code § 25.211, then the registrant shall, prior to fitting and selling a hearing aid to any individual, suggest to that individual in writing that his best interests would be served if he would consult a licensed physician specializing in diseases of the ear, or if no such licensed physician is available, then to a duly licensed physician. If any of the conditions are found to exist as outlined above either by observation of the registrant or by information furnished by the prospective hearing aid user, the registrant shall not sell or fit a hearing aid to such person without a written recommendation from a licensed physician that a hearing aid may be beneficial to such person.
 - b. If appropriate, a medical waiver may be obtained from the individual.
8. Provide that the hearing aid is fitted to the wearer so as to ensure physical and operational comfort to the wearer in the use of the hearing aid and aid has demonstrated benefit.
 - a. Ear mold impressions are a part of the custom fitting process and must be performed by a Pennsylvania registered hearing aid fitter, licensed audiologist, or licensed physician.
 - b. Follow-up tests and evaluations must also be performed by a Pennsylvania registered hearing aid fitter, licensed audiologist, or licensed physician.
9. Review and Provide a state approved disclosure agreement to consumer and obtain required signatures and date/time notations. *See* 35 P.S. § 503.1 and 28 Pa. Code § 25.210.

10. Review and Provide a purchase receipt to consumer and obtain required signatures and date of sale. Ensure certain components and language are included on purchase receipt. If aids being sold are used, note such to consumer and on receipt. *See* 35 P.S. § 505 and 28 Pa. Code § 25.210.
11. Provide a 30-day money-back written guarantee with any sale of a hearing aid to a consumer and obtain proper signatures and date/time notations. Note: 30 -day minimum after delivery of aids. *See* 35 P.S. § 504.1 and 28 Pa. Code § 25.210.
12. Provide a 3-day contract Notice of Rescission when goods or services with a purchase price of \$25 or more are sold or contracted to be sold to a purchaser as a result of or in connection with a contact with or call on the purchaser at the purchaser's residence. *See* 28 Pa. Code § 25.213 and Pennsylvania Unfair trade and Business Practices Law (i.e. PA Consumer Protection Law)
13. Comply with specific requirements for sale of hearing aids to minors.
14. Comply with record retention requirements including copies of tests results and evaluations, disclosure agreement, purchase receipt, written recommendations, waivers, money-back guarantees, notice of rescission, and other records of the transaction. Records are required to be made available upon an inspection by a Department of Health representative.