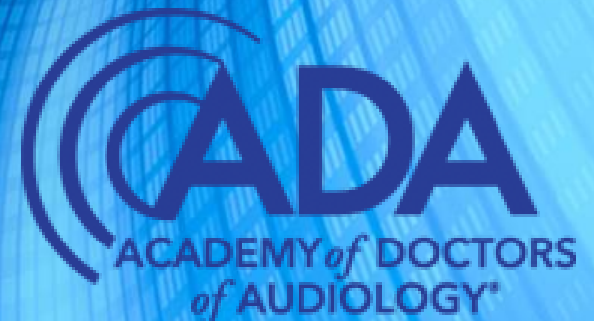


Academy of Doctors of Audiology (ADA) and Over-the-Counter (OTC) Hearing Aids

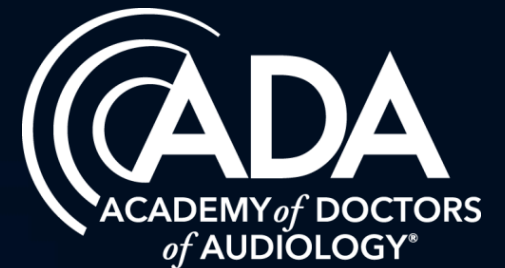
STEPHANIE CZUHAJEWSKI, CAE
EXECUTIVE DIRECTOR, ADA

ALICIA D.D. SPOOR, AU.D.
PRESIDENT-ELECT, ADA



History of ADA

- Academy of Doctors of Audiology
 - Founded as the Academy of Dispensing Audiologist in 1978
- Cutting edge of the future of audiology
 - Dispensing of hearing aids
 - Private practice model
 - Clinical doctorate degree (Au.D.)
- Forward thinking
 - Audiology Patient Choice Act (APCA)
 - Over-the-Counter Hearing Aid Act (OTC HA)

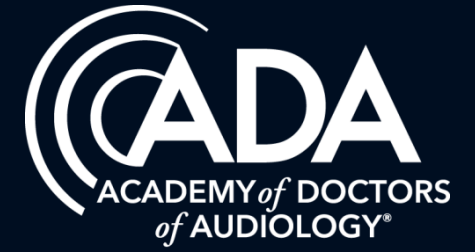


President's Council of Advisors on Science and Technology (PCAST)



- Aging America & Hearing Loss: Imperative of Improved Hearing Technologies, October 2015
- Four recommendations:
 - 1. FDA should designate as a distinct category ("basic" hearing aids) non-surgical, air-condition hearing aids intended to address bilateral, gradual onset, mild-to-moderate age-related hearing loss and adopt distinct rules for such devices.
 - 2. FDA should withdraw its draft guidance of November 7, 2013 on Personal Sound Amplification Products (PSAPs).

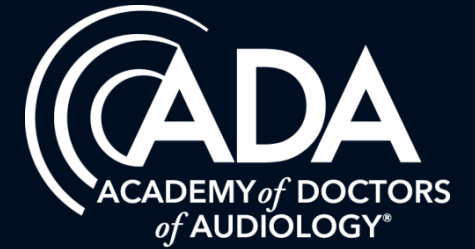
President's Council of Advisors on Science and Technology (PCAST)




3. Analogously to its “Eyeglass Rule,” FTC should require audiologists and hearing-aid dispensers who perform standard diagnostic hearing tests and hearing aid fittings to provide the customer with a copy of their audiogram and the programmable audio profile for a hearing aid at no additional cost and in a form that can be used by other dispensers and by hearing-aid vendors.

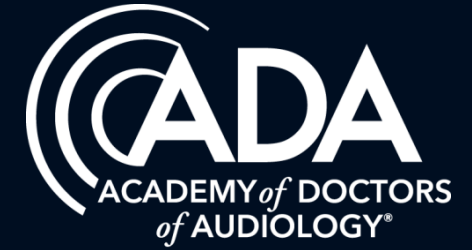
- 4. Similarly in efforts to its “Contact Lens Rule,” FTC should define a process by which patients may authorize hearing-aid vendors (in-state and out-of-state) to obtain a copy of their hearing test results and programmable audio profile from any audiologist or hearing-aid dispenser who performs such a test, and it should require that the testers furnish such results at no additional cost.

PCAST (cont.)



- Aging America & Hearing Loss: Imperative of Improved Hearing Technologies
- ADA provided **qualified support** for all four recommendations. 
 - Quality audiologic care is important to successful patient outcomes.
 - May be confusion of PCAST terms “class” and “category”. Recommend only the use of “category.”
 - Recommend PSAPs be labeled as non-registered devices and encourage development of PSAP standards.
 - Opposed online diagnostic testing; but supportive of online screening tools.

Biggest Barriers to Care
Food and Drug Administration (FDA)

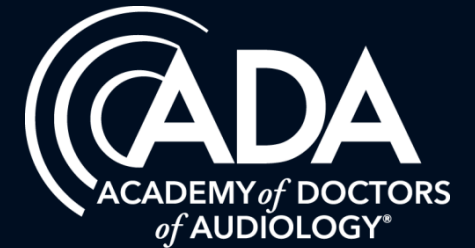


Unclear Pathway to
Care

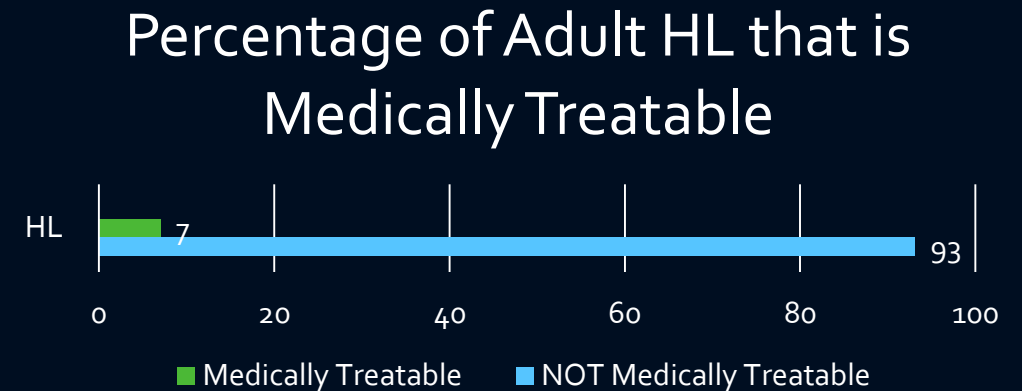


- Streamlining Regulations to Improve Patient Care
 - April 2016
- Biggest barriers to care:
 - Awareness
 - Cost/Affordability
 - Unclear pathway to care/Access

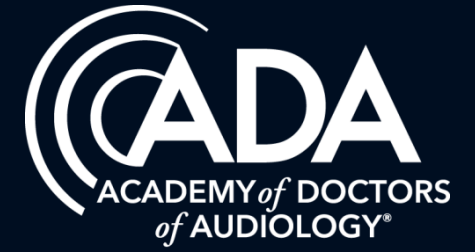
FDA Streamlining Regulations to Improve Patient Care Recommendations from ADA



- 1. Eliminate the need for medical clearance for purchase of a hearing aid.
- 2. Restructure regulations to allow for Class I medical device hearing aids to be sold direct-to-consumers (DTC).
 - Allows for factual information to be presented for the treatment of hearing loss.
 - Require devices to have a **strong recommendation** to obtain an audiologic evaluation.



National Academy of Science, Engineering, and Medicine (NASEM)

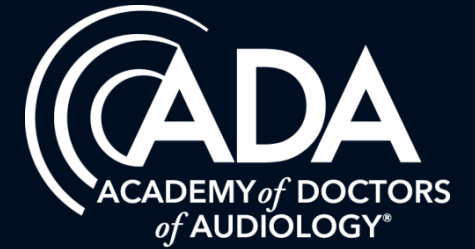


- Hearing Health Care for Adults: Priorities for Improving Access and Affordability (June 2016)
- 12 recommendations



1. Improve Population-Based Information on Hearing Loss and Hearing Health Care.
2. Develop and Promote Measures to Assess and Improve Quality of Hearing Health Care Services.
3. Remove the Food and Drug Administration's Regulation for Medical Evaluation or Waiver.

NASEM (continued)



- 4. Empower Consumers and Patients in Their Use of Hearing Health Care .
- 5. Improve Access to Hearing Health Care for Underserved and Vulnerable Populations.
- 6. Promote Hearing Health Care in Wellness and Medical Visits.
- 7. Implement a New Food and Drug Administration Device Category for Over-The-Counter Wearable Hearing Devices.
- 8. Improve the Compatibility and Interoperability of Hearing Technologies with Communications Systems and the Transparency of Hearing Aid Programming
- 9. Improve Affordability of Hearing Health Care.


NASEM (continued)

- Hearing Health Care for Adults:
Priorities for Improving Access
and Affordability

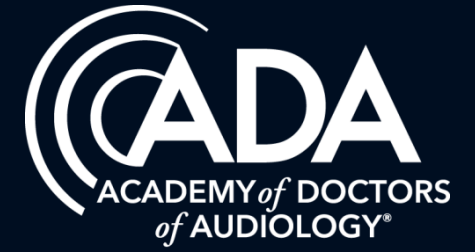



- 10. Evaluate and Implement Innovative Models of Hearing Health Care to Improve Access, Quality, and Affordability.
- 11. Improve Publicly Available Information on Hearing Health.
- 12. Promote Individual, Employer, Private Sector, and Community-Based Actions to Support and Manage Hearing Health and Effective Communication.

NASEM (continued)

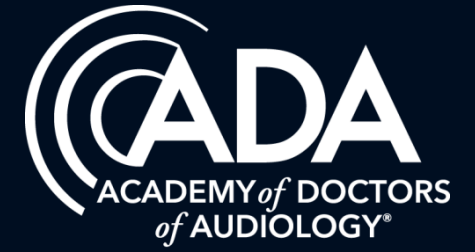
- Hearing Health Care for Adults: Priorities for Improving Access and Affordability
- ADA **supports** all 12 recommendations. 
- NOTE: December, 2016 the FDA proactively stated that it does not intend to enforce the requirement that individuals 18 years and older get a medical evaluation or sign a waiver prior to purchasing hearing aids.

Hearing Aid Assistance Tax Credit Act



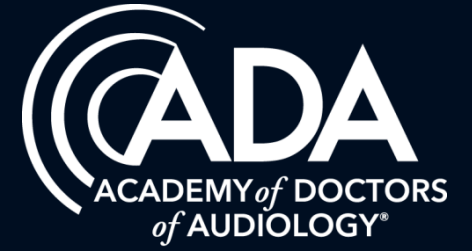
- S. 48/Introduced Jan. 5, 2017
 - Allows a tax credit up to \$500, once every five years for the purchase of a hearing aid that is authorized under the Federal Food, Drug, and Cosmetic Act.
 - Allows for up to two hearing aids per person (\$1,000)
 - Prior House bill has limit of \$200,000 income eligibility cap.
- ADA supports the legislation 

Over-the-Counter Hearing Aid Act of 2017



- S. 670 and HR1652/Introduced Mar. 21, 2017
- Defines what an Over-the-Counter (OTC) hearing aid can be, provides guidelines for regulations to control the OTC hearing aids (e.g. safety, efficacy, output limits, etc.), over-rides state licensure laws, and finalizes the Nov. 7, 2013 FDA guidance on hearing aids and personal sound amplification products (PSAPs).
- **House:**
 - Energy and Commerce Committee heard Testimony on May 2, 2017.
 - May be combined into the MDUFA reauthorization legislation.
- **Senate:**
 - Legislation marked-up on May 10, 2017.

Over-the-Counter Hearing Aid Act of 2017



- ADA supports this legislation.



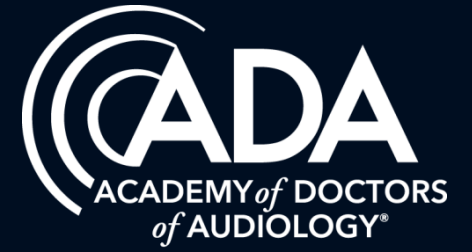
- Consistent with PCAST recommendations.
- Consistent with FDA presentation.
- Consistent with NASEM recommendations.
- Stipulate risks.
- Risk of non-treatment may be greater than risk of self-treatment.
- Safety, efficacy, labeling and reporting addressed.


Audiology Patient Choice Act of 2017 (APCA)

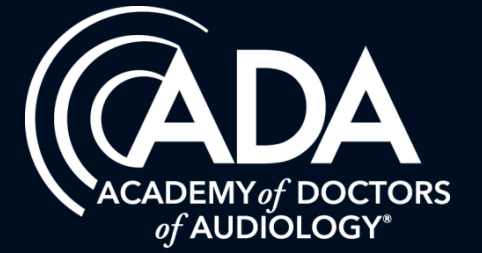


- HR2276/Introduced May 2, 2017
- Update title XVIII of the Social Security Act (Medicare):
 - Allow Medicare Part B patients to have Direct Access to Audiologists.
 - Reimbursement for Medicare-covered services that are allowed under state-defined scope of practice.
 - Categorize Audiologists as Limited Licensed Physicians, in the same taxonomy as other non-MD providers.

Audiology Patient Choice Act of 2017 (APCA)

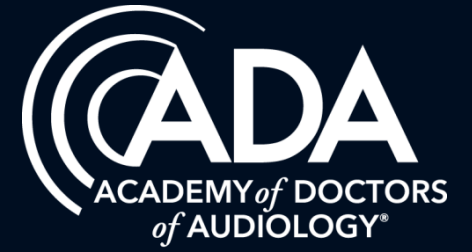


- ADA **wrote/supports** this legislation. 
- Allows patients of traditional and/or OTC hearing aids to access professionals and obtain affordable care.
- Does not include hearing aids.
- Does not add new services to Medicare.



Questions?

Thank you!



- Stephanie Czuhajewski
- Executive Director, ADA
- sczuhajewski@audiologist.org
- Alicia D.D. Spoor, Au.D.
- President-Elect, ADA
- Alicia.Spoor@gmail.com

Academy of Doctors of Audiology (ADA) and Over-the-Counter (OTC) Hearing Aids

STEPHANIE CZUHAJEWSKI, CAE
EXECUTIVE DIRECTOR, ADA

ALICIA D.D. SPOOR, AU.D.
PRESIDENT-ELECT, ADA

