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**Healthcare and Regulatory Issues: What Audiologists Need to Know**

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**Healthcare and Regulatory Issues: What Audiologists Need to Know**

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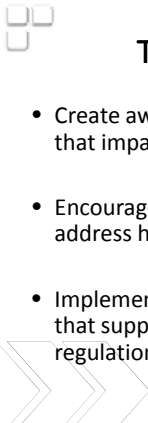
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### Today's Presentation:

- Create awareness of federal and state regulations that impact audiology service providers.
- Encourage written plans and procedures that address healthcare rules, where indicated.
- Implement training and monitoring programs that support compliance with state and federal regulations.

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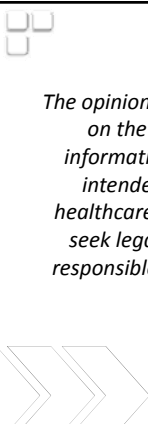
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*The opinions referenced in the presentation are based on the interpretation by the presenters. The information is provided as an overview and is not intended to replace legal representation for a healthcare practice. Participants are encouraged to seek legal counsel to ensure compliance and are responsible for their own knowledge of both federal and state policies.*

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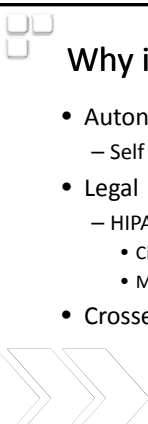
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### Why is Compliance Important?

- Autonomy
  - Self regulation
- Legal
  - HIPAA violations & fines
    - Cignet Health
    - MA General Hospital
- Crosses all practice settings

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### Types of Regulations

Federal	State	Contractual
<ul style="list-style-type: none"><li>• CMS Medicare and Medicaid</li><li>• FDA Hearing Aid Dispensing Guidelines</li><li>• Stark and Anti-kickback</li><li>• HIPAA</li><li>• OSHA - OIG</li></ul>	<ul style="list-style-type: none"><li>• Audiology and Dispensing Guidelines</li><li>• Fee Splitting; Anti-kickback</li></ul>	<ul style="list-style-type: none"><li>• State Specific</li><li>• Terms of Agreement</li></ul>

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### Licensees Beware

- Individual Level of Accountability
- License and provider numbers
- Billing and Reimbursement
- Sanctions and Fines
- Disciplinary Actions and Fines
- When you sign.....



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### State Licensing Regulations

- Licensing Requirements, Training and Competency Assessment
  - Supervision
  - Training Requirements
- Continuing Education Requirements
  - # of Hours, Certain Coursework
  - HIV, Infection Control, Ethics, Laws and Regs
- Sales Requirements
  - Invoicing, required texts, terms of sale, return periods and return fees
  - Advertising and marketing

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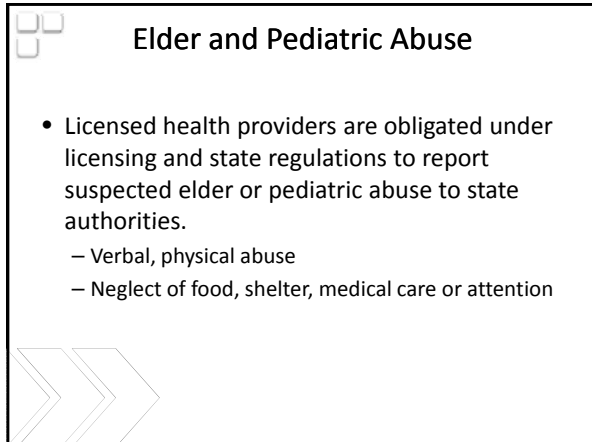
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### Elder and Pediatric Abuse

- Licensed health providers are obligated under licensing and state regulations to report suspected elder or pediatric abuse to state authorities.
  - Verbal, physical abuse
  - Neglect of food, shelter, medical care or attention

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### American Disabilities Act (1992)

- Title IV makes available telecommunications devices and services for the hearing and speech impaired.
- These regulations spell out certain mandatory minimum standards telephone companies must maintain to be in compliance with the ADA.
- More than 15 employees
- Requirements for patient access to offices
  - Ramp for booth
- Handicapped restroom
- Handicapped parking
- Handicapped booth access; restrooms
- Interpreters

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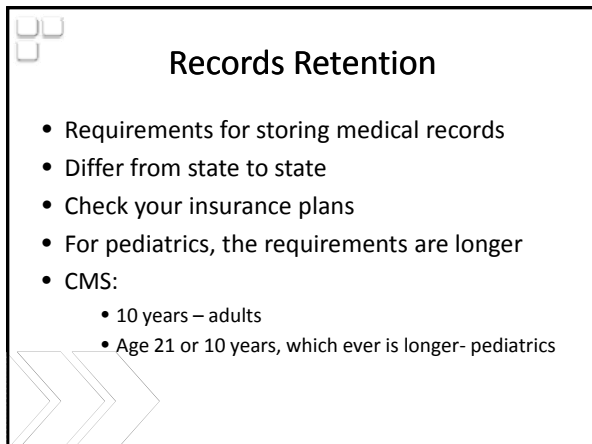
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### Records Retention

- Requirements for storing medical records
- Differ from state to state
- Check your insurance plans
- For pediatrics, the requirements are longer
- CMS:
  - 10 years – adults
  - Age 21 or 10 years, which ever is longer- pediatrics

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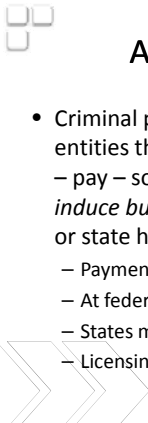
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### Anti-Kickback Statutes

- Criminal penalties (felony) for individuals or entities that directly or indirectly, knowingly offer
  - pay – solicit or receive remuneration in order to *induce business* reimbursed under the Medicare or state health care programs. (1987)
  - Payment for referrals – many different forms
  - At federal, limited to government \$
  - States may address at a local level
  - Licensing Issue

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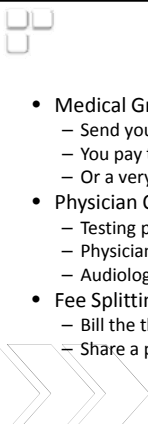
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### Scenarios

- Medical Group/ Nursing Home
  - Send you patient
  - You pay the group X\$ or %\$ for every sale
  - Or a very large birthday or Christmas gift
- Physician Office
  - Testing provided free of charge by audiologist
  - Physician charges 3<sup>rd</sup> party for the testing
  - Audiologist receives free space and hearing aid business
- Fee Splitting
  - Bill the third party for reimbursement
  - Share a portion of that with “Referrer”

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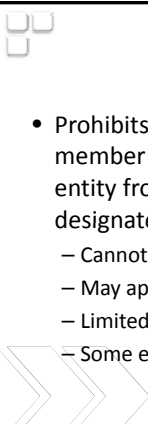
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### Stark Law

- Prohibits a physician or an immediate family member with a financial relationship with an entity from referring patients to the entity for designated health services
  - Cannot bill for Medicare covered services
  - May apply to some Medicaid programs
  - Limited applicability for audiologists
  - Some exceptions and Safe Harbors exist

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**Takeaway**

- Healthcare Attorney



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**Center for Medicare/Medicaid Services**

- Administers Medicare, Medicaid and CHIP
- Coverage Determinations
- Enrollment and Participation/Non-Par
- Solicitation of Medicare Covered Services
  - Criminal penalties for *inducing business* reimbursed under the Medicare or state health care programs.



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**CMS – Fraud Polices**

- Practices that result in unnecessary cost; improper
- Fraud and Abuse
  - Efforts to prevent and detect fraudulent billing practices (1994)
- False Claims Act (1998)
  - Prohibits false claims to obtain payment
  - Expands to fraud against the government (2009)
  - All participants in Federal Health care plans
- Whistleblower protection – financial incentives/rewards
- Cooperation between DHHS, OIG, FBI, DOJ



Centers for Medicare & Medicaid Services

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**Waste, Fraud and Abuse**

- Excessive or improper use of services that are inconsistent with acceptable business or medical practices
- Intentional use of false statement (misuse of authority, ex) or fraudulent schemes (such as kickbacks) to obtain payment
- Using carelessly, extravagantly or to no purpose

**3 Standards:**

- Reasonable & necessary
- Conforms to professionally recognized standards
- Provided at a fair price

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**Examples of Fraud, Waste and Abuse**

- Billing for:
  - Items or services not rendered
  - Services already reimbursed by another insurer
  - Misuse of NPI numbers (including services actually provided by support staff)
  - Unnecessary services
  - Duplicate billing resulting in overpayment
  - Higher fee schedules for Medicare recipients than non-Medicare recipients.



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**Other FWA Examples**

- Utilizing incorrect coding practices
  - Incorrect ICD9 codes to maximize reimbursements
  - Unbundling CPT codes
  - Billing for services provided by students, HAS, technician
- Scripting errors
  - Billing for audiology services without a script
  - Billing/delivering certain hearing aids or supplies prior to receiving physician script
  - Completing portion of script reserved for physician completion
  - Encouraging physician to order medically unnecessary items or services
  - Using a script with provider practice name, not physician
- Routine waiver of deductibles or coinsurance
- Resubmitted claim with different information after initial claim was denied
- OIG Audit- conveying false information

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**Joplin audiologist pleads guilty in Medicaid fraud case**

(name redacted) a Jasper County audiologist, pled guilty to three felony counts of Medicaid fraud following an investigation by the Medicaid Fraud Control Unit of the Missouri Attorney General's office. .... review of subpoenaed records and Medicaid claims found evidence of billing for services and hearing devices that were not provided. ...fraudulently billed more than \$12,000 to Medicaid.

(name) will be sentenced on March 14. She faces up to 7 years in prison for each violation, plus penalties and restitution.

"One of my top priorities as Attorney General is to enforce our laws against those who cheat Missouri taxpayers by committing Medicaid fraud," Koster said. "This kind of outrageous conduct steals medical resources that would otherwise be directed to truly needy Missourians. Those who would steal from Missouri taxpayers must understand that we will find you and prosecute to the fullest extent."

Jan 24, 2011, Carthage Press

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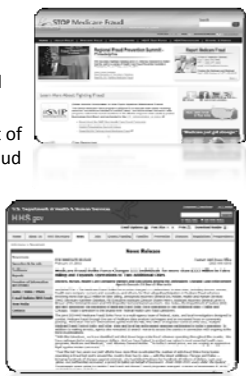
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- \$100 B/Year in MCR and MCD Fraud
- Obama Health Care Reform
- Government has tripled the amount of money recovered from Medicaid fraud
  - \$573M (2004) 1.85B (2010)
- Spent \$200M (57% increase)
- FL, CA, TX

USA Today 10/20/11




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**Office of Inspector General**

- Protect the integrity of the Department of Health and Human Services programs
- Protect health and welfare of program beneficiaries
- Opinions on gifts, Medicare charges, rental space from physicians, cochlear implants, compensation, civil \$ penalties on fraudulent claims, kickback and self referral penalties
- Annual Work Plans

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## National Databanks

- National Practitioners Databank- Healthcare Integrity Protection Databank
- Requires entities to report adverse credentialing events and healthcare entities to query them
- Tracks sanctions and disciplinary acts reported by states
- Tracks malpractice events




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## Takeaway: CMS

- Audits
- Repayments
- Fines
- Sanctions
  - NPDB; HIPDB;OIG; State Licensing Boards
- Disciplinary Actions- Loss of License
- Annual Training Required




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## HIPAA

Privacy Rule	Permitted Disclosures	Forms	PHI Access, Storage, Disposal
<ul style="list-style-type: none"> <li>• Standards for protecting protected health information (PHI)</li> <li>• Limits marketing that can be performed without patient's specific permission</li> <li>• Requires written permission to release records</li> <li>• Allows patient access to health records</li> <li>• Policies regarding answering machine/voice mail messages; telephone inquiries</li> <li>• Oral, written, electronic</li> </ul>	<ul style="list-style-type: none"> <li>• Treatment</li> <li>• Directly involved with referral</li> <li>• Payment</li> <li>• Health plans for reimbursement</li> <li>• Operations</li> <li>• Need to know basis for compliance with audits &amp; internal quality measures</li> </ul>	<ul style="list-style-type: none"> <li>• Notice of Privacy Practices</li> <li>• Posted in clinic and available for patients' review upon request</li> <li>• Consent</li> <li>• Signed by every patient</li> <li>• Acknowledgement indicates patient has been made aware of privacy policy</li> <li>• Authorization</li> <li>• Necessary for personnel not directly involved with the referral- speech pathologist, school nurse, social worker, etc.</li> <li>• BAA</li> </ul>	<ul style="list-style-type: none"> <li>• Access -Passwords</li> <li>• Storage</li> <li>• Working hours access</li> <li>• Non-working hours</li> <li>• Disposal</li> <li>• Alteration</li> </ul>

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**HIPAA HITEC & ARRA**

- Health Information Technology for Economic and Clinical Health Act + American Recovery & Reinvestment Act of 2009
- Secure = rendered “unusable, unreadable or indecipherable to unauthorized individuals”
  - Two methods to ensure “secured” status
    - Encryption- federal guidance determines acceptable methodologies
    - Destruction- National Institute of Standards & Technology determine methodologies




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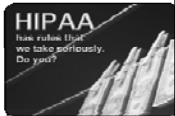
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**HIPAA ARRA & HITEC**

- Mandatory Notification of Breaches
- Relates to “unsecured” PHI breaches
  - Notification timeline
  - Notification inclusions
    - Incident description
    - PHI involved
    - Required protection
    - Investigation plans
    - Information and communication
- HITECH applies certain HIPAA provisions directly to business associates




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**HIPAA - Security Rule**

- National standards for security of electronic PHI
- Secure transmissions – ftp sites/firewalls/password protections
- Emailing unprotected PHI outside of *your domain*
  - Includes single patient information, patient lists, employee lists and any type of protected information that is not encrypted or password protected.
- Requires limited access and password protections
  - Physical safeguards – locks/keys
  - Electronic – guarded access with hierarchy of permissions
- Laptops, cell phones, PDA – secure, password protections
- Cyber Security policies, procedures and trainings




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**HIPAA- Copiers**

- Scanned and copied information is stored on the copier hard drive
- Unsecured, upon disposal and depending on the safeguards of the organization
- Details the steps to take when disposing of the copier; trading in

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**Identity Theft**

- 10M people and \$54B annually
- Prevent, mitigate and detect identity theft
- Identity theft is a threat to your practice!
- HIPAA. Confidentiality. Breach. \$

**Medical ID Theft**

- False entries into health records
- Intentional or theft
- Changes may plague the victim for years

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**Verify Identity**

- Request photo identification at registration
- Drivers license, passport, military ID
- If no photo ID, ask for two forms of non-photo ID - One must be issued by state or federal agency - SS card, utility bill, company- school ID
- Document in contact sheet that ID was reviewed
- Verify patient identity at each visit

**Prevention and Mitigation**

- Monitor patient accounts
- Contact affected patients
- Change passwords & security to a patient account
- Close existing breached account & discontinue attempts to collect on a breached account
- Notify law enforcement
- Train staff on prevention and detection

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**EHR and EMR**

- An Electronic Health Record (EHR) is an electronic version of a patient's medical history that is maintained by one or several providers over time.
- The EHR represents the ability to easily share medical information.
- The Electronic Medical Record (EMR) is the legal record created in hospitals and ambulatory environments that is the source of data for the EHR.
- N/A for Audiologists at this time



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**Takeaway - HIPAA**

- Felony - Imprisonment
- Federal Penalties and Fines
- State Penalties and Fines
- Delayed Reporting Penalties
- Civil Lawsuits



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**Payment Card Industry - DSS**

- Collaborative effort by the major credit card brands (Visa, MasterCard, American Express, Discover and JCB) to ensure that all merchants that process, store or transmit credit card information secure data
- Prevent credit card fraud through increased controls around data and its exposure to compromise. \$8.5B
- Applies to all organizations that hold, process, or exchange cardholder information
- Penalties for non-compliance are to the banks, who control the account holders (merchants) – check your cc agreement

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**FTC- Telemarketing**

- FTS responsible for monitoring business practices of hearing aid dispensers – action against deceptive marketing and business practices
- Requirements related to telemarketing and to the use of commercial email.
- Telemarketing registration requirements and anti-fraud protections
- State laws and regulations may be more restrictive than federal laws and regulations.

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**FTC- Emails**

- The CAN-SPAM Act of 2003 regulates commercial electronic mail on a nationwide basis.
- Certain requirements on senders of commercial electronic mail.
- Compliance:
  - properly represent the nature of commercial email messages in the subject line,
  - not tamper with source and transmission information in the email "header," and obtaining email addresses through lawful means
  - Adhere to specific disclosure requirements of the law by including a physical mail address and a clearly identified and conspicuous "opt-out" mechanism in all commercial email

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**Occupational Safety and Health Administration**

- Infection Control program required for hospitals, clinics, nursing homes – includes audiology providers
- Requires written procedures that address:
  - Ethical and legal responsibilities
  - Definitions of Terms
  - Modes of Transmission
  - OSHA Requirements
  - Protocols for Infection Control
- Make available hepatitis B vaccinations
- Training at hire and annually




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## New Era - Challenges

- Protect patient information
  - HIPAA Golden Rule
  - Beware the Breach
  - Identity theft
- Protect your proprietary information
  - Termed employees
  - Locks, passwords, firewalls
  - Working from home
- Protect your business
  - Trigger one regulation, you are likely to trigger multiple violations at both the state and federal level
  - Criminal penalties
  - \$




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## Play It Safe

- Educate yourself – colleagues – support staff
- Develop P&P
- Read your agreements and third party contracts
- Organize your team and work flow
- Train employees on risks
- Be disciplined in documentation and record keeping
- Create billing procedures and oversight
  - Internal audits
  - Paperwork police

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## Federal Resource Guide

Regulation Description	Compliance Deadline	Federal Regulation	AAA & Other Resources	What's Included
Title I of the Americans with Disabilities Act of 1990 prohibits private employers, state and local governments, employment agencies and labor unions from discriminating against qualified individuals with disabilities in job application procedures, hiring, firing, advancement, compensation, job training, and other terms, conditions, and privileges of employment. The ADA covers employers with 15 or more employees.	January 26, 1992 Amended 2008	American with Disabilities Act (ADA)	<a href="http://www.ada.gov/">http://www.ada.gov/</a> <a href="http://www.eeoc.gov/facts/">http://www.eeoc.gov/facts/</a> <a href="http://www.ada.gov/ada.html">http://www.ada.gov/ada.html</a> <a href="http://www.ada.gov/ada.html#faq">http://www.ada.gov/ada.html#faq</a> <a href="http://www.ada.gov/ada.html#faq">http://www.ada.gov/ada.html#faq</a> <a href="http://www.ada.gov/ada.html#faq">http://www.ada.gov/ada.html#faq</a>	AAA requirements for offices, patient access, Facts about ADA, Effective communication requirements
Section 11286(b) of the Social Security Act (42 U.S.C. 1320a-7b(6)), previously codified at sections 1817 and 1909 of the Act, provides criminal penalties (fines) for individuals or entities that directly or indirectly, knowingly and willfully alter, pay, cause or receive remuneration in order to induce business reimbursed under the Medicare or State health care programs.	1987	Anti Kickback Statute (AKS)	<a href="http://www.auditor.org/health/anti-kickback-statute/">http://www.auditor.org/health/anti-kickback-statute/</a> <a href="http://www.auditor.org/health/anti-kickback-statute/">http://www.auditor.org/health/anti-kickback-statute/</a> <a href="http://www.auditor.org/health/anti-kickback-statute/">http://www.auditor.org/health/anti-kickback-statute/</a>	Anti kickback Statute - (AKS)

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**www.audiology.org**

- [http://www.audiology.org/practice/compliance/Documents/20110303\\_PCC\\_chart\\_fed\\_reg.pdf](http://www.audiology.org/practice/compliance/Documents/20110303_PCC_chart_fed_reg.pdf)
- [www.audiology.org](http://www.audiology.org)
  - Log on using your AAA number & e-mail
  - “Practice Management” tab
  - “Compliance” tab
  - Link under “News Briefs”



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**Resources**

- American Academy of Audiology
- Federal Regulation Summary Guide
- State Licensing Boards
- CMS.gov





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