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Compliance in Audiology: The Ethical and Legal Requirements of Our Profession

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Compliance in Audiology: The Ethical and Legal Requirements of Our Profession

AudiologyOnline 2015

Learning Objectives

After this course, participants will be able to:

- Describe how the federal Anti-Kickback legislation applies to audiology.
- Describe how the CMS Update to Audiology Policies and Revisions and Re-Issuance of Audiology Policies applies to daily practice.
- Describe how the federal False Claims Act applies to daily practice.

The Importance of Codes of Ethics

- Please be aware of :
 - The ethical guidelines outlined in your State licensure law.
 - Failure to comply can result in the loss of your license.
 - Ignorance is not a defense.
 - The Codes of Ethics of organizations which you are a member.
 - Failure to comply can result in you being removed from this organization and/or losing your credentialed status.
 - Also, some of the aspects of a Code of Ethics can also protect you from violating legal statutes, laws, rules, or regulations.

Professional Codes of Ethics

- AAA
 - <http://www.audiology.org/resources/documentlibrary/Pages/codeofethics.aspx>
- ASHA
 - <http://www.asha.org/Code-of-Ethics/>

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Ethical Quandary?

- Would you feel comfortable telling your patient about your:
 - Vendor funded trip?
 - May have OIG implications.
 - Business Development Fund?
 - May have OIG implications.
 - Vendor Payment Arrangement?
 - Gifts from vendors?

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Ethical Practice Guidelines on Financial Incentives from Hearing Instrument Manufacturers

- Created by AAA and ADA in 2003 and updated by AAA in July 2011.
 - http://audiology-web.s3.amazonaws.com/migrated/20140114_EPC_IndustryGuideline.pdf_5382ed0f4cb195.24348078.pdf
 - Arrangements you must avoid:
 - Prid Pro Quo
 - An exchange of goods or services where one transfer is contingent on another
 - Conflicts of Interest
 - Ownership interests in company's whose products you dispense
 - Disclosure of any commercial interests to patients
 - Disclosure of consulting relationship to patients
 - Acceptance of gifts of any value from manufacturers
 - Disclosure of remuneration for research
 - Incentive trips (rewarded for conducting business)
 - Business Development Funds
 - Lease arrangements
 - Cash rebates
 - Sales quotas with manufacturer in order to receive an incentive

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When Ethics Violations Turn Into Legal Problems

- Anti-Kickback legislation:
 - http://oig.hhs.gov/compliance/physician-education/roadmap_web_version.pdf
 - Criminal penalties.
 - It is a felony to knowingly and willfully solicit or receive any remuneration, directly, or indirectly, overtly or covertly, in cash or in kind, in return for purchasing, leasing, or ordering (or recommending the purchase, lease, or ordering) of any item or service reimbursable in whole or in part under a federal health care program (except for the Federal Employees Health Benefits Program).
 - Medicare
 - Medicaid
 - Tricare
 - They create an incentive to overutilize particular goods and services, impinge upon the patient care process, and create an unfair competitive environment to those who refuse to provide remuneration.

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When Ethics Violations Turn Into Legal Problems

- Some examples from Audiology
 - An audiologist furnishes hearing tests to a physician's patients at less than fair market value in exchange for hearing aid referrals where some of these referrals may be for instruments covered under a Federal health program.
 - When an audiologist purchases X number of products and gets X free from a manufacturer and bills a federal payer for any of these products once they have been provided to the patient and does not disclose the "buy one, get one" deal

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When Ethics Violations Turn Into Legal Problems

- As a result you want to avoid:
 - Free hearing tests
 - Providing free hearing tests when you are a Medicare provider appears to be a clear violation of Medicare rules and regulations. Medicare prohibits offering free services such as hearing testing as an inducement to generate other services such as diagnostic audiologic services.
 - http://www.audiology.org/practice/reimbursement/medicare/Pages/Medicare_FAQ.aspx

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When Ethics Violations Turn Into Legal Problems

- Use of referral pads.
- Write-offs of co-pays and deductibles.
- Reminder mailing for annual hearing tests where you are seeking third-party coverage.
 - All could be construed as a solicitation of a Medicare covered service.

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Anti-Kickback

- “Section 1128B(b) of the Social Security Act (42 U.S.C. 1320a-7b(b)), previously codified at sections 1877 and 1909 of the Act, provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration in order to induce business reimbursed under the Medicare or State health care programs. The offense is classified as a felony, and is punishable by fines of up to \$25,000 and imprisonment for up to 5 years.”
- This provision is extremely broad. The types of remuneration covered specifically include kickbacks, bribes, and rebates made directly or indirectly, overtly or covertly, or in cash or in kind. In addition, prohibited conduct includes not only remuneration intended to induce referrals of patients, but remuneration also intended to induce the purchasing, leasing, ordering, or arranging for any good, facility, service, or item paid for by Medicare or State health care programs.

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When Ethics Violations Turn Into Legal Problems

- False Claims Act
 - Criminal penalties.
 - http://www.falseclaimsact.com/common_frauds_healthcare.php
 - Do not submit fraudulent claims to any entity.
 - Claims for services not performed
 - Billing under someone else's provider number.
 - Unbundling.
 - Breaking a code into the sum of its parts.

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False Claims Act

- Upcoding
 - Billing for a comprehensive test when all you did was air conduction.
 - Billing for a comprehensive test and not adding a modifier when you only tested one ear.
 - Billing 10 units of 92621 or 92627
- Billing for services known to not be covered and not adding the appropriate modifier.
 - Hearing aids.
 - Aural rehabilitation.
- Submitting claims for services which were not medically necessary and not adding the appropriate modifier.
 - Annual hearing tests.
 - Tests solely for the sale of a hearing aid,
 - Presence of a physician order does not guarantee medical necessity.

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FDA Requirements

- Many state laws reference the FDA Referral Red Flags:
 - Active drainage within previous 90 days.
 - History of sudden or rapidly progressive hearing loss.
 - Unilateral hearing loss.
 - Conductive hearing loss or air-bone gap.
 - Impacted cerumen or foreign body in the ear canal.
 - Pain or discomfort.
 - Visibly congenital or traumatic deformity of the ear.
 - Acute or chronic dizziness.

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FDA Requirements

- Requirements:
 - <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=801.420>
 - <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=801.421>
 - Receive a User Brochure
 - Medical Clearance or Medical Waiver
 - If over 18 years of age, may sign a medical waiver.
 - Either needs to be in FDA language.

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When in Doubt...

- **Hire legal counsel which specializes in health care and/or Medicare law.**
 - Do not enter into contractual relationships with others parties, including physicians, buying groups, or management services, without legal advice.
 - Can find an attorney via your state bar association or Google.

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The Role of State Licensure

- It is this that dictates your scope of practice.
 - National Associations do not dictate this.
 - Payers do not dictate this.
 - Payers do not have to cover all items and services in your scope of practice.
 - YOU cannot interpret this alone.
- It is very important that you are aware of the requirements of both the hearing aid and/or audiology licensure boards in your state and the scope of practice limitations.

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The Role of State Licensure

- Audiology Assistants, Technicians, and Support Staff.
 - Cannot perform testing on Medicare beneficiaries and legitimately receive payment.
- Be careful of:
 - Scope of practice issues.
 - Lack of licensure.

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CMS Audiology Policies

- Update to Audiology Policies:
 - Effective October, 2008.
 - <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R84BP.pdf>
- Revisions and Re-Issuance of Audiology Policies:
 - Effective September, 2010.
 - <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6447.pdf>

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CMS Audiology Policies

- Address:
 - “Incident to” billing
 - Required physician orders
 - Treatment Services
 - Computerized audiometry
 - Role of technicians and their supervision requirements
 - Role of students, including but not limited to, the final year extern and their supervision requirements
 - Medical necessity
 - Billing of technical and professional components
 - Documentation
 - 92700
 - “Opt Out” (audiologist cannot opt out of Medicare)

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HIPAA

- Health Insurance Accountability and Portability Act of 1996 (HIPAA)
 - <http://www.hhs.gov/ocr/privacy/hipaa/administrative/>
 - Civil and criminal penalties
 - Covers:
 - Standard Transaction and Code Sets
 - National Provider Identifier
 - National Employer Identifier
 - HIPAA 5010
 - Security
 - HITECH (Breach Notification)
 - Privacy
 - Marketing
 - Business Associates

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Standard Transaction and Code Set

- This aspect of HIPAA requires that the following code sets be utilized for documenting and billing all medical items and services:
 - CPT (Current Procedural Terminology)
 - ICD-9 (international Classification of Diseases-9th Revision)
 - Will become ICD-10 on October 1, 2015
 - HCPCS (Healthcare Common Procedure Coding System)

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National Provider Identifier (NPI)

- Requires that each individual provider utilize their own distinct, unique individual provider identification number for all payers.
 - This number stays with the provider as they move from employer to employer.
 - National Provider Identifier (NPI)
 - National Plan and Provider Enumeration System (NPPES)
 - <https://nppes.cms.hhs.gov/NPPES/Welcome.do>
 - This code is placed in box 24J of the CMS 1500 Claim form (or its electronic equivalent).

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National Employer Identifier (EIN)

- Requires that each individual practice or facility utilize their own distinct, unique practice or facility identification number for all payers.
 - This is required for every practice or facility except a sole proprietorship.
 - The EIN is issued by the Internal Revenue Service (IRS).
 - Each practice also needs a facility or practice National Provider Identifier (NPI).
 - National Plan and Provider Enumeration System (NPPES)
 - <https://npiregistry.cms.hhs.gov/NPPESRegistry/NPIRegistryHome.do>

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HIPAA 5010

- This was a systems update that went into effect January 1, 2012 (enforcement began on March 31, 2012) on that required systems updates to allow for transition to ICD-10.
 - Affected software vendors, payers, and clearinghouses much more than providers.
 - Needed to allow increased fields for more digits (for ICD-10).

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Protected Health Information (PHI)

- Names
- Street number and name, city, and last two digits of the zip code
- Dates directly related to the individual (birth date)
- Phone number
- Fax number
- Email address
- Social security number
- Medical record number

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Protected Health Information (PHI)

- Health insurance member number
- Account numbers
- Certificate or license numbers
- Vehicle identifiers and serial numbers
- Device identifiers and serial numbers
 - Hearing aid serial numbers
- URLs

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Protected Health Information (PHI)

- IP addresses
- Biometric indicators
 - Finger, retinal, and voice prints
- Photos
- Any unique identifying number, characteristic or code

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Security

- The Security Rule is an extension of the Privacy Policy.
- Went into effect April 20, 2005.
- Applies to electronic formats.
- Providers need to have:
 - Administrative Safeguards.
 - Physical Safeguards.
 - Technical Safeguards.
- You also need policies and procedures related to operations and documentation.
- <http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/security101.pdf>

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Security Rule

- Covered entities must:
 - “Ensure the confidentiality, integrity, and availability of all e-PHI they create, receive, maintain or transmit.
 - Identify and protect against reasonably anticipated threats to the security or integrity of the information.
 - Protect against reasonably anticipated, impermissible uses or disclosures.
 - Ensure compliance by their workforce.”
 - <http://www.hhs.gov/ocr/privacy/hipaa/understanding/srsu/mmary.html>

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Security Rule: Risk Assessment

- “A risk analysis process includes, but is not limited to, the following activities:
 - Evaluate the likelihood and impact of potential risks to e-PHI.
 - Implement appropriate security measures to address the risks identified in the risk analysis.
 - Document the chosen security measures and, where required, the rationale for adopting those measures.
 - Maintain continuous, reasonable, and appropriate security protections.”
 - <http://www.hhs.gov/ocr/privacy/hipaa/understanding/srsu/mmary.html>
 - <http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/riskassessment.pdf>

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Security Rule: Administrative Safeguards

- Security Measures
 - To reduce risks of breaching protected health information.
- Need a Security Officer
- Information Access Management
 - Regulate who has access to protected health information.
 - Minimum necessary access
- Training and Accountability
 - Authorize access to PHI.
 - Train staff on policies and procedures.
 - Sanction staff who do not comply.
- <http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/adminsafeguards.pdf>

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Security Rule: Physical Safeguards

- Facility access and control
 - Limiting and controlling physical access.
- Workstation and device security
 - Proper use and access to workstations and electronic devices.
 - Policies and procedures related to:
 - Transfer.
 - Removal.
 - Disposal.
 - Re-use.
 - <http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/physsafeguards.pdf>

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Security Rule: Technical Safeguards

- Control of access
 - Passwords to protect access.
 - Audit
 - Safeguards to record and examine access.
 - Integrity control
 - Ensure that PHI is not improperly altered or destroyed.
 - Transmission security
 - Protections against “hacking.”
- <http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/techsafeguards.pdf>

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Security Rule:

Policies, Procedures and Documentation

- You must develop policies and procedures to comply with the security rule.
 - If need guidance, consult an IT consultant who specializes in HIPAA.
- Must have written policies and procedures.
- Need to document staff training, actions, activities, and risk assessments.
- <http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/pprequirements.pdf>

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HITECH-Breach Notification

- Effective date of February 17, 2010.
 - Breach:
 - An “impermissible” or unauthorized use or disclosure of PHI.
 - Breach notification:
 - Must occur within 60 days.
 - Providers and business associates have burden of proof that notifications have been made.
 - Business Associates must notify the covered entity.
 - Notify the individual.
 - Notify the Media:
 - If breach is of more than 500 individuals.
 - Notify Secretary of Health and Human Services:
 - If breach is of more than 500 individuals.
- <http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/index.html>

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Privacy Rule

- Protections of patient's health information and PHI.
 - Effects both paper and electronic records.
 - Effective April 14, 2003.
 - Protects “Individually identifiable health information” is information, including demographic data, that relates to:
 - The individual's past, present or future physical or mental health or condition,
 - The provision of health care to the individual,
 - The past, present, or future payment for the provision of health care to the individual, and that identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual.
 - Individually identifiable health information includes many common identifiers (e.g., name, address, birth date, Social Security Number).
- <http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html>

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Privacy Rule Specifics:

- Keep disclosures to “minimum necessary.”
- Need a Privacy Officer.
- Need training on privacy and that training must be documented.
- Must have a complaint process.
- Must have record safeguards:
 - Storage.
 - Disposal.
 - Access.

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Privacy Rule: Marketing

- The Privacy Rule defines “marketing” as making “a communication about a product or service that encourages recipients of the communication to purchase or use the product or service.”
 - Applies to marketing sent to your database only.
- “An arrangement between a covered entity and any other entity whereby the covered entity discloses protected health information to the other entity, in exchange for direct or indirect remuneration, for the other entity or its affiliate to make a communication about its own product or service that encourages recipients of the communication to purchase or use that product or service.”
- <http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/marketing.html>

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Privacy Rule: Marketing Decision Matrix Poll

- Do you co-op marketing with a third-party?
- Are you an equity member of a buying group whose products you market?
- Do you have a lease or loan from a third-party vendor?
- Do you have a business development fund for products you market?
- Do you go on vendor-funded trips?
- Do you offer discounts, promotions, offers, or discounts?
- Do you participate in Medicaid, Worker's Compensation, or TriCare?

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Privacy: Business Associate

- "A business associate is a person or organization, other than a member of a covered entity's workforce, that performs certain functions or activities on behalf of, or provides certain services to, a covered entity that involve the use or disclosure of individually identifiable health information. Business associate functions or activities on behalf of a covered entity include claims processing, data analysis, utilization review, and billing."
- "Business associate services to a covered entity are limited to legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services."
- Providers are responsible for the actions of their business associates.
- <http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html>

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Omnibus Rule

- Effective September 23, 2013.
- Business associates (any entity that creates, receives, maintains, or transmits PHI on behalf of a provider who supplied this information to them) and their contractors and subcontractors, are required to comply to the updated HIPAA Privacy and Security Rules, including breach notification.
- Patients have the right to request that a copy of their electronic medical record be supplied to them in an electronic format.

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Omnibus Rule

- Patients who are paying privately for an item or service have the right to restrict any disclosure about this item or service to their health plan.
- “Marketing” has been redefined as any patient communication where the provider receives financial remuneration from a third-party whose products or services are being marketed. When “marketing” is being performed using PHI, a patient authorization must be in place prior to sending this marketing communication.
- The sale of PHI is prohibited.
- There must be a defined breach notification process where a situation is presumed to be a breach until the provider, business associate, contractor, or subcontractor determines that there is a low probability that the patient’s privacy has been compromised. A risk assessment must be performed anytime there is a breach of PHI.

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Omnibus Rule

- Allows for broader use of PHI for fundraising opportunities.
- Allows for a streamlined authorization process for use of PHI for research purposes.
- Penalties have increased to up to \$1.5 million maximum per calendar (many fines range between \$100 and \$50,000 per violation and degree of culpability) and up to 10 years in jail.

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What Every Practice Needs:

- 2013 or newer revised Notice of Privacy Practices
- 2013 or newer revised Business Associate Agreement
- 2013 or newer revised Breach Notification Policy
- 2013 or newer revised Marketing Authorization
- Facility NPI
- Use and Disclosure form
- Acknowledgement of Receipt of Notice of Privacy Practices
- Security Policy and Process
- Breach Notification Policy and Process

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What Every Practice Needs:

- Risk Assessment Process
- Independent Contractor Agreement that includes HIPAA Language
- Documentation of Staff Training
- Employee Confidentiality Form

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Your Takeaway...

- READ WHAT NATIONAL ASSOCIATIONS SEND YOU.....
- Do not worry about yesterday; fix tomorrow.
- You can always file a complaint.
- If in doubt, or your gut tells you it might not be a good idea, consult an attorney who specializes in healthcare law.

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