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Ethical and Legal Requirements of Audiology Practice - Staying Compliant

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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 Polices applies to daily practice.
- Describe how the federal False Claims Act applies to daily practice.

4

The HIPAA Golden Rule

5

HIPAA Audits

- HIPAA is now being audited by HHS.
- As a result, it is very important that you follow the requirements set forth.
  - http://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/audit/
  - https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/audit/index.html

6

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

7

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 10 (International Classification of Diseases-10th Revision)
  - HCPCS (Healthcare Common Procedure Coding System)

8

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)
    - Audiologists, hearing aid dispensers and audiology assistants can get NPIs.
      - https://nppes.cms.hhs.gov/NPPES/Welcome.do

9

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/

10

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.
  - https://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/Versions5010andD0/Version_5010.html

11

837 Claims Format

- 837
  - Claims submission format set forth in HIPAA 5010.
  - You should ask your office management vendor or EMR about this format.
- CMS 1500
  - Paper claim form
- http://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/837p-cms-1500.pdf

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

14

HIPAA 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.
- https://www.hhs.gov/hipaa/for-professionals/security/laws-regulations/index.html

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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."

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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."

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Security Rule: Risk Assessment

- What do audiologists need to think about?
  - Computers
  - Phones
  - Tablets
  - Fax Machines
  - Answering Machines
  - Audiometers
  - Test Suites
  - OMS/EMR
  - NOAH

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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.

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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.

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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.”

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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.

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Mobile Devices and HIPAA Security

- Use a password or user authentication.
- Install and enable encryption.
- Install and activate remote wiping and/or remote disabling.
- Disable and do not install or use file sharing applications.
- Install and enable a firewall.
- Install and enable security software.
- Keep your security software up to date.

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Mobile Devices and HIPAA Security

- Maintain physical control.
- Use adequate security to send or receive health information over public Wi-Fi networks.
- Delete all stored health information before discarding or reusing the mobile device.
- https://www.healthit.gov/providers-professionals/how-can-you-protect-and-secure-health-information-when-using-mobile-device
- https://www.healthit.gov/providers-professionals/five-steps-organizations-can-take-manage-mobile-devices-used-health-care-pro

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Telehealth and HIPAA Security

- Telehealth is “the use of electronic information and telecommunications technologies to support and promote long-distance clinical health care, patient and professional health-related education, public health and health administration. Technologies include videoconferencing, the internet, store-and-forward imaging, streaming media, and terrestrial and wireless communications”.
  - Store and forward is asynchronous telehealth.

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Telehealth and HIPAA Security

- Audiologists have to ensure, before they begin providing telehealth, that their transmission systems all meet the HIPAA security requirements that “ensure the confidentiality, integrity, and availability of all e-PHI they create, receive, maintain or **transmit**”.
  - Cannot use Facetime, SMS, Skype, or unencrypted email (to store and forward) for telehealth.
  - Please consult an IT consultant when setting up a telehealth program for your practice.
    - http://www.telehealthresourcecenter.org/sites/main/files/file-attachments/hipaa_for_trcs_2014_0.pdf
    - https://www.hipaajournal.com/hipaa-guidelines-on-telemedicine/

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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."
- Providers are responsible for the actions of their business associates.
- http://www.hhs.gov/hipaa/for-professionals/privacy/guidance/business-associates/index.html
- https://www.hhs.gov/hipaa/for-professionals/covered-entities/sample-business-associate-agreement-provisions/index.html?language=en

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Common Audiology Business Associates

- Hearing aid manufacturers
- Earmold manufacturers
- Accountant
- Lawyer
- OMS vendor
- IT consultant
- Buying/management group

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HITECH-Breach Notification

- Effective date of February 17, 2010.
- Applies to paper and electronic formats.
- Breach:
  - An "impermissible" or unauthorized use or disclosure of PHI.
  - Must do a risk assessment.
- 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.
    - Oftentimes provide identity theft protections.
  - 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/hipaa/for-professionals/breach-notification/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 and updated in January 2013.
- 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/hipaa/for-professionals/privacy/index.html

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Notice of Privacy Practices

- The Privacy Rule provides patients have the right to adequate notice of how a covered entity may use and disclose protected health information about the patient, as well as his or her rights and the covered entity's obligations with respect to that information.
- Required for every practice.
- Must have been updated and must have received an updated acknowledgement of this new notice in 2013.
  - Acknowledgements from prior to 2013 are no longer binding.
- The notice available to any person who asks for it.
- You must prominently post and make available your notice on any web site it maintains that provides information about its customer services or benefits.
- You make a good faith effort to obtain the patient's signed acknowledgment of receipt of the notice.
  - If an acknowledgment cannot be obtained, you must document your efforts to obtain the acknowledgment and the reason why it was not obtained.
- https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/model-notices-privacy-practices/

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Transfer from Paper to Electronic Records

- Consult state medical record retention laws.
- Was it a one to one transfer?
  - If yes, you can properly destroy your paper files.
  - If not, you have to maintain your paper records in accordance with HIPAA and state medical record retention guidelines.

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Privacy: Disclosures That Do Not Require Authorization

- Treatment
  - Ordering/referring physician.
  - Physician/provider you are referring to.
  - Coordination of care.
- Payment
  - Insurance carrier.
- Health Care Operations
  - "Certain administrative, financial, legal, and quality improvement activities of a covered entity that are necessary to run its business"

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Disclosure of Information from Another Provider

- You can disclose information that is in the medical record but that was obtained by another provider.
- https://www.hhs.gov/hipaa/for-professionals/faq/214/may-health-care-provider-disclose-parts-of-medical-record/index.html
- https://www.datafiletechnologies.com/wp-content/uploads/2012/04/120101-DFT-FAQ-WhenToReleaseMedicalInformation-V2.pdf

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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.
  - New hires.
  - Annually
- Must have a complaint process.
- Must have record safeguards:
  - Storage.
  - Disposal.
    - HIPAA: Six years
      - https://library.ahima.org/PdfView?oid=102074
    - Need though to consult state and payer record retention requirements as they can exceed HIPAA.
  - Access.

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Privacy Rule Specifics: Texting and Email

- Email and texting
  - **ePHI should be submitted through encrypted/secured service providers ONLY.**
  - Your practice needs a policy.
  - Add email and text consent to your patient intake and have a separate acknowledgement.
  - http://www.hipaajournal.com/hipaa-compliance-for-email/
  - http://library.ahima.org/doc?oid=105342#.WYMIA62ZNmA
  - http://www.hipaajournal.com/texting-violation-hipaa/
  - https://www.fusemail.com/resource-center/white-papers/ensure-email-ephi-hipaa-compliant/
  - http://www.healthforum.com/connect/resources/pdf-files/imprivatac-2016-0107-w-cioguide.pdf

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Use and Disclosure

- The HIPAA version of a medical release.
  - Could also list who can be disclosed to on intake form.
- This is a specific, HIPAA form.
- Allows the patient to list who can be disclosed to and what can be disclosed.
- Can also restrict disclosures with this form.

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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/hipaa/for-professionals/privacy/guidance/marketing/

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HIPAA and Testimonials

- Patient testimonials can be an important part of a practices' marketing strategy.
- But, in order to do this compliantly, the following must be considered:
  - No PHI can be shared in the testimonial or published review.
  - A patient's written authorization must be obtained prior to public use of their review or testimonial.
  - The Notice of Privacy Practices must outline your policies related to publication or dissemination of testimonials and reviews.
  - Staff must be trained on these policies and that training must be documented.
  - https://www.solutionreach.com/blog/hipaa-and-patient-testimonials-staying-compliant
  - http://www.planethipaa.com/patient-testimonials-putting-hipaa-compliance-risk/

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Marketing versus Education

- Marketing
  - Requires authorization
  - Is a third-party paying for the communication?
  - Are you trying to get a patient to purchase an item or service?
  - Are you "marketing":
    - Price
    - Product
    - Promotion

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Marketing versus Education

- Education
  - Does not require authorization.
  - Informational.
  - Talks about technology, not product
  - No mention of specific products or price.
  - No promotions.
  - To inform patients about new locations, addresses or providers.

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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 of products you market?
- Do you have a business development fund for products you market?
- Do you go on vendor-funded trips for products you market?'

If you answered "yes" to any of the above questions, you need a long-form marketing authorization if you continue to market those products.

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Long Form vs. Short Form Marketing Authorization

- Short form
  - No remuneration, in cash or in kind, exchanges hands in any form for products you market.
  - You pay for all of your own marketing communications, in full, that are sent to your database.
  - Example:
    - By initialing this section and signing below, I authorize _____ to send me educational and/or marketing information on the products and services offered by _____. No remuneration is involved in this communication. I understand that I may revoke this authorization, in writing, at any time.

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Long Form vs. Short Form Marketing Authorization

- Long form
  - Remuneration, in cash or in kind, occurs regarding a product or service you are marketing.
  - The vendor is paying in whole or in part for the communication.
  - One page document.
  - Need assistance of legal counsel to draft.

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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.
- http://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/combined-regulation-text/omnibus-hipaa-rulemaking/

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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
- Providers with individual NPIs
- Facility NPI
- Use and Disclosure form
- Acknowledgement of Receipt of Notice of Privacy Practices
  - Can be added to your intake form.
- Security Policy and Process
- Breach Notification Policy and Process

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What Every Practice Needs:

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

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Differences Between Law and Ethics: https://keydifferences.com/difference-between-law-and-ethics.html

BASIS FOR COMPARISON	LAW	ETHICS
Meaning	The law refers to a systematic body of rules that governs the whole society and the actions of its individual members.	Ethics is a branch of moral philosophy that guides people about the basic human conduct.
What is it?	Set of rules and regulations	Set of guidelines
Governed By	Government	Individual, Legal and Professional norms
Expression	Expressed and published in writing.	They are abstract.
Violation	Violation of law is not permissible which may result in punishment like imprisonment or fine or both.	There is no punishment for violation of ethics.
Objective	Law is created with an intent to maintain social order and peace in the society and provide protection to all the citizens.	Ethics are made to help people to decide what is right or wrong and how to act.
Binding	Law has a legal binding.	Ethics do not have a binding nature.

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Office of the Inspector General

- Also known as OIG.
- They are the "policemen" and "auditors" of Medicare and Medicaid.
- http://oig.hhs.gov

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We Are NOT Immune….

- "Terri L. Schneider, 57, of Lakeland, Florida, was sentenced by U.S. District Judge Steven D. Merryday of the Middle District of Florida, who also ordered Schneider to pay$$2,512,460.27 in restitution, joint and several. In December 2015, a jury in Tampa found Schneider and co-conspirator David Brock Lovelace guilty on all charges, which included conspiracy to commit health care fraud and wire fraud, health care fraud, conspiracy to commit money laundering, money laundering and aggravated identity theft. On March 7, Lovelace was sentenced to 174 months in prison and ordered to pay $2,512,460.27 in restitution, joint and several.
- According to evidence presented at trial, from approximately June 2010 through approximately May 2014, Schneider and her co-conspirators used three purported medical clinics in Florida, Cornerstone Health Specialists, Summit Health Specialists and Coastal Health Specialists, to submit approximately $12,351,046 in false and fraudulent claims to Medicare seeking reimbursement for radiology, audiology, cardiology and neurology services. Medicare paid approximately $2,848,424 in reimbursement on the fraudulent claims. The evidence showed that Schneider and her co-conspirators used forged and falsified documents in the Medicare enrollment process for the medical clinics that they operated under false pretenses, and billed Medicare for services that had not been rendered by physicians. The co-conspirators also paid illegal kickbacks in exchange for access to Medicare patients and Medicare patient information used in the fraud scheme, the evidence showed".
- https://www.justice.gov/opa/pr/florida-audiologist-sentenced-94-months-prison-multimillion-dollar-health-care-fraud-and
- https://www.justice.gov/sites/default/files/opa/legacy/2014/05/13/lovelace-et-al.pdf

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We Are NOT Immune….

- "For example, the defendants promised BCBS subscribers a free pair of high-end sunglasses or a free pair of prescription eyeglasses in exchange for taking a free hearing test. At the conclusion of these hearing tests, the defendants told subscribers that they had slight to mild hearing loss and required them to sign an order for hearing aids in order to receive the free sunglasses or prescription glasses. The defendants promised subscribers that the hearing aids would be provided to them at no cost, and that Anderson Optical & Hearing would not require the subscriber to pay any applicable copayment, coinsurance, or deductible. The defendants also offered BCBS subscribers $100 gift cards in exchange for referring family members and coworkers for free hearing tests.
- The defendants took advantage of BCBS plans offered to employees of American Airlines because prior to 2014, the American Airlines insurance plans administered by BCBS had no maximum limit on the cost of hearing aids and allowed subscribers to obtain hearing aids once per plan year. In 2013, approximately 84.6% of Anderson Optical & Hearing's total income came from BCBS and 99.7% of the BCBS payments were based on claims submitted for American Airlines employees and their dependents.
- The defendants failed to conduct hearing tests that complied with BCBS's medical policies related to the evaluation of hearing impairment. Many of the hearing tests were conducted in an employee break room at DFW Airport and lasted less than five minutes. The defendants then submitted claims to BCBS for reimbursement for hearing aids before dispensing hearing aids to the subscriber, and in some cases for hearing aids that they never delivered to the subscriber. The defendants kept lists of subscribers who had not received hearing aids despite BCBS having paid the claims. One such list contained 103 names.
- The indictment also alleges the defendants falsified patient records, forged patient signatures, and attempted to dispense hearing aids and collect deductibles and coinsurance years after the subscriber was offered a free hearing test and free hearing aids".
- https://www.justice.gov/usao-ndtx/pr/father-and-son-charged-16-million-health-insurance-fraud-scheme

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We Are NOT Immune….

- "According to Assistant United States Attorneys Kirk E. Sherriff and Stanley A. Boone, who prosecuted the case, the evidence introduced at trial showed that SORTINI visited skilled nursing facilities throughout Northern California and billed for hearing tests that were not reimbursable by Medicare because they were routine in nature and were performed without a referring physician's order. He also did not perform all of the tests for which he billed Medicare, and when he was audited by Medicare, he submitted forged physician referrals to justify his Medicare billings. SORTINI billed Medicare for unwarranted and unnecessary hearing tests, including tests for patients with severe mental deterioration including Alzheimer's disease, dementia, and senility, and claimed on certain days to have tested between 25 and 50 or more patients at skilled nursing facilities located more than 100 miles apart. He billed and was paid hundreds of thousands of dollars for these services. This illegal activity continued from January 1998, to January 2003, when the FBI conducted a search warrant at his office in Merced".
- https://www.justice.gov/usao-ndtx/pr/father-and-son-charged-16-million-health-insurance-fraud-scheme

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We Are NOT Immune….

- “An audiologist made arrangements with a nursing facility and affiliated physicians to get orders for hearing exams that were not medically necessary. The audiologist used this access to residents exclusively to market hearing aids. In this case, the facility and physicians, in addition to the audiologist, could be held liable for false or fraudulent claims if they acted with knowledge of the claims for unnecessary services”.
- http://oig.hhs.gov/fraud/docs/alertsandbulletins/sfanursingfacilities.pdf

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We Are NOT Immune….

- "TSEC, whose offices were located in Dallas, provided hearing-related services to Medicare beneficiaries living in nursing homes. These hearing services, however, were not provided and were fraudulently billed to Medicare for reimbursement. In fact, this fraudulent business, created by Harlan and Latecia Hill and Pearle Madere caused Medicare to pay TSEC more than $5.1 million for services never rendered or necessary. The indictment also includes a forfeiture allegation that would require Harlan and Latecia Hill, upon conviction, to forfeit their home in Garland, as well as a Mercedes-Benz and a Maserati Quattraporte”.
- http://oig.hhs.gov/newsroom/media-materials/2016/takedown.asp

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We Are NOT Immune….

- 12-22-2015
- "After it self-disclosed conduct to OIG, Towson University Speech Language & Hearing Center (Towson), Maryland, agreed to pay $10,000 for allegedly violating the Civil Monetary Penalties Law. OIG alleged that Towson submitted claims for audiology services with a National Provider Identification (NPI) number that did not correctly identify the provider that rendered those audiology services. OIG further alleged that for these services to be paid by Medicare, the audiologist must have been credentialed by Medicare as a provider and that audiologist's NPI number must accompany the claim".
- https://oig.hhs.gov/fraud/enforcement/cmp/psds.asp

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We Are NOT Immune….

- **08-19-2016**
- **Pennsylvania Audiology Practice Agrees to Voluntary Exclusion**
- "On August 19, 2016, in connection with the resolution of False Claims Act liability, John Balko & Associates, Inc. d/b/a Senior Healthcare Associates (SHA), agreed to be excluded from participation in all Federal health care programs for a period of ten years under 42 U.S.C. § 1320a-7(b)(7). OIG alleged that SHA knowingly and intentionally submitted or caused to be submitted claims for payment to Medicare for cerumen removal procedures, nail debridement procedures, and evaluation and management services using modifier-25, which were not medically necessary, were not authorized or requested by patients, were not supported by patient medical records, lacked required medical documentation, and/or were provided in reliance upon improper standing orders".
- https://oig.hhs.gov/fraud/enforcement/cmp/cmp-ae.asp

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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.

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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?
  - Business Development Fund?
  - Vendor Payment Arrangement?
  - Gifts from vendors?

The public often knows because of social media!

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Other Ethical Questions

- Should you inform patients of the existence of over the counter amplification options, that could be appropriate for their hearing loss?
  - What if an OTC option is just as appropriate as a provider delivered option? Do you mention it?
- Should you inform patients of their funded and discount benefits from third-party administrators that you do not participate with?
- Should your patients know of your relationships with vendors prior to purchase?
- Should hearing aids be sold which are proprietarily locked? Is this good for the patient?
- What if a vendor offers you cash?

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Other Ethical Questions

- Should you tell your patients that a vendor paid for your training and the travel associated with that training?
  - Does that change if the training is accompanied by resort or "vacation like" activities?
  - What if you post this on social media and your patient sees you?
- Should you make fun of your patients on social media, even if you do not specifically state their names or disclose PHI?
  - What if you show their hearing aids?
- Should you bill insurance differently than you bill your private pay patients, in an attempt to maximize your third-party coverage?

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Other Ethical Questions

- Is it ethical to not provide evidence based care?
- Is it ethical if you do not refer a patient for an auditory osseointegrated device or cochlear implant candidacy determination because you might lose the patient?
- What if the patient can get the same or better technology less expensively at a big box retailer?
  - Do you refer them?
  - Do you mention it?
- What if you bill hearing aids to an insurance company that the patient has yet to receive?

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Ethics Cases

- You work for an audiologist who is submitting fraudulent claims (claims for services not performed) to your state Medicaid program.
  - Do you turn them in to Medicaid or the licensure board?
  - Do you continue working there?

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Ethics Cases

- You see an elderly patient in your office and they are accompanied by their adult, paid caregiver. You suspect, from your interactions with them, that the caregiver is stealing from the patient. You have evidence of this.
  - Do you report the caregiver to authorities?
  - Do you inform the patient?

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Ethics Cases

- You have an employee who is making fun of one of your patients on Facebook.
  - Do you fire the employee?
  - Do you discipline the employee?
  - Do you inform the patient?

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Ethics Cases

- A vendor takes you out to dinner and hands you $5000 in cash. No strings attached. No W-9 tax form. There is no one else at the table with you.
  - Do you accept the money?
  - Do you report this to your employer?
  - Do you report this to authorities?

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Ethics Cases

- Your state requires that you obtain 25 continuing education units every two years. Your renewal deadline arrives and you have only obtained 22 hours.
  - Do you ask for an extension to get the remaining three hours?
  - Do you submit your renewal and just hope that you do not get audited?

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Ethics Cases

- Your employer asks you to sign off on an audiogram that 1) you did not personally perform and 2) was performed by a technician in order to receive payment. This technician is unlicensed and was unsupervised.
  - Do you sign off on the audiogram?
  - Do you continue working for this person?
  - Do you report them to authorities?

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CONTINUED

Federal Regulations

- Anti-kickback
- Stark
- False Claims
  - These apply to items or services paid in whole or in part by a federal healthcare program
    - Medicare
    - Medicaid
    - Tricare
    - Veteran's Administration

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CONTINUED

Federal Regulations

- Some state licensure laws and private payers co-op these regulations for their own use and apply them, in verbatim, to other situations.
  - Please consult your state licensure laws and managed care agreements for this language.

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ANTI-KICKBACK

- 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(or recommending the purchase, lease, or ordering) of any item or service reimbursable in whole or in part under a federal health care program.
- 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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ANTI-KICKBACK

- Some examples from Audiology
  - An audiologist furnishes hearing tests to a physician's patients at less than fair market value (or free) 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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What Can I Give Patients?

- Anything that is less than $15 in value per item or less than $75 per year.
- https://oig.hhs.gov/fraud/docs/alertsandbulletins/OIG-Policy-Statement-Gifts-of-Nominal-Value.pdf
- https://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf
- https://www.mcguirewoods.com/Client-Resources/Alerts/2016/12/OIG-Raises-Nominal-Value-Gifts-Medicare-Medicaid-Beneficiaries.aspx

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What Can I Give Referral Sources/Physicians?

- Gifts of "nominal value" (although they do not define this).
- It is better to give nothing!
- http://www.hhhealthlawblog.com/2013/11/gifts-to-referral-sources-and-patients.html
- http://www.hawleytroxell.com/2011/11/gifts-to-patients-and-potential-referral-sources/

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What Gifts Can I Receive from Industry?

- Nominal value only.
- Education is allowed.
- http://journalofethics.ama-assn.org/2014/04/coet2-1404.html
- http://www.hhhealthlawblog.com/2013/11/gifts-to-referral-sources-and-patients.html
- https://oig.hhs.gov/compliance/physician-education/04vendors.asp

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Case Example

- "Four orthopedic device manufacturers paid $311 million to settle kickback and false claims allegations that the companies bribed surgeons to recommend their hip and knee surgical implant products. The companies allegedly would award physicians with vacations, gifts, and annual "consulting fees" as high as $200,000 in return for the physicians' endorsements of their implants or use of them in operations. Many of the individual orthopedic surgeons at the receiving end of the kickbacks are the subject of ongoing investigations by the Government. One orthopedic surgeon recently paid $650,000 to resolve allegations that the surgeon accepted payments from device manufacturers to use their hip and knee implants".

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Relationships to Vendors

- Sunshine Act: The Sunshine Act (Open Payments Act) requires manufacturers of pharmaceuticals, medical devices, biological and medical supplies covered by Medicare, Medicaid or SCHIP to collect, track and report all financial relationships with physicians and teaching hospitals to CMS.
  - http://www.theatlantic.com/health/archive/2013/02/what-the-sunshine-act-means-for-health-care-transparency/272926/
  - https://www.cms.gov/openpayments/
- There, as a result, is precedent in health care.
- https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Avoiding_Medicare_FandA_Physicians_FactSheet_905645.pdf

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Relationships to Vendors: ETHICAL QUESTIONS

- Is your relationship with the vendor benefiting:
  - The patient or consumer?
  - Your business or practice?
  - You, personally?
  - The vendor?
  - We all need to be more careful and aware of these relationships and have them vetted by our own, personal legal counsel.

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POTENTIAL Anti-Kickback Issues

- 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.asha.org/Practice/reimbursement/medicare/audiology-medicare-prohibitions-FAQs/
    - You need your own legal counsel to help you work through the ramifications of providing free testing given your specific situation.

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POTENTIAL Anti-Kickback Issues

- Use of referral pads.
  - They can be seen as a solicitation.
- Write-offs of co-pays and deductibles.
  - Unless meets established, documented indigent policies.
- Reminder mailing for annual hearing tests where you are seeking third-party coverage from a federal payer.
  - All could be construed as a solicitation of a Medicare covered service.
  - The service might not meet the definition of medical necessity.

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POTENTIAL Anti-Kickback Issues

- Manufacturer business development funds.
- Manufacturer leases.
- Free streamers or accessories.
  - When you charge the patient or payer for the item you were provided for free.

PLEASE seek legal counsel for clarification.

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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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Stark laws

- The Physician Self-Referral Law, commonly referred to as the Stark law, prohibits physicians from referring patients to receive "designated health services" payable by Medicare or Medicaid from entities with which the physician or an immediate family member has a financial relationship, unless an exception applies. Financial relationships include both ownership/investment interests and compensation arrangements.
- This can effect durable medical equipment (i.e. hearing aids and auditory prosthetic devices).
- For audiologists:
  - All relationships with ordering and referring physicians should be in writing and created and vetted by legal counsel, preferably a healthcare attorney.

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Stark and Relationships with Referral Sources

- Ensure all agreements (employment contracts, rental agreements) are in writing.
- Ensure that all compensation is of fair market value.
- Ensure that no prid pro quo exists.

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False Claims Act

- Criminal penalties.
- https://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/SMD032207Att2.pdf
- Do not submit fraudulent claims to any entity.
  - Claims for services not performed.
    - Including hearing aids that have not yet been dispensed.
  - Billing under someone else's provider number.

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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.
    - All codes but 92601-92604 (cochlear implant codes) imply two ears were tested.
    - 52 modifier (reduced services)
- Billing for services known to not be covered and not adding the appropriate modifier.
  - Hearing aids.
  - Aural rehabilitation.
  - Evaluation and Management codes.
    - GY Modifier (item or service statutorily excluded or does not meet the definition of a Medicare benefit).

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False Claims Act

- 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.
      - GY Modifier

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Part C Compliance Training

- Many Medicare Part C (Advantage) programs require providers and staff are trained on compliance.
- This training must be completed within 90 days of a new hire.
- This training must be completed at least annually for all employees and this training must be documented in your employment records.
- https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Fraud-Waste_Abuse-Training_12_13_11.pdf
- https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/MedCandDGenCompdownload.pdf

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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
    - Needed for each fitting of a child under the age of 18 years of age.
    - If over 18 years of age, may sign a medical waiver.
      - The FDA will NOT be policing the lack of use of a medical waiver/clearance.
    - Either needs to be in FDA language.

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FDA Requirements

- "The U.S. Food and Drug Administration today (December 7, 2016) announced important steps to better support consumer access to hearing aids. The agency issued a guidance document explaining that it does not intend to enforce the requirement that individuals 18 and up receive a medical evaluation or sign a waiver prior to purchasing most hearing aids. This guidance is effective immediately. Today, the FDA is also announcing its commitment to consider creating a category of over-the-counter (OTC) hearing aids that could deliver new, innovative and lower-cost products to millions of consumers".
- http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm532005.htm
- You need to find out where your state dispensing board falls on the issue of the medical clearance and medical waiver.
  - This will all be modified when the Over the Counter Hearing Aid Act of 2017 provisions are determined.

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FDA Requirements

- Many state laws still 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 and State Dispensing Laws

- Just because the FDA has indicated that they will not enforce the medical waiver or medical clearance requirement does NOT mean that your state will immediately remove it from your state dispensing laws.
- It is IMPORTANT that, before you discontinue use of the medical clearance and medical waiver for adults, that you contact your state dispensing and/or audiology licensure boards, in writing, and determine if the requirement remains in your state.

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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, healthcare facilities, 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.
  - Just because it is not mentioned do not mean you can do it.
- It is very important that you are aware of the ethical and legal requirements of both the hearing aid and/or audiology licensure boars in your state and the scope of practice limitations.
- Professional liability coverage is often null if the provider is found to be practicing outside their scope of practice.

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The Role of State Licensure

- Mandatory reporting
  - Child abuse
  - Elder abuse
  - Fraudulent or unethical practice
  - Supporting unlawful practice

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Support Staff and Licensure

- Audiology Assistants, Technicians, and Support Staff.
  - Cannot perform testing on Medicare beneficiaries and legitimately receive payment.
  - Audiology assistants can obtain an NPI, although its use depends on the level of independence allowed in both state law and managed care agreements.
  - Be careful of:
    - Scope of practice issues.
    - Supervision requirements.
    - Lack of licensure.
      - You may be allowing them to practice audiology without a license.

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Questions?

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