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Compliance, Legalities and Ethics in Audiology Today

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Compliance, Legalities and Ethics in Audiology Today

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Reality Check

1. Ignorance is NOT a defense
2. Rules, regulations, guidance and laws do not have to be interpreted or manipulated to fit YOUR practice, rather you need to modify or adjust your practice operations to the rules, regulations, guidance or laws
3. There is no excuse for not following the rules
4. Make informed decisions
5. Vendors are not always your friend and not always looking out for you
6. Don't worry about everyone else
7. Utilize the skills of experts when you do not know for sure
8. Enforcement is on the rise!!!!

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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/docs/html/ET2010-00309.html>

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Ethical Questions

- Do we serve the patient or the profession?
 - Licensure laws are, at their core, consumer protection laws...
 - So, is the refusal to aid a patient a violation of a licensure law? Code of Ethics?
- If we serve the profession first, is it ethical to take accept an audiology position with an entity who is dispensing hearing aids in a manner that is potentially illegal?
- Is it ethical to accept cash or gifts from a vendor?

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Ethical Quandary?

- Would you feel comfortable telling your patient about your:
 - Vendor funded trip?
 - Business Development Fund?
 - Vendor Payment Arrangement?
 - Vendor Scholarship?

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Ethical Practice Guidelines and Guidance

- Ethical Practice Guidelines and Guidance
 - These are created as an attempt to keep you and your practice out of potential legal trouble
 - Ignorance is not a defense

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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://www.audiology.org/resources/documentlibrary/Documents/201107_Relationships_Industry_Guideline.pdf
- Arrangements you must avoid:
 - 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

- Laws we need to be aware of:
 - 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
 - VA
 - 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.
 - An audiologist accepts gifts that exceed \$10 per item or \$50 annually from a hearing aid manufacturer in return for fitting their hearing aids where some of these referrals may be for instruments covered under a Federal health program.

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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
 - All could be construed as a solicitation of a Medicare covered service

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When Ethics Violations Turn Into Legal Problems

- “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

- Safe Harbors
 - The Office of the Inspector General created exceptions or "safe harbors" to avoid criminalizing innocent conduct or business arrangements
 - <http://oig.hhs.gov/compliance/provider-compliance-training/files/ListofAKSSafeHarbors508.pdf>
 - They include "arm's length" (which means the parties do not have a close relationship or, in other words, are not related) agreements for the rental or lease of office space or equipment, discounts, waivers of co-payments, and remuneration given to employees
 - All rental agreements must be in writing
 - You must have at least a one year rental agreement
 - The cost must be consistent with fair market value

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When Ethics Violations Turn Into Legal Problems

- Stark Laws
 - Civil penalties
 - Prohibits physician self referrals
 - <http://oig.hhs.gov/compliance/provider-compliance-training/files/StarkandAKSChartHandout508.pdf>
 - <http://oig.hhs.gov/compliance/provider-compliance-training/files/PhysicianSelfReferralExceptionHandout508r2.pdf>
 - That is, the physician nor his immediate family cannot refer patient for specific health services to another entity in which the physician or his immediate family has a financial relationship, unless a specific exception applies
 - Stark has limited application to audiology because we are not the ordering entity

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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
 - 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 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
 - 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
- Requirements:
 - Many state dispensing laws reference these
 - <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfregs/CFRSearch.cfm?FR=801.421>
 - Receive a User Brochure
 - Medical Clearance
 - If over 18 years of age, may sign a medical waiver
 - Either needs to be in FDA language

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CMS Audiology Policies

- Update to Audiology Policies
 - Effective October, 2008
 - <http://www.cms.gov/Regulations-and-Guidance/Transmittals/downloads/R84B.P.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
 - Privacy
 - Marketing
 - Security
 - National Provider Identifier
 - National Employer Identifier
 - HITECH (Breach Notification)
 - HIPAA 5010

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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 and/or contract law

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Useful Links

- **Compliance from AAA**
 - http://www.audiology.org/resources/documentlibrary/Documents/201107_Relationships_Industry_Guideline.pdf
- **Audiology Policies**
 - <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Audiology.html>
- **FDA**
 - <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cf/fr/CFRSearch.cfm?FR=801.421>
- **False Claims**
 - <https://www.cms.gov/smdl/download/SMD03207Att2.pdf>
- **Anti-Kickback**
 - <http://www.netreach.net/~wmanning/fasumm.htm>
- **HIPAA**
 - <http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveridentities/index.html>
 - <http://www.hhs.gov/ocr/privacy/hipaa/understanding/>
