


**FEDERAL REGULATIONS WITH COMPLIANCE STANDARDS FOR
AUDIOLOGY**

REVISED BY THE PRACTICE COMPLIANCE COMMITTEE 2016

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Federal Regulation	Regulation Description	Compliance Deadline	AAA & Other Resources Access to some links may require an AAA password	What's Included
American with Disabilities Act (ADA)	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	http://www.ada.gov/ Introduction to the Americans with Disabilities Act (ADA) U.S. Department of Justice Americans with Disabilities Act Home page ADA Primer for Small Business Revised ADA Regulations Implementing Title I and Title II 2010 ADA Standards for Accessible Design View a power point presentation reviewing the ADA Standards for Accessible Design	ADA overview ADA requirements for offices, patient access 2010 ADA Standards for Accessible Design
ADA			http://www.ada.gov/effective-comm.htm	Facts about ADA Effective communication requirements
Anti-kickback Statute (AKS)	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 (felony) for individuals or entities that directly or indirectly, knowingly and willfully offer, pay, solicit or receive remuneration in order to induce business reimbursed under the Medicare or State health care programs.	1987	2013 Office of the Inspector General Work Plan  Fraud and Abuse Compliance Education PPT OIG Advisory Opinion on Free Hearing Testing to Medicare Beneficiaries (Oct. 2012) OIG Health Professional Roadmap to Avoiding Medicare/Medicaid Fraud and Abuse	Anti-kickback Statute (AKS)

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AKS – Safe Harbors		1987, 1991, 1992, 1993, 1994, 1999	http://oig.hhs.gov/compliance/safe-harbor-regulations/	Safe Harbor regulations
Stark Laws	<p>The Stark Law prohibits a <i>physician</i> (or an immediate family member) who has a “<i>financial relationship</i>” (including compensation and investment / ownership interests) with an entity from <i>referring</i> patients to the entity for “designated health services” covered by Medicare, unless an exception is available. In the event a proscribed referral is made and no exception is available, the entity performing the services is prohibited from submitting a claim for the services to Medicare program or billing any individual, third-party payer or other entity for the services.</p> <p>Certain aspects of the Stark Law also apply to state Medicaid programs. Stark has limited applicability for audiologists. Designated Health Services (DHS) include hospital inpatient/outpatient services + CPT codes 92507 & 92508 (SLP codes); referral can be oral, written or electronic.</p>	Stark I (1-1-92) Stark II (12-6-95) Stark III (12-4-07)	http://starklaw.org/	Stark regulations
			<p>Did You Know... ... Many states have enacted their own Anti-Kickback and Stark laws? It is important to consult with a local attorney experienced in health-care law when considering any new arrangement or relationship with another health-care provider. For more information see the Web site of the state in which you practice for state Anti-Kickback and Stark laws applicable to the provision of health care in your particular state.</p>	State Anti-kick- back and Stark laws
Stark Laws and other federal regs			Ethics in Audiology (Second Edition) CEU Program AAA web site	Legal and Ethical Issues in Audiology Practice

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Center for Medicare & Medicaid Services (CMS)	US federal agency that administers Medicare, Medicaid and the Children's Health Insurance Program.	July 30, 1965 June 25, 1997	http://www.socialsecurity.gov/OP_Home/sact/title18/1861.htm http://www.socialsecurity.gov/pubs/10043.html#part1 http://www.cms.gov/manuals/downloads/Clm104c12.pdf http://www.cms.gov/manuals/Downloads/bp102c15.pdf http://www.cms.gov/LowCostHealthInsFa mChild/	Medicare statute (1861) Electronic Booklet Medicare Claims Processing Manual Chapters 12, 15 CHIP Home Page
CMS - Advanced Beneficiary Notice (ABN)	An ABN is required to bill a Medicare beneficiary for a Medicare allowed service that your practice suspects may be denied in this instance as not reasonable or necessary.	March 1, 2009	http://www.cms.gov/BNI/02_ABN.asp	Advanced Beneficiary Notice Directions on ABN utilization
CMS - National and Local Coverage Determinations (LCD)	These are the coverage decisions set forth by CMS or by the Medicare Area Contractor.	Sept, 26, 2003	http://www.cms.gov/DeterminationProcess/ http://www.cms.gov/DeterminationProcess/Downloads/8a.pdf http://www.cms.gov/DeterminationProcess/Downloads/FR09262003.pdf http://www.cms.gov/center/coverage.asp http://www.cms.gov/DeterminationProcess/02_howtorequestanNCD.asp http://www.cms.gov/DeterminationProcess/04_LCDs.asp#TopOfPage	Definition, flow chart, description of process, how to request a National Coverage Determination, how to locate a Local Coverage Determination policy by state, contractor, or alphabetically

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CMS - Medicare Enrollment and Participation	Audiologists must enroll in the Medicare program as either a participating or non-participating provider if accepting Medicare beneficiaries and must submit claims for covered Medicare services	April 7, 2008 October 1, 2008	http://www.socialsecurity.gov/OP_Home/ssact/title18/1861.htm https://www.cms.gov/Transmittals/downloads/AB01144.pdf http://www.cms.gov/manuals/downloads CMS - Medicare Enrollment and CMS - Medicare Enrollment and Participation Participation C/clm104c01.pdf http://www.cms.gov/medicareprovider_s_upenroll/ http://www.cms.gov/CMSforms/downloads/CMS855I.pdf http://www.cms.gov/cmsforms/downloads/cms855r.pdf https://pecos.cms.hhs.gov/pecos/login.do http://gme.sites.medinfo.ufl.edu/files/2010/03/Physician-Guide-to-Medicare-Services.pdf https://www.cms.gov/manuals/downloads/pim83c04.pdf https://nppes.cms.hhs.gov	Program Memorandum AB-01-144, SSA 1861, Medicare Claims Processing Manual Ch. 1, 855I, 855R, PECOS online enrollment. Guide for Physicians, Medicare Fraud
CMS - Solicitation of a Medicare Covered Service	Section 1128A(a) 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 (defined as anything of value) in order to induce business reimbursed under the Medicare or State health care programs. Penalties include liability for civil money penalties (CMPs) of \$10,000 for each wrongful act. Note: punitive damages may be determined to be up to \$30,000.	August 2002	https://questions.cms.hhs.gov/app/answers/detail/a_id/6759/~/there-is-an-advertisement-in-my-local-newspaper-that-says-if-i-will-come-to-a http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf http://oig.hhs.gov/fraud/docs/alertsandbulletins/2004/FA021904hospitaldiscounts.pdf	Advertising Gifts / Inducements

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CMS-Fraud and Abuse	The effort to prevent and detect fraud is a cooperative one that involves CMS, Medicare beneficiaries, Providers of Medicare services and State and Federal Agencies such as the Department of Health and Human Services Office of the Inspector General (OIG), the Federal Bureau of Investigation (FBI) and the Department of Justice (DOJ).	December 19, 1994	http://www.cignagovernmentservices.com/jc/pubs/pdf/Chpt14.pdf http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html	OIG documents on fraud
CMS - Medicare Gifts and Inducements to Beneficiaries Act	Restricts gifts and inducements that may be provided to beneficiaries, with the understanding that these may cause beneficiaries to seek services they otherwise would not.	August 2002	http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf	
		January 1, 2010	http://www.audiology.org/practice/PQRI/Pages/default.aspx https://www.cms.gov/PQRI/Downloads/EligibleProfessionals.pdf https://www.cms.gov/pqri/ http://www.facs.org/ahp/pqri/2010/2010registryreqs.pdf http://www.cms.gov/PQRI/03_How_To_Get_Started.asp#TopOfPage	PQRI dedicated section on website
CMS – Evaluation & Management (E&M) Codes	CMS – Physicians Quality Reporting Initiative (PQRI)		http://www.cms.gov/MLNProducts/downloads/eval_mgmt_serv_guide.pdf	Use of E/M codes - these are statutorily excluded for audiologists when filing claims to Medicare
CMS- Documentation Requirements	An audiologist should clearly and comprehensively document, for each patient in their individual medical record, the following: * The physician order or referral and/or referral source * The problem or complaint, detailed or comprehensive case history findings * The result of any review of the patient's previous medical record * The items provided or procedures performed * The recommendation provided to the patient and/or the referral source	December 18, 2009	http://www.cms.gov/manuals/downloads/clm104c12.pdf http://www.cms.gov/manuals/Downloads/bp102c15.pdf http://www.audiology.org/practice/reimbursement/medicare/Pages/default.aspx	Medicare Benefit Policy Manual Chapters 12 and 15

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CMS - Update to Audiology Policies	This document outlines the audiology specific regulations related to incident to billing, physician orders, computerized testing, scope of practice, use of technicians and students, documentation and National Provider Identifier (NPI).	April 1, 2008 October 1, 2008 February 29, 2008 August 18, 2008 August 11, 2010	https://www.cms.gov/transmittals/downloads/R84BP.pdf https://www.cms.gov/transmittals/downloads/R1470CP.pdf http://www.cms.gov/transmittals/downloads/R129BP.pdf http://www.cms.gov/transmittals/downloads/R1550CP.pdf https://www.cms.gov/mlnmattersarticles/downloads/MM6447.pdf	CMS Transmittals 84, 1470, 1550, 129 (audiology services)
Electronic Health Records (EHR) / Electronic Medical Records (EMR)	EHR is an electronic system for storing and analyzing patient health data. The terms EMR (Electronic Medical Record) and EHR (Electronic Health Record) are used interchangeably. The EHR should be a complete electronic copy of the patient's record. EHR tend to be computerized medical records that are part of a stand-alone health information system that allows storage, retrieval and manipulation of records.		http://www.audiology.org/practice/reimbursement/medicare/Documents/electronic_health_records2.pdf http://www.cms.gov/EHRIncentivePrograms/	Olsson, Frank and Weeda, PC opinion (2006) CMS Guidelines for EHR systems, downloads of related documents
False Claims Act (FCA)			http://www.audiology.org/practice/reimbursement/medicare/Documents/electronic_health_records2.pdf	Olsson, Frank and Weeda, PC opinion (2006)
Food & Drug Administration (FDA) Hearing Aid Dispensing Guidelines	These guidelines involve the required use of a medical clearance, medical waiver, and referral for the Red Flags of Ear Disease, the user brochure and the statements, which should be contained in a purchase agreement.	August, 1977 April 1, 2009	http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?fr=801.420 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?FR=801.421 http://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm?st=cochlear%2Bimplants	FDA Waiver Medical Clearance State licensure laws Warning Signs of Ear Disease

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Federal Trade Commission (FTC) Red Flag & Address Discrepancy Rules (RFR)	This Rule requires that practices create and implement written identity theft prevention, detection and management policies and procedures in an attempt to protect their patients from identity theft including medical identity theft. While similar in nature to the privacy practices within HIPAA and the banking industry, the Red Flag Rule is designed to avert identity theft by ensuring that organizations are alert to signs that an identity thief is using someone else's identifying information fraudulently to obtain products or services, including medical care.	June 1, 2010 - extended January 11, 2011 – physicians and small business (less than 20 employees) may be exempt (9-14-10)-	audiology.org/practice_management/compliance/ftc-red-flag-and-address-discrepancy-rule%E2%80%94effective-december-31-2010 http://www.audiology.org/advocacy/congress-acts-federal-trade-commissions-ftc-red-flag-and-address-discrepancy-rule http://www.ama-assn.org/amednews/2010/06/28/pr120628.htm	Overview possible exemptions
Health Insurance Portability & Accountability Act (HIPAA)	<p>The Office for Civil Rights enforces the HIPAA Privacy Rule, which protects the privacy of individually identifiable health information; the HIPAA Security Rule, which sets national standards for the security of electronic protected health information; and the confidentiality provisions of the Patient Safety Rule, which protects identifiable information being used to analyze patient safety events and improve patient safety.</p> <p>These regulations surround the transaction and code sets, privacy, NPI, EIN/TIN (unique identifiers), security, and HI-TECH Standards.</p>	October 16, 2003 (Transaction and Code Sets) April 14, 2003 (Privacy) April 21, 2005 (Security) January 1, 2011 and January 1, 2013(HITECH)	https://webportal.audiology.org/Purchase/ProductDetail.aspx?Product_code=6fa19f1d-9136-e311-b59c-984be173585f http://www.audiology.org/practice_management/compliance/how-do-i-become-hipaa-complianthttp://www.audiology.org/	HIPAA privacy manual HIPAA security manual How to become HIPAA Compliant
HIPAA		February 17, 2010 August 18, 2010	http://www.audiology.org/practice/compliance/Pages/20100203_HIPAA.aspx	Academy webpage updated with most current 2010 information on HIPAA.

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HIPAA		February 22, 2010	https://webportal.audiology.org/Purchase/ProductDetail.aspx?Product_code=fed0079c-1510-df11-af97-001321c90fe0	35-minute Online E-Learning overview HIPAA Seminar - Due to the American Recovery for Reinvestment Act of 2009 (ARRA, also known as the "Stimulus Bill"), there are new HIPAA requirements. Information about business agreements, data breaches, and electronic health records and incentives are included.
HIPAA		February 22, 2010	https://webportal.audiology.org/Purchase/ProductDetail.aspx?Product_code=6a3850d4-5710-df11-af97-001321c90fe0	2-hour Online E-Learning Seminar - Due to the American Recovery for Reinvestment Act of 2009 (ARRA, also known as the "Stimulus Bill"), there are new HIPAA requirements. Information about business agreements, data breaches, and electronic health records and incentives are included.
HIPAA- HITECH		February 22, 2010	http://www.btlaw.com/files/ALERT%20%20Healthcare HITECH%20Act%20Breach%20Notification%20Rule.pdf	Summary of notification requirements upon discovery of a breach of unsecured protected health information. HIPAA changes due to ARRA ("stimulus bill")
HIPAA			http://www.audiology.org/practice/compliance/Documents/OCR_privacy.pdf	

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HIPAA - privacy			http://www.cbsnews.com/video/watch?id=6412572n&tag=related;photovideo http://www.audiology.org/practice/compliance/Pages/Compliance20100506.aspx	CBS news video about data stored on copy machines, potential for privacy breach from data stored on digital copiers & privacy Practice Compliance Committee (PCC) notice.
NPI	Audiologists are required to have their own unique NPI, which stays with the audiologist for his or her career. Tests completed by audiologists should not be billed incident-to. Audiologists providing services to Medicare beneficiaries are required to have a Provider Transaction Access Number (PTAN)	May 23, 2007	https://nppes.cms.hhs.gov/NPPES/StaticForward.do?forward=static.instructions http://www.audiology.org/practice/reimbursement/medicare/Pages/medicare20080301.aspx	Obtaining NPI
OSHA	According to OSHA, healthcare facilities include hospitals, clinics, dental offices, outpatient surgery centers, birthing centers and nursing homes. Applicability to audiology includes primarily blood borne pathogens and sterilization.	January 19, 1988 August 15, 1988 February 27, 1990	http://www.audiology.org/resources/documentlibrary/Pages/InfectionControl.aspx http://www.audiology.org/Documents/AN2009Handouts/LM501_Klodd.pdf http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=directives&p_id=2570 http://www.osha.gov/SLTC/healthcarefacilities/index.html	OSHA requirements, general information
Medical Records	The length of time you should retain a document depends on the action, expense or even the document records. Guidance may be different from state to state; each state's insurance commission should be consulted for that state's specific guidance.		http://www.audiology.org/practice/compliance/Pages/medicalrecordsretention.aspx	General guidelines and timetables on retaining records

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OIG	The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452 (as amended), is to protect the integrity of Department of Health and Human Services (HHS) programs, as well as the health and welfare of the beneficiaries of those programs.	December 19, 1994 February 2000 August 2002 September 2010	http://oig.hhs.gov/ http://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html http://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf http://www.oig.hhs.gov/fraud/hotline/ http://www.oig.hhs.gov/report_fraud/OIGFradForm.asp http://www.oig.hhs.gov/index.asp	Opinion on gifts Opinion on Medicare charges General information Hotline Rental space-physicians Opinion on cochlear implant manufacturer repair warranty compensation Medicare Self-Referral Disclosure Protocol
OIG Fraud Alert			http://oig.hhs.gov/fraud/docs/alertsandbulletins/office%20space.htm hotline.oig@dc.gov http://oig.hhs.gov/fraud/docs/advisoryopinions/2010/AdvOpn10-16.pdf http://www.cms.gov/PhysicianSelfReferral/65_Self_Referral_Disclosure_Protocol.asp#TopOfPage	
OIG Work Plan	The OIG Work Plan sets forth various projects to be addressed during the fiscal year by the Office of Audit Services, Office of Evaluation and Inspections, Office of Investigations and Office of Counsel to the Inspector General. The Work Plan includes projects planned in each of the Department's major entities including CMS.		http://oig.hhs.gov/publications/docs/workplan/2010/Work_Plan_FY_2010.pdf	2010 OIG work plan (to be updated annually)