What Every EHDI Professional Should Know about Regulatory Issues

Judith A. Marlowe, Ph.D., FAAA, CCC-A
Executive Director
Audiology & Professional Relations
Natus Medical Incorporated

Disclaimer

- This is a non-commercial presentation that will not name specific products.
- The information presented has been obtained from regulatory attorneys and from regulatory affairs professionals, but does not constitute legal or regulatory advice.
- For specific questions contact an attorney specializing in regulatory issues or a regulatory affairs/risk management professional at your facility.

Early Hearing Detection:

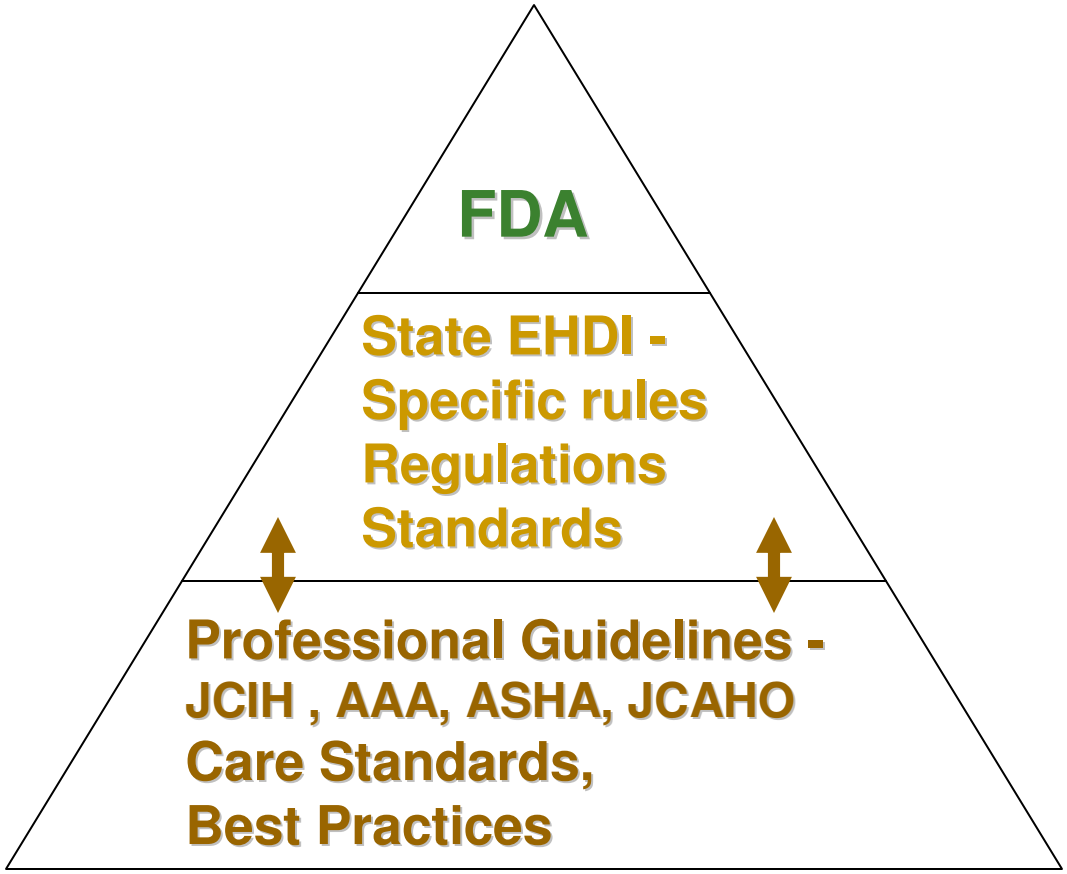
Technology Driven & Technology Dependent

- JCIH 2007 Position Statement:
  - "Hospital-based programs should consider screening technology (ie, OAE or automated ABR testing); validity of the specific screening device; screening protocols, including the timing of screening relative to nursery discharge; availability of qualified screening personnel; suitability of the acoustical and electrical environments; follow-up referral criteria; referral pathways for follow-up; information management; and quality control and improvement. (p.903)

JCIH 2007 Position Statement: Technology Guidance

- “Interpretive criteria for pass/fail outcomes should reflect clear scientific rationale and should be evidence based. Screening technologies that incorporate automated-response detection are necessary to eliminate the need for individual test interpretation, to reduce the effects of screener bias or operator error on test outcome, and to ensure test consistency across infants, test conditions, and screening personnel.” (p.903)

The Regulatory Guidance Pyramid



FDA

- Principal consumer protection agency of US federal government.
- Authority to monitor and regulate manufacture and/or sale of all medical devices in interstate commerce
- Safety and effectiveness are objectives

FDA – Medical Device Classes

- The Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act established three regulatory classes for medical devices based on the degree of control necessary to assure they are safe and effective.
- **Class I** –Minimal potential for harm to the user and often simpler in design than Class II or Class III devices. Examples: enema kits, elastic bandages, hearing aids. 47% of medical devices fall under this category and 95% of these are exempt from the regulatory process.
- **Class II** – Most medical devices. Examples: powered wheelchairs, some pregnancy test kits, hearing screeners, impedance testers, audiometers, 43% of medical devices fall under this category.
- **Class III** – These devices usually sustain or support life, are implanted, or present potential unreasonable risk of illness or injury. Examples of Class III devices include implantable pacemakers, cochlear implants. 10% of medical devices fall under this category.

Section 510(k) of the Food, Drug and Cosmetic Act

- A 510(k) is a premarketing submission made by the manufacturer or agent in the case of a product manufactured outside the US to FDA to demonstrate that the device to be marketed is safe and effective.

What's in a 510(k)?

Indications for use.

- A general description of the disease or condition to be diagnosed, treated, cured, mitigated, or prevented, including a description of the patient population for which the device is intended.

Device description.

- An explanation of how the device functions, significant physical and performance characteristics of the device, and basic scientific concepts that form the basis for the device.

Other device labeling.

- Other device labeling that includes contraindications, warnings and precautions and/or promotional materials – User Manuals

Risks.

- A summary of all adverse safety and effectiveness information and identification of the risks presented by the device as well as any mechanisms or procedures which will control the risk.

The Language of Safety in FDA labeling

- **Warning**: Identifies conditions or practices that might present danger or possible injury to the patient and/or user
- **Important**: An instruction provided to help ensure correct clinical results
- **Caution**: an instruction that, if not followed, can result in a condition that could damage the device.

What's in a 510(k)?

Alternative practices and procedures.

- A description of alternative practices or procedures for diagnosing, treating, preventing, curing, or mitigating the disease or condition for which the device is intended.

Summary of preclinical and clinical data.

- Conclusions drawn from studies that support the safety and effectiveness of the device, and address adverse effects on health.
- Brief description of the objective of the studies, experimental design, how the data were collected and analyzed, and the results of the studies, whether positive, negative, or inconclusive.
- Discussion of the subject inclusion and exclusion criteria, the study population, reasons for patient discontinuations, and results of statistical analyses.

Bibliography.

- A copy of each key reference, a brief summary of the salient features of each key reference, and a brief discussion of why the reference is relevant to an evaluation of the safety and effectiveness of the device.

Validation Requirements

- Manufacturer must prepare a written validation protocol specifying procedures (and tests) to be conducted data to be collected.
- The purpose for which data are collected must be clear, the data must reflect facts and be collected carefully and accurately.
- The protocol should specify a sufficient number of replicate process runs to demonstrate reproducibility and provide an accurate measure of variability among successive runs. The test conditions for these runs should encompass upper and lower processing limits and circumstances, including those within standard operating procedures, which pose the greatest chance of process or product failure compared to ideal conditions; such conditions have become widely known as "worst case" conditions. (They are sometimes called "most appropriate challenge" conditions.)
- Validation documentation should include evidence of the suitability of materials and the performance and reliability of equipment and components of the system.

Postmarket Requirements: Clearance is just the beginning

- Medical device manufacturers as well as firms involved in the distribution of devices must follow certain requirements and regulations once devices are on the market:
  - tracking systems,
  - registering the establishments where devices are produced or distributed,
  - reporting of device malfunctions, serious injuries or deaths.

510(k): Once is not enough!

- Technology developments may require new 510(k)
  - Modifications of intended use
  - New features that may affect safety or effectiveness
  - New claims
- Regulatory review of clearance process
- Decision/documentation responsibility of manufacturer

Questions to Ask & Answer

- **FDA status of the device**: Has this device received 510(k) clearance? What is the "intended use" claimed and cleared in the 510(k)?
- **Population intended for use:** Was the device intended for a specific population? Expanding its use to other populations may not be assumed; e.g., validation for adults does not confirm that a device is appropriate for newborns.
- **Conditions or pre-requisites for use:** Are additional tests or procedures indicated in the 510(k) submission to accompany use of the device?

Questions to Ask & Answer

- **Ability to use the device exclusively as intended and cleared by FDA:** Are there conditions or restrictions (intended use, training requirements, interpretation of results, etc.) which will lead to off-label use and create liability given the circumstances in your institution?

What is "Off-Label Use" and Why should I care?

- Claims and labeling include any written or oral representations about the device safety and effectiveness.
- Only claims and labeling submitted in the 510(k) are reviewed by FDA and cleared.
  - Process and requirements for further device development
- "Off-label Use" occurs when device is operated for a purpose or in a manner not reviewed and cleared by FDA.
- Liability risk is increased in event of a safety or effectiveness failure.

Advancing Safe and Effective EHDI

- Professional awareness and education: ask questions and expect answers regarding technology claims
  - www.fda.gov/MedicalDevices : releasable 510(k) database from 1999-present
- Eliminate or reduce risk by staying within FDA clearance with all medical devices
- Make User Manual and information regarding safe and effective use available to all program personnel to ensure uniform practices

The Exception to the Rule

Many things we need can wait, the child cannot. Now is the time his bones are formed, his blood is made, his mind developed. To him we cannot say "tomorrow," his name is TODAY

Gabriela Mistral –
Educator/poet recipient of 1945 Nobel Prize in Literature