Standards for Accessible Medical Diagnostic Equipment (MDE) & Access to Quality Pelvic Health Care for Women with Mobility Impairments
Barriers Affecting Accessibility and Usability of Medical Diagnostic Equipment

- 75% - examination tables moderately difficult to impossible to use
- 68% - radiology equipment moderately difficult to impossible to use
- 53% - weight scales moderately difficult to impossible to use
- 50% - examination chairs moderately difficult to impossible to use

Rehabilitation Engineering Research Center on Accessible Medical Instrumentation 2004 national Survey
MDE - Background

- Section 4203 of Patient Protection and Affordable Care Act
  - (Public Law 111-148, 124 Stat. L. 119)

- Added Section 510 to the Rehabilitation Act of 1973 on March 23, 2010

- Title: “ESTABLISHMENT OF STANDARDS FOR ACCESSIBLE MEDICAL DIAGNOSTIC EQUIPMENT”
- Examination tables and chairs
- Weight scales, x-ray machines
- Radiological and mammography equipment
Rule does not cover personal devices or positioning aids – “diagnostic equipment” only
MDE - Background

• Mandate is to establish technical criteria
• Scope issues not addressed:
  when, how many, and existing equipment issues determined in appropriate regulatory or administrative context
• Final Standards issued by Access Board will be voluntary
• Must be adopted by DOJ to be enforceable under Americans with Disabilities Act
• Reference Standard for FDA to verify labelling of MDE
Federal Partners

- U.S. Food and Drug Administration, Department of Health and Human Services
- Disability Rights Section, Department of Justice
- Department of Veterans Affairs
MDE - Background

- ANSI/AAMI HE75 – 2009
  Human Factors Engineering
  – Design of Medical Devices
  Chapter 16 – Accessibility Considerations

- RERC on Accessible Medical Instrumentation
MDE - Background

ADA and ABA Accessibility Guidelines
Research Data

Principle Source:
Data Collected for the Wheeled Mobility Anthropometry Project

Additional:
Study on The Impact of Transfer Setup on the Performance of Independent Wheelchair Transfers (Phase I)
MDE - Rulemaking Steps

- Notice of Proposed Rulemaking (NPRM)
- Comment Period
- Public Hearings
- Advisory Committee
- Final Rule
Responses to NPRM

• 46 questions were posed in the preamble

• 51 commenters

• Range of comments
MDE - Advisory Committee

Advise on matters addressed in the NPRM for the proposed Standards and issues raised in public comments.
Advisory Committee Recommendations

• 55 Recommendations Made
• 9 Issue Areas Addressed
• Final Report
Overview of Standards
Organization of Standards

- M1 Application and Administration
- M2 Scoping Requirements
- M3 Technical Criteria

By patient position supported
- Supine, Prone, or Side Lying
- Seated
- in Wheelchair
- Standing

Across all types of equipment
- Communication
- Operable Parts
Supine, Prone, or Side-lying Position - M301

Seated Position - M302

Key Issues: transfers, obstructions supports, and lift use
Transfer Surface Height

17 inches minimum and 19 inches maximum proposed – could be fixed height
Committee recommended

- height adjustability for transfers:
  - “high” height of 25”
  - “low” height – no consensus options for 19”, 18”, and 17”
Transfer Surface Size

M301.2.2 Size

M302.2.2 Size

two distinct requirements proposed for each equipment category – difference is width
Transfers at End
28” wide min. by 17” deep min.

Transfers at Sides
28” wide min. by 28” min. deep

Advisory Committee Recommendations
Wheelchair Spaces

The Standard does NOT address clear floor space for transfers
Transfer Surface Size – M301

Advisory Committee Recommendations
M301.3 and M302.3 Supports

Proposed provisions for:

- transfer supports
- leg supports – stirrups
- head and back support – reclined positions

Positioning supports not addressed
Example of relevant ADA-ABA 2004 Guidelines provisions

Section 609 Grab Bars cross section specifications

Non-circular Cross Section

Circular Cross Section
Transfer Supports

structural strength not addressed as ADA and ABA Standards do for grab bars

More variables, Industry Standards address
Location and Configuration for Transfer Supports

Committee recommended more detailed provisions based on ADA/ABA Standards and discussion in NPRM
Stirrups

Proposed provision: Method of supporting, positioning, and securing patient’s legs.

Committee recommended: Alternate method to support, position, and secure patient’s legs. Method to supplement or substitute stirrup.
Portable Lift Compatibility

around base clearances

in base clearances
Portable Lift Compatibility

around base clearances

in base clearances

base is permitted to increase in width at a rate of 1 inch (25 mm) in width for each 3 inches (75 mm) in depth within clearance
Committee Recommendation:

overhead lift in lieu of base clearances where not feasible for imaging equipment
Questions?

Board’s webpage about the MDE Rulemaking:

www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking