Billing Code 8150-01-P

ARCHITECTURAL AND TRANSPORTATION BARRIERS COMPLIANCE BOARD

36 CFR Part 1195

[Docket No. ATBCB-2012-0003]

RIN 3014-AA40

Medical Diagnostic Equipment Accessibility Standards

AGENCY: Architectural and Transportation Barriers Compliance Board.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Architectural and Transportation Barriers Compliance Board (Access Board) is proposing accessibility standards for medical diagnostic equipment. The proposed standards contain minimum technical criteria to ensure that medical diagnostic equipment, including examination tables, examination chairs, weight scales, mammography equipment, and other imaging equipment used by health care providers for diagnostic purposes are accessible to and usable by individuals with disabilities. The standards will allow independent entry to, use of, and exit from the equipment by individuals with disabilities to the maximum extent possible. The standards do not impose any mandatory requirements on health care providers or medical device manufacturers. However, other agencies, referred to as an enforcing authority in the standards, may issue regulations or adopt policies that require health care providers subject to their jurisdiction to acquire accessible medical diagnostic equipment that conforms to the standards.

DATES: Submit comments by [INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Hearings will be held on the proposed standards on the following dates:

1. March 14, 2012, 9:30 a.m. to 12:00 p.m., Washington, DC.

2. May 8, 2012, 9:30 a.m. to 12:00 p.m., Atlanta, GA.

ADDRESSES: Submit comments by any of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Regulations.gov ID for this docket is ATBCB-2012-0003.
- E-mail: docket@access-board.gov. Include docket number ATBCB-2012-0003 in the subject line of the message.
- Fax: 202-272-0081.
- Mail or Hand Delivery/Courier: Office of Technical and Informational Services, Access Board, 1331 F Street, NW, suite 1000, Washington, DC 20004-1111.

All comments**,** including any personal information provided, will be posted without change to http://www.regulations.gov and are available for public viewing.

The hearing locations are:

1. Washington, DC: Access Board Conference Room, 1331 F Street, NW., Suite 800, Washington, DC 2004.

2. Atlanta, GA: Hilton Atlanta (Meeting Rooms 309-311), 255 Courtland Street, NE., Atlanta, GA 30303.

FOR FURTHER INFORMATION CONTACT: Earlene Sesker, Office of Technical and Information Services, Architectural and Transportation Barriers Compliance Board, 1331 F Street NW, Suite 1000, Washington, DC 20004-1111. Telephone: (202) 272-0022 (voice) or (202) 272-0091 (TTY). E-mail address sesker@access-board.gov.

SUPPLEMENTARY INFORMATION:

Table of Contents for Preamble

1. Public Participation and Request for Comments

The preamble includes questions that request comments on issues that the Access Board is particularly interested in receiving information from the public. The Access Board encourages all persons interested in the rulemaking to submit comments on the proposed standards and the questions in the preamble. Instructions for submitting and viewing comments are provided above under Addresses. The Access Board will consider all the comments and may change the proposed standards based on the comments.

2. Establishment of Advisory Committee

The Access Board has used advisory committees consisting of representatives of interest groups that are affected by its guidelines and standards to assist in developing the guidelines and standards. Advisory committees provide significant expertise on issues and an opportunity for interest groups to reach consensus on issues. The Access Board plans to convene an advisory committee when the comment period on the rulemaking closes to assist the Board in reviewing the comments and make recommendations on issues addressed in the rulemaking. The Access Board will issue a separate notice in the Federal Register announcing the establishment of the advisory committee and seeking nominations for membership on the advisory committee to represent the interests of individuals with disabilities, medical device manufacturers, health care providers, standards setting organizations, and other interested parties. Advisory committee meetings will be announced in advance in the Federal Register and will be open to the public.

3. Background

A. Access Board

The Access Board is an independent federal agency established by Section 502 of the Rehabilitation Act (29 U.S.C. 792).[1] The Access Board is responsible for developing accessibility guidelines and standards under various laws to ensure that individuals with disabilities have access to and use of buildings and facilities, transportation vehicles, and information and communication technology.[2] Pursuant to these laws, other federal agencies have adopted the Access Board's guidelines and standards as mandatory requirements for entities subject to their jurisdiction.[3]

B. Patient Protection and Affordable Care Act and Section 510 of the Rehabilitation Act

Section 4203 of the Patient Protection and Affordable Care Act (Pub. L. 111-148, 124 Stat. 570) amended Title V of the Rehabilitation Act, which establishes rights and protections for individuals with disabilities, by adding Section 510. Section 510 of the Rehabilitation Act (29 USC 794f) requires the Access Board, in consultation with the

[1] The Access Board consists of 13 members appointed by the President from the public, a majority of which are individuals with disabilities, and the heads of 12 federal agencies or their designees whose positions are Executive Level IV or above. The federal agencies are: The Departments of Commerce, Defense, Education, Health and Human Services, Housing and Urban Development, Interior, Justice, Labor, Transportation, and Veterans Affairs; General Services Administration; and United States Postal Service.

[2] The Access Board has issued accessibility guidelines and standards under the following laws: Section 504 of the Americans with Disabilities Act (42 U.S.C. 12204) for buildings and facilities, and transportation vehicles; Section 502 of the Rehabilitation Act (29 U.S.C. 792) for buildings and facilities; Section 508 of the Rehabilitation Act (29 U.S.C. 794d) for electronic and information technology; and Section 255 of the Telecommunications Act (47 U.S.C. 255) for telecommunications equipment and customer premises equipment. Additional information on the guidelines and standards is available at: http://www.access-board.gov.

[3] The following federal agencies have adopted the Access Board's guidelines and standards as mandatory requirements for entities subject to their jurisdiction: Department of Justice (see 28 CFR 35.104 and 35.151; and 28 CFR 36.104 and 36.401 to 36.406); Department of Transportation (see 49 CFR 37.9 and Appendix A to 49 CFR part 37; and 49 CFR part 38); Federal Acquisition Regulatory Council (see 48 CFR 39.203); Federal Communications Commission (see 47 CFR part 6); General Services Administration (see 41 CFR 102-77.65); and United States Postal Service (see 39 CFR 254.1). See also Deputy Secretary of Defense Memorandum on Access for People with Disabilities, October 31, 2008 at: http://www.access-board.gov/ada-aba/dod-memorandum.htm. Some agencies have adopted the guidelines and standards with additions and modifications.

Commissioner of the Food and Drug Administration, to issue standards that contain minimum technical criteria to ensure that medical diagnostic equipment used in or in conjunction with medical settings such as physicians' offices, clinics, emergency rooms, and hospitals is accessible to and usable by individuals with disabilities. The statute provides that the standards must allow for independent access to and use of the equipment by individuals with disabilities to the maximum extent possible. The statute lists examination tables, examination chairs, weight scales, mammography equipment, and other imaging equipment as examples of equipment to which the standards will apply. However, this list is not exclusive and the statute covers any equipment used by health care providers for diagnostic purposes. The statute does not cover medical devices used for monitoring or treating medical conditions such as glucometers and infusion pumps.

Section 510 of the Rehabilitation Act requires the standards to be issued not later than 24 months after the enactment of the Patient Protection and Affordable Care Act. The Patient Protection and Affordable Care Act was enacted on March 23, 2010. Accordingly, the statutory deadline for issuing the standards is March 23, 2012. The statute also requires the Access Board, in consultation with the Commissioner of the Food and Drug Administration, to periodically review and amend the standards, as appropriate.

Section 510 of the Rehabilitation Act does not require any entity to comply with the standards that the Access Board issues under this law. Compliance with the standards becomes mandatory only when an enforcing authority adopts the standards as mandatory requirements for entities subject to its jurisdiction. As discussed below, the Department

of Justice (DOJ) may adopt the standards as mandatory requirements for health care providers pursuant to its authority under Titles II and III of the Americans with Disabilities Act. Other federal agencies may adopt the standards as mandatory requirements for health care providers pursuant to their authority under Section 504 of the Rehabilitation Act.

C. Americans with Disabilities Act and Section 504 of the Rehabilitation Act

The Americans with Disabilities Act (ADA) and Section 504 of the Rehabilitation Act are civil rights laws that prohibit discrimination on the basis of disability. Title II of the ADA (42 U.S.C. 12131 to 12165) applies to state and local governments, and Title III of the ADA (42 U.S.C. 12189 to 12189) applies to private entities that are public accommodations such as health care providers. Section 504 of the Rehabilitation Act (29 U.S.C. 792) applies to recipients of federal financial assistance such as Medicaid and federally conducted programs. DOJ is responsible for issuing regulations to implement Titles II and III of the ADA.[4] Federal agencies that provide federal financial assistance are responsible for issuing regulations to implement Section 504 of the Rehabilitation Act for recipients of such assistance. Federal agencies also are responsible for issuing regulations to implement Section 504 of the Rehabilitation Act for their federally conducted programs. DOJ is responsible for overall enforcement of Titles II and III of the ADA, and Section 504 of the Rehabilitation Act as it applies to recipients of federal

[4] The Department of Transportation is responsible for issuing regulations to implement certain sections of Titles II and III of the ADA relating to transportation.

financial assistance from DOJ and federal financial assistance from other federal agencies when those agencies refer complaints to DOJ for enforcement purposes.[5]

D. Department of Justice Activities Related to Health Care Providers and Medical Equipment

Pursuant to the ADA and Section 504 of the Rehabilitation Act, health care providers must provide individuals with disabilities full and equal access to their health care services and facilities. DOJ has entered into settlement agreements with health care providers to enforce the ADA and Section 504 of the Rehabilitation Act.[6]

In July 2010, DOJ and the Department of Health and Human Services issued a guidance document for health care providers regarding their responsibilities to make their services and facilities accessible to individuals with mobility disabilities under the ADA and Section 504 of the Rehabilitation Act. See Access to Medical Care for Individuals with Mobility Disabilities available at: http://www.ada.gov/medcare_ta.htm. The

[5] In its regulations implementing Title II of the ADA, DOJ has delegated responsibility for investigating complaints and conducting compliance reviews in specific subject matter areas to other federal agencies, but at its discretion DOJ may retain complaints for investigation and appropriate disposition. See 28 CFR 35.190. DOJ has delegated responsibility for investigating complaints and conducting compliance reviews relating to the provision of health care services by state and local governments to the Department of Health and Human Services. Federal agencies that provide federal financial assistance also investigate complaints and conduct compliance reviews regarding compliance with Section 504 of the Rehabilitation Act by recipients of such assistance. See Appendix A to 28 CFR part 41. The federal agencies can refer matters that are not resolved successfully to DOJ for enforcement.

[6] The settlement agreements by DOJ with health care providers and matters addressed in the agreements include: United States of America v. Inova Health System (March 30, 2011) auxiliary aids and services, including sign language interpreters; HCA Health Services of New Hampshire (Portsmouth Regional Hospital) (November 23, 2010) auxiliary aids and services, including sign language interpreters; Beth Israel Deaconess Medical Center (October 22, 2009) accessible facilities and accessible medical equipment; Gillespie v. Dimensions Health Corporation (July 12, 2006) auxiliary aids and services, including sign language interpreters; Washington Hospital Center (November 2, 2005) accessible facilities and accessible medical equipment; Valley Radiologists Medical Group, Inc. (November 2, 2005) accessible imaging equipment; Exodus Women's Center (March 26, 2005) accessible examination tables; Dr. Robila Ashfaq (January 12, 2005) accessible examination table; and Georgetown University Hospital (October 31, 2001) providing assistance for transferring from a wheelchair to an examination table The settlement agreements are available at: http://www.ada.gov/settlemt.htm.

guidance document includes information on accessible examination rooms and the clear floor space needed adjacent to medical equipment for individuals who use mobility devices to approach the equipment for transfer; accessible medical equipment (e.g., examination tables and chairs, mammography equipment, weight scales); patient lifts and other methods for transferring individuals from their mobility devices to medical equipment; and training health care personnel.

In July 2010, DOJ also issued an advance notice of proposed rulemaking (ANPRM) announcing that, pursuant to the obligation that has always existed under the ADA for covered entities to provide accessible equipment and furniture, it was considering amending its regulations implementing Titles II and III of the ADA to include specific standards for the design and use of accessible equipment and furniture that is not fixed or built into a facility in order to ensure that programs and services provided by state and local governments and by public accommodations are accessible to individuals with disabilities.[7] See 75 FR 43452 (July 26, 2010). Among other things, the ANPRM stated that DOJ was considering amending its ADA regulations to specifically require health care providers to acquire accessible medical equipment and that it would consider adopting the standards issued by the Access Board. DOJ also indicated its intention to include in its ADA regulations scoping requirements that specify the minimum number of types of accessible medical equipment required in different types of

[7] The ANPRM requested public comment on several categories of equipment and furniture, including medical equipment (e.g., medical examination and treatment tables and chairs, scales, radiological diagnostic equipment, lifts, infusion pumps, rehabilitation equipment, hospital beds and gurneys, ancillary equipment such as positioning straps or cushions, protective padding, leg supports for gynecological examinations, rails and bars for patient safety and comfort, and call buttons); exercise equipment and furniture; accessible golf cars; beds in accessible guest rooms and sleeping rooms; beds in nursing homes and other care facilities; and electronic and information technology such as kiosks (i.e., interactive computer terminals that provide services), interactive transaction machines, point of sale devices, and automated teller machines.

health care facilities. If DOJ proposes to amend its ADA regulations as announced in the ANPRM, it will publish a notice of proposed rulemaking (NPRM) requesting public comment.

E. Private Enforcement Efforts

Private parties, including individuals with disabilities, have also entered into settlement agreements with health care providers to enforce the ADA and Section 504 of the Rehabilitation Act.[8]

F. Consultation with Food and Drug Administration

The Commissioner of the Food and Drug Administration has designated the Director of the Center for Devices and Radiological Health (FDA-CDRH) to consult with the Access Board on the development of standards for accessible medical diagnostic equipment. The Access Board has worked closely with the FDA-CDRH in developing the proposed standards. The FDA-CDRH may develop a guidance document to inform manufacturers how it intends to apply its regulatory authority to clearance or approval of medical devices addressed in the Access Board's standards. If the FDA-CDRH develops such a guidance document, it will provide the public notice and opportunity to comment on a draft of the guidance document in accordance with its procedures for issuing guidance documents. See 21 CFR 10.115.

G. ANSI/AAMI HE 75

[8] The settlement agreements by private parties and matters addressed in the agreements include: Massachusetts General Hospital and Brigham and Women's Hospital (June 26, 2009) accessible facilities, accessible medical equipment, and auxiliary aids and services; Thompson v. Sutter Health (July 11, 2008) accessible facilities, accessible medical equipment, and auxiliary aids and services; University of Southern California Medical Center (May 15, 2008) accessible facilities, accessible medical equipment, and auxiliary aids and services; and Metzler v. Kaiser Permanente (March 2001) accessible facilities and accessible medical equipment. The settlement agreements are available at: http://thebarrierfreehealthcareinitiative.org/?page_id=16.

In 2009, the Association for the Advancement of Medical Instrumentation issued ANSI/AAMI HE 75, a recommended practice on human factors design principles for medical devices. Chapter16 of ANSI/AAMI HE 75 contains recommended practices regarding accessibility for patients and health care personnel with disabilities. Chapter 16 of ANSI/AAMI HE 75 is available at: http://www.aami.org/he75/.

The Access Board is committed to using voluntary consensus standards where practical and consistent with the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note). The Access Board has considered the recommended practices in Chapter16 of ANSI/AAMI HE 75 in developing the technical criteria for the proposed standards. The technical criteria are generally consistent with and supplement the recommended practices in Chapter 16 of ANSI/AAMI HE 75. The Access Board seeks to promote harmonization of its guidelines and standards with voluntary consensus standards and plans to participate in future revisions to ANSI/AAMI HE 75.

Question 1. Are there other voluntary consensus standards for medical diagnostic equipment that address accessibility for patients with disabilities, or are considering addressing accessibility for patients with disabilities in future revisions to the standards?

H. Barriers Affecting Accessibility and Usability of Medical Diagnostic Equipment

The Rehabilitation Engineering Research Center on Accessible Medical Instrumentation conducted a national survey in 2004 to collect information on the types of medical equipment that is most difficult for individuals with disabilities to access and use.[9] The survey was completed by a diverse sample of individuals with a wide range of

[9] The results of the survey are reported in Jill M. Winters, Molly Follette Story, Kris Barnekow, June Isaacson Kailes, Brenda Premo, Erin Schier, Sarma Danturthi, and Jack M. Winters, "Results of a National Survey on Accessibility of Medical Instrumentation for Consumers," in "Medical Instrumentation

disabilities, including mobility disabilities and sensory disabilities. Survey respondents who had experience with specific medical equipment rated their degree of difficulty when attempting to access or use the equipment as follows:

- 75 percent rated examination tables as moderately difficult to impossible to use;
- 68 percent rated radiology equipment as moderately difficult to impossible to use;
- 53 percent rated weight scales as moderately difficult to impossible to use; and
- 50 percent rated examination chairs as moderately difficult to impossible to use.

Survey respondents reported difficulties with getting on and off the equipment, positioning their bodies on the equipment, physical comfort and safety, and communication issues.

A subsequent study that involved focus group sessions of individuals with diverse disabilities provided additional information on barriers that affect the accessibility and usability of examination tables, examination chairs, imaging equipment, and weight scales.[10] The equipment characteristics that the focus group participants identified as affecting their ability to access and use the equipment included the dimensions of the equipment (e.g., height, width, length), contact surfaces (e.g., stiffness, comfort, color

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Accessibility and Usability Considerations," edited by Jack M. Winters and Molly Follette Story (Boca Raton, CRC Press, 2007), 13-27.

[10] The results of the focus group sessions are reported in Molly Follette Story, Erin Schwier, and June Isaacson Kailes, "Perspectives of Patients with Disabilities on the Accessibility of Medical Equipment: Examination Tables, Imaging Equipment, Medical Chairs, and Weight Scales," Disability and Health Journal 2 (2009), 169-179.

contrast), supports for transferring onto and off of equipment and positioning their bodies on the equipment (e.g., handholds, armrests, side rails), controls (e.g., ease of operation), and displays and devices (e.g., legibility, understandability).

The Access Board held a public meeting in July 2010 that featured panel discussions and presentations by experts and researchers on medical equipment accessibility, health care providers, medical device manufacturers, and other interested parties to provide information for developing the proposed standards. The transcript of the meeting is available at: http://www.access-board.gov/medical-equipment.htm.

The technical criteria in the proposed standards address most of the barriers that have been identified as affecting the accessibility and usability of medical diagnostic equipment. However, it is not possible to address every barrier in the proposed standards, especially given the statutory deadline for issuing the standards. Research may be needed on some equipment characteristics that affect the accessibility and usability of equipment such as stiffness, comfort, and color contrast of contact surfaces. Section 510 of the Rehabilitation Act requires the Access Board to periodically review and amend the standards, as appropriate. The Access Board will address other barriers in future updates to the standards.

Question 2. What other barriers that affect the accessibility and usability of medical diagnostic equipment should be addressed in future updates to the standards? Comments should include information on sources to support the development of technical criteria to address the barriers, where possible.

4. Organization of Technical Criteria

Medical diagnostic equipment is typically designed to support patients in certain positions. For example, imaging equipment can be designed for use by patients lying on a platform bed, in a standing or seated position, or seated in a wheelchair. Examination chairs can be designed to recline and be used as examination tables. The technical criteria for providing patients with disabilities access to and use of each of these equipment types would differ based on the patient positions that the equipment is designed to support. Therefore, the technical criteria in the proposed standards are organized functionally by the patient positions that the equipment is designed to support instead of by types of equipment. Where equipment is designed to support more than one patient position, the equipment would have to meet the technical criteria for each position supported.

The table below shows the four basic patient positions that medical diagnostic equipment can be designed to support; the equipment features that are addressed in the technical criteria for each of the patient positions; and the types of equipment to which the technical criteria apply for each of the patient positions. For example, X-ray equipment that is designed for use in a standing position for certain procedures would have to meet the technical criteria for slip resistant standing surface and standing supports for patients who use mobility aids such as canes or crutches, or who have limited stamina or other conditions that affect their ability to maintain balance. Mammography equipment that is designed for use by patients seated in a wheelchair would have to meet the technical criteria for wheelchair spaces, changes in level at entry to the wheelchair space, and height of the breast platform. The types of equipment listed in the last column

of the table are meant to be illustrative. The technical criteria apply to any type of medical diagnostic equipment that is designed to support the patient positions indicated.

Patient Positions Equipment Designed to Support	**Equipment Features Addressed in Technical Criteria**	**Types Of Equipment To Which Technical Criteria Applies**
Supine, prone, or side-lying position (M301)	Transfer surface, including height, size, and transfer sides Transfer supports, stirrups, and head and back support Lift compatibility	Examination tables Imaging equipment designed for use with platform beds Examination chairs designed to recline and be used as examination tables
Seated position (M302)	Transfer surface, including height, size, and transfer sides Transfer supports, armrests, and head and back support Lift compatibility	Examination chairs Imaging equipment designed for use with a seat Weight scales designed for use with a seat
Seated in a wheelchair (M303)	Wheelchair space, including orientation, width, depth, knee and toe clearance, and surface slope Changes in level at entry to wheelchair space, including ramps Components capable of examining body parts of patients seated in a wheelchair, including height of breast platforms	Imaging equipment designed for wheelchair use Weight scales designed for wheelchair use
Standing position (M304)	Slip resistant standing surface Standing supports	Imaging equipment designed for use in standing position Weight scales designed for use in standing position

The proposed standards also include technical criteria for supports (see M305), for instructions or other information communicated to patients through the equipment (see M306), and for operable parts used by patients (see M307).

Question 3. In organizing the technical criteria functionally by the patient positions that medical diagnostic equipment is designed to support, is it clear which technical criteria apply to different types of equipment? If not, how should the technical criteria be organized so it is clear which technical criteria apply to different types of equipment?

5. Discussion of Proposed Standards

The proposed standards consist of three chapters. Chapter M1 addresses the application and administration of the proposed standards. Chapter M2 addresses scoping. Chapter M3 contains the technical criteria. The sections in each chapter are discussed below. Although the standards do not impose any mandatory requirements on health care providers or medical device manufacturers, the standards use mandatory language (i.e., shall) because other agencies, referred to as an enforcing authority in the standards, may issue regulations or adopt policies that require health care providers subject to their jurisdiction to acquire accessible medical diagnostic equipment that conforms to the standards. Sections marked as advisory provide guidance on the standards and are not mandatory.

The Access Board is committed to writing standards that are clear, concise, and easy to understand so that persons who use the standards know what is required.

Question 4. Is there language in the proposed standards that is ambiguous or not clear? Comments should identify specific language in the proposed standards that is ambiguous or not clear and, where possible, recommend alternate language that is clear.

Chapter M1 Application and Administration

M101.1 Purpose

The proposed standards contain technical criteria for medical diagnostic equipment that is accessible to and usable by patients with disabilities. The standards provide for independent access to and use of diagnostic equipment by patients with disabilities to the maximum extent possible.

M101.2 Application

As discussed above under Organization of Technical Criteria, the technical criteria are to be applied to medical diagnostic equipment based on the following patient positions that the equipment is designed to support:

- Equipment used by patients in a supine, prone, or side-lying position (see M301);
- Equipment used by patients in a seated position (see M302);
- Equipment used by patients seated in a wheelchair (see M303); and
- Equipment used by patients in a standing position (see M304).

The diagnostic equipment's labeling, instructions, and promotional material usually identify the patient positions that the equipment is designed to support. Where diagnostic equipment is designed to support more than one patient position, the technical criteria for each patient position supported are to be applied to the equipment. Advisory

M101.2 includes examples of diagnostic equipment designed to support more than one patient position and the technical criteria that apply to the equipment.

M101.3 Equivalent Facilitation

The use of alternative designs and technologies that result in substantially equivalent or greater accessibility than specified in the proposed standards is permitted. Generally, alternative designs or technologies that rely on assisted transfer only (e.g., use of a patient lift) are not permitted because they do not provide for independent access to and use of diagnostic equipment by patients with disabilities to the maximum extent possible. However, the standards include technical criteria for clearance in or around the base of the equipment for lift compatibility to allow the use of a patient lift by patients with disabilities for whom independent transfer may not be possible, and the use of alternative designs or technologies for lift compatibility is permitted.

M101.4 Dimensions

The standards are based on adult dimensions and anthropometrics. Dimensions that are not stated as "maximum" or "minimum" are absolute.

M101.5 Dimensional Tolerances

Dimensions are subject to conventional industry tolerances for manufacturing processes, material properties, and field conditions.

Question 5. What information or resources are available concerning conventional industry tolerances for manufactured equipment such as medical diagnostic equipment?

M102.1 Defined Terms

The following terms are defined in the proposed standards: Enforcing authority, medical diagnostic equipment, operable parts, and transfer surface.

The definition of medical diagnostic equipment is based on Section 510 of the Rehabilitation Act and means equipment used in or in conjunction with medical settings by health care providers for diagnostic purposes. For convenience purposes, the shorter term diagnostic equipment is used in place of medical diagnostic equipment after that term is first used in the standards. Examination tables, examination chairs, weight scales, mammography equipment, and other imaging equipment are examples of diagnostic equipment to which the standards apply.

The definitions of enforcing authority, transfer surface, and operable parts are discussed respectively under M201.1; M301.2 and M302.2; and M307.

Question 6. Should other terms in the proposed standards be defined? Comments should identify specific terms in the proposed standards that should be defined and, where possible, recommend definitions.

M102.2 Undefined Terms

Collegiate dictionaries are used to define terms that are not defined in the proposed standards or in regulations or policies issued by the enforcing authority.

M102.3 Interchangeability

Singular and plural words, terms, and phrases are used interchangeably.

Chapter M2 Scoping

M201.1 Enforcing Authority

The proposed standards do not include scoping requirements that specify the minimum number of types of accessible diagnostic equipment required in different types of health care facilities because Section 510 of the Rehabilitation Act authorizes the Access Board to issue only technical criteria. Other agencies, referred to as an enforcing

authority in the standards (see defined terms in M102.1), may adopt the standards as mandatory requirements for entities subject to their jurisdiction. An enforcing authority can be a federal, state, or local government agency that enforces laws prohibiting discrimination on the basis of disability, or regulates health care facilities. As discussed above under Department of Justice Activities Related to Health Care Providers and Medical Equipment, DOJ issued an ANPRM in July 2010 announcing that it was considering amending its regulations implementing Titles II and III of the ADA to specifically require health care providers to acquire accessible medical equipment and that it would consider adopting the standards issued by the Access Board. DOJ also indicated its intention to include in its ADA regulations scoping requirements that specify the minimum number of types of accessible medical equipment required in different types of health care facilities.

Chapter M3 Technical Criteria

Chapter M3 provides technical criteria for accessible diagnostic equipment based on the patient positions that the equipment is designed to support, including equipment used by patients in a supine, prone, or side-lying position (see M301); equipment used by patients in a seated position (see M302); equipment used by patients seated in a wheelchair (see M303); and equipment used by patients in a standing position (see M304). Chapter M3 also provides technical criteria for supports (see M301.3, M302.3, M304.3, and M305); instructions and information communicated to patients though diagnostic equipment (see M306); and operable parts used by patients (see M307). The technical criteria specify measurements in inches and millimeters. The values stated in each system may not be exact equivalents, and each system should be used independently

of the other. When discussing the technical criteria below, the measurements are stated in inches only.

Figures showing example applications of the technical criteria to diagnostic equipment are available on the Access Board's web site at: http://www.access-board.gov/medical-equipment.htm. The figures are provided to help readers understand how the technical criteria apply to diagnostic equipment.

Question 7. Comments are requested on whether the figures can be improved to help readers better understand how the technical criteria apply to diagnostic equipment.

Sources for Technical Criteria

The sources discussed below were used to develop the technical criteria.

2004 ADA and ABA Accessibility Guidelines

The Access Board has developed and updated accessibility guidelines for buildings and facilities for over 30 years. The Access Board's current guidelines for buildings and facilities were issued in 2004 and are known as the Americans with Disabilities Act and Architectural Barriers Act Accessibility Guidelines (hereinafter referred to as the "2004 ADA and ABA Accessibility Guidelines"). The 2004 ADA and ABA Accessibility Guidelines are codified at 36 CFR part 1191 and are available at: http://www.access-board.gov/ada-aba/final.cfm.

The following technical criteria in the proposed standards are based on the 2004 ADA and ABA Accessibility Guidelines:

- Height of transfer surfaces on diagnostic equipment used by patients in a supine, prone, or side-lying position and diagnostic equipment used by patients in a seated position (see M301.2.1 and M302.2.1);

- Wheelchair spaces, including knee and toe clearance, and change in level at entry to the wheelchair spaces at diagnostic equipment used by patients seated in a wheelchair (see M303.2 and M303.3);
- Structural strength of transfer supports (see M305.2.2); and
- Operable parts (see M307).

The Access Board is also considering additional technical criteria based on the 2004 ADA and ABA Accessibility Guidelines for cross section dimensions and clearances around gripping surfaces on transfer and standing supports, and for reach ranges for operable parts on diagnostic equipment that are used by patients. Questions are included under the applicable sections requesting comments on whether the additional technical criteria under consideration would be appropriate for the equipment features or whether alternative technical criteria would be appropriate.

Wheeled Mobility Anthropometry Project

There have been dramatic changes in mobility devices and the characteristics of people who use these devices. The Access Board and the National Institute on Disability and Rehabilitation Research sponsored a Wheeled Mobility Anthropometry Project to collect measurements of approximately 500 people using a variety of mobility devices, including manual wheelchairs, power wheelchairs, and scooters. The Wheeled Mobility Anthropometry Project was conducted by the Center for Inclusive Design and Environmental Access. The final report on the Wheeled Mobility Anthropometry Project was issued in 2010 and is available at: http://www.udeworld.com/anthropometrics.html.

Data from the Wheeled Mobility Anthropometry Project showed that the seat heights of many mobility devices are above the range specified in the 2004 ADA and

ABA Accessibility Guidelines for certain architectural features that involve transfers and that the dimensions for wheelchair spaces, including knee and toe clearance, do not accommodate many people in the sample. Data from the Wheeled Mobility Anthropometry Project also showed that many people in the sample needed a lower operating force to activate certain operable parts. The Wheeled Mobility Anthropometry Project included recommendations for specifications that would accommodate a broader range of people who use mobility devices. The data and recommendations from the Wheeled Mobility Anthropometry Project are discussed in connection with the following technical criteria:

- Height of transfer surfaces on diagnostic equipment used by patients in a supine, prone, or side-lying position and diagnostic equipment used by patients in a seated position (see M301.2.1 and M302.2.1);
- Wheelchair spaces, including knee and toe clearance, at diagnostic equipment used by patients while seated in a wheelchair (see M303.2); and
- Operating force required to activate operable parts used by patients (see M307.4).

The Access Board is considering specifying alternative technical criteria in the final standards based on the Wheeled Mobility Anthropometry Project. Questions are included under the applicable sections requesting comments on the alternative technical criteria.

ANSI/AAMI HE 75

As discussed in the relevant sections below, the Access Board considered the recommended practices regarding accessibility in Chapter 16 of ANSI/AAMI HE 75 in

developing the technical criteria. The technical criteria are generally consistent with and supplement the recommended practices in ANSI/AAMI HE 75.

Other Sources

The Access Board used anthropometric data and other standards for the width of transfer surfaces on diagnostic equipment used by patients in a seated position (see M302.2.2), height of breast platforms on mammography equipment used by patients seated in a wheelchair (see M303.4.1), and standing supports in a vertical position for diagnostic equipment used by patients in a standing position (see M305.3.2). The sources are referenced in the relevant sections below.

The Access Board also considered information provided at the July 2010 public meeting that featured panel discussions and presentations by experts and researchers on medical equipment accessibility, health care providers, medical device manufacturers, and other interested parties. The transcript of the meeting is available at: http://www.access-board.gov/medical-equipment.htm. In addition, the Access Board considered public comments relating to medical equipment that were submitted in response to DOJ's ANPRM on equipment and furniture. The public comments on DOJ's ANPRM on equipment and furniture are available at http://www.regulations.gov (Docket ID: DOJ-CRT-2010-0008).

Economic and Technical Impacts

The technical criteria in Chapter 3 address the features that make diagnostic equipment accessible to and usable by patients with disabilities. Comments are requested on the economic and technical impacts of the technical criteria in questions that follow the discussion of the technical criteria. Comments are welcomed from all sources.

Manufacturers that currently incorporate accessible features in some of their products or plan to do so in the future are encouraged to comment particularly on Questions 8, 9, and 10. The Access Board will use the information provided in response to the questions to evaluate the economic and technical impacts of the technical criteria.

Question 8. To what extent does diagnostic equipment currently incorporate features that conform to the technical criteria proposed in Chapter M3? If equipment conforms to some but not all of the technical criteria proposed in Chapter M3, the comments should identify which features conform to the technical criteria proposed in Chapter M3.

Question 9. If diagnostic equipment does not currently incorporate features that conform to all the technical criteria proposed in Chapter M3, which technical criteria can be easily incorporated into the design or redesign and manufacture of equipment with little difficulty or expense? Which technical criteria would have the greatest incremental costs on the design or redesign and manufacture of equipment? Comments should include estimates of the incremental costs, where possible.

Question10. How often is diagnostic equipment redesigned? Would incorporating features that conform to the technical criteria proposed in Chapter M3 in the planned redesign of equipment lessen the economic and technical impacts?

Question 11. Are there types of diagnostic equipment that cannot conform to certain technical criteria proposed in Chapter M3 because of the structural or operational characteristics of the equipment? Comments should identify the specific technical criteria which the equipment cannot conform to and discuss alternative methods for making the equipment accessible to patients with disabilities.

Question 12. Do the technical criteria proposed in Chapter M3 have any positive or negative unintended consequences?

M301 Diagnostic Equipment Used by Patients in Supine, Prone, or Side-Lying Position

M302 Diagnostic Equipment Used by Patients in Seated Position

M301 provides technical criteria for diagnostic equipment used by patients in a supine, prone, or side-lying position, and M302 provides technical criteria for diagnostic equipment used by patients in a seated position. The purpose of these sections is to facilitate independent transfer onto and off of diagnostic equipment by patients with disabilities, including those who use mobility devices or aids, and to provide supports for patients with disabilities when positioning their bodies on the equipment. The sections also include provisions for clearance in and around the base of the equipment for lift compatibility to allow the use of a patient lift by patients with disabilities for whom independent transfer may not be possible. Except for the size of the transfer surface (see M301.2.2 and M302.2.2) and certain supports (see M301.3.2 for stirrups, and M302.3.2 for armrests), the technical criteria in these sections are the same and are discussed together below. The technical criteria for transfer surface size and for stirrups and armrests are discussed separately for diagnostic equipment used by patients in a supine, prone, or side-lying position and for diagnostic equipment used by patients in a seated position.

Transfer Surface (M301.2 and M302.2)

The technical criteria in M301.2 and M302.2 address the height and size of the transfer surface, and the transfer sides. The transfer surface is the part of the diagnostic equipment onto which patients who use mobility devices or aids transfer when moving

onto and off of the equipment (see defined terms in M102.1). Depending on the configuration of the equipment, the transfer surface may coincide with the seat area of an examination chair, or occupy only a portion of an examination table or imaging bed platform. The technical criteria do not address the overall width and depth of patient support surfaces because of the diverse shape and size of these surfaces.

Transfer Surface Height (M301.2.1 and M302.2.1)

For many patients who use mobility devices, independent transfer is possible only if the height of the transfer surface is at or near the seat height of their mobility device. The transfer surface height is also critical for patients who use mobility aids such as walkers and canes and may find it difficult to get up onto or down from an examination chair or table or imaging bed platform, and for facilitating assisted transfers.

M301.2.1 and M302.2.1 would require the height of the transfer surface during patient transfer to be 17 inches minimum and 19 inches maximum measured from the floor to the top of the transfer surface. This height range is based on provisions in the 2004 ADA and ABA Accessibility Guidelines for architectural features that involve transfers (e.g., toilet seats, shower seats, dressing benches). Patient support surfaces can be adjusted to heights outside the specified dimensions when not needed for patient transfer such as when performing diagnostic procedures.

Where patient support surfaces are contoured or upholstered for patient comfort or to support patient positioning during diagnostic procedures, the height of the transfer surface measured from the floor may vary across the transfer surface. The highest and lowest points of the transfer surface on such equipment would have to be within the specified dimensions.

Where patient support surfaces are cushioned (e.g., polyurethane on top of cell foam), the upholstery may compress or deflect during use. If the height of the transfer surface is measured from the floor to the rigid platform under the cushion, the top of the upholstery may be outside the specified dimensions. Measuring the height of the transfer surface from the floor to the top of the upholstery under static conditions, without compression or deflection in the transfer surface, would provide a consistent method of measurement given the variety of materials used to cushion patient support surfaces and the differences in how the materials compress or deflect during use.

Question 13. Should the technical criteria specify that the height of the transfer surface from the floor be measured to the top of the upholstery under static conditions, without compression or deflection in the transfer surface? Or should the technical criteria allow for more dynamic conditions and limit the amount of deflection permitted when a specific load is applied to the transfer surface?

Adjustable Height Range Considered

The technical criteria allow the height of transfer surfaces to be either fixed or adjustable within the 17 inches minimum and 19 inches maximum range. Based on the information discussed below, the Access Board is considering requiring in the final standards that the height of transfer surfaces be adjustable from 17 inches minimum to 25 inches maximum during patient transfer. Patient support surfaces can be adjusted outside this range when not needed for patient transfer such as when performing diagnostic procedures

Many types of diagnostic equipment used by patients in a supine, prone, or side-lying position, and diagnostic equipment used by patients in a seated position currently

provide adjustable height patient support surfaces. ANSI/AAMI HE75 recommends that the height of patient support surfaces "should be easy to adjust (ideally, powered) to suit the needs of health care professionals and patients." ANSI/AAMI HE75 further recommends that the height of patient support surfaces "should be adjustable to a position high enough to accommodate tall health care providers and the range of medical procedures that could occur . . . [and] to a position low enough [19 inches maximum] to allow for the comfort of providers who choose to work in a seated position, to enable patients to keep their feet on the floor while seated, and to accommodate patients who need to transfer laterally between the platform and a chair or wheelchair alongside." See ANSI/AAMI HE 75, section 16.4.4.

Transfer surfaces that are adjustable to the same heights as the seat heights of mobility devices reduce the effort needed to transfer since patients do not have to lift their body weight to make up the difference between the two surfaces, in one direction or the other. The Wheeled Mobility Anthropometry Project shows the occupied seat heights for people who use mobility devices vary considerably. See Analysis of Seat Heights for Wheeled Mobility Devices at: http://udeworld.com/analysis-of-seat-height-for-wheeled-mobility-devices. The seat heights ranged from 16.3 inches to 23.9 inches for manual wheelchair users; 16.2 inches to 28.9 inches for power wheelchair users; and 18.8 inches to 25.3 inches for scooter users. Seat heights for males were typically higher than for females. Thirty (30) percent of male manual wheelchair users and 6 percent of male power wheelchair users had seat heights equal to or less than 19 inches. All the male manual wheelchair users and 92 percent of the male power wheelchair users had seat heights equal to or less than 25 inches. Thus, transfer surfaces that are adjustable from 17

inches minimum to 25 inches maximum during patient transfer accommodate significantly more patients who use mobility devices.

Ideally, transfer surfaces should be adjustable to any height within the 17 inches minimum and 25 inches maximum range. However, intermediate heights may need to be established within the range because of different methods for providing adjustability (e.g., power, mechanical) or other equipment limitations. The distance between the intermediate heights should be small.

Question 14. Comments are requested on the following questions regarding the adjustable height range (17 inches minimum to 25 inches maximum during patient transfer) that the Access Board is considering requiring in the final standards for transfer surfaces on diagnostic equipment used by patients in a supine, prone, or side-lying position, and diagnostic equipment used by patients in a seated position:

a) What types of equipment currently provide patient support surfaces that are height adjustable? If there are several models of the same type of equipment, does at least one model provide patient support surfaces that are height adjustable? What is the range of adjustable heights? If the range of adjustable heights does not include 17 inches to 25 inches, what would be the incremental costs to achieve this range?

b) What types of equipment do not currently provide patient support surfaces that are height adjustable? What would be the incremental costs for the design or redesign and manufacture of the equipment to provide patient support surfaces that are height adjustable within the above range?

c) Are there types of equipment that cannot provide patient support surfaces that are height adjustable within the above range because of the structural or operational characteristics of the equipment? Comments should discuss alternative methods for making the equipment accessible to patients with disabilities.

d) Should intermediate heights be established within the above range? What intermediate heights within the above range would be appropriate to facilitate independent transfer by patients who use mobility devices and aids?

Transfer Surface Size: Equipment Used by Patients in Supine, Prone, or Side-Lying Position (M301.2.2)

As noted earlier, the technical criteria do not address the overall width and depth of patient support surfaces because of the diverse shape and size of these surfaces. ANSI/AAMI HE75 recommends that patient support surfaces "should allow patients to transfer themselves on and off safely and easily and to assume and maintain positions safely and comfortably." For surfaces on which patients lie down, ANSI/AAMI HE75 recommends that "patients should be able to roll to a side or prone position with minimal need to lift or shift their center of gravity." ANSI/AAMI HE75 notes that a standard examination table is 27 inches wide and a bariatric table is approximately 30 to 32 inches wide and recommends wider surfaces to make repositioning easier. See ANSI/AAMI HE 75, section 16.4.7.

On diagnostic equipment used by patients in a supine, prone, or side-lying position, M301.2.2 would require the size of the transfer surface (i.e., part of the diagnostic equipment onto which patients who use mobility devices or aids transfer when

moving onto and off of the equipment) to be 30 inches wide minimum and 15 inches deep minimum. The 30 inches minimum width is based on comments submitted by the Disability Rights Education and Defense Fund (DREDF) regarding medical equipment dimensions in response to DOJ's ANPRM on equipment and furniture. The 30 inches minimum width and 15 inches minimum depth also are generally consistent with the dimensions specified in the 2004 ADA and ABA Accessibility Guidelines for rectangular seats in roll-in showers.

The transfer surface dimensions do not include headrests, footrests, or similar supports for body extremities that do not support the patient's overall body position. A transfer surface is permitted to be contoured; however, the minimum dimensions would have to fit within the contoured surface and cannot be reduced to accommodate an asymmetrical shape.

As discussed under the technical criteria for transfer sides (see M301.2.3 and M302.2.3), the transfer surface would be located at a corner of the diagnostic equipment (e.g., foot of an examination table) to allow different approaches to the surface and a variety of transfers. The Access Board is considering requiring in the final standards that transfer surfaces be provided at more than one location on diagnostic equipment used by patients in a supine, prone, or side-lying position to accommodate the different ways patients with disabilities may transfer and reposition their bodies from a sitting to a lying position on such equipment.

Question 15. Comments are requested on the following questions regarding the minimum dimensions (30 inches wide and 15 inches deep) proposed for the transfer surface on diagnostic equipment used by patients in a supine, prone, or side-lying

position and whether transfer surfaces should be provided at more than one location on such equipment:

a) Do the above dimensions provide sufficient space for patients with disabilities to safely and easily transfer to the equipment?

b) Should the width of the patient support surface be at least as wide as the width of the transfer surface (30 inches minimum) to allow patients with disabilities to reposition their bodies to a lying down position and maintain positions safely and comfortably? What would be the incremental costs for the design or redesign and manufacture of the equipment to make the patient support surface at least as wide as the width of the transfer surface?

c) Would alternative dimensions be appropriate for transfer surfaces? Comments should include information on sources to support alternative dimensions, where possible.

d) Should an adjustable feature (e.g., extendable platform) be permitted to meet the transfer surface dimensions?

e) If transfer surfaces are required to be provided at more than one location on the equipment, where should the transfer surfaces be located?

Transfer Surface Size: Equipment Used by Patients in a Seated Position (M302.2.2)

Seats on diagnostic equipment used by patients in a seated position typically provide back and arm support for patient comfort and stability. The space available for transfer on diagnostic equipment used by patients in a seated position is smaller than the space available on diagnostic equipment used by patients in a supine, prone, or side-lying position.

On diagnostic equipment used by patients in a seated position, M302.2.2 would require the size of the transfer surface to be 21 inches wide minimum and 15 inches deep minimum. The 21 inches minimum width is based on the ideal chair width recommended in Architectural Graphic Standards for auditorium seating. See The American Institute of Architects, Architectural Graphic Standards (10^{th} edition, 2000), page 919. The 15 inches minimum depth is generally consistent with the dimension specified in the 2004 ADA and ABA Accessibility Guidelines for rectangular seats in roll-in showers.

The transfer surface dimensions do not include headrests, footrests, or similar supports for body extremities that do not support the patient's overall body position. A transfer surface is permitted to be contoured; however, the minimum dimensions would have to fit within the contoured surface and cannot be reduced to accommodate an asymmetrical shape.

Question 16. Comments are requested on the following questions regarding the minimum dimensions (21 inches wide and 15 inches deep) proposed for the transfer surface on diagnostic equipment used by patients in a seated position:

a) Do the above dimensions provide sufficient space for patients with disabilities to safely and easily transfer to the equipment?

b) Would alternative dimensions be appropriate for transfer surfaces? Comments should include information on sources to support alternative dimensions, where possible.

Transfer Sides (M301.2.3 and M302.2.3)

M301.2.3 and M302.2.3 would require the transfer surface to be located so as to provide patients who use mobility devices the option to transfer onto the short side and

the long side of the surface, and that each transfer side provide unobstructed access to the transfer surface. These sections would result in the transfer surface being located at a corner of the equipment and the two transfer sides adjoining at the edges of the equipment (e.g., foot of an examination table). Patients who use mobility devices would have the choice to approach parallel to the deep dimension of the transfer surface, parallel to the wide dimension of the transfer surface, or at an angle to the corner of the transfer surface and be able to perform a variety of transfers. Locating the transfer surface at a corner of the equipment and providing unobstructed access to the two transfer sides also would facilitate assisted transfers. Enforcing authorities may specify the clear floor space to be provided adjacent to the transfer sides of equipment in health care facilities.

The transfer sides are permitted to be obstructed temporarily by features such as armrests, side rails, footrests, and stirrups provided they can be repositioned (e.g., folding armrests, removable side rails, retractable footrests and stirrups) to permit transfer. This is consistent with ANSI/AAMI HE 75 which recommends that "side rails, arm rests, leg supports . . . should be positioned, or able to be moved out of the way, so as not to interfere with the ability of users to transfer." See ANSI/AAMI HE 75, section 16.4.5. Otherwise, no part of the equipment can project beyond the edge of the transfer sides and obstruct access to the transfer surface. This is consistent with ANSI/AAMI HE 75 which recommends that the "base of any patient-support platform should not extend horizontally beyond the edge of the support surface . . . [and] should not impede a patient's ability to orient a wheelchair next to the support surface." See ANSI/AAMI HE 75, section 16.4.2.

The Access Board is considering whether the final standards should permit equipment parts to extend horizontally 3 inches maximum beyond the edge of the transfer sides provided they do not extend above the top of the transfer surface. This would allow handholds and other features which may facilitate transfer to be located on the transfer sides. The 2004 ADA and ABA Accessibility Guidelines provide a gap of 3 inches between the edge of a shower seat and the shower compartment entry, and the gap does not appear to interfere with transferring onto and off of the shower seat.

Question 17. Comments are requested on the following questions regarding obstructions on the transfer sides:

a) Should equipment parts be permitted to extend horizontally 3 inches maximum beyond the edge of the transfer sides provided they do not extend above the top of the transfer surface?

b) If equipment parts are not permitted to extend horizontally 3 inches maximum beyond the edge of the transfer sides, would any diagnostic equipment need to be redesigned?

Supports (M301.3, M302.3, and M305.2)

ANSI/AAMI HE 75 recommends that handholds be "integrated into the device . . . [to] increase safety and assist patients in transferring on and off, positioning or repositioning their bodies, and maintaining static position." See ANSI/AAMI HE 75, section 16.4.6. M301.3, M302.3, and M305.2 provide technical criteria for transfer and positioning supports on diagnostic equipment used by patients in a supine, prone, or side-lying position, and diagnostic equipment used by patients in a seated position. Some supports such as armrests and side rails can be used for transferring and positioning. As

discussed under M301.2.3 and M302.2.3, transfer and positioning supports on the transfer sides of transfer surfaces would have to be capable of being repositioned (e.g., folding armrests, removable side rails, retractable footrests and stirrups) to permit transfer.

Transfer Supports (M301.3.1, M302.3.1, and M305.2)

M301.3.1 and M302.3.1 would require transfer supports to be provided for use with the transfer sides. M305.2.1 would require the transfer supports to be located within reach of the transfer surface and not obstruct transfer onto the surface when in position. M305.2.2 would require the transfer supports and their connections to be capable of resisting vertical and horizontal forces of 250 pounds applied to all points of the transfer support. M305.2.3 would require the transfer supports to not rotate within their fittings. These technical criteria are based on provisions in the 2004 ADA and ABA Accessibility Guidelines for grab bars.

Question 18. Comments are requested on the following questions regarding the structural strength of transfer supports:

a) Are transfer supports that can be repositioned (e.g., folding armrests, removable side rails) currently capable of resisting vertical and horizontal forces of 250 pounds applied to all points of the transfer support? If the transfer supports are not currently capable of resisting these forces, what would be the incremental costs for the design or redesign and manufacture of the equipment to provide transfer supports that are capable of resisting these forces?

b) Would alternative technical criteria be appropriate for the structural strength of transfer supports? Comments should include information on sources to support the alternative technical criteria, where possible.

Additional Technical Criteria Considered for Transfer Supports

As discussed below, the Access Board is considering whether additional technical criteria would be appropriate for transfer supports.

Location and Size

Midmark Corporation provided information based on input from accessibility experts regarding side rails on examination tables in comments submitted in response to the DOJ's ANPRM on equipment and furniture. The side rails are similar in shape to grab bars and are located on each of the long sides of the table. Each side rail can be removed to permit patients to transfer onto and off of the table, and to permit health care personnel to perform diagnostic procedures. The side rails can also be relocated along the table surface (from foot-end to head-end) for patients to position or reposition their bodies, and to maintain static positions. The side rails are 20 inches minimum in length, 6 inches minimum in height above the table surface, and 1 inch measured horizontally from the adjacent edge of the table surface.

The Access Board is considering whether the following technical criteria would be appropriate for the location and size of transfer supports on diagnostic equipment used by patients in a supine, prone, or side-lying position, and diagnostic equipment used by patients in a seated position:

- At least one transfer support would be provided on the side of the transfer surface that is 15 inches deep minimum. The transfer support would be

located on the side of the transfer surface that is opposite the transfer side (see M301.2.3 and M302.2.3) similar to the provisions in the 2004 ADA and ABA Accessibility Guidelines for grab bars provided at bathtubs and shower compartments with seats. This would be a minimum requirement. Where possible, it is recommended that supports be provided on each side of the transfer surface that is 15 inches deep minimum for patients to maintain position after they have transferred onto the equipment, and that the supports be repositionable to permit transfer.

- The transfer support would extend horizontally the entire depth of the transfer surface and would be 15 inches minimum in length.
- The gripping surface of the transfer support would be located 1½ inches maximum measured horizontally from the adjacent edge of the transfer surface. This would ensure that the transfer support is within reach and can be effectively used during transfers.

The above technical criteria would likely result in the transfer surface being located at the foot end of examination tables and allow the use of transfer supports similar to the side rails described in the information provided by Midmark Corporation.

Question 19. Comments are requested on the following questions regarding the above technical criteria for the location and size of transfer supports on diagnostic equipment used by patients in a supine, prone, or side-lying position, and diagnostic equipment used by patients in a seated position:

a) Are the above technical criteria for the location and size of transfer supports sufficient to facilitate transfer and maintain position on the equipment?

b) Can transfer supports on different types of equipment meet the above technical criteria for the location and size of the supports?

c) What would be the incremental costs for the design or redesign and manufacture of transfer supports that meet the above criteria?

d) Would alternative technical criteria be appropriate for the location and size of transfer supports? Comments should include information on sources to support the alternative technical criteria, where possible.

e) Should angled or vertical transfer supports be permitted?

Height

The Access Board is considering whether 6 inches minimum and 19 inches maximum above the transfer surface would be an appropriate height for transfer supports on diagnostic equipment used by patients in a supine, prone, or side-lying position, and diagnostic equipment used by patients in a seated position. The minimum height is consistent with the information provided by Midmark Corporation on examination table side rails, and the maximum height is generally consistent with the height of grab bars above shower seats in the 2004 ADA and ABA Accessibility Guidelines.

Question 20. Comments are requested on the following questions regarding the above height range (6 inches minimum and 19 inches maximum above the transfer surface) for transfer supports on diagnostic equipment used by patients in a supine, prone or side-lying position, and diagnostic equipment used by patients in a seated position:

a) Are transfer supports within the above height range usable by patients with disabilities?

b) Can transfer supports on different types of equipment meet the above height range?

c) Would alternative technical criteria be appropriate for the height of transfer supports? Comments should include information on sources to support the alternative technical criteria, where possible.

Cross Section of Gripping Surfaces

The 2004 ADA and ABA Accessibility Guidelines specify the following dimensions for grab bars to enable individuals with disabilities to firmly grasp the grab bars and support themselves during transfers:

- Grab bars with circular cross sections must have an outside diameter of 1¼ inches minimum and 2 inches maximum.
- Grab bars with non-circular cross sections must have a cross section dimension of 2 inches maximum and a perimeter dimension of 4 inches minimum and 4.8 inches maximum.

The Access Board is considering whether the above cross section dimensions would be appropriate for the gripping surfaces of transfer supports on diagnostic equipment used by patients in a supine, prone, or side-lying position, and diagnostic equipment used by patients in a seated position.

Question 21. Comments are requested on the following questions regarding the above cross section dimensions for the gripping surfaces of transfer supports on diagnostic equipment used by patients in a supine, prone, or side-lying position, and diagnostic equipment used by patients in a seated position:

a) Can the gripping surfaces of transfer supports on different types of equipment meet the above cross section dimensions?

b) Can handholds that meet the above cross section dimensions be integrated into the design of armrests that are cushioned to support arms and elbows?

c) Are there alternative designs for the gripping surfaces of transfer supports that enable patients with disabilities to firmly grasp the supports and support themselves during transfer?

Clearances Around Gripping Surfaces

The 2004 ADA and ABA Accessibility Guidelines specify the following clearances around grab bars to ensure sufficient space for a person to grasp the grab bar: 1½ inches absolute clearance between grab bars and the adjacent wall surfaces; 1½ inches minimum clearance between grab bars and projecting objects below and at the ends of grab bars; and 12 inches minimum clearance between grab bars and projecting objects above grab bars.

The Access Board is considering whether 1½ inches minimum clearance around the gripping surface would be appropriate for transfer supports on diagnostic equipment used by patients in a supine, prone, or side-lying position, and diagnostic equipment used by patients in a seated position.

Question 22. Can transfer supports on different types of equipment provide 1½ inches minimum clearance around the gripping surface?

Stirrups (M301.3.2)

Where stirrups are provided on diagnostic equipment used by patients in a supine, prone, or side-lying position, M301.3.2 would require the stirrups to provide a method of

supporting, positioning, and securing the patient's legs. This is consistent with ANSI/AAMI HE75 which recommends that "[f]or patients with limited leg strength and control, instead of stirrups that support only the foot and require active user leg strength, leg supports that support both the foot and the leg should be used to assist patients in keeping their legs in an appropriate position." See ANSI/AAMI HE 75, section 16.4.7 (g).

Question 23. Comments are requested on the following questions regarding stirrups:

a) What would be the incremental costs for the design or redesign and manufacture of stirrups that provide a method of supporting, positioning, and securing the patient's legs?

b) Should diagnostic equipment used by patients in a seated position that provide stirrups such as urodynamics study chairs be required to provide a method of supporting, positioning, and securing the patient's legs?

Armrests (M302.3.2)

M302.3.2 would require armrests to be provided on diagnostic equipment used by patients in a seated position. This is consistent with ANSI/AAMI HE75 which recommends that "[f]or support surfaces that require the patient to assume a seated position, armrests should be provided to enhance patient comfort, stability, and ease of transfer." See ANSI/AAMI HE 75, section 16.4.7 (e). Where armrests serve as transfer supports, the armrests would be required to meet the technical criteria in M305.2 for the location and structural strength of transfer supports. Otherwise, there are no technical criteria for armrests.

Head and Back Support (M301.3.3 and M302.3.3)

Where diagnostic equipment used by patients in a supine, prone, or side-lying position, and diagnostic equipment used by patients in a seated position can be adjusted to reclined positions, M301.3.3 and M302.3.3 would require head and back support to be provided throughout the entire range of the incline. This is consistent with ANSI/AAMI HE75 which recommends that the "support surface needs to be adjustable or have adjustable support features (e.g., for the head, neck, back, lumbar region, leg, knee, and foot, as appropriate) to support patients in various postures and body positions in a manner that optimizes their comfort." See ANSI/AAMI HE 75, section 16.4.7 (h). Although not required by the proposed standards, examination tables that can be adjusted to a sitting position and then reclined to a horizontal position may be easier for patients with disabilities to transfer onto and off of than examination tables that are horizontal only.

Positioning Supports Considered

The Board is considering requiring in the final standards positioning supports such as rails, bars, or panels with handholds to be provided along the sides of diagnostic equipment used by patients in a supine, prone or side-lying position, and diagnostic equipment used by patients in a seated position that can be adjusted to a reclined position. As noted above, ANSI/AAMI recommends that handholds be "integrated into the device . . . [to] increase safety and assist patients in transferring on and off, positioning or repositioning their bodies, and maintaining static position." See ANSI/AAMI HE 75, section 16.4.6. Pillows, wedges, and other padding can be used to stabilize and position

patients on diagnostic equipment, but are not addressed in the proposed standards because they are not part of the diagnostic equipment.

Question 24. Comments are requested on the following questions regarding positioning supports along the sides of diagnostic equipment used by patients in a supine, prone or side-lying position, and diagnostic equipment used by patients in a seated position that can be adjusted to a reclined position:

a) Should the technical criteria address the configuration of positioning supports (e.g., length, height above the patient support surface, location) to ensure their effectiveness? Or should the technical criteria require that positioning supports be provided within reach and provide flexibility for designing the supports based on the intended use of the equipment?

b) What would be the incremental costs for the design or redesign and manufacture of positioning supports?

c) Are there types of equipment that cannot provide positioning supports along the sides of the equipment because of the structural or operational characteristics of the equipment? Comments should discuss alternative methods to assist patients with disabilities safely position or reposition their bodies, and maintain a static position.

Lift Compatibility (M301.4 and M302.4)

M301.4 and M302.4 would require diagnostic equipment used by patients in a supine, prone, or side-lying position, and diagnostic equipment used by patients in a seated position to be usable with a patient lift for patients with disabilities for whom independent transfer may not be possible. A patient lift may be the only means of

providing access to certain equipment that cannot meet the technical criteria for transfer surface height (see M301.2.1 and M302.2.1) because of the structural or operational characteristics of the equipment. For example, full body bone densitometers usually have components that move beneath the length of the patient support surface and may prevent the equipment from meeting the technical criteria for transfer surface height. Requiring the equipment to be usable with a patient lift is critical for ensuring the safety of both patients with disabilities and health care personnel assisting with transfers.

ANSI/AAMI HE 75 recommends that the "base of the device needs to have space underneath or along both sides (if the equipment is narrow) to accommodate the legs of portable mechanical lift equipment so that the patient can be suspended over the support surface before being lowered onto it." See ANSI/AAMI HE 75, section 16.4.3. Portable floor lifts have legs with wheels that need to fit under or around the base of the diagnostic equipment. Lifts can vary in width along their length, and are usually the widest at the front casters and narrower at the patient sling location. Manufacturers of portable floor lifts usually recommend that the lifts be used with the legs extended in the widest position to maintain stability when lifting and lowering patients.

As discussed below, the technical criteria provide two options for accommodating portable floor lifts consistent with ANSI/AAMI HE75: clearance in the base or clearance around the base. The clearances would be required at the side of the equipment where the portable floor lift is deployed so that the boom of the lift can maneuver far enough over the equipment and safely lower and raise the patient onto and off of the examination surface. The clearances do not restrict the overall size of the equipment base.

Clearance in Base (M301.4.1 and M302.4.1)

Clearance in the base of the equipment allows the legs of a portable floor lift to fit under the base of the equipment. The clearance can be an open area between the supporting posts beneath the equipment, or the equipment can be configured with a wide slot that is recessed into the base enclosure. M301.4.1 and M302.4.1 would require the clearance in the base to be 44 inches wide minimum, 6 inches high minimum measured from the floor, and 36 inches deep minimum measured from the edge of the examination surface. Where the width of the examination surface is less than 36 inches, the clearance depth would be required to extend the full width of the equipment. Equipment components are permitted to be located within 8 inches maximum of the centerline of the clearance width.

Question 25. Comments are requested on the following questions regarding the proposed dimensions for clearance in the base of the equipment to allow the use of portable floor lifts:

a) Are the proposed dimensions for clearance in the base sufficient to accommodate the various portable floor lifts used in health care facilities?

b) Do the proposed dimensions exclude certain types of lifts?

c) Should the clearance in the base be configured differently to allow additional flexibility for the use of portable floor lifts and, if so, how should it be configured?

Clearance Around Base (M301.4.2 and M302.4.2)

Clearance around the base of the equipment allows the legs of a portable floor lift to straddle the base. This option accommodates equipment with solid base enclosures that sit on or close to a floor. M301.4.2 and M302.4.2 would require the base of the

equipment to provide a clearance 6 inches high minimum measured from the floor and 36 inches deep minimum measured from the edge of the examination surface. The width of the base permitted within this clearance would be 26 inches wide maximum at the edge of the examination surface and is permitted to increase at a rate of 1 inch in width for each 3 inches in depth. The permitted rate of increase in width can be distributed to each side of the base.

Question 26. Comments are requested on the following questions regarding the proposed dimensions for clearance around the base of the equipment to allow the use of portable floor lifts:

a) Are the proposed dimensions sufficient to accommodate the various portable floor lifts used in health care facilities?

b) Do the proposed dimensions exclude certain types of lifts?

c) Should the clearance around the base be configured differently to allow additional flexibility for the use of portable floor lifts and, if so, how should it be configured?

Overhead Lifts

The technical criteria do not address overhead lifts that are usually mounted on the ceiling and operate on tracks suspended over the diagnostic equipment because the configuration of the equipment does not affect the operation of overhead lifts. Overhead lifts and portable floor lifts are used in health care facilities, and the technical criteria should not be viewed as preferring portable floor lifts. Overhead lifts may be the only option for certain diagnostic equipment because the structural or operational

characteristics of the equipment prevent sufficient clearance in or around the base of the equipment for a portable floor lift.

Question 27. If diagnostic equipment is designed for use with overhead lifts, should the equipment be exempted from providing clearance in or around the base for portable floor lifts?

Folding Seats on Equipment Used by Patients Seated in a Wheelchair (M302.4 Exception)

M302.4 includes an exception for diagnostic equipment that is designed for use by patients seated in a wheelchair and provides a folding seat. The exception does not require the equipment to comply with the technical criteria for lift compatibility because patients can use the equipment seated in a wheelchair. However, the folding seat would be required to meet the other technical criteria in M302 for transfer surfaces and supports.

Question 28. Where diagnostic equipment is designed for use by patients seated in a wheelchair and provides a folding seat, should the folding seat be required to comply with the technical criteria in M302 for transfer surfaces and supports?

M303 Diagnostic Equipment Used by Patients Seated in Wheelchair

M303 provides technical criteria for diagnostic equipment used by patients seated in a wheelchair. M303 allows patients who use wheelchairs to position their wheelchairs at equipment typically used in a standing position such as mammography equipment, and also applies to equipment specifically designed for patients seated in a wheelchair such as weight scales and examination chairs.

Wheelchair Spaces (M303.2)

M303.2 would require a wheelchair space to be provided at diagnostic equipment used by patients seated in a wheelchair. M303.2 includes technical criteria for orientation, width, depth, and knee and toe clearance at wheelchair spaces.

M303.2.1 would require wheelchair spaces to be designed so that patients seated in a wheelchair orient in the same direction that patients not seated in a wheelchair orient when using the equipment. For example, if an equipment component used to make images of body parts can be placed at different angles when used by patients who stand and by patients seated in a wheelchair, and patients who stand orient facing the component when it is in place for them, then the wheelchair space would be designed so that patients seated in a wheelchair orient facing the component when it is place for them. If the equipment is designed so that patients not seated in a wheelchair can orient their bodies in various directions when using the equipment, the wheelchair space would be designed so that patients seated in a wheelchair can orient their bodies in the same directions. For example, if patients who stand can orient their bodies facing forwards or sideways in relation to the equipment when in use, the wheelchair space would be designed so that patients seated in a wheelchair can orient their bodies facing forwards or sideways in relation to the equipment when in use (i.e., wheelchair space can be entered from both the front or rear and from the side).

M303.2.2 would require wheelchair spaces to be 36 inches (915 mm) wide minimum. This dimension is based on provisions in the 2004 ADA and ABA Accessibility Guidelines for maneuvering clearance where a clear floor or ground space is confined on all or part of three sides.

M303.2.3 would require wheelchair spaces that can be entered from the front or rear to be 48 inches deep minimum, and wheelchair spaces that can be entered only from the side to be 60 inches deep minimum. These dimensions are based on provisions in the 2004 ADA and ABA Accessibility Guidelines. The Wheeled Mobility Anthropometry Project showed that the 48 inches deep dimension for wheelchair spaces entered from the front or rear does not accommodate many people in the sample, and that increasing the depth of wheelchair spaces entered from the front or rear to 58 inches minimum would accommodate 95 percent of the people in the sample. See Final Report of the Wheeled Mobility Anthropometry Project, pages 86-88. The Access Board is considering requiring in the final standards wheelchair spaces that can be entered from the front or rear to be 58 inches deep minimum.

Question 29. Comments are requested on the following questions regarding the depth dimension (58 inches minimum) that the Access Board is considering requiring in the final standards for wheelchair spaces that can be entered from the front or rear:

a) What would be the incremental costs for the design or redesign and manufacture of the equipment to provide a wheelchair space that is 58 inches deep minimum?

b) Are there types of equipment that cannot provide a wheelchair space that is 58 inches deep minimum because of the structural or operational characteristics of the equipment?

Diagnostic equipment with wheelchair spaces on raised platforms such as weight scales typically provide low barriers or curbs on the sides of the platform that are not used for entering and exiting the equipment to prevent wheelchairs from slipping off the

platform (i.e., edge protection). The Access Board is considering requiring edge protection at wheelchair spaces on raised platforms in the final standards.

Question 30. Is there diagnostic equipment with wheelchair spaces on raised platforms that does not currently provide edge protection? If so, what would be the incremental costs to provide edge protection on such equipment?

Exceptions Considered for Wheelchair Spaces on Raised Platforms

The Access Board is considering adding exceptions in the final standards to the minimum width in M303.2.2 and the minimum depth in M303.2.3 for diagnostic equipment with wheelchair spaces on raised platforms.

The exception to the minimum width in M303.2.2 would apply where ramped surfaces are provided on the opposite sides of the raised platform so that patients using wheelchairs can enter and exit the platform facing the same direction. The exception would permit the width of the wheelchair space between the edge protection to be reduced to 32 inches wide minimum at the platform level. This dimension is based on provisions in the 2004 ADA and ABA Accessibility Guidelines that allow accessible routes, which normally must be 36 inches wide minimum, to be 32 inches wide minimum for short distances such as at door openings. The exception would require a space 36 inches wide minimum to be provided outside the perimeter of the raised platform and above any edge protection so that patients using a manual wheelchair can extend their arms and elbows when they push on the wheel rims to maneuver onto and off of the platforms.

The exception to the minimum depth in M303.2.3 for wheelchair spaces entered from the front or rear would permit a portion of the 48 inch minimum depth of the

wheelchair space that accommodates the wheelchair footrests to extend beyond the raised platform and over any edge protection. For example, the wheelchair footrests would be allowed to extend beyond the depth of the raised platform and over any edge protection on wheelchair weight scales used by patients seated in a wheelchair.

If exceptions are permitted to the minimum width and depth of wheelchair spaces on raised platforms, the technical criteria would specify the minimum and maximum height for any edge protection to prevent wheelchairs from slipping off the platform, but also allow the wheelchair footrests to extend over the edge protection where the wheelchair space extends beyond the depth of the platform.

Question 31. Comments are requested on the following questions regarding adding exceptions in the final standards to the minimum width in M303.2.2 and the minimum depth in M303.2.3 for diagnostic equipment with wheelchair spaces on raised platforms:

a) What is the typical distance between the front caster wheels of manual and power wheelchairs and the tips of the toes of the wheelchair user? How much of the 48 inch minimum depth of a wheelchair space that can be entered from the front or rear should be permitted to extend beyond the raised platform and over any edge protection? Comments should include information on sources to support the dimensions, where possible.

b) What should be the maximum height for any edge protection to allow the wheelchair footrests to extend over the edge protection where the wheelchair space extends beyond the depth of the platform? Comments should include information on sources to support the dimensions, where possible.

c) Where the equipment provides supports for patients who stand (e.g., handrails), should the exceptions prohibit the supports from obstructing the 36 inch wide minimum and 48 inch deep minimum space outside the perimeter of the raised platform and above any edge protection?

Scooters have different wheelbases than manual and power wheelchairs. Diagnostic equipment with wheelchair spaces on raised platforms should also be usable by patients who use scooters. Patients who use scooters may have other options for using equipment with wheelchair spaces on raised platforms. For example, a weight scale with a raised platform for wheelchair use may provide a folding seat and supports for patients who can transfer independently from their mobility device to the scale.

Question 32. Comments are requested on the following questions regarding diagnostic equipment with wheelchair spaces on raised platforms and the use of such equipment by patients who use scooters:

a) Is equipment with wheelchair spaces on raised platforms such as wheelchair scales currently usable by patients who use scooters?

b) If the equipment is not currently usable by patients who use scooters, should the width and depth of the raised platform be changed so that the equipment is usable by patients who use scooters? Comments should include information on sources to support the dimensions, where possible.

c) Should folding seats and supports be required on equipment with wheelchair spaces on raised platforms for patients who can transfer independently from their mobility device to the raised platform?

d) If folding seats and supports are provided on equipment with wheelchair spaces on raised platforms, should the raised platform also accommodate scooters?

Question 33. If exceptions are not permitted in the final standards to the minimum width and depth of wheelchair spaces on diagnostic equipment with raised platforms, comments are requested on the following questions:

a) What would be the incremental costs for the design or redesign and manufacture of equipment with raised platforms to provide a wheelchair space that that can be entered from the front or rear and conforms to the dimensions proposed in M303.2.2 and M303.2.3 (i.e., 36 inches wide minimum and 48 inches deep minimum)?

b) What would be the incremental costs for the design or redesign and manufacture of equipment with raised platforms to provide a wheelchair space that can be entered from the front or rear and conforms to the dimensions recommended by the Wheeled Mobility Anthropometry Project (i.e., 36 inches wide minimum and 58 inches deep minimum)?

Knee and Toe Clearance (M303.2.4)

M303.2.4 would require the depth of wheelchair spaces to include knee and toe clearance of 17 inches minimum and 25 inches maximum. Knee and toe clearance under breast platforms would be 25 inches deep. Knee and toe clearance are critical where patients seated in a wheelchair need to position their knees and toes next to or underneath a component of the diagnostic equipment. The component can be deeper than the 25 inches maximum depth required for knee and toe clearance, but a portion of the

wheelchair space would be required to include knee and toe clearance of 17 inches minimum and 25 inches maximum under the component.

The dimensions for toe clearance in M303.2.4.1 and knee clearance in M303.2.4.2 are based on the 2004 ADA and ABA Accessibility Guidelines and are shown in the second column of the table below. The Wheeled Mobility Anthropometry Project showed that these dimensions do not accommodate many people in the sample and recommended alternative dimensions that would accommodate 95 percent of the people in the sample. The alternative dimensions recommended by Wheeled Mobility Anthropometry Project are shown in the last column of the table below. See Final Report of the Wheeled Mobility Anthropometry Project, pages 89-92. The Access Board is considering requiring in the final standards the dimensions for toe clearance and knee clearance recommended by the Wheeled Mobility Anthropometry Project.

	Proposed Dimensions Based on 2004 ADA and ABA Accessibility Guidelines	**Dimensions Recommended by Wheeled Mobility Anthropometry Project**
Toe Clearance	6 inches deep maximum at 9 inches above the floor	5 inches deep maximum at 14 inches above the floor
Knee Clearance	11 inches deep minimum at 9 inches above the floor, and 8 inches deep minimum at 27 inches above the floor Between 9 inches and 27 inches above the floor, knee clearance is permitted to reduce at rate of 1 inch in depth for every 6 inches in height	12 inches deep minimum at 28 inches above the floor Knee clearance is same depth throughout and not sloped

Question 34. Comments are requested on the following questions regarding the dimensions for toe clearance and knee clearance recommended by the Wheeled Mobility

Anthropometry Project that the Access Board is considering requiring in the final standards:

a) What would be the incremental costs for the design or redesign and manufacture of the equipment to include toe clearance and knee clearance that meets the dimensions recommended by the Wheeled Mobility Anthropometry Project?

b) Are there types of equipment that cannot include toe clearance and knee clearance that meets the dimensions recommended by the Wheeled Mobility Anthropometry Project because of the structural or operational characteristics of the equipment?

M303.2.5 would require wheelchair space surfaces to not slope more than 1:48 in any direction. This is consistent with the 2004 ADA and ABA Accessibility Guidelines.

Changes in Level at Entry to Wheelchair Spaces (M303.3)

M303.3 includes technical criteria for changes in level at the entry to a wheelchair space as may occur at wheelchair weight scales with raised platforms. The technical criteria are consistent with the 2004 ADA and ABA Accessibility Guidelines. Level changes up to ¼ inch high are permitted to be vertical. Level changes between ¼ inch high and ½ inch high would be required to be beveled with a slope not steeper than 1:2. Level changes greater than ½ inch high would be required to be ramped. Ramp runs would be required to have a running slope not steeper than 1:12 and a cross slope not steeper than 1:48. The clear width of ramp runs would be required to be 36 inches minimum. Ramps with drop offs ½ inch or greater would be required to provide edge

protection 2 inches high minimum on each side to prevent users from inadvertently travelling off the sides of the ramped surface.

Additional Technical Criteria Considered for Handrails on Ramps

M303.3.3.5 would require handrails to be provided on each side of the ramp when the vertical rise of the ramp exceeds 6 inches. This is consistent with the 2004 ADA and ABA Accessibility Guidelines. The Access Board is considering whether the technical criteria for handrails on ramps in section 505 of the 2004 ADA and ABA Accessibility Guidelines would be appropriate for handrails on diagnostic equipment ramps. These technical criteria are available at http://www.access-board.gov/ada-aba/final.cfm#a505 and address continuity, height, clearance, gripping surface, cross section, surfaces, fittings, and handrail extensions.

Question 35. Comments are requested on the following questions regarding the technical criteria for handrails in section 505 of the 2004 ADA and ABA Accessibility Guidelines:

a) Can handrails on diagnostic equipment ramps meet these technical criteria?

b) What would be the incremental costs for the design or redesign and manufacture of the equipment to provide handrails on diagnostic equipment ramps that conform to these technical criteria?

Components (M303.4)

M303.4 would require the components of diagnostic equipment used to examine specific body parts to be capable of examining the body parts of a patient seated in a wheelchair. The height of the component and any adjustable feature would have to accommodate patients seated in a wheelchair. For example, an X-ray platform on which

a patient places their arm or hand would have to be capable of examining the arm or hand of a patient seated in a wheelchair.

Mammography equipment was the subject of considerable discussion at the public meeting held by the Access Board in July 2010. The discussion highlighted the need for mammography equipment that is accessible to patients seated in a wheelchair. In addition to providing knee and toe clearance at the breast platform (see M303.2.4), the height of the breast platform was identified as critical to ensuring that mammography equipment is accessible to patients seated in a wheelchair. Mammography equipment with adjustable breast platforms is available. M303.4.1 would require the height of the breast platform to be 30 inches (760 mm) high minimum and 42 inches (1065 mm) high maximum above the floor when mammography equipment is used by patients seated in a wheelchair. The Wheeled Mobility Anthropometry Project showed that the seat heights of 96 percent of women using manual wheelchairs and 98 percent of women using power wheelchairs in the sample was between 17 inches and 24 inches above the floor. See Analysis of Seat Heights for Wheeled Mobility Devices at: http://udeworld.com/analysis-of-seat-height-for-wheeled-mobility-devices. Other anthropometric data show the heights of the midpoint of the breast to be 13 inches for the 5th percentile woman and 18 inches for the 95th percentile woman when measured from seat height. See Laura Peebles and Beverley Norris, Adultdata: The Handbook of Adult Anthropometric and Strength Measurements: Data for Design Safety (London, Department of Trade and Industry, 1998), page 71. The proposed height range for the breast platform is based on the above anthropometric data. Breast platforms can be located outside the proposed height range when not used by patients seated in a wheelchair.

Question 36. Comments are requested on the following questions regarding breast platforms:

a) Is the proposed height range for the breast platform (30 inches high minimum and 42 inches high maximum above the floor) sufficient to accommodate patients seated in a wheelchair?

b) Are there other features of the breast platform that the technical criteria should address to ensure accessibility and, if so, how should they be addressed? Comments should include information on sources to support the technical criteria for the features, where possible.

M304 Diagnostic Equipment Used by Patients in Standing Position

M304 provides technical criteria for diagnostic equipment used by patients in a standing position such as a weight scale and X-ray equipment that is used in a standing position for certain diagnostic procedures. M304.2 and M304.3 would require a slip resistant standing surface and standing supports to accommodate patients with mobility disabilities who ambulate, patients who have limited stamina, and patients who have other conditions that affect their ability to maintain the balance needed to position themselves on the equipment or to maintain a standing posture at an equipment component.

The proposed standards do not require diagnostic equipment to support more than one position. Where possible, it is recommended that diagnostic equipment be usable by patients with disabilities in as many positions as possible (i.e., standing position, seated position, and seated in a wheelchair). For example, mammography equipment with adjustable breast plates can be used by patients with disabilities in a standing position

where standing supports are provided, in a seated position where a folding or removable seat is provided, and seated in a wheelchair where a wheelchair space is provided. A weight scale with a wheelchair space and ramped entry also can be used by patients with disabilities in a standing position where standing supports are provided and in a seated position where a folding or removable seat is provided.

Question 37. Comments are requested on the following questions regarding whether a folding or removable seat should be required on diagnostic equipment used by patients in a standing position:

a) Should a folding or removable seat be required on weight scale platforms?

b) Should a folding or removable seat be required on other types of diagnostic equipment used by patients in a standing position?

c) What would be the incremental costs for the design or redesign and manufacture of the equipment to provide a folding or removable seat on weight scale platforms or other types of diagnostic equipment used by patients in a standing position?

d) If folding or removable seats are provided on diagnostic equipment used by patients in a standing position, should the equipment be required to meet the technical criteria in M302 regarding transfer surfaces, supports, and lift compatibility for diagnostic equipment used by patients in a seated position?

Standing Supports (M304.3 and M305.3)

M304.3 would require standing supports to be provided on each side of the standing surface on diagnostic equipment used by patients in a standing position.

M305.3 would require the standing supports to provide continuous support throughout the use of the diagnostic equipment and to not rotate within their fittings.

M305.3 also provides technical criteria for standing supports in horizontal and vertical positions. Standing supports can be provided in a horizontal position, vertical position, or a combination of horizontal and vertical positions, as long as the minimum length of gripping surface is provided for the support position used on each side of the standing surface. Standing supports that adjust from horizontal to vertical positions and at angles in between, such as a bar that folds up and locks into multiple positions, can be used. These kinds of adjustable supports are not required but would accommodate a broad range of patients with disabilities, particularly where a patient needs to assume multiple body positions for a diagnostic procedure or needs to step up onto a surface and then maintain balance afterwards.

For standing supports in a horizontal position, M305.3.1 would require the gripping surface to be 4 inches long minimum. The top of the gripping surface would be required to be 34 inches minimum and 38 inches maximum above the standing surface. The minimum length of the gripping surface is based on anthropometric data that provides specifications for men and women grasping cylinder grips which are stated as a range from 3.6 inches to 4.5 inches. See Henry Dreyfuss Associates and Alvin R. Tilley, The Measure of Man & Woman: Human Factors in Design, (New York, John Wiley and Sons, 2002), page 43. Where possible, it is recommended that a longer gripping surface or multiple horizontal supports be provided. The minimum and maximum height of the gripping surface above the standing surface is based on the provisions for handrails in the 2004 ADA and ABA Accessibility Guidelines.

For standing supports in a vertical position, M305.3.2 would require the gripping surface to be 18 inches long minimum. The bottom of the support would be required to be 34 inches minimum and 37 inches maximum above the standing surface. The minimum length of the gripping surface is based on provisions for vertical grab bars at accessible bathing fixtures and toilets in ICC A117.1-2009 Accessible and Usable Buildings and Facilities. The minimum and maximum height of the bottom of the support above the standing surface is based on anthropometric data for the 1th percentile woman (minimum) and the 99th percentile man (maximum). See Henry Dreyfuss Associates and Alvin R. Tilley, The Measure of Man & Woman: Human Factors in Design, (New York, John Wiley and Sons, 2002), pages 13, 14, and 28.

Question 38. Comments are requested on the following questions regarding standing supports for diagnostic equipment used by patients in a standing position:

a) What standing support configurations are currently provided and are they effective for patients with disabilities?

b) Would alternative technical criteria for standing supports be appropriate? Comments should include information on sources to support the alternative technical criteria, where possible.

c) Are angled standing supports effective for patients with disabilities and should technical criteria be provided for angled standing supports? Comments should include information on sources to support the technical criteria for angled standing supports, where possible.

d) Are there industry standards for the structural strength of standing supports?

The 2004 ADA and ABA Accessibility Guidelines specify the following dimensions for grab bars to enable individuals with disabilities to firmly grasp the grab bars and support themselves during transfers:

- Grab bars with circular cross sections must have an outside diameter of 1¼ inches minimum and 2 inches maximum.
- Grab bars with non-circular cross sections must have a cross section dimension of 2 inches maximum and a perimeter dimension of 4 inches minimum and 4.8 inches maximum.

The Access Board is considering whether the above cross section dimensions would be appropriate for the gripping surfaces of standing supports on diagnostic equipment used by patients in a standing position.

Question 39. Comments are requested on the following questions regarding the above cross section dimensions for the gripping surfaces of standing supports on diagnostic equipment used by patients in a standing position:

a) Can the gripping surfaces of standing supports on different types of equipment meet the above cross section dimensions?

b) Are there alternative designs for the gripping surfaces of standing supports that enable patients with disabilities to firmly grasp the supports?

The Access Board is also considering whether a 1½ inches minimum clearance around the gripping surface of standing supports would be appropriate to ensure that the surface can be grasped.

Question 40. Can standing supports on different types of equipment provide 1½ inches minimum clearance around the gripping surface without encountering obstructions?

M305 Supports

M305 provides the technical criteria for transfer supports and standing supports. The technical criteria for transfer supports are discussed under M301 Diagnostic Equipment Used by Patients in Supine, Prone, or Side-Lying Position and M302 Diagnostic Equipment Used by Patients in Seated Position. The technical criteria for standing supports are discussed under M304 Diagnostic Equipment Used by Patients in Standing Position.

M306 Communication

Where diagnostic equipment communicates instructions or other information to the patient, M306 would require the instructions or other information to be provided in at least two of the following methods: audible, visible, or tactile. For example, magnetic resonance imaging (MRI) and X-ray computed tomography (CT) equipment may instruct the patient to hold their breath for a short period during a scan by means of a flashing light or icon. A flashing light or icon would be sufficient to notify a patient who is deaf to hold their breath, but a voice prompt, sound alert, or tactile vibration would be needed to notify a patient who is blind to hold their breath. For MRI equipment, auditory methods may not be effective due to the noise generated by the equipment and a tactile vibration may be the only effective method to notify a patient who is blind to hold their breath. ANSI/AAMI HE 75 recommends that vibration "be used as a redundant mode for

transmitting information such as an attention getting signal." See ANSI/AAMI HE 75, section 16.3.5.6.

Question 41. Comments are requested on the following questions regarding methods of communication provided by diagnostic equipment:

a) Should diagnostic equipment that communicates instructions or other information to the patient be required to provide the instructions or other information in all three methods of communication (i.e., audible, visible, and tactile)?

b) What would be the incremental costs for the design or redesign and manufacture of the equipment to provide all three methods of communication (i.e., audible, visible, and tactile)?

M307 Operable Parts

M307 provides technical criteria for operable parts used by patients to activate, deactivate, or adjust the diagnostic equipment (see defined terms in M102.1). For example, equipment used for an auditory examination may require the patient to press a button when sounds are heard. M307 does not apply to controls used only by health care personnel or others who are not patients.

M307.2 would require operable parts to be tactilely discernible without activation. Patients who are blind or have low vision have difficulty distinguishing a flat membrane button or similar control unless it is tactilely discernible from the surrounding surface and any adjacent controls. The most common method to ensure that buttons and similar controls are tactilely discernible is to raise part or all of the control surface above the surrounding surface and at a distance from any adjacent controls such that a relief of each

individual control can be determined by touch. This also prevents unintended or accidental activation of the operable parts. M307.2 is consistent with recommendations in ANSI/AAMI HE 75 that "features should be operable from controls that are tactilely discernible and that can be explored without being activated." See ANSI/AAMI HE 75, section 16.3.5.5.

M307.3 would require operable parts such as dials, switches, and levers to be operable with one hand without tight grasping, pinching, or twisting of the wrist. M307.4 would require the force to activate operable parts to not exceed 5 pounds. M307.3 and M307.4 are based on provisions for operable parts in the 2004 ADA and ABA Accessibility Guidelines. M307.3 and M307.4 are also consistent with recommendations in ANSI/AAMI HE 75 that "devices should have at least one mode of use that does not require fine motor control or the performance of simultaneous actions." ANSI/AAMI HE 75 includes additional recommended practices for accessible controls. See ANSI/AAMI HE 75, section 16.3.3.

The Wheeled Mobility Anthropometry Project recommended that "operable parts that require fine grips preferably should not require exertion of lateral pinch grip forces in excess of 2 pounds force to accommodate the vast majority of … users having at least some grasping capability." The Wheeled Mobility Anthropometry Project recommended that the 5 pounds maximum force be retained for other types of operable parts. See Final Report of the Wheeled Mobility Anthropometry Project, page 105. The Access Board is considering requiring in the final standards that operable parts used by patients that require fine grips to not exceed 2 pounds maximum operating force.

Question 42. Comments are requested on the following questions regarding the operating force (2 pounds maximum) that the Access Board is considering requiring in the final standards for operable parts used by patients that require fine grips:

a) What would be the incremental costs for the design or redesign and manufacture of the equipment to provide operable parts that meet the above operating force?

b) Are there types of equipment that cannot provide operable parts that meet the above operating force because of the structural or operational characteristics of the equipment?

The 2004 ADA and ABA Accessibility Guidelines require that operable parts be placed within certain reach ranges. For an unobstructed forward reach or side reach, the reach ranges are 48 inches maximum for a high reach and 15 inches minimum for a low reach. ANSI/AAMI HE 75 provides guidance on reach ranges based on provisions in an earlier version of accessibility guidelines for buildings and facilities issued by the Access Board, the 1991 Americans with Disabilities Act Accessibility Guidelines (ADAAG). ANSI/AAMI HE 75 also recommends a remote control as an alternative to a direct reach. See ANSI/AAMI HE 75, section 16.3.2.2. The reach ranges in the 2004 ADA and ABA Accessibility Guidelines provide greater accessibility than the reach ranges in the 1991 ADAAG.

Question 43. Comments are requested on the following questions regarding reach ranges for operable parts on diagnostic equipment that are used by patients:

a) Would the reach ranges in the 2004 ADA and ABA Accessibility Guidelines for an unobstructed forward reach or side reach (48 inches maximum for a

high reach and 15 inches minimum for a low reach) be appropriate for operable parts on diagnostic equipment that are used by patients?

b) Would alternative technical criteria be appropriate for reach ranges for operable parts on diagnostic equipment that are used by patients? Comments should include information on sources to support the alternative technical criteria, where possible.

6. Regulatory Analyses

Executive Order 13563 (Improving Regulation and Regulatory Review) and Executive Order 12866 (Regulatory Planning and Review): Preliminary Regulatory Assessment

The Office of Management and Budget has reviewed this proposed rule in accordance with Executive Orders 13563 and 12866. Among other things, Executive Order 13563 directs agencies to propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs; tailor the regulation to impose the least burden on society, consistent with obtaining the regulatory objectives; and, in choosing among alternative regulatory approaches, select those approaches that maximize net benefits. Executive Order 13563 recognizes that some benefits and costs are difficult to quantify and provides that, where appropriate and permitted by law, agencies may consider and discuss qualitatively values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts.

The Access Board has prepared a preliminary regulatory assessment for the proposed standards. The preliminary regulatory assessment is available on the Access Board's web site at: http://www.access-board.gov/medical-equipment.htm. The preliminary regulatory assessment is summarized below.

Need for and Benefits of the Proposed Standards

The U.S. Census Bureau reports that 54.4 million Americans, about one in five U.S. residents, reported some level of disability in 2005.[11] The number of individuals with disabilities is almost equal to the combined total population of California and Florida. The U.S. Census Bureau provides this breakdown of the population of people aged 15 and older:

- 27.4 million (11.9 percent) had difficulty with ambulatory activities of the lower body;
- 22.6 million (9.8 percent) had difficulty walking a quarter of a mile;
- 21.8 million (9.4 percent) had difficulty climbing a flight of stairs;
- 10.2 million (4.4 percent) used a cane, crutches, or walker to assist with mobility;
- 3.3 million (1.4 percent) used a wheelchair or other wheeled mobility device;
- 7.8 million (3 percent) had difficulty seeing words or letters in ordinary newspaper print, including 1.8 million who are completely unable to see; and
- 7.8 million (3 percent) had difficulty hearing conversations, including 1 million who are unable to hear conversations at all.

The prevalence of disability increases with age. The Administration on Aging reports that there were 39.6 million persons age 65 or older in the United States in 2009,

[11] "Americans with Disabilities: 2005" (2008) available at: http://www.census.gov/prod/2008pubs/p70-117.pdf.

and that this population is expected to increase to 55 million in 2020.[12] Among this population, 37 percent reported some type of disability in 2005.[13]

A national survey collected information on the types of medical equipment that is most difficult for individuals with disabilities to access and use.[14] The survey was completed by a diverse sample of individuals with a wide range of disabilities, including mobility disabilities and sensory disabilities. Survey respondents who had experience with specific medical equipment rated their degree of difficulty when attempting to access or use the equipment as follows:

- 75 percent rated examination tables as moderately difficult to impossible to use;
- 68 percent rated radiology equipment as moderately difficult to impossible to use;
- 53 percent rated weight scales as moderately difficult to impossible to use; and
- 50 percent rated examination chairs as moderately difficult to impossible to use.

Survey respondents reported difficulties with getting on and off the equipment, positioning their bodies on the equipment, physical comfort and safety, and

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[12] "A Profile of Older Americans: 2010" available at: http://www.aoa.gov/AoARoot/Aging_Statistics/Profile/index.aspx.

[13] See footnote 11.

[14] The results of the survey are reported in Jill M. Winters, Molly Follette Story, Kris Barnekow, June Isaacson Kailes, Brenda Premo, Erin Schier, Sarma Danturthi, and Jack M. Winters, "Results of a National Survey on Accessibility of Medical Instrumentation for Consumers," in "Medical Instrumentation Accessibility and Usability Considerations," edited by Jack M. Winters and Molly Follette Story (Boca Raton, CRC Press, 2007), 13-27.

communication issues. Focus group sessions of individuals with disabilities reported that participants find examination tables, imaging equipment, and other diagnostic equipment not only difficult but unsafe to use, and that these negative health care experiences can result in their not scheduling regular medical examinations and diagnostic procedures.[15]

A report on the "The Current State of Health Care for People with Disabilities" issued by the National Council on Disability found that individuals with disabilities experienced significant health disparities and barriers to health care, as compared to individuals without disabilities.[16] Among the key barriers cited in the report is the lack of accessible examination equipment. A report on the "Importance of Accessible Examination Tables, Chairs and Weight Scales" issued by the Center for Disability Issues and the Health Professions discusses how the lack of accessible equipment reduces the likelihood that individuals with disabilities will receive timely and appropriate health care.[17] Health care providers may not perform some diagnostic procedures for patients with disabilities because they lack accessible equipment. This can result in suboptimal examinations, missed or delayed diagnoses, and worsening conditions that require more expensive and extensive treatments.

The proposed standards address many of the barriers that have been identified as affecting the accessibility and usability of diagnostic equipment by individuals with disabilities. The standards will improve the quality of health care for individuals with

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[15] The results of the focus group sessions are reported in Molly Follette Story, Erin Schwier, and June Isaacson Kailes, "Perspectives of Patients with Disabilities on the Accessibility of Medical Equipment: Examination Tables, Imaging Equipment, Medical Chairs, and Weight Scales," Disability and Health Journal 2 (2009), 169-179.

[16] The report is available at: http://www.ncd.gov/publications/2009/Sept302009.

[17] The report is available at: http://www.cdihp.org/products.html#tables.

disabilities and ensure that they receive examinations, diagnostic procedures, and other health care services equal to those received by individuals without disabilities. The standards will facilitate independent transfers by individuals with disabilities onto and off of diagnostic equipment, and enable them to maintain their independence, confidence, and dignity. The standards will lessen the need for health care personnel to assist individuals with disabilities when transferring on and off of diagnostic equipment. Where assisted transfers are necessary, the proposed standards will also facilitate such transfers. The proposed standards will reduce the risk of injury during transfers to both health care personnel and patients.[18] The proposed standards will result in more positive health care experiences for individuals with disabilities and health care providers.

Entities Potentially Affected by Proposed Standards

The proposed standards do not impose any mandatory requirements on health care providers or medical device manufacturers. Thus, there are no compliance costs that can be attributed to the proposed standards. As discussed below, if an enforcing authority such as DOJ adopts the standards as mandatory requirements for entities subject to its jurisdiction, health care providers may experience some compliance costs. Medical device manufacturers may have an economic incentive to produce accessible products that conform to the standards for health care providers who need to acquire accessible medical diagnostic equipment.

Health Care Providers

[18] Lifting and transferring patients is a major risk factor for back injury among nurses and health aides. See Alan Hedge, "Back Care for Nurses" available at: http://www.spineuniverse.com/wellness/ergonomics/back-care-nurses.

As discussed under Department of Justice Activities Related to Health Care Providers and Medical Equipment, health care providers must provide individuals with disabilities full and equal access to their health care services and facilities to comply with the ADA and Section 504 of the Rehabilitation Act. Both the federal government through DOJ and private parties, including individuals with disabilities, have entered into settlement agreements with health care providers to enforce the ADA and Section 504 of the Rehabilitation Act. In July 2010, DOJ and the Department of Health and Human Services issued a guidance document for health care providers regarding their responsibilities to make their services and facilities accessible to individuals with mobility disabilities under the ADA and Section 504 of the Rehabilitation Act. See Access to Medical Care for Individuals with Mobility Disabilities available at: http://www.ada.gov/medcare_ta.htm. The guidance document includes information on accessible examination rooms and the clear floor space needed adjacent to medical equipment for individuals who use mobility devices to approach the equipment for transfer; accessible medical equipment (e.g., examination tables and chairs, mammography equipment, weight scales); patient lifts and other methods for transferring individuals from their mobility devices to medical equipment; and training health care personnel. In July 2010, DOJ also issued an ANPRM announcing that, pursuant to the obligation that has always existed under the ADA for covered entities to provide accessible equipment and furniture, it was considering amending its regulations implementing Titles II and III of the ADA to include specific standards for the design and use of accessible equipment and furniture that is not fixed or built into a facility in order to ensure that programs and services provided by state and local governments and by

public accommodations are accessible to individuals with disabilities. See 75 FR 43452 (July 26, 2010). Among other things, the ANPRM stated that DOJ was considering amending its ADA regulations to specifically require health care providers to acquire accessible medical equipment and that it would consider adopting the standards issued by the Access Board. DOJ also indicated its intention to include in its ADA regulations scoping requirements that specify the minimum number of types of accessible medical equipment required in different types of health care facilities. If DOJ proposes to amend its ADA regulations as announced in the ANPRM, it will publish a notice of proposed rulemaking (NPRM) requesting public comment and will prepare a regulatory assessment in accordance with Executive Orders 13563 and 12866.

Medical Device Manufacturers

If DOJ amends its ADA regulations as announced in the ANPRM, medical device manufacturers may have an economic incentive to produce accessible products that conform to the standards for health care providers who need to acquire accessible medical diagnostic equipment. The size of the economic incentive will depend on the amount of accessible medical diagnostic equipment health care providers need to acquire and the manufacturers' incremental costs to design or redesign and manufacture accessible products that conform to the standards.

Many medical device manufacturers currently incorporate accessible features in some of their products such as patient support surfaces that are height adjustable, transfer and positioning supports, and scales designed for use by patients seated in a wheelchair. The incremental costs for manufacturers to conform these products to the standards are expected to be small because the features may already meet or closely meet the standards.

The incremental costs may be greater for manufacturers that do not currently incorporate accessible features in their products but plan to do so in future designs or redesigns of their products. The incremental costs to design or redesign and manufacture accessible products that conform to the standards will be incurred voluntarily by manufacturers that choose to produce them for health care providers who need to acquire accessible medical diagnostic equipment. Some manufacturers may choose not to design or redesign and manufacture accessible products that conform to the standards, or may produce accessible products with less market appeal than that of their competitors, thereby losing market share and incurring losses. These economic impacts are not regulatory costs and are not generally social costs because for the most part, one manufacturer's loss is another manufacturer's gain.

The following questions in the preamble request comments on the incremental costs to design or redesign and manufacture accessible products that conform to the technical criteria in the proposed standards, as well as alternative and additional technical criteria that the Access Board is considering:

- Questions 9 and 10 on the technical criteria in Chapter M3;
- Questions 14 (a) and (b) on height adjustable patient support surfaces;
- Question 15 (b) on width of patient support surfaces on equipment used by patients in a supine, prone, or side-lying position;
- Question 18 (a) on structural strength of repositionable transfer supports;
- Question 19 (c) on location and size of transfer supports;
- Question 23 (a) on stirrups;
- Question 24 (b) on positioning supports;

- Question 29 (a) on alternative dimension for minimum depth of wheelchair spaces;
- Question 30 on edge protection for wheelchair spaces on raised platforms:
- Questions 33 on dimensions for wheelchair spaces on raised platforms;
- Question 34 (a) on alternative dimensions for toe clearance and knee clearance at wheelchair spaces;
- Question 35 (b) on handrails on diagnostic equipment ramps;
- Question 37 (c) on a folding or removable seat on weight scale platforms or other types of diagnostic equipment used by patients in a standing position;
- Question 41 (b) on audible, visible, and tactile communications; and
- Question 42 (a) on operating force for operable parts.

The Access Board will consider the information provided in the comments when preparing the final standards, and will provide an analysis of the incremental costs with the final standards.

Product Data and Unit Costs

The Access Board and its contractor, Eastern Research Group, collected product data and unit costs for a broad sample of examination tables and weight scales, including products with accessible features. The Access Board and Eastern Research Group did not evaluate the products for conformance with the proposed standards and do not endorse any of the products included in the sample. The Access Board and Eastern Research Group used the Internet to collect the product data and unit costs. Medical equipment suppliers typically list the manufacturer suggested retail price (MSRP) for the products

on their web sites and sell the products at discounted prices. The discounted prices for the same product can vary widely among medical equipment suppliers. Health care providers typically purchase the products for less than the MSRP (i.e., actual price paid is less than MRSP). The unit costs in the tables below are the MSRP, and are shown as a range of lower cost and higher cost products rounded to the nearest $50. The data shows that there are a wide variety of examination tables and weight scales available to meet almost every budget.

Product data and unit costs for examination chairs and imaging equipment will be provided when the final standards are issued.

Examination Tables

Product data and unit costs were collected for examination tables produced by five manufacturers. The manufacturer's web sites typically grouped the tables by the following types: treatment tables, manual tables, and power tables. The number of each type of table made by the manufacturers, the number of tables included in the sample, and range of lower cost and higher cost products are summarized below.

Table Type	Products	Products in Sample	Lower Cost Products MSRP	Higher Cost Products MSRP
Treatment	74	20	$400 - $850	$850 - $1,450
Manual	15	9	$1,250	$2,250
Power	30	25	$1,650 - $2,900	$3,650 -$16,800

Question 44. Does the above sample fairly reflect the range of costs for examination tables?

Treatment tables typically have a flat top. Some models have adjustable backrests, but the backrests typically cannot support patients in a sitting position.

Treatment tables typically have a fixed height of 31 inches measured from the floor to the top of the table. The lower cost products have an open base with an H-brace or shelf. The higher cost products have cabinets, drawers, or shelves. Adjustable height treatment tables are available, but are not included in the sample. The MSRP for adjustable height treatment tables ranged from $1,500 to $2,400.

Manual tables typically have a fully articulated, pneumatic backrest. The backrests typically can support patients in a seated position and recline to a lying position. Manual tables typically have a fixed height of 32 inches measured from the floor to the top of the table. Manual tables typically have cabinets, drawers, or shelves.

Power tables have an electric motor that can adjust the table height to as low as 18 inches and as high as 40 inches above the floor on some products. The higher cost products have a fully articulated, pneumatic or powered, backrest that can support patients in a seated position and recline to a lying position. Some power tables have armrests, grab rails, side rails, and cabinets or drawers.

Weight Scales

Product data and unit costs were collected for weight scales produced by eight manufacturers. The scales are grouped by the following types: stand-on scales and wheelchair scales. Within each group, there are mechanical and digital scales. Unit costs are presented for stand-on scales with and without handrails. Unit costs are presented for wheelchair scales with raised platforms and with flush platforms in the floor. The number of each type of scale made by the manufacturers, the number of scales included in the sample, and range of lower cost and higher cost products are summarized below.

Stand-On Scales	Products	Products in Sample	Lower Cost Products	Higher Cost Products

			MSRP	MSRP
Mechanical without Handrails	22	3	$250	$550
Mechanical with Handrails	1	1	$700	$700
Digital without Handrails	50	15	$300 - $600	$700 - $1,200
Digital with Handrails	21	9	$600 - $1,050	$1,750 - $2,600

Question 45. Does the above sample fairly reflect the range of costs for stand-on scales?

Stand-on mechanical scales typically have a weight capacity ranging from 400 to 500 pounds. Stand-on digital scales without handrails typically have a weight capacity ranging from 400 to 750 pounds, and the higher cost products typically have larger platforms. Stand-on digital scales with handrails typically have a weight capacity ranging from 500 to 1,000 pounds, and the higher cost products typically are bariatric scales.

Wheelchair Scales	Products	Products in Sample	Lower Cost Products MSRP	Higher Cost Products MSRP
Mechanical with Ramped Platform	2	2	$1,200	$2,900
Digital with Ramped Platform	32	15	$800 - $1,700	$2,100 - $4,950
Digital with Flush Platform in Floor	8	5	$3,300	$6,500

Question 46. Does the above sample fairly reflect the range of costs for wheelchair scales?

Wheelchair mechanical scales with a ramped platform typically have a weight capacity ranging from 350 to 500 pounds. Wheelchair digital scales with a ramped platform typically have a weight capacity ranging from 800 to 1,000 pounds. Wheelchair digital scales with a flush platform in the floor typically have a weight capacity of 1,000 pounds. Some wheelchair digital scales have standard or optional handrails for use as a stand-on bariatric scale.

The Access Board has made a preliminary determination based on the preliminary regulatory assessment that the benefits of the proposed standards will justify the costs; that the proposed standards will impose the least burden on society, consistent with obtaining the regulatory objectives; and that the regulatory approach selected will maximize net benefits.

Regulatory Flexibility Act: Initial Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires agencies to consider the impacts of their regulatory proposals on small entities, analyze alternatives that minimize the impacts on small entities, and make the analysis available for public comment. The proposed standards do not impose any mandatory requirements on any entity, including small entities. Nonetheless, in keeping with the Regulatory Flexibility Act, the Access Board has prepared this initial regulatory flexibility analysis.

Reason the Access Board is issuing the proposed standards

Section 510 of the Rehabilitation Act (29 USC 794f) requires the Access Board, in consultation with the Commissioner of the Food and Drug Administration, to issue

standards that contain minimum technical criteria to ensure that medical diagnostic equipment used in or in conjunction with medical settings such as physicians' offices, clinics, emergency rooms, and hospitals is accessible to and usable by individuals with disabilities.

Objective of, and legal basis for, the proposed standards

The objective of the proposed standards is to ensure that medical diagnostic equipment is accessible to and usable by individuals with disabilities. The proposed standards address barriers that affect the accessibility and usability of medical diagnostic equipment by individuals with disabilities. The legal basis for the proposed standards is Section 510 of the Rehabilitation Act.

Small entities potentially affected by proposed standards

The proposed standards do not impose any mandatory requirements on health care providers or medical device manufacturers. As discussed below, if an enforcing authority such as DOJ adopts the standards as mandatory requirements for entities subject to its jurisdiction, small health care providers may experience some compliance costs. Small medical device manufacturers may have an economic incentive to produce accessible products that conform to the standards for health care providers who need to acquire accessible medical diagnostic equipment.

Health Care Providers

As discussed under Department of Justice Activities Related to Health Care Providers and Medical Equipment, health care providers must provide individuals with disabilities full and equal access to their health care services and facilities to comply with the ADA and Section 504 of the Rehabilitation Act. Both the federal government

through DOJ and private parties, including individuals with disabilities, have entered into settlement agreements with health care providers to enforce the ADA and Section 504 of the Rehabilitation Act. In July 2010, DOJ and the Department of Health and Human Services issued a guidance document for health care providers regarding their responsibilities to make their services and facilities accessible to individuals with mobility disabilities under the ADA and Section 504 of the Rehabilitation Act. See Access to Medical Care for Individuals with Mobility Disabilities available at: http://www.ada.gov/medcare_ta.htm. The guidance document includes information on accessible examination rooms and the clear floor space needed adjacent to medical equipment for individuals who use mobility devices to approach the equipment for transfer; accessible medical equipment (e.g., examination tables and chairs, mammography equipment, weight scales); patient lifts and other methods for transferring individuals from their mobility devices to medical equipment; and training health care personnel. In July 2010, DOJ also issued an ANPRM announcing that, pursuant to the obligation that has always existed under the ADA for covered entities to provide accessible equipment and furniture, it was considering amending its regulations implementing Titles II and III of the ADA to include specific standards for the design and use of accessible equipment and furniture that is not fixed or built into a facility in order to ensure that programs and services provided by state and local governments and by public accommodations are accessible to individuals with disabilities. See 75 FR 43452 (July 26, 2010). Among other things, the ANPRM stated that DOJ was considering amending its ADA regulations to specifically require health care providers to acquire accessible medical equipment and that it would consider adopting the standards issued by

the Access Board. DOJ also indicated its intention to include in its ADA regulations scoping requirements that specify the minimum number of types of accessible medical equipment required in different types of health care facilities. If DOJ proposes to amend its ADA regulations as announced in the ANPRM, it will publish a notice of proposed rulemaking (NPRM) requesting public comment and will prepare an initial and final regulatory flexibility analyses in accordance with the Regulatory Flexibility Act.

Medical Device Manufacturers

If DOJ amends its ADA regulations as announced in the ANPRM, small medical device manufacturers may have an economic incentive to produce accessible products that conform to the standards for health care providers who need to acquire accessible medical diagnostic equipment. The size of the economic incentive will depend on the amount of accessible medical diagnostic equipment health care providers need to acquire and the manufacturers' incremental costs to design or redesign and manufacture accessible products that conform to the standards.

Many medical device manufacturers currently incorporate accessible features in some of their products such as patient support surfaces that are height adjustable, transfer and positioning supports, and scales designed for use by patients seated in a wheelchair. The incremental costs for manufacturers to conform these products to the standards are expected to be small because the features may already meet or closely meet the standards. The incremental costs may be greater for manufacturers that do not currently incorporate accessible features in their products but plan to do so in future designs or redesigns of their products. The incremental costs to design or redesign and manufacture accessible products that conform to the standards will be incurred voluntarily by manufacturers that

choose to produce them for health care providers who need to acquire accessible medical diagnostic equipment. Some manufacturers may choose not to design or redesign and manufacture accessible products that conform to the standards, or may produce accessible products with less market appeal than that of their competitors, thereby losing market share and incurring losses. These economic impacts are not regulatory costs and are not generally social costs because for the most part, one manufacturer's loss is another manufacturer's gain.

The preamble requests comments on the incremental costs to design or redesign and manufacture products that conform to the technical criteria in the proposed standards, as well as alternative and additional technical criteria that the Access Board is considering. The Access Board will consider the information provided in the comments when preparing the final standards, and will provide an analysis of the incremental costs with the final standards.

Compliance requirements in proposed standards

The proposed standards contain technical criteria for accessible medical diagnostic equipment. The proposed standards do not impose any mandatory requirements on medical device manufacturers or health care providers.

Other relevant federal rules and guidance documents

As discussed above, DOJ and the Department of Health and Human Services issued a guidance document for health care providers regarding their responsibilities to make their services and facilities accessible to individuals with mobility disabilities under the ADA and Section 504 of the Rehabilitation Act. DOJ also issued an ANPRM announcing that it was considering amending its regulations implementing Titles II and

III of the ADA to ensure that equipment and furniture used in programs and services provided by state and local governments and by public accommodations are accessible to individuals with disabilities. See 75 FR 43452 (July 26, 2010). Among other things, the ANPRM stated that DOJ was considering amending its ADA regulations to specifically require health care providers to acquire accessible medical equipment and that it would consider adopting the standards issued by the Access Board. DOJ also indicated its intention to include in its ADA regulations scoping requirements that specify the minimum number of types of accessible medical equipment required in different types of health care facilities.

The Access Board worked closely with the FDA-CDRH in developing the proposed standards. The FDA-CDRH may develop a guidance document to inform manufacturers how it intends to apply its regulatory authority to clearance or approval of medical devices addressed in the Access Board's standards. If the FDA-CDRH develops such a guidance document, it will provide the public notice and opportunity to comment on a draft of the guidance document in accordance with its procedures for issuing guidance documents. See 21 CFR 10.115.

Significant alternatives

Questions are included in the preamble requesting comments on the economic and technical impacts of the technical criteria in the proposed standards, and whether alternative technical criteria would be appropriate. The Access Board plans to convene an advisory committee when the comment period on the rulemaking closes to assist the Board in reviewing the comments and make recommendations on issues addressed in the rulemaking. The Access Board will analyze the comments submitted in response to the

questions and the advisory committee's recommendations, including alternatives that achieve the statutory objectives of ensuring that medical diagnostic equipment is accessible to and usable by individuals with disabilities and minimize any significant impacts of the standards on small entities. The Access Board will prepare a final regulatory flexibility analysis when the final standards are issued that discusses any significant alternatives considered.

Executive Order 13132 (Federalism)

The proposed standards do not impose any mandatory requirements on state and local governments. The proposed standards do not have any direct effects on the state governments, the relationship between the national government and state governments, or the distribution of power and responsibilities among the various levels of government. The proposed standards do not preempt state law. Therefore, the consultation and other requirements of Executive Order 13132 (Federalism) do not apply.

Unfunded Mandates Reform Act

The proposed standards do not impose any mandatory requirements on state, local, or tribal governments or the private sector. Therefore, the Unfunded Mandates Reform Act does not apply.

List of Subjects in 36 CFR Part 1195

Health care, Individuals with disabilities, Medical devices.

_____

Nancy Starnes,
Chair.

For the reasons stated in the preamble, the Access Board proposes to add part 1195 to title 36 of the Code of Federal Regulations to read as follows:

PART 1195 –STANDARDS FOR ACCESSIBILE MEDICAL DIAGNOSTIC EQUIPMENT

Sec.

Authority: 29 U.S.C. 794f.

§ 1195.1 Standards.

The standards for accessible medical diagnostic equipment are set forth in the appendix to this part. Other agencies, referred to as an enforcing authority in the standards, may adopt the standards as mandatory requirements for entities subject to their jurisdiction.

Appendix to Part 1195 –Standards for Accessible Medical Diagnostic Equipment

Chapter M1: Application and Administration

M101 General

M101.1 Purpose. The standards contain technical criteria for medical diagnostic equipment that is accessible to and usable by patients with disabilities. The standards provide for independent access to and use of diagnostic equipment by patients with disabilities to the maximum extent possible.

M101.2 Application. The standards shall be applied to diagnostic equipment based on the patient positions that the equipment is designed to support. Where

diagnostic equipment is designed to support more than one patient position, the standards for each patient position supported shall be applied to the equipment.

Advisory M101.2 Application. The following examples illustrate how the standards apply to diagnostic equipment designed to support more than one patient position:

- An examination chair converts to an examination table. The technical criteria in M302 for diagnostic equipment used by patients in a seated position; and in M301 for diagnostic equipment used by patients in a supine, prone, or side-lying position apply.
- A weight scale can be used by patients seated in a wheelchair, or seated on a built-in folding seat, or standing and holding onto supports. The technical criteria in M303 for diagnostic equipment used by patients seated in a wheelchair; in M302 for diagnostic equipment used by patients in a seated position; and in M304 for diagnostic equipment used by patients in a standing position apply.

M101.3 Equivalent Facilitation. The use of alternative designs or technologies that result in substantially equivalent or greater accessibility and usability than specified in the standards is permitted.

M101.4 Dimensions. The standards are based on adult dimensions and anthropometrics.

Dimensions that are not stated as "maximum" or "minimum" are absolute.

M101.5 Dimensional Tolerances. Dimensions are subject to conventional industry tolerances for manufacturing processes, material properties, and field conditions

M102 Definitions

M102.1 Defined Terms. For the purpose of the standards, the following terms have the indicated meaning:

Enforcing Authority. An agency that adopts the standards as mandatory requirements for entities subject to its jurisdiction.

Medical Diagnostic Equipment (Diagnostic Equipment). Equipment used in or in conjunction with medical settings by health care providers for diagnostic purposes.

Operable Parts. A component of diagnostic equipment that is used by the patient to activate, deactivate, or adjust the equipment.

Transfer Surface. Part of diagnostic equipment onto which patients who use mobility devices or aids transfer when moving onto and off of the equipment.

M102.2 Undefined Terms. The meaning of terms not defined in M102.1 or in regulations or policies issued by an enforcing authority shall be defined by collegiate dictionaries in the sense that the context implies.

M102.3 Interchangeability. Words, terms, and phrases used in the singular include the plural and those used in the plural include the singular.

Chapter M2: Scoping

M201 General

M201.1 Enforcing Authority. The enforcing authority specifies the minimum number of types of accessible diagnostic equipment that are required to comply with the standards in different types of health care facilities.

Chapter M3: Technical Criteria

M301 Diagnostic Equipment Used by Patients in Supine, Prone, or Side-Lying Position

M301.1 General. Where diagnostic equipment is used by patients in a supine, prone, or side-lying position, it shall comply with M301.

M301.2 Transfer Surface. A transfer surface shall be provided and shall comply with M301.2.

M301.2.1 Height. The height of the transfer surface during patient transfer shall be 17 inches (430 mm) minimum and 19 inches (485 mm) maximum measured from the floor to the top of the transfer surface.

Advisory M301.2.1 Height. The transfer surface is permitted to be positioned outside of the specified height range when not needed to facilitate transfer.

M301.2.2 Size. The transfer surface shall be 30 inches (760 mm) wide minimum and 15 inches (381mm) deep minimum.

Advisory M301.2.2 Size. The size requirements in this section apply only to the portion of the diagnostic equipment used for transfer.

M301.2.3 Transfer Sides. The transfer surface shall be located to provide options to transfer from a mobility device onto one short side (depth) and one long side (width) of the surface. Each transfer side shall provide unobstructed access to the transfer surface.

EXCEPTION: Temporary obstructions shall be permitted provided that they can be repositioned to permit transfer.

Advisory M301.2.3 Transfer Sides: Exception. Arm rests, footrests, side rails, and stirrups are examples of obstructions.

M301.3 Supports. Transfer supports, stirrups, and reclining surfaces shall comply with M301.3.

M301.3.1 Transfer Supports. Transfer supports shall be provided for use with the transfer sides required by M301.2.3 and shall comply with M305.2.

M301.3.2 Stirrups. Where stirrups are provided, they shall provide a method of supporting, positioning, and securing the patient's legs.

M301.3.3 Head and Back Support. Where the diagnostic equipment is used in a reclined position, head and back support shall be provided. Where the incline of the back support can be modified while in use, head and back support shall be provided throughout the entire range of the incline.

M301.4 Lift Compatibility. Diagnostic equipment shall be usable with a patient lift and shall comply with M301.4.1 or M301.4.2.

M301.4.1 Clearance in Base. The base of the equipment shall provide a clearance 44 inches (1120 mm) wide minimum, 6 inches (150 mm) high minimum measured from the floor, and 36 inches (915 mm) deep minimum measured from the edge of the examination surface. Where the width of the examination surface is less than 36 inches (915 mm), the clearance depth shall extend the full width of the equipment. Equipment components are permitted to be located within 8 inches (205 mm) maximum of the centerline of the clearance width.

M301.4.2 Clearance Around Base. The base of the equipment shall provide a clearance 6 inches (150 mm) high minimum measured from the floor and 36 inches (915 mm) deep minimum measured from the edge of the examination surface. The width of the base permitted within this clearance shall be 26 inches (660 mm) wide maximum at

the edge of the examination surface and shall be permitted to increase at a rate of 1 inch (25 mm) in width for each 3 inches (75 mm) in depth.

M302 Diagnostic Equipment Used by Patients in Seated Position

M302.1 General. Where diagnostic equipment is used by patients in a seated position, it shall comply with M302.

M302.2 Transfer Surface. A transfer surface shall be provided and shall comply with M302.2.

M302.2.1 Height. The height of the transfer surface during patient transfer shall be 17 inches (430 mm) minimum and 19 inches (485 mm) maximum measured from the floor to the top of the transfer surface.

Advisory M302.2.1 Height. The transfer surface is permitted to be positioned outside of the specified height range when not needed to facilitate transfer.

M302.2.2 Size. The transfer surface shall be 21inches (610 mm) wide minimum and 15 inches (381 mm) deep minimum.

Advisory M302.2.2 Size. The size requirements in this section apply only to the portion of the seat used for transfer.

M302.2.3 Transfer Sides. The transfer surface shall be located to provide options to transfer from a mobility device onto one short side (depth) and one long side (width) of the surface. Each transfer side shall provide unobstructed access to the transfer surface.

EXCEPTION: Temporary obstructions shall be permitted provided that they can be repositioned to permit transfer.

Advisory M302.2.3 Transfer Sides: Exception. Armrests, footrests, and side rails are examples of obstructions.

M302.3 Supports. Transfer supports, armrests, and reclining surfaces shall comply with M302.3.

M302.3.1 Transfer Supports. Transfer supports shall be provided for use with the transfer sides required by M302.2.3 and shall comply with M305.2.

M302.3.2 Armrests. Where diagnostic equipment is used by patients in a seated position, armrests shall be provided.

Advisory M302.3.2 Armrests. Armrests on transfer sides are not permitted to obstruct access to the transfer surface. See M302.2.3 Exception.

M302.3.3 Head and Back Support. Where the diagnostic equipment is used in a reclined position, head and back support shall be provided. Where the incline of the back support can be modified while in use, head and back support shall be provided throughout the entire range of the incline.

M302.4 Lift Compatibility. Diagnostic equipment shall be usable with a patient lift and shall comply with M302.4.1 or M302.4.2.

EXCEPTION: Where diagnostic equipment meets the requirements of M303 and provides a folding seat, the equipment shall not be required to comply with M302.4.

M302.4.1 Clearance in Base. The base of the equipment shall provide a clearance 44 inches (1120 mm) wide minimum, 6 inches (150 mm) high minimum measured from the floor, and 36 inches (915 mm) deep minimum measured from the edge of the examination surface. Where the width of the examination surface is less than 36 inches (915 mm), the clearance depth shall extend the full width of the equipment.

Equipment components are permitted to be located within 8 inches (205 mm) maximum of the centerline of the clearance width.

M302.4.2 Clearance Around Base. The base of the equipment shall provide a clearance 6 inches (150 mm) high minimum measured from the floor and 36 inches (915 mm) deep minimum measured from the edge of the examination surface. The width of the base permitted within this clearance shall be 26 inches (660 mm) wide maximum at the edge of the examination surface and shall be permitted to increase at a rate of 1 inch (25 mm) in width for each 3 inches (75 mm) in depth.

M303 Diagnostic Equipment Used by Patients Seated in a Wheelchair

M303.1 General. Diagnostic equipment used by patients seated in a wheelchair shall comply with M303.

M303.2 Wheelchair Spaces. A wheelchair space complying with M303.2 shall be provided at diagnostic equipment.

Advisory M303.2 Wheelchair Spaces. A wheelchair space can be used to accommodate patients who use wheelchairs as well as other mobility devices and seating.

M303.2.1 Orientation. Wheelchair spaces shall be designed so that a patient seated in a wheelchair orients in the same direction that a patient not seated in a wheelchair orients when the diagnostic equipment is in use.

M303.2.2 Width. Wheelchair spaces shall be 36 inches (915 mm) wide minimum.

M303.2.3 Depth. Where wheelchair spaces can be entered from the front or rear, the wheelchair space shall be 48 inches (1220 mm) deep minimum. Where wheelchair

spaces can be entered only from the side, the wheelchair space shall be 60 inches (1525 mm) deep minimum.

M303.2.4 Knee and Toe Clearance. Wheelchair spaces shall include knee and toe clearance complying with M303.2.4. The depth of the wheelchair space shall include knee and toe clearance of 17 inches (430 mm) minimum and 25 inches (635 mm) maximum. Knee and toe clearance under breast platforms shall be 25 inches (635 mm) deep.

M303.2.4.1 Toe Clearance. Toe clearance shall be provided at a height of 9 inches (230 mm) above the floor to a depth of 6 inches (150 mm) maximum.

M303.2.4.2 Knee Clearance. Knee clearance shall be provided at a depth of 11 inches (280 mm) minimum and 25 inches (635 mm) maximum at 9 inches (230 mm) above the floor and at a depth of 8 inches (205 mm) minimum at 27 inches (685 mm) above the floor. Between 9 inches (230 mm) and 27 inches (685 mm) above the floor, the knee clearance shall be permitted to reduce at a rate of 1 inch (25 mm) in depth for every 6 inches (150 mm) in height.

M303.2.5 Surfaces. Wheelchair space surfaces shall not slope more than 1:48 in any direction.

M303.3 Entry. Where there is a change in level at the entry to a wheelchair space, the change in level shall comply with M303.3.

M303.3.1 Vertical. Changes in level of ¼ inch (6.4 mm) high maximum shall be permitted to be vertical.

M303.3.2 Beveled. Changes in level between ¼ inch (6.4 mm) high and ½ inch (13 mm) high maximum shall be beveled with a slope not steeper than 1:2.

M303.3.3 Ramped. Changes in level greater than ½ inch (13 mm) high shall be ramped and shall comply with M303.3.3.

M303.3.3.1 Running Slope. Ramp runs shall have a running slope not steeper than 1:12.

M303.3.3.2 Cross Slope. The cross slope of ramp runs shall not be steeper than 1:48.

M303.3.3.3 Clear Width. The clear width of ramp runs shall be 36 inches (915 mm) minimum.

M303.3.3.4 Edge Protection. Ramps with drop offs ½ inch (13 mm) or greater shall provide edge protection 2 inches (50 mm) high minimum on each side.

M303.3.3.5 Handrails. Ramps with a rise greater than 6 inches (150 mm) shall provide handrails on each side.

M303.4 Components. Where components of diagnostic equipment are used to examine specific body parts, the components shall be capable of examining the body parts of a patient seated in a wheelchair. Breast platforms shall comply with M303.4.1.

M303.4.1 Breast Platforms. The height of the breast platform shall be 30 inches (760 mm) high minimum and 42 inches (1065 mm) high maximum above the floor when in use by a patient seated in a wheelchair.

M304 Diagnostic Equipment Used by Patients in Standing Position

M304.1 General. Diagnostic equipment used by patients in a standing position shall comply with M304.

M304.2 Standing Surface. The surface on which the patient stands shall be slip resistant.

M304.3 Standing Supports. Standing supports shall be provided on each side of the standing surface and shall comply with M305.3.

M305 Supports

M305.1 General. Supports shall comply with M305, as applicable.

M305.2 Transfer Supports. Transfer supports shall comply with M305.2.

M305.2.1 Location. Transfer supports shall be located within reach of the transfer surface and shall not obstruct transfer onto or off of the surface when in position.

M305.2.2 Structural Strength. Transfer supports and their connections shall be capable of resisting vertical and horizontal forces of 250 pounds (1,112 N) applied at all points on the transfer support.

M305.2.3 Fittings. Transfer supports shall not rotate within their fittings.

M305.3 Standing Supports. Standing supports shall provide continuous support throughout use of the diagnostic equipment and shall comply with M305.3.

M305.3.1 Horizontal Position. Where the support is horizontal, the top of the gripping surface shall be 34 inches (865 mm) minimum and 38 inches (965 mm) maximum above the standing surface. The gripping surface shall be 4 inches (100 mm) long minimum.

M305.3.2 Vertical Position. Where the support is vertical, it shall be 18 inches (455 mm) minimum in length and the bottom end of the support shall be 34 inches (865 mm) high minimum and 37 inches (940 mm) high maximum above the standing surface.

M305.3.3 Fittings. Standing supports shall not rotate within their fittings.

M306 Communication

M306.1 General. Where instructions or other information is communicated to the patient through the diagnostic equipment, the instructions and other information shall be provided in at least two of the following methods: audible, visible, or tactile.

Advisory M306.1 General. Patients should not be required to adjust position to receive audible, visible, or tactile communications. A volume control can be helpful, particularly in diagnostic equipment where hearing aids cannot be worn. In selecting the methods of communication it is important to consider the diagnostic equipment characteristics. For example, audible communication may not be effective for magnetic resonance imaging (MRI) equipment due to the noise level when the equipment is in use.

M307 Operable Parts

M307.1 General. Operable parts for patient use shall comply with M307.

M307.2 Tactilely Discernible. Operable parts shall be tactilely discernible without activation.

M307.3 Operation. Operable parts shall be operable with one hand and shall not require tight grasping, pinching, or twisting of the wrist.

M307.4 Operating Force. The force required to activate operable parts shall be 5 pounds (22.2 N) maximum.

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