

Final Regulatory Assessment
Medical Diagnostic Equipment Accessibility Standards
(36 CFR Part 1195)



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Executive Summary

Section 510 of the Rehabilitation Act, as amended by the Patient Protection and Affordable Care Act, requires the Access Board, in coordination with the Food and Drug Administration, to issue accessibility standards that contain minimum technical criteria to ensure that medical diagnostic equipment is accessible to and usable by patients with disabilities. The U.S. Access Board (hereafter, “Access Board” or “Board”) is now issuing the final rule pursuant to this authority. The final rule includes technical standards for accessible medical diagnostic equipment (MDE Standards) that would allow individuals with mobility or communication disabilities to enter, use, and exit from medical diagnostic equipment independently, to the maximum extent possible. Examples of such diagnostic equipment include examination tables and chairs, weight scales, mammography equipment, and other imaging equipment.

The final rule does not directly impose any obligations on health care providers or medical device manufacturers, because the Board has no statutory authority to implement or enforce the accessibility requirements in the MDE Standards. Only when another federal agency, through separate rulemaking, adopts the MDE Standards (in whole or in part) as mandatory for entities under its jurisdiction will compliance be required. At this point, the Access Board does not know whether enforcing authorities will adopt the MDE Standards, nor (if they do) to what extent health care practices or particular types of medical diagnostic equipment will be required to comply with the Standards’ technical requirements. For this reason, the Access Board cannot estimate the incremental monetary or quantitative impact of the final rule.

Nevertheless, the Access Board is able to characterize qualitatively some of the potential impacts of these Standards. If and when the MDE Standards are adopted by enforcing agencies as mandatory for entities regulated under their jurisdiction, the Standards could affect health care providers, medical device manufacturers, and individuals with disabilities. Once health care providers and facilities are required to acquire accessible medical equipment, they could incur compliance costs, to the extent that their equipment is not already accessible. Medical device manufacturers would then decide whether to incur incremental costs to meet the demand for accessible equipment, and some or many manufacturers may have an economic incentive to produce accessible equipment. Finally, given the many barriers to health care that patients with disabilities encounter due to inaccessible medical diagnostic equipment, individuals with mobility and communication disabilities will benefit from access to and use of diagnostic equipment meeting the MDE Standards. As a consequence, they may be able to receive health care comparable to that received by their non-disabled counterparts.

In addition, the Standards could yield some more immediate benefits, even before any adoption by implementing agencies in formal rulemaking. First, the technical specifications for accessible MDE incorporated in the Standards will benefit enforcing agencies that are considering similar accessibility requirements for entities under their jurisdiction. Although enforcing agencies have full authority over whether to adopt the Access Board’s final rule (in whole or in part), the technical specifications in the MDE Standards reflect the input from a diverse set of stakeholders and provide solid groundwork for any future rulemaking in the area of accessibility in medical diagnostic equipment. Second, the Standards will serve as a best-practice document for the medical device industry and for health care providers and facilities. While the MDE Standards are non-binding, health care providers can use this final rule as guidance on how to provide equitable access to medical diagnostic equipment for people with mobility and communication disabilities. Manufacturers can also use the MDE Standards as they target their

research and development efforts at producing diagnostic equipment that can be used by a larger segment of population – one that includes more people with disabilities and older adults.

The Access Board thus concludes that the potential benefits of the MDE Standards justify its potential costs; that the MDE Standards will impose the least burden on society, consistent with achieving the regulatory objectives; and that the regulatory approach selected will maximize net benefits.

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1. Introduction

The Access Board has prepared this final regulatory assessment (Final RA) in support of the agency's final accessibility standards for medical diagnostic equipment (MDE Standards or final rule). The Board has developed these MDE Standards pursuant to Section 510 of the Rehabilitation Act, an amendatory provision enacted in 2010 that tasked the Access Board with establishment of minimum technical criteria to ensure the accessibility of medical diagnostic equipment for persons with disabilities.¹ The MDE Standards lay out the minimum technical criteria necessary to ensure that medical diagnostic equipment is accessible to and usable by patients with mobility and communication disabilities. Examples of such diagnostic equipment include examination tables and chairs, weight scales, mammography equipment, and other imaging equipment.

Achieving actual accessibility for medical diagnostic equipment via regulatory means is a two-step process. The MDE Standards are the first step. The MDE Standards contain technical specifications to make the covered diagnostic equipment accessible; however, they do not impose any requirements on health care providers or medical device manufacturers because the Access Board has no statutory authority to implement or enforce the Standards. The second step of this two-step regulatory scheme would be when one or more federal agencies, through separate rulemakings, adopt the MDE Standards (whether in whole or in part) as mandatory for entities under their jurisdiction. Subsequent rulemakings by these "enforcing agencies" will identify the entities that must comply with the MDE Standards, and the extent to which medical diagnostic equipment must conform to the MDE Standards. Since the Access Board does not know if and how enforcing authorities will adopt the MDE Standards, it has no way of estimating what costs (if any) manufacturers, providers, or others will incur as a result of this rule, or what level of societal benefits will be accrued.

Instead, this Final RA offers a qualitative discussion of some of the possible future impact of the MDE Standards. First, the Final RA examines the barriers to health care facing individuals with disabilities due to inaccessible diagnostic equipment, and it explains how the barriers will be reduced when patients with disabilities can access and use medical diagnostic equipment complying with the MDE Standards. Second, the Final RA discusses the potential impacts on health care providers and medical device manufacturers in cases where enforcing agencies adopt the MDE Standards as mandatory for entities regulated under their jurisdiction.

In addition, the Final RA provides a brief overview of commonly used diagnostic equipment in the current U.S. market to give a sense of how technical requirements in the MDE Standards are or are not met among the products sold at present. Building on the market information provided in the Preliminary Regulatory Assessment (Preliminary RA), as well as a search of online information from manufacturers, the Final RA presents product and price information for select diagnostic equipment. It indicates the extent to which different types of diagnostic equipment are already available with features similar to those required by the technical specifications of this final rule, and it notes where products do not currently offer similar features, meaning that they would require redesign should an enforcing authority adopt these MDE Standards in the future.

¹ Specifically, Section 4203 of the Patient Protection and Affordable Care Act amended Title V of the Rehabilitation Act by adding Section 510. *See* Patient Protection and Affordable Care Act § 4203, Pub. L. 111-148, 124 Stat. 570 (2010) (codified at 29 U.S.C. § 794f).

2. Statutory Background

Section 510 of the Rehabilitation Act requires the Access Board, in consultation with the Food and Drug Administration (FDA) of the Department of Health and Human Services, to issue standards that set forth minimum technical criteria for “medical diagnostic equipment used in (or in conjunction with) physician’s offices, clinics, emergency rooms, hospitals, and other medical settings. The standards shall ensure that such equipment is accessible to, and usable by, individuals with accessibility needs, and shall allow independent entry to, use of, and exit from the equipment by such individuals to the maximum extent possible.”² However, as noted earlier, Section 510 of the Rehabilitation Act does not grant the Access Board implementation or enforcement authority, nor does it authorize the Board to develop scoping or application requirements. The Access Board’s statutory authority is limited to developing minimum technical criteria. As a result, the Access Board’s MDE Standards are not binding unless and until adopted by other federal agencies as mandatory accessibility requirements for entities subject to their jurisdiction.

3. Rulemaking History

Promulgation of the MDE Standards completes a rulemaking process that began four years ago. First, in July 2010, the Access Board kicked off its regulatory efforts with an informal, on-the-record public meeting that featured panel discussions and presentations on medical diagnostic equipment and accessibility by, among others, experts, researchers, manufacturers, and disability advocates.

Thereafter, in February 2012, the Access Board formally began the rulemaking process by issuing a notice of proposed rulemaking (NPRM), which set forth proposed technical accessibility criteria for equipment that health care providers use for diagnostic purposes in medical settings (e.g., examination tables and chairs, weight scales, mammography equipment, and other types of imaging equipment).³ The proposed accessibility standards, as discussed in the preamble to the NPRM, were informed by a variety of sources, including: research studies addressing barriers affecting the accessibility and usability of medical diagnostic equipment by persons with disabilities; recommended consensus practices on human factors design principles for medical devices (i.e., ANSI/AAMI HE 75, Chapter 16); consultations with the FDA’s Center for Device and Radiological Health; implementation and enforcement efforts by other federal agencies (including the Departments of Justice (DOJ) and Health and Human Services (HHS)) concerning the accessibility of medical equipment under their own statutory authorities; and the agency’s

² 29 U.S.C. § 794f. Section 510 also directed the Access Board to promulgate these technical criteria within two years of the statutory effective date (i.e., March 2012). As noted in Section 3 below (Regulatory History), while the Access Board issued proposed rules by this deadline, various considerations (e.g., the technical nature of these standards, required consultations with the Food and Drug Administration and other federal agencies, and the need to seek expert assistance from an Advisory Committee) precluded issuance of a final rule within this statutory timeframe. The instant final rulemaking now completes the Access Board’s initial regulatory responsibilities under Section 510. Future rulemakings may update or revise the MDE Standards to, for example, incorporate technological changes or better address the access needs of particular beneficiary populations.

³ U.S. Access Board, Notice of Proposed Rule: Medical Diagnostic Equipment Accessibility Standards (NPRM), 77 FR 6915 (Feb. 9, 2012). In support of the proposed standards, the Access Board also provided a Preliminary RA discussing the need for rulemaking and presenting product and unit cost information concerning examination tables and weight scales. See US Access Board, *Preliminary Regulatory Assessment for Medical Diagnostic Equipment Standards* (Jan. 30, 2012). The Preliminary RA, along with other agency documents that serve as part of the MDE rulemaking record, are posted on the Access Board’s website (access-board.gov).

own existing accessibility guidelines and standards for the built environment.⁴ Collectively, the technical standards in the proposed rule were aimed at addressing the most significant barriers identified as affecting the accessibility and usability of medical diagnostic equipment, which were barriers faced by persons with mobility and communication disabilities.⁵

Public comment on the proposed MDE standards was received in two forms. First, during the comment period, the Access Board held two public hearings on the NPRM – one in Washington DC and the other in Atlanta, Georgia – at which 27 individuals testified. The written comments and the transcripts of two public hearings are available at <https://www.regulations.gov/docket?D=ATBCB-2012-0003>. Second, fifty-six individuals and organizations submitted written comments during the 120-day comment period.

In July 2012, following the close of the public comment period, the Access Board established a Medical Diagnostic Equipment Accessibility Standards Advisory Committee (MDE Advisory Committee) to assist on matters raised by public comments, provide technical expertise, and provide an opportunity for interest groups to reach consensus on regulatory issues.⁶ The MDE Advisory Committee consisted of representatives from 24 organizations, including medical services providers and diagnostic equipment manufacturers, among others.⁷ The Committee held meetings over a 10-month period. In December 2013, the Committee presented 54 recommendations to the Access Board on accessibility specifications for medical diagnostic equipment, including recommendations addressing transfer surface size and height, transfer supports, armrests, stirrups, lift compatibility, and wheelchair space. The committee members reached a consensus on all of their recommendations except for the minimum height of transfer surfaces. The Committee's final report is available at <https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report>.

After carefully considering the public comments, the MDE Advisory Committee report, and other relevant materials from the Committee meetings, the Access Board is now promulgating a final rule that establishes minimum technical criteria for accessibility of medical diagnostic equipment for persons with mobility and communication disabilities. The agency is promulgating these MDE Standards in compliance with its statutory obligations under Section 510 of the Rehabilitation Act. *See, supra*, Executive Summary, Sections 1 & 2 (summarizing the Access Board's mandate under Section 510 to promulgate minimum technical standards for MDE accessibility); *see also* Sections 5.1 & 5.2 (describing the barriers to medical equipment and health care facing people with mobility and communication disabilities).

⁴ *Ibid.* at 6917 – 19.

⁵ *See, e.g., Ibid.* at 6919 – 32.

⁶ See US Access Board, Notice of Establishment; Appointment of Members - Medical Diagnostic Equipment Accessibility Standards Advisory Committee, 77 Fed. Reg. 39,656 (July 5, 2012); see also NPRM, 77 Fed. Reg. at 6916 (noting intent to establish MDE Advisory Committee).

⁷ The MDE Advisory Committee had members representing the following organizations: The ADA National Network, Boston Center for Independent Living, Brewer Company, Conference of Radiation Control Program Directors, Inc., Duke University and Medical Center, Equal Rights Center, Evan Terry Associates, P.C., GE Healthcare, Harris Family Center for Disability and Health Policy at Western University of Health Sciences, Hausmann Industries, Inc., Hill-Rom Company, Inc., Hologic, Inc., Medical Positioning, Inc., Medical Technology Industries, Inc., Midmark Corporation, National Council on Independent Living, Paralyzed Veterans of America, Phillips Healthcare, Scale-Tronix, Inc., Siemens Medical Solutions USA, Inc., Stryker Medical, Sutter Health, United Spinal Association, and University of the Sciences in Philadelphia, Department of Occupational Therapy.

4. Overview of the MDE Standards

The MDE Standards provide the minimum accessibility specifications for diagnostic equipment used in medical settings. As in the proposed Standards, the final rule organizes accessibility requirements into four types of patient positions that the diagnostic equipment is designed to support: (1) supine, prone, or side-lying position; (2) seated position; (3) seated in a wheelchair; and (4) standing position. The rationale for organizing the requirements in this way—rather than by specific type or function of equipment, for example—is that medical diagnostic equipment is typically designed to support patients in specific positions for examination. For example, an ophthalmology chair is designed to be used while the patient is in a seated position. A stand-on weight scale is designed to be used in a standing position. Some types of equipment are designed to be used in more than one position; for example, a fluoroscopy machine may support patient use in prone and standing positions. Equipment that supports patients in more than one position generally must conform to the requirements for each position in which it is designed to support patients.

Table 1 below summarizes the features that make equipment covered by the MDE Standards accessible. For each of the four patient positions of equipment covered by the Standards, the table indicates the features that make that category of equipment accessible (when the accessibility features are provided consistent with the technical specifications for each feature as stated in the Standards). The last column of the table gives examples of the types of equipment that fall into each category. The types of equipment listed in the last column are meant to be illustrative, and not exhaustive.

Table 1: Summary of Accessibility Features of MDE Standards, by Functional Category of Patient Position(s) Supported by Equipment

Patient Position Supported by the Equipment	MDE Standards – Summary of Accessibility Features	Illustrative Equipment Types
Supine, prone, or side-lying position (M301)	Transfer surface, including adjustability, size, and unobstructed transfer Transfer supports, leg supports, and head and back support Lift compatibility	Examination tables Imaging equipment designed for use with platform beds, such as a CT scanner Radiology tables
Seated position (M302)	Transfer surface, including adjustability, size, and unobstructed transfer Transfer supports, leg supports, and head and back support Lift compatibility	Examination chairs Imaging equipment designed for use with a seat Chair scales
Seated in a wheelchair (M303)	Space for the wheelchair within the equipment; minimal slope of the wheelchair surface; edge protection of the wheelchair surface; beveled or ramped entry	Imaging equipment designed for wheelchair use

Patient Position Supported by the Equipment	MDE Standards – Summary of Accessibility Features	Illustrative Equipment Types
	<p>Same orientation to equipment as non-wheelchair users would orient</p> <p>Knee and toe clearance within or below the equipment</p> <p>Components capable of examining body parts of patients seated in a wheelchair, including breast platforms</p>	<p>Weight scales designed for wheelchair use</p>
<p>Standing position (M304)</p>	<p>Slip resistant standing surface</p> <p>Standing supports</p>	<p>Imaging equipment with a standing surface</p> <p>Weight scales designed for use in a standing position</p>

In addition, the final rule includes 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).

The final rule reflects some significant changes from the proposed standards. The Access Board made three general types of changes. The first type of changes aimed to make diagnostic equipment as accessible and usable as possible for patients with disabilities. For example, the MDE Standards not only specify the minimum and maximum height of transfer surfaces of equipment used by patients in a seated position, but now also require additional adjustability within the minimum and maximum height range. A second set of changes incorporates well-known and relevant accessibility requirements in the Americans with Disabilities Act (ADA) and the Architectural Barriers Act (ABA) Accessibility Guidelines, to allow for easier implementation of the MDE Standards in the future. In the final rule, for instance, the technical requirements for transfer supports track ADA and ABA Accessibility Guidelines provisions related to the shape and size of a grab bar. Finally, the third type of changes ensures that the Standards do not compromise functionality and safety of the equipment while they seek to increase accessibility. To that end, the MDE Standards allow a number of general and specific exceptions, and they further clarify certain technical criteria such as knee and toe clearance for mammography equipment. A detailed discussion of all the changes made to the proposed standards can be found in the Preamble and Section-by-Section Analysis accompanying the final rule text.

5. Potential Benefits and Beneficiaries of the MDE Standards

The MDE Standards are intended to allow for independent access to and use of medical diagnostic equipment by individuals with disabilities to the maximum extent possible. This section will examine the barriers to health care that individuals with disabilities encounter due to inaccessible medical equipment, and then explain how diagnostic equipment conforming to the MDE Standards will benefit individuals with disabilities.

5.1. Barriers to Medical Equipment and Health Care

Accessible medical diagnostic equipment appears not to be available at many health care providers and facilities. While the Access Board is unaware of any national data on the prevalence of accessible medical diagnostic equipment currently installed in medical facilities, data from specific states and types of equipment indicates that much of that equipment is not accessible. In California, a recent study of about 2,400 primary care facilities serving Medicaid patients in the state found that only 8.4 percent of the facilities had a height-adjustable examination table and less than 4 percent had a weight scale that could be used by patients who have mobility or activity limitations or who exceed the standard weight scale limit.⁸ Similarly, one medical device manufacturer that participated in the MDE Advisory Committee estimates that approximately 70% of examination rooms in the United States have only fixed-height tables, which present difficulties to many patients with disabilities.⁹

Evidence from surveys and focus groups confirms that individuals with disabilities face many significant barriers to accessing medical devices and technology. A 2004 national consumer survey collected information on the types of medical equipment that are most difficult for individuals with disabilities to access and use.¹⁰ A diverse sample of individuals with a wide range of disabilities completed the survey, including people with mobility, visual, hearing, and speech impairments, as well as individuals with cardiopulmonary conditions resulting in activity intolerance, orthopnea, and dyspnea. Survey respondents rated their degree of difficulty when attempting to access or use the equipment as follows:

- 75 percent rated examination tables as moderately difficult, extremely difficult, or impossible to use;
- 68 percent rated radiology equipment as moderately difficult, extremely difficult, or impossible to use;
- 53 percent rated weight scales as moderately difficult, extremely difficult, or impossible to use; and
- 50 percent rated examination chairs as moderately difficult, extremely difficult, or impossible to use.¹¹

⁸ Nancy R. Mudrick et al., "Physical accessibility in primary health care settings: Results from California on-site reviews," *Disability and Health Journal* 5 (2012): 159-167.

⁹ Comment of Midmark, Notice of Proposed Rulemaking for Medical Diagnostic Equipment (June 13, 2012), available at <https://www.regulations.gov/document?D=ATBCB-2012-0003-0061>.

¹⁰ Jill M. Winter et al., "Results of a National Survey on Accessibility of Medical Instrumentation for Consumers," in *Medical Instrumentation Accessibility and Usability Considerations*, eds. Jill M. Winters and Mary Follette Story (New York: CRC Press, 2006), 13.

¹¹ The study also reported the four categories of medical devices that were ranked as most difficult to use or access by type of disability. For respondents with visual impairments, the four most difficult categories to use (in rank order) were examination tables, weight scales, radiology equipment, and exercise and rehabilitation equipment; for respondents with hearing impairments, the top four were radiology equipment, exam tables, communication aids, and dental equipment; for respondents with speech impairments, the top four were radiology equipment, exam tables, exam chairs, and communication aids; for respondents with mobility impairments, the top four were exam tables, radiology equipment, exercise and rehabilitation equipment, and exam chairs; and for respondents with

Survey respondents reported difficulties of getting on and off the equipment, positioning their bodies on the equipment, feeling physical comfort and safety, interpreting visual displays and markings, and undertaking activities requiring fine motor movements.

To identify the critical barriers to accessibility and usability, the consumer-survey researchers conducted an in-depth focus group study of individuals with disabilities.¹² The researchers delved into specific equipment-related difficulties. Among other things, the participants commented on lack of physical supports for patients with disabilities to transfer their bodies onto and off the equipment and lack of support to achieve and maintain body positions while on the equipment. Expressing a range of emotions such as fear, frustration, embarrassment, and indignation, the focus group participants described some medical equipment (e.g., examination tables, imaging equipment, medical chairs, and weight scales) as not only inaccessible but also scary and unsafe. Some even reported that the negative health care experiences affected their willingness to schedule regular medical examinations and diagnostic procedures.

Furthermore, according to the National Council on Disability (NCD), the lack of accessible examination equipment is one of the greatest barriers to quality health care. NCD's 2009 report entitled "The Current State of Health Care for People with Disabilities" states:

For many people with mobility disabilities, access to examination and diagnostic equipment such as mammogram machines can be difficult or impossible if the equipment is not height-adjustable. Medical office staff members often are not trained to provide lifting assistance and are unwilling to lift patients onto inaccessible examination tables. Some patients do not wish to be lifted, out of fear that they will be dropped or injured. Health care providers, therefore, frequently conduct examinations or diagnostic tests while patients are seated in their wheelchairs, which can generate inaccurate test results or conceal physical evidence required for appropriate diagnosis and treatment.¹³

The Center for Disability Issues and the Health Professions (CDHP) also stresses that the lack of accessible equipment reduces the likelihood that individuals with disabilities will receive timely and appropriate health care. Health care providers may not perform some diagnostic procedures for patients with disabilities because the providers lack accessible equipment. This can result in suboptimal examination, missed or delayed diagnoses, and worsening conditions that require more expensive and extensive treatments.¹⁴

cardiopulmonary impairments, the top four were exam tables, radiology equipment, exercise and rehabilitation equipment, and exam chairs.

¹² Mary Follette Story, Erin Schwier, and June Isaacson, "Perspectives of patients with disabilities on accessibility of medical equipment, medical chairs, and weight scales," *Disability and Health Journal* 2 (2009): 169-179.

¹³ National Council on Disability, *The Current State of Health Care for People with Disabilities* (Washington, DC: National Council on Disability, 2009).

¹⁴ Harris Family Center for Disability and Health Policy, *Importance of Accessible Examination Tables, Chairs and Weight Scales* (Pomona, CA: Harris Family Center for Disability and Health Policy, 2010), accessed August 31, 2016. <http://webhost.westernu.edu/hfcdhp/wp-content/uploads/1-Brief-Tables-Scales.pdf>

5.2. Potential Benefits of the MDE Standards

The MDE Standards aim to lower the barriers that individuals with mobility and communication disabilities encounter while attempting to access and use medical diagnostic equipment. More specifically, many technical specifications in the Standards are intended to reduce barriers facing individuals with mobility disabilities, while one provision (concerning communication through diagnostic equipment) aims to help people with vision or hearing impairments. Medical diagnostic equipment complying with the technical requirements of the MDE Standards will increase accessibility by facilitating independent entry to, use of, and exit from such equipment by persons with mobility and communication disabilities, thereby improving the overall quality of their health care. By allowing individuals with disabilities to receive examinations, diagnostic procedures, and other health care services comparable to those received by individuals without disabilities, accessible medical diagnostic equipment will contribute to the improvement of the overall quality of health care for individuals with disabilities. The following examples demonstrate how the technical requirements of the MDE Standards will address specific barriers that people with mobility and communication disabilities face when trying to use the noted types of medical diagnostic equipment.

Examination Tables

The examination tables used in many examination rooms in the United States are fixed-height and are therefore not accessible.¹⁵ The surface of fixed-height examination tables is usually at least 30 inches off the floor—too high for a person in a wheelchair to transfer independently onto the table. These examination tables typically lack handholds or other transfer supports that help individuals transfer from a mobility device to the table surface. Consequently, individuals who use mobility devices are rendered dependent on the assistance of others to transfer them onto a table, with or without a portable patient lift. Not every doctor's office has a portable patient lift, and transfer without proper equipment can pose a risk of injury both to the person being transferred and to the person assisting with the transfer. As a result, some medical practices routinely have patients remain in their wheelchairs during an examination, instead of transferring the patients to an examination table for a proper exam. Such substandard care can prevent proper diagnosis and treatment of serious medical conditions. For example, in a complaint filed against a major health maintenance organization (HMO), a plaintiff described how when he had sought medical care for pressure sores, the doctor never personally examined the sores because the facility did not provide any way for the plaintiff to transfer from his wheelchair to the facility's fixed-height examination tables.¹⁶ The plaintiff stated that he had no way of knowing the severity of his condition, and if he was being properly treated.

Under the MDE Standards, accessible examination tables must be height-adjustable, with a low transfer height of 17-19 inches, a high transfer height of 25 inches, and 4 intermediate transfer heights (M301.2.1). If a patient is able to transfer independently to an examination table, this adjustability allows the patient to select the best transfer height for the examination table; the table can then be raised to an appropriate level for diagnosis and later lowered so that the patient may transfer back to his or her mobility device. The MDE Standards also ensure that the transfer surface of an accessible examination

¹⁵ See Comment of Midmark, Notice of Proposed Rulemaking for Medical Diagnostic Equipment, (June 13, 2012), available at <https://www.regulations.gov/document?D=ATBCB-2012-0003-0061> (estimating that approximately 70% of all exam rooms in the United States have a manual exam table).

¹⁶ Complaint at 4-5, *Meltzer et al. v. Kaiser Foundation Health Plan, Inc. et al.*, No. 829265-2 (Super. Ct. Alameda settled Apr. 12, 2001).

table is appropriately wide for transfer (M301.2.3), that the surface is unobstructed during transfer (M301.2.4), and that transfer supports are provided to facilitate transfer (M301.3.1). For patients who are not able to transfer independently, the MDE Standards require accessible examination tables to be compatible with a portable patient lift (M301.4) so that the patients can transfer via the lift, if there is one. Examination tables meeting the MDE Standards will allow patients to receive examinations on an exam table comparable to those patients without disabilities receive.

Weight Scales

Many doctor's offices have stand-on weight scales with a small standing surface and no handrails. Such scales pose challenges for individuals who use wheelchairs, who have balance issues, or who have other mobility impairments. Accurately assessing weight is critical for appropriate diagnosis and treatment of certain conditions. Individuals unable to use the scale provided at their doctor's office report being asked to guess their weight.¹⁷ The potential use of an inaccurate weight is particularly concerning when medical professionals use that reported weight in prescribing or evaluating medication dosages. Individuals report that it is difficult to maintain balance on stand-on scales as there is nothing to hold on to. Even wheelchair scales are not necessarily fully accessible: some wheelchair users indicate that they are asked to stand once on the scale to be weighed without the weight of the wheelchair, and that this posed a challenge for them.

The MDE Standards provide technical specifications that can be applied to stand-on scales, wheelchair scales, and chair scales to make each type of scale more accessible. For accessible stand-on scales, the MDE Standards require that the standing surface be slip-resistant (M304.2.1) and that standing supports be provided (304.2.2). For accessible wheelchair scales, the MDE Standards require a sufficiently large platform to provide wheelchair access (M303.2.2 and M303.2.3), minimal slope in the platform surface (M303.2.5), edge protection to keep the wheelchair from rolling off a raised platform (M303.2.6), appropriate ramping or beveled edge at the entry of a raised platform (M303.3), and a standing support if the scale is also to be used by patients in a standing position (M304.2.2). Under the MDE Standards, accessible chair scales must be height-adjustable (M302.2.1), must have transfer supports (M302.3), and must provide for unobstructed transfer (M302.2.5). These technical requirements address transfer and balance issues that patients with disabilities face when using weight scales at medical facilities.

Examination Chairs

When patients with disabilities seek specialized medical care, they may confront inaccessible examination chairs that are difficult to transfer into and out of. Further, specialized examination chairs are typically designed with special features to assist in diagnosis, and these features may not be compatible with certain types of disabilities. For example, standard heel stirrups used on many obstetrics and gynecology (OB/GYN) chairs are insufficient to position properly the legs of a patient with limited leg strength. Phlebotomy chairs are often fixed-height, with much of the transfer surface permanently obstructed by fixed armrests. Dental chairs have integrated leg rests, and attached equipment often fully obstructs one side of the chair. This configuration presents serious challenges to patient transfer, requiring that transfer occur on a specific side of the chair, typically without the presence of transfer supports. Due to the inaccessibility of specialized examination chairs, individuals with disabilities may

¹⁷ Mary Follette Story, Erin Schwier, and June Isaacson, "Perspectives of patients," 176.

go for years without specialty medical care. For example, a woman who uses a wheelchair reported that because her HMO provider did not have sufficiently accessible equipment, she was routinely examined while seated in her wheelchair.¹⁸ As a result, the woman had not had a gynecological exam in 15 years. Another woman with lower-body paralysis indicated that for her to have a gynecological exam, two people are needed to hold her feet in the stirrups.¹⁹

The MDE Standards require accessible examination chairs to be height-adjustable for transfer (M302.2.1), and that the transfer surface be unobstructed during transfer (M302.2.5). Further, they require a patient to be able to transfer from two different sides of the chair, either from the front and the side, or for chairs with an integrated leg rest (such as a dental chair), from either side of the chair (M302.2.4). Accessible examination chairs must also have transfer supports that patients can use to facilitate transfer (M302.3.1). These requirements allow an accessible examination chair to be repositioned to a height that is optimal for a particular patient to transfer, provide an unobstructed surface so the patient does not need to navigate around equipment or armrests, allow the patient to use his or her stronger side for transfer, and have transfer supports for stability during transfer. In addition to the requirements related to patient transfer, the MDE Standards require that if stirrups are provided, they must support, position, and secure the patient's legs, so that she need not rely on her own leg strength for proper diagnostic positioning (M305.4). MDE Standards require head and back support while an examination chair is reclined to support patients who lack back and neck muscle strength (M302.3.3). These technical requirements facilitate independent transfer into specialty examination chairs, and provide independent positioning support for proper diagnostic use.

Imaging Equipment

Several types of imaging equipment pose challenges to people with disabilities. For example, it is well documented that women with mobility disabilities are less likely to obtain mammograms.²⁰ To use a typical mammography machine, a patient must stand during imaging, with her breast positioned on a platform. Some patients with disabilities do not have the lower body strength to stand for this procedure. The MDE Standards address access to mammograms by providing technical specifications for mammography machines that are used while a patient is seated in a wheelchair (M303). The MDE Standards specify technical requirements for the height of the breast platform, which must be adjustable enough to allow use by an individual in a wheelchair (M303.4.1), and for clearances that will allow a wheelchair to fit under a breast platform (M303.2.4.1).

Other types of imaging equipment also present barriers to access. Fixed-height radiology tables are difficult for patients to transfer onto, as are fixed-height CT scanners and MRI beds. Imaging equipment rarely have any type of transfer supports. In addition, fluoroscopy machines that rotate patients from a lying position to a standing position do not have standing supports when they are used in a standing position. The MDE Standards require the examination surface of accessible imaging tables to be adjustable (M301.2.1) unless such adjustability is impossible to achieve due to structural or operational characteristics (M201.2). In addition, the Standards also require transfer supports and an unobstructed

¹⁸ Complaint at 5, *Meltzer et al.*

¹⁹ Mary Follette Story, Erin Schwier, and June Isaacson, "Perspectives of patients," 173.

²⁰ Ana Todd and Alexa Stuijbergen, "Breast Cancer Screening and Disability," *Rehabilitation Nursing* 37 (2012): 74-79 (discussing research indicating that women with major mobility impairments are substantially less likely to report having had a mammogram in the previous two years than women without such impairments).

transfer surface to facilitate patient transfer. The MDE Standards also specify that accessible imaging tables be compatible with portable patient lifts (M301.4), so even if a patient is unable to transfer independently onto imaging equipment, he or she can be transferred using a lift. Standing supports are required for accessible equipment that has a standing surface, such as a fluoroscopy machine, which will allow patients with limited leg strength or balance issues greater stability while the machine is in a standing position.

In sum, when applied, the technical requirements of the MDE Standards will remove specific barriers to the use of medical diagnostic equipment by persons with mobility or communication disabilities. Equipment complying with these MDE Standards will allow many individuals with such disabilities to transfer independently onto and off of diagnostic equipment, receive improved diagnostic procedures, and maintain their sense of independence, confidence, and dignity while using medical services.

5.3. Potential Beneficiaries – People with Disabilities

The U.S. Census Bureau estimates that approximately 56.7 million people, or 18.7%, of the U.S.'s civilian non-institutionalized population had some level of disability in 2010.²¹ To put this in perspective, the number of individuals with disabilities in the United States is very close to the combined total population of California and Florida. The Census Bureau provides the following estimates regarding the number of people aged 15 and older with specific disabilities:

- 30.6 million individuals (almost 10% of the entire 2010 population) had limitations associated with ambulatory activities of the lower body—for example, they had difficulty walking or climbing stairs, or they required the use of a wheelchair, cane, crutches, or walker;
- 19.9 million individuals had difficulty with physical tasks relating to upper body functioning, including difficulty lifting and grasping;
- 8.1 million individuals had difficulty seeing words and letters in ordinary newsprint, including 2.0 million who were unable to see at all; and
- 7.6 million individuals had difficulty hearing conversations, including 1.1 million who were unable to hear conversations at all.

Moreover, the need for accessible MDE will increase in the coming decades for demographic reasons. The prevalence of disability increases with age: the U.S. Census Bureau's American Community Survey shows that in 2014, 36% of people age 65 and over had some type of disability, compared with 10.5 % of people who are younger (ages 18-64).²² And this group is growing: already, 46.2 million persons – or one in 7 Americans – were at least 65 years old in 2014, and the elderly population is projected to more than double over the next 35 years, to approximately 98 million in 2060.²³

²¹ United States Census, *Americans with Disabilities: 2010* (2012), accessed on August 31, 2016. <http://www.census.gov/prod/2012pubs/p70-131.pdf>

²² United States Census, *American Community Survey Sex by Age by Disability Status* (2014), accessed August 31, 2016. http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ACS_14_5YR_B18101&prodType=table

²³ Administration on Aging, *A Profile of Older Americans: 2014* (Washington, DC: AOA, 2014), accessed on August 31, 2016. http://www.aoa.acl.gov/aging_statistics/profile/2014/docs/2014-profile.pdf

Medical equipment conforming to the MDE Standards will benefit many people with mobility and communication disabilities when they seek health care services, with particular benefits for those individuals who have the greatest health care needs. The final report submitted by the MDE Advisory Committee describes the varying degrees of health care needs by individuals with disabilities as follows:

On one level, most persons with disabilities require the same services recommended for all individuals to maintain their health and diagnose diseases at early, more treatable stages. . . Many persons also require specific diagnostic and therapeutic services because of the health conditions causing their functional impairments and disability. Other persons might need diagnostic testing or therapeutic treatments to address secondary disabilities or conditions related to their primary disabilities. In addition, as they age, persons with disabilities experience many of the same chronic conditions as do other in late middle-age and older years, such as hypertension, diabetes, cardiovascular and pulmonary diseases, and cancers, necessitating the full range of diagnostic and therapeutic health care services.²⁴

6. Entities Potentially Affected by MDE Standards

The MDE Standards do not impose any requirements on health care providers or medical device manufacturers; as a result, there are no compliance costs to be attributed to the MDE Standards. However, if an enforcing authority, such as the Department of Justice (DOJ), adopts the Standards as mandatory for entities under its jurisdiction, health care providers may experience some compliance costs. In addition, 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. This section explores the costs and incentives that could result from a future adoption of the MDE Standards; however, the Access Board notes that the costs and incentives discussed in this section are purely speculative, given the lack of a statutory requirement for agencies to adopt these Standards.

6.1. Health Care Providers

Health care providers must provide individuals with disabilities “full and equal” access to their health care services and facilities under the ADA and Section 504 of the Rehabilitation Act, which 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. §§ 12181 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.

Enforcing agencies have undertaken various enforcement and guidance activities under these statutes. The Department of Justice (DOJ) has entered into settlement agreements with several major health care providers to ensure compliance with the ADA and Section 504 of the Rehabilitation Act.²⁵ In

²⁴ MDE Advisory Committee, *Advancing Equal Access to Diagnostic Services: Recommendations on Standards for the Design of Medical Diagnostic Equipment for Adults with Disabilities* (December 13, 2013), accessed August 31, 2016. <https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report>

²⁵ See e.g. Settlement Agreement, *Disability Rights Council et al. v. Washington Hospital Center*, No. 1:03CV02434 (D.D.C. 2005).

July 2010, DOJ and the Department of Health and Human Services issued a guidance document for health care providers spelling out their responsibility to make their services and facilities accessible to individuals with mobility disabilities under the ADA and Section 504 of the Rehabilitation Act.²⁶ The guidance document includes information on: accessible examination rooms and the clear floor space needed for individuals who use mobility devices to transfer to medical equipment; 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 for health care personnel.

In July 2010, DOJ announced its intent to move toward more systematic enforcement when it issued an advance notice of proposed rulemaking (ANPRM) on accessible equipment and furniture.²⁷ The ANPRM announced that, pursuant to the obligation that has always existed under the ADA for covered entities to provide accessible equipment and furniture, DOJ was considering amending its regulations implementing Titles II and III of the ADA to add specific standards for the design and use of accessible equipment and furniture. Among other things, the ANPRM stated that DOJ would consider adopting the standards issued by the Access Board for accessible equipment. DOJ also stated its intent to provide scoping requirements that specify the minimum number of certain types of accessible medical equipment that would be required in different types of health care facilities. If DOJ pursues its intent to amend its ADA regulations as announced in the ANPRM, it will publish a notice of proposed rulemaking requesting public comment, and it will prepare a regulatory assessment in accordance with Executive Orders 13563 and 12866.

If DOJ adopts the MDE Standards in the future, then health care providers could incur compliance costs. The amount of the compliance costs would depend on a number of factors, including the scope of equipment coverage at each health care facility and the extent that the health care provider's equipment is not already accessible.

Additionally, as documented in the MDE Advisory Committee report and other studies, the Access Board anticipates that savings to health care providers from a reduction in injuries to health care workers (such as nurses, aides and orderlies) who are currently required to lift and/or transfer patients with mobility disabilities may offset some of the potential costs from MDE-related regulations issued by DOJ; these savings should be factored into any such analysis. Medical providers are likely to see reductions in insurance and workman's compensation costs, as well as productivity gains from the reduced time off due to workplace injuries.

6.2. Medical Device Manufacturers

Future rulemakings, such as the one DOJ announced in its 2010 ANPRM, could affect medical device manufacturers. If health care providers are required to provide accessible medical diagnostic equipment that complies with the Standards, manufacturers may have an economic incentive to produce conforming products. The size of the incentive will depend on the health care providers' resulting

²⁶ U.S. Dept. of Justice and U.S. Dept. of Health and Human Services, *Access to Medical Care for Individuals with Mobility Disabilities* (July 2010), accessed on August 31, 2016. http://www.ada.gov/medcare_ta.htm.

²⁷ U.S. Dept. of Justice, Advance Notice of Proposed Rulemaking: Nondiscrimination on the Basis of Disability by State and Local Governments and Places of Public Accommodation; Equipment and Furniture, 75 FR 43452 (July 26, 2010).

demand for accessible medical diagnostic equipment, as well as the incremental costs that manufacturers will incur as they design and manufacture products that conform to the Standards.

Many medical device manufacturers already incorporate accessibility features in some of their products, such as height-adjustable examination surfaces, transfer supports, and scales designed for use by patients seated in a wheelchair. In the case of these products, the incremental costs for manufacturers to conform to the Standards are expected to be small, because the products' features may already meet or nearly meet the Standards. For manufacturers that do not currently incorporate accessible features into their products but plan to do so in future designs or redesigns of their products, the incremental costs may be greater. However, it is unlikely that enforcing authorities will issue standards that require MDE manufacturers to produce accessible equipment; manufacturers will thus likely remain free to choose whether or when to offer products that conform to accessibility standards that may be promulgated by other federal agencies in the future. Other manufacturers may choose not to produce accessible medical diagnostic equipment, or may produce accessible products with less market appeal than those of their competitors; in that case, they may lose market share and incur losses. Where this rule would result in a share of the market moving from one manufacturer to another manufacturer, this would represent an economic transfer as part of the rule. Where the rule would result in a manufacturer needing to undertake additional research and development, that would represent a marginal cost to the manufacturer. Where a manufacturer would lose revenue because of this rule, that lost revenue also represents a cost to the manufacturer.

While the MDE Standards impose no mandatory requirements on medical device manufacturers, the manufacturers could use the Standards as an industry best practice for accessible diagnostic equipment design. Since manufacturers periodically update product lines and features, they may incorporate more accessibility features in their products over time, which could result in lower incremental costs. By the time any enforcing agency issues regulations incorporating the Standards, more products conforming to the Standards might be readily available in the market.

7. Medical Diagnostic Equipment in the Market

This section attempts to provide a snapshot of commonly used types of diagnostic equipment currently sold in the U.S. retail market, building on the market information provided in the Preliminary RA. The Preliminary RA presented product and unit cost information for examination tables and weight scales. This Final RA updates that information, while also providing product information (and price information, in the case of examination chairs) for two other categories of MDE: examination chairs and imaging equipment. For all four categories, the Final RA identifies whether there are versions of these products that offer features similar to the technical requirements of the MDE Standards.

This brief market overview offers the public a general sense of the extent to which currently available diagnostic equipment already provides features similar to the technical specifications in the MDE Standards. This overview may also provide enforcing agencies that may adopt the MDE Standards (or similar requirements) in the future with some baseline information against which to assess the incremental costs of a proposed regulation. The information presented below is accurate at the time of the Access Board's promulgation of the MDE Standards. However, the market for medical diagnostic equipment may change prior to any future rulemaking that implements the MDE Standards. The Access Board expects that when rulemaking agencies propose to enforce the Standards, they will carry out regulatory assessments that provide specific cost and benefit estimates relevant to their rules.

7.1. Informal Collection of Product and Price Information

To collect information on the diagnostic equipment on the market today, between January and July 2016 the Access Board reviewed information publicly available on the internet for products in four categories of medical diagnostic equipment that are covered by the MDE Standards: (1) examination tables; (2) weight scales; (3) examination chairs; and (4) imaging machines. For each of the four categories, the Access Board checked major medical equipment suppliers' websites, selected several major manufacturers of each type of diagnostic equipment, and reviewed each manufacturer's website for models in those product categories²⁸.

While the Access Board reviewed information on individual products, it did not undertake a systematic review of every feature of every product to assess potential compliance with the MDE Standards. The level of specificity of publicly available information regarding each product varies by manufacturer and product line, and it would have been impossible to compare every feature of every product. Further, such a robust, systematic study would be inappropriate at this point, given that the MDE Standards have no mandatory application.

Throughout its informal review of publicly available information on currently available medical diagnostic equipment, the Access Board sought to collect information on the market as a whole, rather than assessing whether individual products would meet the MDE Standards. The Board relied on the suppliers' and manufacturers' websites for its information collection, including photographs, schematics, and other specification lists and descriptions provided by the manufacturer online. The Board did not directly contact any manufacturers to discuss their products, nor did it rely on manufacturers' characterization of products as "accessible" when determining whether a product category contained available models with features similar to the Standards; the term "accessible" is not currently regulated with respect to diagnostic medical equipment. The Access Board does not endorse any product that it reviewed for this Final RA.

After reviewing product features for each manufacturer's full line of equipment in a particular category, the Access Board sought to build a price range for each category of product using the prices of a portion of those models for which pricing was available online. Prices of exam tables, weight scales, and exam chairs were generally available for most (but not all) reviewed manufacturers; however, pricing information for imaging equipment was almost nonexistent online. For products where prices were available online, the Access Board obtained pricing for several models in each category. A number of online MDE suppliers listed both the manufacturer suggested retail prices (MSRPs) and discounted prices. As the actual price paid for a certain piece of medical equipment can vary widely depending on the supplier from which it is purchased and the type of contract a purchaser may have, the Access Board sought to collect and review MSRP data to control for variations in actual purchase price. MSRP data were not publicly available online for all products; thus the prices for each type of product reflect pricing for some of the models where the MSRPs were available. The prices reported here are likely higher than the actual prices that MDE purchasers would pay, because purchasers typically pay less than the MSRP, due to a special sale, volume discount, or other reasons. Nevertheless, the price estimates below provide

²⁸ The Board selected several manufacturers in each category whose products appear frequently for sale in its internet search of online websites and catalogs. With respect to imaging equipment, the Board reviewed products made by well-known manufacturers, products frequently for sale on the secondary market, and, in a few cases, products noted in online articles or settlement documents as having features that made the equipment more accessible.

a snapshot for the range of products available in a given product type. Appendix A contains links to the public websites where the Access Board obtained the product and price information.

In the sections below, the Access Board summarizes the findings for each category of commonly used medical diagnostic equipment addressed by the final rule. The summary generally describes the equipment, notes the technical specifications that are provided under the MDE Standards, indicates how many manufacturers and products the Board reviewed, and provides a general assessment of the availability of products with features similar to those required by the Standards. In addition, for each category of product, the Board provides a price range for the available models, and where possible, provides some general observations about the products that fall in the high and low ends of the price range.

7.2. Examination Tables

There are two general types of examination tables: (a) treatment tables and (b) exam or procedure tables. Treatment tables are the most basic type of examination tables, and are commonly found in first aid stations, school nurse offices, and other places where basic medical attention is provided. Treatment tables typically have a flat table-top examination surface. Some treatment tables have adjustable backrests that support patients in a reclined position; typically, they do not support patients in a seated position. Basic treatment tables are fixed-height, with a variety of base options including H-frame open bases and closed cabinet bases. Bases can be made out of wood, particle board, or metal, and some bases offer shelves and/or drawers. Treatment tables also come in adjustable-height models that are powered by either an electric motor or a hydraulic crank.

Exam/procedure tables typically have articulating backrests and can support patients in both seated and reclined positions. Exam/procedure tables can be either “power” or “manual” tables, with the two types differentiated by how the articulating backrest operates. Power exam/procedure tables have an electronic motor that can adjust the table height and control an articulated backrest from a flat, fully reclined position to a straight-seated position. Manual tables have a non-motorized, mechanical device such as a handle or button for the backrest adjustment; articulating backrests on manual tables support from a flat, fully reclined position to a semi-reclined position. These manual tables do not support a seated position, and the heights of their examination surfaces are typically not adjustable.

For both treatment tables and exam procedure tables, the fixed height and adjustable-height tables typically comprise separate product lines. The fixed-height tables tend to be more basic in materials and design than adjustable-height models. Adjustable-height tables may have a separate set of features, such as different upholstery, different configurations of shelves and cabinets, and headrest and footrests. As separate product lines, they may also have a separate set of available options, such as pillows, straps or safety rails, which may not be available for fixed-height models. The width of the examination surfaces varies widely between models.

Under the MDE Standards, examination tables are covered by the technical specifications for diagnostic equipment that supports patients in a supine, prone, or side-lying position (M301). Exam/procedure tables that also support patients in a seated position must also comply with the requirements for diagnostic equipment that supports patients in a seated position (M302). *See* M101.2 (applying the MDE Standards to diagnostic equipment based on the “positions” they support). However, the primary difference between the specifications of M301 and M302 is the required width of the transfer surface. M301 requires a transfer surface with a width of 28 inches minimum, while M302 requires a width of 21 inches minimum. Thus, as long as the examination table has an “end” transfer surface at the

seat end of the table and meets all other requirements of M301, the requirements for M302 will also be met. The technical requirements of M301 specify adjustability of transfer surface (examination surface) height (M301.2.1), the dimensions of transfer surface (M301.2.3), the provision of transfer supports (M301.3), and sufficient clearance in and around the base for a portable patient lift (M301.4).²⁹

The Access Board reviewed treatment and exam/procedure tables built by five manufacturers. With respect to treatment tables, the five manufacturers produce a total of approximately 135 fixed-height models, and 35 adjustable-height models. Only three of the five manufacturers produce adjustable-height models. Some adjustable-height treatment tables adjust to a low height of 18.5 or 19 inches, which is within the low transfer height range of 17 to 19 inches specified by M301.2.1; however, a substantial portion of adjustable-height treatment tables lower only to 26 or 27 inches, which would not conform to the Standards.³⁰ Treatment tables are available in varying widths, from approximately 24 inches to approximately 40 inches (for bariatric models). Several adjustable-height tables meet or exceed the 28-inch width requirement of M301.2.3. Most treatment tables appear to offer clearance for a lift either in or around the base (M301.4). Fixed-height treatment tables do not typically appear to offer any type of transfer supports, the provision of which is specified by M301.3. However, some adjustable-height treatment tables are available with optional “safety rails” on each side of the examination surface. The safety rails can be repositioned individually below the transfer surface during patient transfer, but it is not apparent from publicly available information whether the safety rails would meet the MDE Standards’ technical specifications for transfer supports, as described in M305.2.

With respect to exam/procedure tables, the five manufacturers reviewed by the Access Board produce approximately 28 total models of manual tables and 43 total models of power tables. Manual tables are not height-adjustable, and thus, would not meet the specifications for height adjustability of M301.2.1. Power exam/procedure tables are universally height-adjustable, and some adjust to within the 17 to 19-inch minimum low transfer height range of M301.2.1. Some power exam/procedure tables meet the 28-inch transfer surface width requirement of M301.2.3. Three of the reviewed manufacturers offer standard or optional grab bars, armrests, or safety supports for their power exam/procedure table models, but insufficient information was available to determine whether these grab bars, armrests, and safety supports would meet the technical requirements for transfer supports under M305.2. Most exam/procedure tables appear to meet at least one of the lift compatibility requirements of M301.4.

The table below summarizes our observations on the accessibility features currently available with treatment table models.

²⁹ Head and back support is also required if the table reclines (M301.3.3), and where stirrups are provided, the equipment must meet leg support requirements (M301.3.2).

³⁰ The adjustability requirement of M301.2.1 states that in addition to a low and high transfer height, equipment should have at least four intermediate transfer positions, separated by one-inch increments. While manufacturers typically provide a low and high height in the specifications for examination tables, the Board did not observe information on intermediate transfer heights. We were thus unable to ascertain from publicly available sources whether examination tables with intermediate transfer heights are commonly available in the market.

Table 2: Treatment Tables - Accessibility Features on Sampling of Commercially Available Equipment (Based on USAB Informal Market Research)

MDE Standards' Specifications for Accessibility	Fixed-Height Treatment Tables	Adjustable-Height Treatment Tables
Transfer Surface Dimensions (M301.2.3)	Width of transfer surface ranges from 24 to 30 inches. There are many 30-inch models available, which exceed the Standards' technical specification of 28 inches.	Width of transfer surface ranges from 27 inches to 40 inches for bariatric models.
Height Adjustability (M301.2.1)	Fixed-height treatment tables do not adjust. Tables typically measure 31 to 32 inches from the floor to the top of the table.	All models are height-adjustable, with some lowering to within the Standards' low transfer height range.
Base Clearance for Patient Lift (M301.4)	All models appear to have sufficient clearance either in or around the base to accommodate a portable patient lift.	All models appear to have sufficient clearance either in or around the base to accommodate a portable patient lift.
Transfer Supports (M301.3.1 and M305.2)	None observed.	Some models are available with optional "safety rails," which can be repositioned below the transfer surface. It is not clear from available information whether these safety rails meet the Standards' technical specifications for transfer supports.

The table below summarizes our observations on the accessibility features currently available with existing exam/procedure table models.

Table 3: Exam/Procedure Tables - Accessibility Features on Sampling of Commercially Available Equipment (Based on USAB Informal Market Research)

MDE Standards' Specifications for Accessibility	Manual Exam/Procedure Tables	Power Exam/Procedure Tables
Transfer Surface Dimensions (M301.2.3)	Width of transfer surface ranges from 26 to 28.5 inches, with tables from two manufacturers meeting the 28-inch transfer surface minimum width.	Width of transfer surface ranges from 26 to 34 inches (most models between 27 and 30 inches). Several meet the 28-inch transfer surface minimum width.

MDE Standards' Specifications for Accessibility	Manual Exam/Procedure Tables	Power Exam/Procedure Tables
Height Adjustability (M301.2.1)	No models have height adjustability. Examination surfaces measure 31 to 33 inches high, from the floor to the top of the table.	All models are height-adjustable. Several models adjust to a low height of 18 or 19 inches, which is within the Standards' range for low transfer height.
Base Clearance for Patient Lift (M301.4)	All models appear to have sufficient clearance around the base to accommodate a patient lift.	All models appear to have sufficient clearance around the base to accommodate a patient lift.
Transfer Supports (M301.3.1 and M305.2)	None observed.	Three manufacturers offer grab bars, armrests, or safety supports as options. Available information is insufficient to determine whether they meet the Standards' technical specifications for transfer supports.

Table 4: Examination/Procedure Tables - Price Ranges for Sampling of Commercially Available Equipment (Based on USAB Informal Market Research)

Table Type	Lower-Cost Products (MSRP)	Higher-Cost Products (MSRP)
Fixed-Height Treatment Tables	\$500 – \$850	\$950 – \$1,600
Adjustable-Height Treatment Tables	\$1,800 – \$2,100	\$5,050 – \$5,800
Manual Exam/Procedure Tables	\$1,050	\$2,500
Power Exam/Procedure Tables	\$2,150 – \$3,500	\$5,000 – \$15,150

The price differential between lower and higher cost treatment tables appears to relate primarily to the type of base the table offers. Lower-cost treatment tables typically have an open base. By contrast, higher-cost fixed-height treatment tables have cabinets, drawers, or shelves in the base, and higher-cost adjustable-height treatment tables typically have a shrouded (metal encased) base. Manual exam/procedure tables typically offer cabinets, drawers, or shelves and, if marketed for OB/GYN use, they may have additional accessories such as pull-out footrests and attachable stirrups. Manual exam/procedure tables offer roughly the same options and functionality, regardless of price. Lower-priced power exam/procedure tables have open bases, pneumatic backrests, and manual footrests. Higher-priced power exam/procedure tables typically have premium upholstery, fully powered backrests, and power footrests.

Overall, fixed-height treatment tables and exam/procedure tables are significantly less expensive than adjustable-height models. The price differentials between fixed-height and adjustable-height models represent simply different products packaged with different parts. As discussed earlier, the fixed-height treatment tables and exam/procedure tables differ from adjustable-height models in terms of transfer

height adjustability, but also in several other respects such as the width of the transfer surface and the presence of transfer supports. For example, adjustable-height models typically have wider transfer surfaces than fixed height tables. From our online search, we could not readily tease out the unit cost of each component in each model we reviewed.³¹ If the MDE Standards are adopted by an enforcing authority, fixed-height tables will not meet accessibility requirements, because they are not height-adjustable. One medical diagnostic equipment manufacturer has estimated that approximately 70% of all exam rooms in the United States feature a manual exam table.³² If this estimate is correct, a large number of healthcare providers may at some point need to acquire height-adjustable equipment, should a future rulemaking by an enforcing authority so require. In that case, the manufacturer providing the estimate indicated that it would not redesign manual examination tables to conform to the Standards, rather it would recommend that customers seeking accessible models instead purchase powered, height-adjustable tables and chairs that already conform.

7.3. Examination Chairs

The Access Board reviewed product and cost information for five types of examination chairs: obstetrics and gynecology (OB/GYN) chairs, dental chairs, optometry/ophthalmology chairs, phlebotomy chairs, and podiatry chairs. These chairs are associated with commonly used specialty medical practices. Each type of specialty chair has certain defining features. For example, OB/GYN chairs typically have pelvic tilt and stirrup options, whereas podiatry chairs have reclining backrests and leg-rests that articulate 90 degrees. We observed that particular models of chairs are marketed for more than one purpose. For example, optometry chairs may also be marketed as “Ears, Nose, and Throat” (ENT) exam chairs. Podiatry chairs may also be marketed as “procedure chairs,” “exam chairs,” or “aesthetic medicine chairs.” When determining in which category each particular model should be included, we relied on the

³¹ The wide variation in product specifications and combinations of features available in any given product model, coupled with a lack of publicly-available feature-by-feature price information for MDE products, has precluded the Access Board, in this Final RA, from assessing incremental unit costs for “accessible” components or products. Publicly available information does not typically provide a breakdown of product price by individual features. Further, in some cases, an accessible component is the absence of obstructions, which is difficult to evaluate from written product materials. It also bears noting that despite requests for public comment on MDE price/cost information, we received very little cost or price information from MDE manufacturers, health care providers, or other commenters, in response to the MDE NPRM. The Access Board did receive information one cost-related item concerning accessible examination tables from the MDE Advisory Committee. In one of the minority reports to the MDE Advisory Committee Report, four manufacturers of examination tables asserted that commercially available examination tables with a conforming low minimum height of 19-inches would be 24% more expensive if they also included leg and transfer supports that complied with the then-proposed MDE Standards. See Recommendation of 19-inch Lower Adjustable Height as the Minimum Accessibility Standard (Joint Report of The Brewer Company, Hausmann Industries, Medical Technology Industries, Inc., and Midmark Corporation) (Sept. 27, 2013), available at <https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report/appendix-a-minority-reports>. However, this one cost-related item was insufficient, standing alone to assess incremental unit costs for accessible examination tables, let alone unit costs for accessible features on all types of medical diagnostic equipment.

³² Comment of Midmark, Notice of Proposed Rulemaking for Medical Diagnostic Equipment (June 13, 2012), available at <https://www.regulations.gov/document?D=ATBCB-2012-0003-0061>.

manufacturer's characterization of the chair and the Board's own assessment of the chair's primary features.

Examination chairs are covered by the technical specifications for medical equipment that supports patients in a seated position (M302). The specifications include: height adjustability of the unobstructed transfer surface (seat surface), with a low transfer height between 17 and 19 inches, and a high transfer height of 25 inches (M302.2)³³; transfer supports (M302.3.1); and lift compatibility (M302.4), among other things. The technical specifications call for a transfer surface on the seat measuring 21 inches minimum in width and 17 inches minimum in length (M302.2.3), accompanied by a transfer support on one side (M302.3.1). Attached obstructions may be repositioned or removed during transfer to allow for unobstructed transfer (M302.2.5). If stirrups are provided, they must secure, position, and support the patient's legs (M302.3.2 and M305.4). If the equipment is used in a reclined position, it must support the patient's head and back while reclined (M302.3.3 and 305.5). As previously noted, examination chairs that also support patients in a supine position must also meet the requirements of M301. However, if the chair is always positioned in a seated position for transfer, and reclines to a supine position for diagnosis only after the patient has transferred, the chair does *not* need to comply with the requirements of M301 (M301.1 exception).

OB/GYN Chairs/Tables

OB/GYN diagnostic equipment comes in both chair and table designs. OB/GYN tables are typically examination tables with an articulating backrest, a "pelvic tilt" option, stirrups, and a pullout footrest. Several of the general use manual examination tables that we reviewed offer optional stirrups for OB/GYN diagnostic purposes. OB/GYN chairs typically resemble a standard examination chair with the addition of adjustable stirrups and the option for a "pelvic tilt." OB/GYN chairs typically have an articulating backrest that reclines the equipment to a flat table position. Like OB/GYN tables, OB/GYN chairs accommodate patients in both seated and reclined positions. OB/GYN chairs are typically only available in power models.

The Access Board reviewed product information for thirteen OB/GYN chairs and tables produced by five manufacturers, including manual and power models. One of the unique features of OB/GYN chairs and tables are the stirrups that are provided to position the patient's legs during the exam. Standard stirrups provide heel supports only, and would not be consistent with the MDE Standards' technical specifications for leg supports, which require that where stirrups are provided, a method of supporting, positioning, and securing the patient's legs must also be provided (M305.4). However, "knee crutches," which support patients' legs at the knee, are offered as an optional accessory by various manufacturers, and when used in conjunction with stirrups would be consistent with the Standards' technical specifications. The Access Board's observations are confirmed by two manufacturers who commented in

³³ M302.2 also requires four intermediate transfer heights at one-inch minimum increments. As with examination tables, manufacturers typically do not indicate in their product specifications whether an examination chair has intermediate incremental heights between the high and low height for the chair. A chair that is continuously adjustable between the high and low heights via a power motor would likely meet the intermediate incremental heights requirement; however, since information regarding intermediate heights is not typically provided online for most models, the Board cannot conclude whether chairs with intermediate incremental transfer heights are commonly available in the market.

response to the MDE NPRM that they already offer optional knee or leg crutch systems that would meet the leg support requirement, with the cost ranging from \$500 to \$1,100 per set.

Manual OB/GYN tables and power OB/GYN chairs have very different designs, and although they are used for similar types of exams, they are distinct products. Manual OB/GYN tables are fixed-height, and thus necessarily do not offer the height adjustability of the transfer surface specified by the Standards. Some models have bases constructed from plywood and laminate; others are made out of plastic. Some models offer electrical outlets within the base; others do not. The bases often include a pull-out step, flat pull out leg rest, and some have drawers or cabinets. Manual OB/GYN tables typically do not have transfer supports. Width of the examination surface varies by model.

Power OB/GYN chairs, however, are typically height adjustable, and all appear to meet the width requirements for the transfer surface for diagnostic equipment used in the seated position. Whether or not these chairs must also meet the requirements for equipment that supports patients in a supine position depends on whether a patient would only transfer onto the equipment in a seated position (M301.1 Exception). One of the reviewed models was sufficiently wide to meet the transfer surface width requirements for diagnostic equipment that supports patients in a supine position.

Some power chairs have moveable armrests that can be positioned during patient transfer; however, it is not apparent from publicly available information whether the armrests meet the technical requirements for transfer supports. While specific base dimensions were not available online, estimating from the size of the transfer surface, it appears that both manual and power models typically have enough clearance around the base for use with a portable patient lift.

The table below summarizes the Access Board’s observations on the accessibility features currently available with existing OB/GYN table and chair models.

Table 5: OB/GYN Tables and Chairs - Accessibility Features on Sampling of Commercially Available Equipment (Based on USAB Informal Market Research)

MDE Standards’ Specifications for Accessibility	Manual Tables	Power Chairs and Tables
Transfer Surface Dimensions (M302.2.3 and M301.2.3)	Transfer surface dimensions meet requirements for seated MDE. They may not meet requirements for supine MDE.	Transfer surface dimensions meet requirements for seated MDE. At least one model also meets the requirements for supine MDE.
Height Adjustability (M302.2.1)	Manual tables are typically at least 30 inches high. They are not height-adjustable.	Transfer surface is typically adjustable. Some models meet the low transfer height specifications.
Base Clearance for Patient Lift (M302.4)	Most manual tables appear to have sufficient clearance around the base for use with a portable patient lift, although base specifications information is not provided online.	Most power chairs appear to have sufficient clearance around the base for use with a portable patient lift, although base specifications information is not provided online.

Transfer Supports (M302.3.1 and M305.2)	Manual tables do not appear to offer standard or optional transfer supports.	Moveable armrests are provided on some models; however, it is not clear from available information whether the armrests meet the technical specifications for transfer supports.
Stirrups that support, position, and secure legs (M302.3.2 and M305.4)	Manual tables are typically offered with optional traditional stirrups that do not provide leg support and positioning.	Some manufacturers offer optional knee crutches, which support, position, and secure the patients' legs.

Table 6: OB/GYN Tables and Chairs - Price Ranges for Sampling of Commercially Available Equipment (Based on USAB Informal Market Research)

OB/GYN Chairs	Lower-Cost Products (MSRP)	Higher-Cost Products (MSRP)
Manual Tables	\$1,050 - \$1,150	\$1,850 - \$2,400
Power Chairs and Tables	\$2,950 - \$3,700	\$6,100 - \$7,500

Lower-priced OB/GYN power chairs and tables have a height-adjustable electric-powered base, and they typically have a pneumatic backrest and a manually adjustable leg rest. Higher-priced OB/GYN power chairs and tables also have a height-adjustable electric-powered base, but typically have an electric-powered articulating backrest. Manual tables have similar features, functionality, and aesthetics, regardless of price.

Again, manual tables are significantly less expensive than power chairs and tables. As discussed above, the manual tables differ from power models in terms of transfer height adjustability, but also in several other respects, such as the width of transfer surfaces and the presence of transfer supports. From our online search, we could not readily distinguish the unit costs of different components.

Dental Chairs

Dental chairs are typically narrower than other types of examination chairs, to allow for provider access to the patient. They are typically powered hydraulically with a fully adjustable backrest, integrated fixed footrest, double articulating headrest, and fixed or swing-away armrests.

We reviewed 24 dental chairs made by five manufacturers. Many dental chairs are height-adjustable; some are not. At least some current models appear to have continuous height adjustability spanning the full transfer height range specified by the MDE Standards. The length and width of the examination seat of most dental chairs typically exceeds the required dimensions of the transfer surface of diagnostic equipment used in a seated position. Due to their integrated footrests that prevent patient transfer on the end of the examination surface, accessible dental chairs must accommodate unobstructed patient transfer from either long side of the examination surface. Existing models of dental chairs typically have armrests, most of which can be moved out of the way during patient transfer. It is unclear from publicly available information on the internet whether these armrests currently meet transfer support technical requirements.

Dental chairs are typically cantilevered off of a solid base. Thus, it does not appear that dental chairs typically meet requirements for clearance in the base. It is not apparent from information available on the internet whether there are dental chairs that currently meet the “clearance around base” requirements.

The table below summarizes our observations on the accessibility features currently available with dental chairs.

Table 7: Dental Chairs - Accessibility Features on Sampling of Commercially Available Equipment (Based on USAB Informal Market Research)

MDE Standards’ Specifications for Accessibility	Dental Chairs
Transfer Surface Dimensions (M302.2.3)	The seat of most dental chairs meets the minimum specifications for transfer surface size.
Height Adjustability (M302.2.1)	The transfer surface (seat) height is adjustable for many chairs; some chairs have continuous (rather than discrete) seat height adjustability.
Transfer Supports (M302.3.1 and M305.2)	Moveable armrests are available on many models. It is not apparent whether these armrests meet the technical specifications for transfer supports.
Base Clearance for Patient Lift (M302.4)	It is unclear from available specifications whether sufficient clearance around the base exists with most models for patient lift compatibility.

Table 8: Dental Chairs - Price Ranges for Sampling of Commercially Available Equipment (Based on USAB Informal Market Research)

Dental Chairs	Lower-Cost Products (MSRP)	Higher-Cost Products (MSRP)
Power Chairs	\$6,300 - \$7,700	\$8,850 - \$11,650

Dental chairs appear to have fairly consistent functionality, appearance, and technology across models. The disparity in price appears to relate to the quality of the upholstery, the degree to which the chair tilts and swivels, the type of headrest, and features such as heat and massage systems.

Optometry/Ophthalmology Chairs

Optometry (and ophthalmology) chairs typically are upright, upholstered chairs with a headrest, leg rest, armrests, and flat footrest or foot bar. Optometry chairs typically rotate 330 to 360 degrees atop a solid base, which may or may not raise and lower the examination surface of the chair. There are three

main types of chairs: chairs whose backrest manually reclines, chairs that tilt backward as an entire unit, and chairs with a fully articulating electrically powered backrest. Some manual chairs remain in fixed upright position and do not recline.

We reviewed product information for 21 optometry/ophthalmology chairs made by five manufacturers. Of the models we reviewed, some had seat widths exceeding the MDE Standards’ specified transfer surface width of 21 inches; some had seat widths of less than 20 inches. Due to their integrated fixed footrests that prevent patient transfer from in front of the equipment, the technical requirements of the MDE Standards would require that optometry chairs accommodate unobstructed patient transfer from either side of the seat. Optometry chairs typically have armrests that can be moved out of the way during patient transfer. It is unclear from information available on the internet whether these armrests currently meet the technical requirements for transfer supports. A main feature of optometry chairs is their ability to tilt a patient back for examination. All optometry chairs reviewed universally appear to provide the patient with head support while in a reclined or tilted position, which is consistent with the technical specifications of the rule. Optometry chairs typically rotate on a solid base. It appears that some models have sufficient clearance around the base for compatibility with a portable patient lift. None of the models reviewed appeared to lower to a height within the low transfer height range of 17 to 19 inches, although some models came close to the higher end of the range, lowering to 19.5 or 19.75 inches.

The table below summarizes our observations on the accessibility features currently available with optometry and ophthalmology chairs.

Table 9: Optometry/Ophthalmology Chairs - Accessibility Features on Sampling of Commercially Available Equipment (Based on USAB Informal Market Research)

MDE Standards’ Specifications for Accessibility	Optometry/Ophthalmology Chairs
Transfer Surface Dimensions (M302.2.3)	Some, but not all, models meet the minimum specifications.
Height Adjustability (M302.2.1)	Seat height is adjustable for many optometry/ophthalmology chairs; however, they did not seem to adjust as low as the 17 to 19-inch low transfer height range. Some models came within half an inch of a low transfer height consistent with the technical specifications.
Transfer Supports (M302.3.1 and M305.2)	Models typically have armrests that can be moved out of the way. It is not apparent from available information whether these armrests would meet the technical specifications for transfer supports.
Head and Back Support (M302.3.3 and M305.5)	All chairs appear to support the patient’s head and back in reclined and/or tilted positions.
Base Clearance for Patient Lift (M302.4)	Base specifications are not available; however, some chairs appear to have sufficient clearance around the base for patient lift compatibility.

Table 10: Optometry/Ophthalmology Chairs - Price Ranges for Sampling of Commercially Available Equipment (Based on USAB Informal Market Research)

Optometry/Ophthalmology Chairs	Lower-Cost Products (MSRP)	Higher-Cost Products (MSRP)
Full Power Procedure Chairs	\$5,850	\$7,350 - \$8,000
Tilt Chairs	\$4,600 - \$5,550	\$6,350 - \$7,000
Manual Recline Chairs	\$3,450	\$4,200 - \$5,800

Optometry chair price ranges seem to create a continuum with manual chairs at the low end and full power chairs at the high end. Within each product group, the price range seemed to reflect aesthetic design, the amount of contouring and cushioning, and the type of upholstery. The functionality of the models within each product group is similar, with the exception that some of the manual chairs do not recline.

Phlebotomy Chairs

Phlebotomy chairs, also called “Blood Drawing” chairs, position the patient so that a technician can draw blood from the patient’s arm. Phlebotomy chairs typically have at least one wide armrest and a “flip arm” attached to the end of the armrest that is repositioned in front of the patient after he or she is seated. This additional armrest can swing either up or out from the chair to allow patient access. There are three types of phlebotomy chairs: fixed chairs, which sit at a fixed height on four legs; hydraulic chairs, which sit on a round metal base, and can be raised and lowered with a foot pedal; and power chairs, which are raised and lowered by an electric motor.

We reviewed 56 phlebotomy chairs made by eight manufacturers. None of the reviewed phlebotomy chair models met the MDE Standards’ transfer height requirements. As noted above, the main clinical feature of phlebotomy chairs is their wide armrests upon which a medical provider positions a patient’s arm to draw blood. Phlebotomy chairs typically have wide armrests on each side of the seat. The armrests are often height-adjustable and usually completely removable; however, with most models, the stationary posts that secure the armrests to the chair protrude above the seat surface and cannot be repositioned. Such stationary posts would obstruct the transfer surface of the chair, which is inconsistent with the technical specifications of the MDE Standards calling for an unobstructed transfer surface.

Fixed phlebotomy chairs are not height-adjustable; thus, none of the fixed chairs would comply with the Standards’ technical requirements for height adjustability of the transfer surface. Hydraulic and power phlebotomy chairs typically have adjustable height ranges of approximately 20 inches above the floor to 29 inches above the floor; none of the reviewed chairs had a low transfer height of 17 inches to 19 inches as required by the Standards. With respect to transfer surface dimensions, we observed that while all models have seats that are at least 17 inches long, the width of the seats varies from approximately 18 inches wide to 30 inches wide (in bariatric models). Thus, some models have sufficiently wide seats consistent with the MDE Standards’ specifications for transfer surface dimensions. Although specific dimensions are not provided online, the manufacturers’ photographs suggest that several models of phlebotomy chairs would meet the base clearance requirement for portable patient lifts.

Our observations with respect to the accessibility features currently available with existing phlebotomy chairs are summarized in the chart below.

Table 11: Phlebotomy Chairs - Accessibility Features on Sampling of Commercially Available Equipment (Based on USAB Informal Market Research)

MDE Standards' Specifications for Accessibility	Phlebotomy Chairs
Transfer Surface Dimensions (M302.2.3)	Seats are typically at least 17 inches long, which meet the required length in the Standards. The width of the seats ranges from 18 to 30 inches; only seats with widths of at least 21 inches meet the technical specifications for transfer surface dimensions.
Height Adjustability (M302.2.1)	Seat height is not adjustable for fixed chairs; however, for hydraulic and power chairs, seat height is adjustable and ranges from 20 to 29 inches. None of the height-adjustable chairs reviewed meets the low transfer height specification of 17 to 19 inches.
Unobstructed Transfer Surface (M302.2.5)	Chairs typically have wide armrests on each side of the chair, which are used to position the patient's arm for blood draw. The armrests are usually adjustable and removable; however, some products have stationary posts that secure armrests to the chair, which protrude above the height of the top of the transfer surface, and would obstruct the patient transfer.
Transfer Supports (M302.3.1 and M305.2)	Chairs typically have wide armrests, which may exceed the 2-inch cross-section dimension for transfer supports.
Base Clearance for Patient Lift (M302.4)	Many models appear to have sufficient clearance around the base for use with a portable patient lift.

Table 12: Phlebotomy Chairs - Price Ranges for Sampling of Commercially Available Equipment (Based on USAB Informal Market Research)

Phlebotomy Chairs	Lower-Cost Products (MSRP)	Higher-Cost Products (MSRP)
Fixed Chairs	\$400 - \$850	\$900 - \$1,300
Hydraulic Chairs	\$1,000 - \$1,250	\$1,300 - \$1,500
Power Chairs	\$1,800 - \$2,050	\$2,600 - \$2,850

Within each product group, the products had similar functionality. The difference in price between the various models often reflected whether the seats were made out of molded plastic or padded upholstery, and whether they had an attached drawer for supplies. The higher cost products in both the fixed chair and power chair categories typically were bariatric models.

Podiatry Chairs

Podiatry chairs are typically fully powered exam chairs with a cushioned upholstery exam surface. Podiatry chairs tend to have fully articulating backrests with a fixed or integrated headrest; some models allow the entire chair to tilt back as a unit. The defining feature of a podiatry chair is an adjustable leg rest. Some models have separate leg rests for each leg that are independently adjustable. Many models are equipped with a debris tray within or underneath the leg rest.

We reviewed 12 podiatry chairs constituting the full line of podiatry chairs from five manufacturers. The width of the transfer surface (seat) for podiatry chairs ranges from 24 inches to 30 inches (bariatric models), which exceeds the transfer surface width specifications of the MDE Standards. The leg rests on podiatry chairs typically adjust down 90 degrees from the seat, and can therefore be positioned during transfer so as not to obstruct the transfer surface. Podiatry chairs typically have moveable armrests that can be flipped up out of the way during patient transfer. It is unclear from information available on the internet whether these armrests currently meet the technical requirements for transfer supports. All podiatry chairs reviewed appear to provide the patient with head support while in a reclined or tilted position. Podiatry chairs are typically height-adjustable, and some lower to 19 inches, which falls within the range of the low transfer height as specified in the MDE Standards. Podiatry chairs typically sit atop a solid base; thus, it does not appear that podiatry chairs would likely meet requirements for clearance in the base. However, some models may have sufficient clearance around the base to make them compatible with a portable patient lift.

The table below summarizes our observations on the accessibility features currently available with podiatry chairs.

Table 13: Podiatry Chairs - Accessibility Features on Sampling of Commercially Available Equipment (Based on USAB Informal Market Research)

MDE Standards' Specifications for Accessibility	Podiatry Chairs
Transfer Surface Dimensions (M302.2.3)	All chairs reviewed exceed the Standards' specifications for minimum width of the transfer surface.
Height Adjustability (M302.2.1)	Seat height was adjustable for all reviewed models; some models lower to 19 inches within the low transfer height specifications of the Standards.
Transfer Supports (M302.3.1 and M305.2)	All reviewed chairs have armrests that can be flipped up during patient transfer. It is not apparent from available information whether these armrests meet the Standards' technical specifications for transfer supports.
Unobstructed Transfer Surface (M302.2.5)	Leg rests adjust down 90 degrees from the seat, and thus do not obstruct the patient's access or use of the transfer surface. Armrests can also swing away from the transfer surface.
Head and Back Support (M302.3.3 and M305.5)	All chairs appear to support the patient's head and back in reclined positions.

MDE Standards' Specifications for Accessibility	Podiatry Chairs
Base Clearance for Patient Lift (M302.4)	Some models may have sufficient clearance around the base for use with a patient lift.

Table 14: Podiatry Chairs - Price Ranges for Sampling of Commercially Available Equipment (Based on USAB Informal Market Research)

Podiatry Chairs	Lower-Cost Products (MSRP)	Higher-Cost Products (MSRP)
Power Chairs	\$4,350 - \$7,200	\$7,900 - \$9,800

All reviewed chairs have similar functionality. The higher priced products may have higher quality upholstery and/or a wider seat. Two of the reviewed manufacturers do not list MSRPs online; thus, although we reviewed the products of five manufacturers, the price ranges in the table reflect three manufacturers' pricing.

7.4. Weight Scales

We reviewed three types of weight scales: stand-on scales, wheelchair scales, and chair scales. We updated product data and unit costs of stand-on scales and wheelchair scales included in the Preliminary RA, and obtained recent product data for chair scales for this Final RA. We reviewed only models marketed for professional use. All three types of scales are available in mechanical and digital formats, although mechanical scales are increasingly uncommon.

Stand-On Scales

Stand-on scales are covered under the MDE Standards' specifications for diagnostic equipment used by patients in a standing position (M304). The technical criteria under M304 of the final rules includes the provision of a slip-resistant standing surface (M304.2.1) and standing supports (M304.2.2). Although scales communicate information, the communication requirements of M306 do not apply to scales, because no information necessary for performance of the diagnostic procedure is being communicated directly to the patient; the medical professional performing the diagnostic procedure can complete the procedure without the scale communicating the patient's weight directly to the patient.

We reviewed product information for 84 stand-on scales made by seven manufacturers. Stand-on scales are scales that have a platform upon which the patient stands to be weighed. Stand-on scales have platforms of varying sizes, and the MDE Standards do not provide specifications for the size of stand-on scale platforms. Some stand-on scale models are available with handrails; 23 of the models we reviewed offer some type of handrail. However, it is not apparent from information provided on the internet whether these handrails meet the technical specifications for standing supports. Most stand-on scales with handrails are digital; one reviewed stand-on mechanical scale was available in a version with a

handpost at a slightly higher cost. Manufacturers’ typically describe stand-on scales as having an “anti-slip” or “skid-proof” surface.

The tables below summarize our observations on the accessibility features currently available with stand-on scales.

Table 15: Stand-On Scales - Accessibility Features on Sampling of Commercially Available Equipment (Based on USAB Informal Market Research)

MDE Standards’ Specifications for Accessibility	Stand-On Scales
Slip-Resistant Standing Surface (M304.2.1)	Most scales are marketed as having an “anti-slip” or “skid-proof” surface.
Standing Supports (M304.2.2)	Handrails are available on many models; however, there is not enough information available to determine whether they typically meet the technical specifications for standing supports.

Table 16: Stand-On Scales - Price Ranges for Sampling of Commercially Available Equipment (Based on USAB Informal Market Research)

Models	Lower-Cost Products (MSRP)	Higher-Cost Products (MSRP)
Mechanical without handrails	\$300	\$400
Mechanical with handpost (1 model)	\$500	\$500
Digital without handrails	\$350 - \$650	\$700 - \$1,250
Digital with handrails	\$750 - \$1,000	\$1,700 - \$2,600

Higher-cost scales without handrails tend to have larger platforms, and higher-cost products with handrails are typically bariatric scales. While there is less variation in medical scales than with exam tables or chairs, there is still substantial variation in product design. Some models with handrails have larger standing platforms and elevated digital displays in contrast to products without handrails. As a result, we were able to figure out the unit costs of accessible features specified in the MDE Standards. There are too few mechanical scales with handposts on the market to draw meaningful cost comparison.

Wheelchair Scales

Wheelchair scales are covered under the specifications for diagnostic equipment used by patients seated in a wheelchair (M303). The technical criteria under M303 include sufficient space for a wheelchair to enter, exit, and remain on the platform during use (M303.2.2 and M303.2.3); edge protection to prevent a wheelchair from sliding off a raised platform (M303.2.6); and minimal change in level at entry (M303.3.1).

Wheelchair scales typically have a platform that is either installed flush with the floor or raised from the floor and accessed via one or two ramps.³⁴ The MDE Standards specify the minimum dimensions for a single-ramped entry wheelchair scale as well as for a dual-ramped scale permitting pass-through from one end to the other. The technical specifications of the MDE Standards would require that a single-ramped entry platform wheelchair scale must have platform dimensions of 32 inches wide and 48 inches deep. A dual-ramped platform wheelchair scale allowing pass-through is permitted a depth of 40 inches. Wheelchair scales installed flush with the floor must be 36 inches wide, and 40 inches deep, assuming that the scale offers entry and exit on opposite ends of the scale.

We reviewed product information for 36 wheelchair scales (only one of which was mechanical), constituting the full line of wheelchair scales made by seven manufacturers. We observed that many of the reviewed products conform to the Standards' minimum dimensions for platforms; however, some models had platform depths of 32 to 36 inches, which is not quite deep enough to meet the requirements. Some, but not all models, offer edge protection on ramps and raised platforms.

The table below summarizes our observations on the accessibility features currently available with wheelchair scales.

Table 17: Wheelchair Scales - Accessibility Features on Sampling of Commercially Available Equipment (Based on USAB Informal Market Research)

MDE Standards' Specifications for Accessibility	Wheelchair Scales
Platform Dimensions (M303.2.2 and M303.2.3)	Many, but not all, models meet or exceed the minimum requirements.
Edge Protection (M303.2.6)	Many, but not all, scales have ramp and/or platform edge protection.

General Price Range for Wheelchair Scales

Table 18: Wheelchair Scales - Price Ranges for Sampling of Commercially Available Equipment (Based on USAB Informal Market Research)

Wheelchair Scales	Lower-Cost Products (MSRP)	Higher-Cost Products (MSRP)
Mechanical with Ramped Platform (1 model)	\$3,100	\$3,100
Digital with Ramped Platform	\$900 - \$1,800	\$2,450 - \$5,850
Digital with Flush Platform	\$3,900	\$7,300

Less expensive ramped platform wheelchair scales tended to be portable models with smaller platforms. The most expensive products had handrails, a fold-down seat, and wireless capability. The

³⁴ A limited number of wheelchair scales have two separate rails or spaces for wheels instead of a flat platform. We did not review these models.

cost of wheelchair scales with platforms flush with the floor generally correlated to the size of the platform – the bigger the platform, the more expensive the scale.

Chair Scales

Chair scales, which consist of a molded plastic chair suspended by a metal frame, weigh patients in a seated position. Typically, a chair scale has armrests and a footrest that is designed to ensure that the scale captures the patient’s full weight. Some chair scales have wheels attached to the base for ease of transporting the scale.

Chair scales are covered by the technical requirements for diagnostic equipment used in a seated position (M302). As discussed above with respect to examination chairs, the relevant requirements for diagnostic equipment used in a seated position include specifications for the height and size of the transfer surface (seat) (M302.2), and a requirement for transfer supports (M302.3.1), and lift compatibility (M302.4). The transfer surface of diagnostic equipment used in a seated position must be 21 inches wide minimum and 17 inches long minimum (M302.2.3).

We reviewed product information for 20 chair scales that comprise the full line of chair scales made by 8 manufacturers. Chair scales are not typically height-adjustable, so that the currently available models we reviewed do not meet the minimum height specifications of the MDE Standards. Chair scales typically have seats that meet the minimum dimensions for transfer surfaces; however, some chair scales are not sufficiently wide to meet the 21-inch width requirement. Chair scales typically have armrests, although from the available information, it is not clear if these meet the technical specifications for transfer supports. Some models have armrests that swing up to allow unobstructed patient transfer, as required by M302.2.5. The footrests on chair scales are typically adjustable but not necessarily removable. Chair scales typically have open bases; thus, it appears that some models may have sufficient clearance within the base to accommodate a patient lift, as described in M302.4.1. Most models appear to have sufficient clearance around the base to accommodate a patient lift, as described in M302.4.2.

The table below summarizes our observations on the accessibility features currently available with chair scales.

Table 19: Chair Scales - Accessibility Features on Sampling of Commercially Available Equipment (Based on USAB Informal Market Research)

MDE Standards’ Specifications for Accessibility	Chair Scales
Transfer Surface Dimensions (M302.2.3)	Many scales meet or exceed the minimum dimension requirements for the transfer surface.
Height Adjustability (M302.2.1)	Seat height is not adjustable for most chair scales, which would not meet the transfer surface adjustability requirements.
Transfer Supports (M302.3.1 and M305.2)	Chair scales typically have armrests, although from the available information, it is not clear if these meet the technical specifications for transfer supports.
Unobstructed Transfer (M302.2.5)	Some models have armrests that can swing up during transfer. Footrests may obstruct patient transfer.
Base Clearance for Patient Lift (M302.4)	Many chair scales appear to have sufficient clearance around the base.

Table 20: Chair Scales - Price Ranges for Sampling of Commercially Available Equipment (Based on USAB Informal Market Research)

Chair Scales	Lower-Cost Products (MSRP)	Higher-Cost Products (MSRP)
Mechanical Chair Scales	\$700	\$750
Digital Chair Scales	\$800 - \$1,250	\$1,600 - \$2,400

The chair scales reviewed had similar functionality, features, and aesthetics. Products at the very high end of the range had wireless capability to print patient results to a wireless printer. As shown above, digital chair scales are more expensive than mechanical models; the price differentials appear more related to the technology of the weighing mechanism and display rather than features relevant to the accessibility of the scale.

7.5. Imaging Equipment

Imaging equipment is typically used in a supine, prone, or side-lying position (such as a bone density scanner); or in a standing position (such as an x-ray machine). Persons with disabilities may also use imaging equipment while seated in a wheelchair (such as a mammography machine). Imaging equipment that typically is used in a supine, prone, or side-lying position (such as an x-ray table) may occasionally be used in a seated position depending on the image sought by the healthcare provider. Imaging equipment seeking to comply with the MDE Standards would be subject to the requirements for each patient position that the equipment supports.

The four types of imaging equipment the Access Board reviewed include: (1) imaging machines with bores such as magnetic resonance imaging (MRI) machines and computed tomography (CT) scanners; (2) bone density scanners; (3) radiology and fluoroscopy machines; and (4) mammography machines. Due to a lack of detailed product information available on the internet, we were unable to assess with specificity the extent to which existing products have features that are similar to the technical specifications in the MDE Standards.

In addition, because no pricing of new imaging equipment was publicly available on the internet, we are unable to present a general price range for these products. However, the Access Board has been told that the prices of imaging equipment are substantially higher than prices of the other three categories of diagnostic equipment discussed above. While a typical examination table may cost several hundred dollars and an exam chair several thousand, imaging equipment may cost hundreds of thousands or millions of dollars. The high price of imaging equipment reflects the advanced technology of imaging machines. In some instances, a manufacturer may produce a line of equipment that has physically similar models, which feature different types of technology to produce an image. Available technology ranges from analog (traditional film) to several generations of digital technology that link directly to workflow management software systems. Analog systems may be referred to as “value” or “economy” in marketing materials, suggesting lower prices for this type of technology.

Below, we provide a general overview of product information for existing models of certain types of imaging equipment.

Imaging Equipment with Bores

Several types of imaging equipment move a patient through a bore while he or she lies on a table, including magnetic resonance imaging (MRI) machines and computed tomography (CT) scanners. The table may be integral to the equipment, or it may separate and move via casters or wheels, allowing the patient to be transferred and prepared in another room before transport to the imaging equipment. The width of the bore dictates the maximum width of the table, as the table must fit through the bore for proper functioning of the equipment.

Imaging equipment with a bore is covered by the technical criteria for equipment that supports patients in a supine, prone, or side-lying position (M301). The technical requirements under M301 include: a transfer surface with a width of 21 inches minimum (M301.2.3); height adjustability of the transfer surface with a low transfer height between 17 and 19 inches (M301.2.1); transfer supports (M301.3); clearance in or around the base for compatibility with a portable patient lift (M301.4), among other requirements. The MDE Standards also require that information communicated through the equipment to the patient be communicated in at least two formats (M306).

We reviewed product information for 12 wide-bore MRI machines from five manufacturers and eight CT scanners from five manufacturers. Wide-bore MRIs typically have table widths exceeding 21 inches, ranging from approximately 25 to 29 inches. CT scanners, on the other hand, typically have table width of less than 21 inches, ranging from approximately 16 to 20.5 inches. Both types of equipment have height-adjustable tables. Wide-bore MRI tables have minimum heights ranging from approximately 17 to 27 inches, while CT scanners tend to range from approximately 17 inches to 23 inches high. Neither wide-bore MRI machines nor CT scanners have clearance within the base for compatibility with a portable patient lift. However, both types of equipment appear to have sufficient space around the base to accommodate a patient lift.

Neither wide-bore MRI machines nor CT scanners have transfer supports. The Medical Imaging & Technology Alliance (MITA), an association of imaging equipment manufacturers, asserted in a public comment in response to the MDE NPRM that the incorporation of support structures could have an impact on image quality, although it did not elaborate on how the image quality could be impacted.³⁵ MITA indicated that redesign to incorporate transfer supports would involve a “significant technical impact,” but could not provide an estimate for the incremental cost of such a redesign. MITA noted generally, however, that the “economic impact would be lessened if features conforming to the Standards are incorporated in a [regularly scheduled] major new design plan.”

Imaging equipment with bores typically have communication features so that a medical provider can communicate instructions to the patient while the patient is inside the bore. Wide-bore MRI machines typically have gantry mounted LCD screens and intercom systems, and CT scanners have visual breath hold indicators and prerecorded messages. It is not apparent whether the instructions communicated to patients via these devices are communicated in more than one method; however, MITA indicated that the provision of two of the three communication methods (audible, visible, and tactile) could be incorporated into new designs.³⁶

³⁵ See Comment of MITA, Notice of Proposed Rulemaking for Medical Diagnostic Equipment, (June 12, 2012), available at <https://www.regulations.gov/document?D=ATBCB-2012-0003-0050>.

³⁶ *Ibid.*

The table below summarizes our observations on the accessibility features currently available with imaging equipment.

Table 21: Imaging Equipment - Accessibility Features on Sampling of Commercially Available Equipment (Based on USAB Informal Market Research)

MDE Standards' Specifications for Accessibility	Wide-Bore MRI Machines	CT Scanners
Transfer Surface Dimensions (M301.2.3)	Width of the transfer surface ranges from 25 to 29 inches, all exceeding the minimum specification of 21 inches.	Width of transfer surface ranges from 16 to 20.5 inches, none of which meet the minimum specification of 21 inches.
Height Adjustability (M301.2.1)	All models are height-adjustable; however, only a few of the reviewed models lowered to within the low transfer height range of 17 to 19 inches.	All models are height-adjustable. Several, but not all, adjust to within the low transfer height range.
Base Clearance for Patient Lift (M301.4)	Models appear to offer sufficient clearance around the base.	Models appear to offer sufficient clearance around the base.
Transfer Supports (M301.3.1 and M305.2)	None observed.	None observed.
Communication of Information (M306)	An intercom system is typically provided inside the bore. It does not appear that communications are offered by an additional method.	Visual indicators and pre-recorded messages are provided to patients inside the bores. It does not appear that these communications provide the same information, or that information is provided via more than one method.

Bone Density Scanners

Bone density scanners, also called DEXA or DXA machines, are used by patients in a supine, prone, or side-lying position. They typically consist of a solid base fixed-height table, and a C-arm scanner that moves back and forth over a patient lying on the tabletop. The C-arm scanner is attached to a large x-ray system located within the base of the table. DXA machines are typically operated by a technician within the room who assists the patient with proper positioning; thus, DXA machines do not include communication features.

DXA scanners are covered by the requirements of M301 for diagnostic equipment used by patients in a supine, prone, or side-lying position (M301). The technical requirements under M301 address the minimum width of a transfer surface (M301.2.3); height adjustability of the transfer surface with a low transfer height between 17 and 19 inches (M301.2.1); transfer supports (M301.3); and clearance in or around the base for compatibility with a portable patient lift (M301.4), among other requirements.

We reviewed product information for 16 DXA scanners made by three manufacturers. We observed that DXA scanner tabletops are fairly wide, ranging from approximately 34 to 51.5 inches,

which exceeds the Standards’ technical specifications for a transfer surface width of 28 inches. DXA scanners do not typically offer transfer supports, which the Standards require of all accessible diagnostic equipment used in the supine, prone, or side-lying position. DXA scanners are not typically height adjustable, although there are a few models that adjust between 27 and 30 inches in height. Industry representatives have indicated that the technology used in DXA machines, which is located inside the base of the table, cannot be reduced in size such that the scanners could be redesigned to meet the Standards’ height adjustability requirements, or low transfer height.³⁷ Currently, most DXA scanners have fixed-height tables that appear to range in height from approximately 25 to 29 inches high. The Standards provide a general exception for structural or operational characteristics that prevent conformance with an applicable technical requirement. If structural or operational characteristics prevent conformance with an applicable technical requirement, the Standards require compliance to the maximum extent practicable (M201.2). If height adjustability is not achievable, and if the height of the table cannot be lowered due to technology that cannot be changed, the Standards do not require that those specifications be met. Some DXA scanners may have sufficient clearance around the base such that they are compatible with portable patient lifts to assist in patient transfer.

The table below summarizes our observations on the accessibility features currently available with bone density scanners.

Table 22: Bone Density (DXA) Scanners - Accessibility Features on Sampling of Commercially Available Equipment (Based on USAB Informal Market Research)

MDE Standards’ Specifications for Accessibility	Bone Density (DXA) Scanners
Transfer Surface Dimensions (M301.2.3)	The width of the transfer surface ranges 34 to 51.5 inches; all exceed the minimum specifications.
Height Adjustability (M301.2.1)	Most models are not height-adjustable. A few scanners adjust between 27 to 30 inches in height, which is higher than the transfer height range specified by the Standards.
Base Clearance for Patient Lift (M301.4)	Some models may have sufficient clearance around the base for compatibility with the patient lift; others may be too wide.
Transfer Supports (M301.3.1 and M305.2)	None provided.

Radiography and Fluoroscopy Machines

Radiography (x-ray) systems and fluoroscopy systems can typically be used in both a supine and standing position. Radiography machines are typically mounted to the ceiling or to a post, and can be positioned both over a large flat radiography table and in front of a wall stand with a “bucky,” the drawer-like sleeve that holds an x-ray cassette and grid, for use in a standing position. In some models, the x-ray machine is attached to the radiography table by a C-arm. To use this model in the standing position, the entire table and C-arm is rotated 90 degrees. The patient then stands between the table and the C-arm while the image is captured. A wheelchair can also be positioned between the table and C-arm for imaging while the patient remains in his or her wheelchair, if clinically appropriate. Radiography

³⁷ See e.g., Testimony of Glenn Nygard, Holigic Corporation, U.S. Access Board Public Hearing (May 8, 2012).

machines are available in analog (film) and digital models, but have similar physical structures regardless of the type of technology they employ.

Fluoroscopy machines, which produce x-ray imaging in motion, typically feature a fluoroscopy mechanism that is attached to a table on a C-arm. Combination radiography/fluoroscopy machines also have a C-arm attaching the combo x-ray/fluoroscopy mechanism to the table. Fluoroscopy machines and combo machines are designed to tilt 90 degrees while the patient is on the table. The table has a foot platform upon which the patient stands with his or her back or front flush with the table. The table tilts while the image is captured.

Accessible radiography and fluoroscopy systems would conform to the Standards' requirements of diagnostic equipment used in a supine, prone, or side-lying position (M301) as well as those used in a standing position (M304). Where a patient remains seated in a wheelchair, requirements for diagnostic equipment for patients seated in a wheelchair would also be met (M303).³⁸

We reviewed product information for 12 radiology and fluoroscopy machines made by four manufacturers. Limited technical specifications were publicly available online for radiology and fluoroscopy machines. Information on table width was available only for three of the reviewed models, but all exceeded the required 28-inch width. Manufacturers' photographs of other models for which specifications were not provided suggest that most tables meet or exceed the 28-inch width requirement. Seven of the 11 reviewed models indicated height adjustability of the table, and two models provided specifications indicating that they could adjust to 19 inches, which is within the low transfer height range of the Standards. None of the reviewed tables appeared to offer transfer supports, although several tables appeared to have sufficient clearance around the base to accommodate a patient lift. Fluoroscopy machines that tilt to a standing position did not appear to offer standings supports. Information about the standing surface was not provided, thus it is unknown if the surface is slip-resistant.

The table below summarizes our observations on the accessibility features currently available with X-ray and fluoroscopy machines.

Table 23: X-Ray and Fluoroscopy Machines - Accessibility Features on Sampling of Commercially Available Equipment (Based on USAB Informal Market Research)

MDE Standards' Specifications for Accessibility	X-Ray & Fluoroscopy Machines
Transfer Surface Dimensions (M301.2.3)	The tables generally appear to meet the 28-inch width requirement, although width specifications were available for only three models.
Height Adjustability (M301.2.1)	Several models are height-adjustable, and at least two lower to the low transfer height range of the Standards.
Base Clearance for Patient Lift (M301.4)	Some models appear to have sufficient clearance around the base for use with a patient lift.

³⁸ Depending on the image sought by a care provider, some patients might be instructed to remain in a seated position atop an x-ray table. Thus, theoretically an accessible x-ray table must also meet the requirements of M302 for diagnostic equipment used in a seated position. However, because the requirements of M302 are less restrictive than those of M301 for diagnostic equipment used a supine, prone, or side-lying position, equipment meeting the requirements of M301 necessarily also meets the requirements of M302.

MDE Standards' Specifications for Accessibility	X-Ray & Fluoroscopy Machines
Transfer Supports (M301.3.1 and M305.2)	None provided.
Slip-Resistant Standing Surface (M304.2.1)	Insufficient information was available to assess whether fluoroscopy machines that tilt to a standing position have a slip-resistant standing surface.
Standing Supports (M304.2.2)	Fluoroscopy machines, which tilt to a standing position, do not appear to offer standing supports.

Mammography Machines

Mammography machines are typically used by patients in a standing position. For patients that cannot comfortably stand or are unable to stand, some mammography machines can be used with a specialized chair, or while a patient is seated in her wheelchair. Mammography machines typically feature a central column with a height-adjustable breast platform that positions and compresses the breast for imaging. The breast platform may tilt to the left or right for better positioning. Mammography machines sometimes offer handholds for arm positioning, but they are not intended for use as standing supports.

The MDE Standards provide technical specifications for mammography machines only when used to diagnose patients while seated in a wheelchair. These specifications include provision of a wheelchair space oriented in the same direction as a patient not seated in a wheelchair would be oriented (M303.2.1). The breast platform must be continuously adjustable from a low height of 26 inches to a high height of 42 inches (M303.4.1). In addition, clearance beneath the breast platform for the knees and toes of the patient must comply with technical specifications (M303.2.4.1).

We reviewed eight mammography machines made by five manufacturers.³⁹ For all of these machines, patients seated in a wheelchair orient in the same direction as patients who use the equipment while standing. All appear to have a height-adjustable breast platform, and several are consistent with the height range required by the Standards. Although the exact specifications are not available, the knee and toe space provided under the breast platform of most models appears to be consistent with the Standards' technical specifications for knee and toe clearance.

The table below summarizes our observations on the accessibility features currently available with mammography machines.

³⁹ The Board included in its review one model of mammography machine that has been discontinued, but is referenced in a DOJ settlement agreement as a wheelchair accessible model. We reviewed secondary sources regarding that particular model. Discontinued imaging equipment is relevant because of the robust secondary market for imaging equipment. See Testimony of Tony Roder, Regulatory Affairs Director for GE Healthcare, U.S. Access Board Public Hearing in Atlanta (May 8, 2012) (indicating that when top tier medical facilities upgrade their imaging equipment, they sell their old imaging systems on the secondary market to the next tier down of hospitals).

Table 24: Mammography Machines - Accessibility Features on Sampling of Commercially Available Equipment (Based on USAB Informal Market Research)

MDE Standards' Specifications for Accessibility	Mammography Machines Designed to be Used by Patients Seated in a Wheelchair
Orientation for Wheelchair User Same as Non-Wheelchair User (M303.2.1)	All models provide for orientation in the same direction as patients who use the equipment while standing.
Height Adjustability of Breast Platform (M303.4.1)	Several models are height-adjustable, and at least two lower to the low height range of the Standards.
Knee and Toe Clearance (M303.2.4.1)	Specifications of this space are not provided online; however, the knee and toe space provided under the breast platform of most models appears to be consistent with the technical specifications.

8. Other Potential Regulatory Alternatives

The technical specifications contained in the final MDE Standards were developed with the input of various stakeholders and through a multi-year deliberative process, during which many alternatives were considered. To gather a spectrum of alternative design options, the Access Board published the proposed standards, sought public comments, and established an advisory committee consisting of diverse stakeholders, including MDE manufacturers, health care providers, and disability rights advocates. The Advisory Committee considered a number of alternative design options for different types of MDE and the committee made recommendations on amendments to the proposed standards. Alternatives considered by the Advisory Committee are discussed at length in the committee's report, available at <https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report>.

After extensive discussion of the various design options for the MDE equipment, the committee members reached consensus on all of their recommendations, except for the minimum height for adjustable transfer surfaces (e.g., exam table surfaces).

For the lowest height for transfer surfaces, the Access Board considered two options put forth by different stakeholders. One option was to set the minimum height at 17 inches from the floor and the other option was to set the minimum height at 19 inches from the floor. Each option seemed to have clear advantages and disadvantages. For example, many MDE manufacturers were concerned about challenges of designing and manufacturing the equipment that could be lowered to 17 inches from the floor; on the other hand, patient advocates argued that lowering the equipment to 17 inches from the floor could allow safer and easier transfer for some patients for whom a 19-inch transfer surface would be too high.

After carefully considering the comments and materials supplied by the public and by the Advisory Committee members, the Access Board has decided to use a range for the minimum height – that is, for equipment used by patients in a supine, prone, or side-lying position or in a seated position, a low transfer position would be required at a height of 17 inches minimum and 19 inches maximum. The final MDE Standards also include a provision that this minimum height specification will expire in 5 years of the rule publication.

In our view, the range for minimum height of transfer surface in the final MDE Standards strikes a balance between accessibility and potential costs based on currently available research. In the coming years, we will gather more information about the population that may benefit from a different transfer height standard and about changing technology that may affect manufacturing costs.

9. Conclusion

Pursuant to Section 510 of the Rehabilitation Act, as amended by the Patient Protection and Affordable Care Act (29 U.S.C. § 794f), the Access Board has developed the MDE Standards to ensure that people with disabilities can access and use independently medical diagnostic equipment. The MDE Standards contain technical specifications to make diagnostic equipment accessible; however, the Standards impose no requirements on health care providers or medical device manufacturers, because the Board has no statutory authority to enforce them. At present, little is known regarding what next step the agencies with enforcing authority will take to make any or all of the MDE Standards mandatory. For this reason, this Final RA does not present any quantitative impacts of the MDE Standards on individuals with disabilities, health care providers, and medical device manufacturers.

This Final RA, instead, has discussed some of the potential ultimate impacts of these Standards in qualitative terms if these standards are adopted in the future by an enforcing agency. Given the many barriers to health care that patients with disabilities encounter due to inaccessible medical diagnostic equipment, individuals with disabilities will benefit from access to and use of diagnostic equipment meeting the MDE Standards. Equipment complying with the Standards will facilitate independent transfers by many patients with mobility and communication disabilities onto and off of diagnostic equipment and enable them to maintain their independence, confidence, and dignity. Accessible diagnostic equipment could contribute to more positive health care experiences for individuals with disabilities and enable them to receive health care comparable to that received by their non-disabled counterparts, but only once these standards are adopted by an enforcing agency.

If the MDE Standards are adopted by other agencies as mandatory for entities regulated under their jurisdiction, the Standards could affect health care providers and medical device manufacturers. Once health care providers and facilities are required to acquire accessible medical equipment, they could incur compliance costs to the extent that their equipment is not already accessible. Medical device manufacturers would then decide whether to incur incremental costs to meet the demand for accessible equipment, and some or many manufacturers may have an economic incentive to produce accessible equipment.

In addition, the Standards could yield some immediate benefits, even before any adoption by enforcing agencies through formal rulemaking. First, the technical specifications for accessible MDE incorporated in the Standards will benefit enforcing agencies that are considering similar accessibility requirements for entities under their jurisdiction. Although enforcing agencies have full authority over whether to adopt the Access Board's final rule (in whole or in part), the technical specifications in the MDE Standards reflect the input from a diverse set of stakeholders and provide solid groundwork for any future rulemaking pertaining to the accessibility in medical diagnostic equipment. Second, the Standards will serve as a best-practice document for the medical device industry and for health care providers and facilities. While the MDE Standards are non-binding, health care providers can use this final rule as guidance on how to provide equitable access to medical diagnostic equipment for people with mobility and communication disabilities. Manufacturers can also use the MDE Standards as they target their

research and development efforts at producing diagnostic equipment that can be used by a larger segment of the population – one that includes more people with disabilities and older adults.

The Access Board thus concludes that the benefits of the MDE Standards justify the costs of the final rule; that the Standards will impose the least burden on society, consistent with achieving the regulatory objectives; and that the regulatory approach selected will maximize net benefits. This Final RA has met the requirements of Executive Order 13563 (Improving Regulation and Regulatory Review) and Executive Order 12866 (Regulatory Planning and Review). Among other things, Executive Order 13563 directs agencies to: propose or adopt a regulation only after reaching a reasoned determination that its benefits justify its costs; tailor the regulation to impose the least burden on society possible while 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; such values include equity, human dignity, and fairness.