ARCHITECTURAL AND TRANSPORTATION BARRIERS COMPLIANCE BOARD

36 CFR Part 1195

RIN 3014–AA40

Standards for Accessible Medical Diagnostic Equipment

AGENCY: Architectural and Transportation Barriers Compliance Board.

ACTION: Final rule.

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

DATES: The final rule is effective February 8, 2017.

FOR FURTHER INFORMATION CONTACT: Earlene Sesker, U.S. Access Board, 1331 F Street NW., Suite 1000, Washington, DC 20004–1111. Telephone numbers: 202–272–0022 (voice) or 202–272–0091 (TTY). Email address: *sesker@access-board.gov*. Or Rex Pace, U.S. Access Board, 1331 F Street NW., Suite 1000, Washington, DC 20004–1111. Telephone numbers: 202–272–0023 (voice) or 202–272–0050 (TTY). Email address: *pace@access-board.gov*.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose and Legal Authority

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

On March 23, 2010, Section 4203 of the Patient Protection and Affordable Care Act (ACA) amended Title V of the Rehabilitation Act, which established the rights and protections for individuals with disabilities, by adding Section 510. Public Law 111–148, 124 Stat. 570). Section 510 of the Rehabilitation Act charges the Access Board, in consultation with the Commissioner of the Food and Drug Administration, with issuing standards that set forth the minimum technical criteria to ensure that medical diagnostic equipment (diagnostic equipment) used in (or in conjunction with) ''physician's offices, clinics, emergency rooms, hospitals, and other medical settings, 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.'' 29 U.S.C. 794f.

The statute gives examples of diagnostic equipment, including ''examination tables, examination chairs (including chairs used for eye examinations or procedures, and dental examinations or procedures), weight scales, mammography equipment, x-ray machines, and other radiological equipment commonly used for diagnostic purposes by health professionals.'' 29 U.S.C. 794f. This list is not considered exhaustive, but is illustrative of types of medical diagnostic equipment.

Section 510 of the Rehabilitation Act instructs the Access Board to promulgate technical standards regarding accessibility of medical diagnostic equipment, but does not give the Access Board authority to enforce these standards. Compliance with the MDE Standards becomes mandatory only when an enforcing authority adopts the MDE Standards as mandatory for entities subject to its jurisdiction. Additionally, the enforcing agencies will determine the application and scope of these standards, such as who must comply and the extent to which medical diagnostic equipment used by covered entities must comply with these MDE Standards. As discussed below, the U.S. Department of Justice (DOJ) may adopt the MDE Standards as mandatory requirements for health care providers pursuant to its authority under Titles II and III of the Americans with Disabilities Act. Other federal agencies may adopt the standards as mandatory requirements for health care providers pursuant to their authority under Section 504 of the Rehabilitation Act.

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

The Commissioner of the Food and Drug Administration designated the Director of the Center for Devices and Radiological Health (FDA–CDRH) to consult with the Access Board on the development of the MDE Standards. The Access Board has worked throughout the process with the FDA–CDRH in developing these Standards.

B. Summary of Major Provisions and Organization of Technical Criteria

The Access Board has divided the MDE Standards into separate technical criteria based on how the diagnostic equipment is used by the patient: (1) Supine, prone, or side lying position (M301); (2) seated position (M302); (3) while seated in a wheelchair (M303); and (4) standing position (M304). For each category the Access Board has provided technical criteria to allow independent access to and ensure the diagnostic equipment was usable by patients with disabilities to the maximum extent possible. The technical requirements for diagnostic equipment used by patients in the supine, prone, or side-lying position and diagnostic equipment used by patients in the seated position focus on ensuring the patient can transfer from a mobility device onto the diagnostic equipment. The other two categories, M303 and M304, focus on the necessary technical requirements to allow the patient to use the diagnostic equipment while seated in their wheeled mobility device, or while standing, respectively.

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

C. Costs and Benefits

The MDE Standards are advisory and are not binding until adopted by an enforcing authority. The Access Board's mandate was to establish only the minimum technical criteria, however enforcing authorities may establish scoping requirements in the future. As

such, the final rule does not directly impose any obligations on health care providers or medical device manufacturers. 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 Board cannot estimate the incremental monetary or quantitative impacts of the final rule.

Nevertheless, the Board is able to characterize qualitatively some of the potential impacts of these Standards. If enforcing agencies adopt the MDE Standards 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 mobility and communication 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. Consequently, they may be able to receive health care comparable to that received by their non-disabled counterparts.

In addition, the Standards could yield some 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 pertaining to the accessibility of 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 disability and older adults.

The 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.

II. Rulemaking History

Section 510 of the Rehabilitation Act requires the Access Board to issue standards for medical diagnostic equipment to ensure such equipment is accessible to, and usable by, individuals with disabilities no later than 24 months after the date of the enactment of the ACA. 29 U.S.C 794f.[1] On July 29, 2010, after the Rehabilitation Act was amended, the Access Board held a public meeting that featured panel discussions and presentations by experts and researchers on medical equipment accessibility, health care providers, medical device manufacturers, and other interested parties to provide information for developing the proposed standards. The transcript of the meeting is available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/background/public-information-meeting.*

On February 9, 2012, the Access Board formally commenced the rulemaking process and issued a notice of proposed rulemaking proposing accessibility standards for medical diagnostic equipment. Notice of Proposed Rulemaking—Medical Diagnostic Equipment Accessibility Standards, 77 FR 6916 (February 9, 2012) (hereinafter MDE NPRM). The proposed standards contained minimum technical criteria to ensure that medical diagnostic equipment, including, but not limited to, examination tables, examination chairs, weight scales, mammography equipment, and other imaging equipment used by health care providers for diagnostic purpose is accessible to, and usable by, individuals with disabilities. *Id.* The Access Board held two public hearings during the comment period, March 14, 2012 in Washington, DC and May 8, 2012 in Atlanta, GA. At the public hearings, 27 witnesses presented testimony regarding the need for accessibility standards for medical diagnostic equipment, the difficulty of obtaining health care for persons with disabilities, the current state of medical equipment and, the ability of medical diagnostic equipment to meet the proposed standards. The transcripts of the public meetings are available at *https://www.regulations.gov/docket?D=ATBCB-2012-0003.*

The public comment period for the proposed rule ended on June 6, 2012. Comments were submitted by persons with disabilities, governmental agencies, disability rights organizations, and representatives of the medical diagnostic equipment industry and the medical community. In all, 59 comments were received; twenty-four from individuals, thirteen from the medical diagnostic equipment industry and the medical community, nine from disability rights organizations, four from accessibility consultants, three from academics, two from state and federal organizations, and four duplicate submissions. The public comments are available at *https://www.regulations.gov/docket?D=ATBCB-2012-0003.*

On March 13, 2012, the Access Board published a notice of intent to establish an advisory committee to advise the Board on matters addressed in the MDE NPRM and issues raised in the public comments. Notice of Intent to Establish Advisory Committee—Medical Diagnostic Equipment Accessibility Standards, 77 FR 14706 (March 13, 2012). On July 5, 2012, the Access Board established the Medical Diagnostic Equipment Accessibility Standards Advisory Committee (MDE Advisory Committee). Notice of Establishment; Appointment of Members—Medical Diagnostic Equipment Accessibility Standards Advisory Committee, 77 FR 39656 (July 5, 2012). The MDE Advisory Committee was comprised of individuals from 24 organizations representing a range of stakeholders and ex officio members from the FDA, Department of Justice, and the

[1] Patient Protection and Affordable Care Act, Public Law 111–148, 124 Stat. 570 (2010).

Department of Veterans Affairs.[2] The MDE Advisory Committee met from September 2012 through May 2013 and much of the work occurred within five subcommittees that addressed the major categories of MDE and the issues raised by commenters: Examination Tables and Chairs; Stretchers; Diagnostic Imaging Equipment; Mammography Equipment; and Weight Scales. In June 2013, the MDE Advisory Committee presented 54 recommendations to the Access Board. The committee members reached a consensus on all of their recommendations, except for the recommended lowest or minimum height for adjustable-height transfer surfaces. The MDE Advisory Committee made recommendations regarding transfer surface height, transfer surface size, transfer sides, transfer supports, armrests, stirrups, lift compatibility, wheelchair spaces, and standing supports. The final report of the Medical Diagnostic Equipment Accessibility Standards Advisory Committee (December 6, 2013), is available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report* (hereinafter, MDE Advisory Committee Report).

III. Summary of Comments

In all 60 comments were received; the comments are available at: *https://www.regulations.gov/docket?D=ATBCB-2012-0003.* Overall the comments provided detailed responses to the questions posed in the preamble to the MDE NPRM. They provided many alternatives and recommended changes to the proposed requirements, which are discussed throughout this preamble. The disability rights organizations generally supported the proposed rule and recommended multiple ways to increase accessibility. The manufacturers provided a great deal of information on what types of accessible equipment is currently on the market, what the providers are requesting for accessible equipment, and the limitations of certain diagnostic equipment in meeting some of the requirements in the proposed standards. Most of these comments and recommendations are discussed below in the Significant Changes and the Section-by-Section Analysis. In addition, some commenters also raised concerns with the accessibility of diagnostic equipment to providers who have disabilities, weight and patient load, the need for training of staff on how to properly assist patients with disabilities, and requirements to ensure the room is accessible. While valid and important issues about accessibility, most of these concerns are outside the purview of the Access Board as they relate to issues unrelated to the equipment itself or the built environment, and therefore, have not been addressed by the MDE Standards.

In the preamble to the MDE NPRM, the Access Board identified the following barriers to accessibility, as documented in the Rehabilitation Engineering Research Center on Accessible Medical Instrument National Survey,[3] including equipment characteristics that affect patients ability to access and use medical equipment, such as: Dimensions of the equipment (*e.g.,* height, width, length,) contact surfaces (*e.g.,* stiffness, comfort, color contrast), supports for transferring onto and off of equipment and positioning their bodies on the equipment (*e.g.,* handholds, armrests, side rails), controls (*e.g.,* ease of operation), and displays and devices (*e.g.,* legibility and understandability). The Access Board sought public input on what other barriers affect the accessibility and usability of medical diagnostic equipment. NPRM, 77 FR at 6919, question 2. Nine commenters responded (two manufacturers, four accessibility consultants, three disability rights organizations, and an individual) and provided examples of additional barriers that they believe should be addressed in future updates of the MDE Standards. These recommendations included the accessibility of offices of healthcare providers, user positioning, communication, device operation, feature controls, compatibility of medical diagnostic equipment with assistive technology, weight capacity, and adding space to accommodate a patient's durable medical equipment. Additionally, the commenters noted that the proposed standards focused mostly on individuals with mobility disabilities and recommended providing standards to encompass individuals with autism, Alzheimer's, sensory disabilities, cognitive disabilities, and bariatric patients.

The technical criteria in the final rule addresses most of the barriers that were identified in the study as affecting the accessibility and usability of medical diagnostic equipment. However, at this time it is not possible for the MDE Standards to address every barrier. The Access Board is very interested in the additional barriers raised by public commenters and believes that further research is needed on some of the recommendations; such as equipment characteristics of stiffness, comfort, and color contrast of contact surfaces, and ensuring the accessibility of people with sensory and cognitive disabilities, and pediatric and bariatric patients. Section 510 of the Rehabilitation Act requires the Access Board to periodically review and amend the standards, as appropriate. The Access Board will address other barriers in future updates to the MDE Standards.

Additionally, commenters noted other areas of medical diagnostic equipment and issues of patient accessibility and recommended multiple changes or additions to the final rule. Specifically, commenters recommended adding weight capacity or patient load requirements, ensuring that the room is accessible, developing a manner to evaluate and measure the accessibility of equipment to give to patients, requiring staff training on how to use accessible equipment and how to provide assistance to people with disabilities, and requiring patient support surfaces. Based on the Access Board's review of these issues, many of the commenters concerns are outside the scope of this rulemaking but are issues that may be addressed by enforcing authorities when they provide scoping and application requirements in adopting the MDE Standards. Additionally, the Board may elect to address the accessibility of examination rooms and other spaces containing diagnostic equipment under its authority to develop guidelines for buildings and facilities subject to the ADA and ABA. The other issues of weight capacity and patient support surfaces will be added to the additional barriers list above, and considered for inclusion when the MDE Standards are updated.

The Access Board received nine comments asserting that figures help the reader to better understand the technical

[2] 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. 77 FR 39656.

[3] This survey was conducted in 2004 to collect information on the types of medical equipment that is most difficult for individuals with disabilities to access and use. The results of the focus group sessions are reported in Molly Follette Story, Erin Schwier, and June Issacson Kailes, ''Perspectives of Patients with Disabilities on the Accessibility of Medical Equipment: Examination Tables, Imaging Equipment, Medical Chairs, and Weight Scales,'' Disability and Health Journal 2 (2009), 169–179.

criteria; these commenters recommended some minor changes to the advisory figures and strongly supported the usefulness of the figures. The Office of the Federal Register does not permit advisory materials to be published in the Code of Federal Regulations. Consequently, as the figures are advisory, only the version of the final rule posted on the Access Board's Web site will include advisory text and figures. The online version of the final rule, as well as other materials related to this rulemaking, can be found here *http://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking.*

IV. Significant Changes to the MDE NPRM

This section of the preamble addresses significant changes made from the MDE NPRM to the final rule in response to the comments received, recommendations from the MDE Advisory Committee, and other information that has come to the Access Board's attention during the rulemaking process. Individual provisions of the rule are discussed in detail under the Section-by-Section Analysis below.

A. Chapter 2: M201 Scoping

In the final rule, Chapter 2 establishes that the enforcing authority will determine the number and types of diagnostic equipment to which the MDE Standards will apply. There was only one significant change to this section, which added a general exception for diagnostic equipment that is unable to meet one or more of the requirements in the final rule.

1. General Exception

The MDE NPRM proposed several limited exceptions to certain provisions addressing the limitations of current technology and design. Through testimony at the public hearings, comments, and MDE Advisory Committee discussions, the manufacturers of imaging equipment consistently raised concerns about inherent barriers to compliance with the proposed MDE Standards due to the location of imaging and mechanical components necessary to achieve the diagnostic aims. Some specific examples include: Dual Energy X-Ray Absorptiometry (DXA) machines, with a mechanism that moves imaging components along a track beneath the patient surface precluding height adjustability for the transfer surface; prone biopsy tables that must be of a sufficient height to permit health care providers access beneath the patient surface to perform procedures, precluding the equipment from meeting the minimum transfer surface height; and mammography machines with low dose radiation detectors that are larger in size than conventional configurations and required to be in locations that partially obstruct clearances for knee and toe space beneath the breast platform. While the MDE NPRM proposed several specific technical exceptions in Chapter 3, the exceptions did not address the manufacturers' overall concerns regarding imaging equipment. Section 510 of the Rehabilitation Act requires the MDE Standards to provide independent access ''to the maximum extent possible.'' The Access Board interprets this language as recognizing that, in some situations, current technology may preclude diagnostic equipment from meeting all of the technical requirements in the MDE Standards. Therefore, the Access Board has added a general exception to Chapter 2 allowing compliance to the maximum extent practicable for the rare circumstance where full compliance would alter diagnostically required structural or operational characteristics of the equipment, and would prevent the use of the equipment for its intended diagnostic purpose. Any equipment utilizing this exception is still required to meet all other applicable provisions of the MDE Standards. We anticipate that this exception will be employed on a very limited basis for a few specialized equipment types, primarily imaging equipment. This provision is not intended to exempt a piece of diagnostic equipment from the MDE Standards as a whole. Limitations resulting from existing equipment designs or manufacturing practices that could be altered to meet the requirements are not a basis for invoking this exception; only diagnostically required structural or operational characteristics that cannot be made to comply with the technical requirements without preventing the use of the equipment for its intended diagnostic purpose are covered by this provision.

B. M301 Diagnostic Equipment Used by Patients in a Supine, Prone, or Side-Lying Position and M302 Diagnostic Equipment Used by Patients in a Seated Position

In the final rule M301 and M302 provide the technical requirements for diagnostic equipment used in the supine, prone, or side-lying position, and diagnostic equipment used by patients in the seated position. Sections M301 and M302, which ensure that patients can transfer from their mobility devices onto the diagnostic equipment, share many technical requirements. Therefore, the Significant Changes Section addresses the transfer surface and lift compatibility requirements for M301 and M302 together. New exceptions pertaining to weight scales and to the type of equipment that must comply with M301 and the decision to remove the armrest requirements from M302, are also discussed below.

1. Transfer Surface

a. Transfer Surface Adjustability

The MDE NPRM proposed that the same transfer surface height range of 17 inches minimum to 19 inches maximum be applied to both diagnostic equipment used in the supine, prone, or side-lying position and diagnostic equipment used in the seated position (proposed M301.2.1 and M302.2.1, respectively). The Board considered it likely that diagnostic equipment would be adjustable in height to serve practitioners' needs however, the transfer surface could be fixed within the proposed height range. The Access Board sought public comment in the MDE NPRM preamble on whether the final standards should require the height of the transfer surface to be adjustable from 17 inches minimum to 25 inches maximum. NPRM, 77 FR at 6922–6933, questions 13 and 14. The majority of commenters, including manufacturers and disability advocates, supported both an adjustability requirement and the proposed high transfer height, but disagreed on what should be the low transfer height.

The MDE Advisory Committee recommended a high transfer height of at least 25 inches and recommended that the transfer surface be adjustable in small, virtually continuous increments. MDE Advisory Committee Report, 67–71, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* However, the MDE Advisory Committee did not achieve consensus on what should be the minimum low height. *Id.*

After considering the public comments and the recommendations from the MDE Advisory Committee, the Access Board has decided to include in the final rule the following requirements for diagnostic equipment used in the supine, prone or side-lying position, and for diagnostic equipment used in the seated position: An adjustable transfer height range with a minimum high and low height; four intermediate transfer heights within the adjustable range; and a specific method to measure the transfer heights. These new

requirements are incorporated into the transfer height provision for diagnostic equipment used in the supine, prone, or side-lying position, and for diagnostic equipment used in the seated position, in the final rule (M301.2.1 and M302.2.1, respectively). These provisions have been renamed ''Adjustability,'' and are discussed in detail below.

(1) Adjustability: Minimum High Transfer Height

In the preamble to the MDE NPRM, the Access Board sought comment in question 14 on whether the final rule should require an adjustable height range of 17 inches to 25 inches; whether equipment currently met this proposed requirement and, if not, what would the cost be to achieve that range; and whether intermediate heights should also be required within the adjustable height range. NPRM, 77 FR at 6923. While 20 commenters responded to question 14, only four commenters explicitly addressed the proposed minimum high height of 25 inches. Of these, two commenters (an accessibility consultant and a state agency concerned with accessibility) concurred with a minimum high height of 25 inches. One commenter, a manufacturer, recommended increasing the minimum high height to 28 inches for all diagnostic equipment except magnetic resonance imaging (MRI) equipment, which has limitations that may prevent it from reaching 28 inches. Another manufacturer gave examples of the height ranges of its beds and stretchers, each of which met the 25-inch minimum high height.

After reviewing the comments and other evidence before it, the MDE Advisory Committee recommended a high transfer height requirement of 25 inches noting that:

[t]he anthropometric data referenced . . . in the Wheeled Mobility Anthropometry Project shows seat heights for people who use mobility devices are above 19 inches. For manual wheelchair user's seats measured up to 23.9 inches; for power wheelchair users up to 28.9 inches; and for scooter users to 25.3 inches. Seat heights for males were typically higher than for females. All the male manual wheelchair users and 92 percent of the male power wheelchair users had seat heights equal to or less than 25 inches. Therefore, transfer surfaces that are adjustable to a 25-inch maximum during patient transfer accommodate most patients who use mobility devices. Since one key factor in ease of transfer is locating the transfer surface near or at the same height as the seat of the wheeled mobility device, moving the minimum high point for adjustability of transfer surfaces, improves access for many. This particularly benefits persons using powered mobility devices and scooters with higher seat heights.

MDE Advisory Committee Report, 69, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.*

The Access Board was persuaded by the arguments of commenters and the MDE Advisory Committee in favor of requiring a minimum high transfer surface height of 25 inches. A 25-inch minimum high height will ensure that the transfer surface can be raised up to the height of the vast majority of wheelchair seat heights, which are 25 inches high or lower. The final rule requires a minimum high transfer surface height of 25 inches for both diagnostic equipment used in the supine, prone or side-lying position (M301.2.1), as well as diagnostic equipment used in the seated position (M302.2.1). Nothing in the rule prohibits a manufacturer from providing a high transfer height above 25 inches as long as transfer is provided within the range specified up to 25 inches.

(2) Adjustability: Minimum Low Transfer Height

The Access Board received many comments from disability rights organizations, individuals, accessibility consultants, and a health care provider supporting the need for lower height adjustable tables. Specifically, these commenters explained the need for adjustable height tables to facilitate and promote independent or semi-independent transfer. These commenters explained the delay in diagnosis and treatment when patients are unable to transfer from their wheeled mobility device to the examination surface and are inadequately examined while remaining in their wheelchair. These commenters also explained that adjustable tables would enhance both the safety of patients, by reducing the risk of falls and injury incurred from assisted transfer, as well as reducing injury to medical staff and caregivers by lessening the likelihood of back and other lifting injuries. One individual commenter recalled being bruised when she was dragged onto medical equipment that was too high, while another commenter noted that the risk to healthcare workers increases when access to medical diagnostic equipment is not optimized.

In addressing what the low transfer height should be, 12 commenters responded to question 14 specifically addressing the proposed minimum low transfer surface height. Six commenters (an individual, a state agency concerned with accessibility, two accessibility consultants and two disability rights advocates, one whose comment was supported by 50 disability rights organizations) supported requiring a low transfer height of 17 inches. These commenters asserted that the lower height would provide more accessibility, safety for both patients and healthcare providers, and allow more patients to transfer independently or semi-independently. One commenter, a medical association, supported allowing a minimum low height range of 17 to 19 inches recommending as much latitude for manufacturers as possible. The remaining six commenters (manufacturers and a medical association) voiced strong concerns about the cost of complying with a minimum low height of 17 inches, the potential consequences of being unable to raise the equipment up to a height comfortable for practitioners, and whether current technology and designs would allow diagnostic equipment to reach such a low height. Additionally, some of the manufacturers and medical associations voicing support for a minimum low height of 19 inches, indicated that either their equipment currently meets or would be capable of meeting a 19-inch low height requirement.

Like the public commenters, the MDE Advisory Committee was divided on this issue and was unable to reach consensus regarding a minimum low transfer surface height. MDE Advisory Committee Report, 70, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* Individual Committee members' recommendations for a low transfer surface height requirement were split across three options: 17 inches, 18 inches (viewed as compromise to some and a preferred minimum height by others), and 19 inches. *Id.* at 139–143. The Committee devoted considerable time to examining available evidence, consulting experts, and discussing the merits of the three height options. *Id.* Additionally, the Examination Tables and Chairs Subcommittee held six meetings, discussed this issue in-depth, and developed a Subcommittee recommendation for the MDE Advisory Committee of 19 inches as the minimum transfer surface height standard, with 17 inches as the ''best practice.'' *Id.* The MDE Advisory Committee members heard presentations from several clinicians and manufacturers on the topic of minimum transfer surface

height.[4] Advisory Committee members also considered a presentation from Edward Steinfeld, ArchD on the findings from the Anthropometry of Wheeled Mobility Project, which was conducted at the Center for Inclusive Design and Environmental Access (IDeA) at the State University of New York at Buffalo.[5] *Id.*

After careful consideration of the available information, the MDE Advisory Committee was unable to agree upon a recommendation for a transfer surface height, and Committee members were invited to submit minority reports supporting their view of the issue.[6] The MDE Advisory Committee Report states that ''[a] full reading of these Minority Reports is critical to understanding the range of views guiding the various stakeholder organizations that served on the MDE Advisory Committee about the recommendation for the minimum transfer height.'' *Id.* at 143. (The minority reports are available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report/appendix-a-minority-reports*).

The minority reports submitted by the disability advocates and academics supported a minimum low height of 17 inches. *See* Minority Reports from Boston Center for Independent Living Inc., National Network for ADA Centers, and Medical Diagnostic Equipment Advisory Committee,[7] available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report/appendix-a-minority-reports.* These minority reports explained the importance of accessible care and of ensuring as many independent transfers as possible. *Id.* The reports noted that both patients and providers risk injuring themselves during assisted transfer. *Id.* In their reports, disability advocates and academics asserted that a 17-inch low height provides the greatest number of individuals the opportunity to transfer independently. *Id.* Additionally, the reports pointed to current accessibility standards for toilet seats, shower seats, and tub seats, which require a height of 17 inches minimum and 19 inches maximum. *Id.* These reports argued that if the MDE Standards moved away from this range, then the Access Board must adopt the lowest end of the range, 17 inches, to provide the most accessibility. *Id.* Additionally, the National Council on Independent Living asserted that:

> Most manufacturers on the Committee had a 19 to 21-inch surface available currently, with at least one having a product at 18. Their argument has always been that providing the lowest transfer heights would be an extraordinary expense and burden on the business community (their consumer), not based on how it benefitted a patient with a disability. This effort was never supposed to be about the manufacturers or the doctors. It is the charge of this committee to answer questions and come up with recommendations for accessibility, based by some members on engineering and others by experience. NCIL's 30-plus years of experience as advocates for people with disabilities dictates that we continue to strongly insist that the U.S. Access Board maintain the low accessible height at 17 inches above the floor in order for medical and diagnostic equipment to be accessed by the greatest number of people.

Minority Report from National Council on Independent Living (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.*

The minority reports submitted by manufacturers supported a minimum low height of 19 inches. *See* Minority Reports from Hologic, Inc., Midmark Corporation, MITA Advisory Committee Members,[8] and Recommendation of 19-inch Lower Adjustable Height as the Minimum Accessibility Standard (Joint Report),[9] available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report/appendix-a-minority-reports.* Similar to the minority reports supporting a minimum low height of 17 inches, these minority reports relied on the existing accessibility standards, such as those for shower seats, tub seats, amusement park rides, toilets, and benches. However, unlike the minority reports from members supporting a minimum 17-inch low height, these reports asserted that because 19 inches is a permissible transfer height under existing accessibility standards, it is similarly acceptable for medical diagnostic equipment. The manufacturers also noted that currently there are not any accessible diagnostic tables on the market that meet a 17-inch low height requirement. The Brewer Company, LLC stated that:

> Brewer has been manufacturing adjustable height examination tables since 2002. These tables were designed specifically for wheelchair accessibility by meeting the 19-inch height referenced in the ADA/ABA Accessibility Guidelines. Brewer is ISO 13485 certified. ISO requires a robust method for recording customer, end user, and clinician feedback. In the 11 years we have been selling adjustable height examination tables we do not have a single complaint on record regarding the accessibility of our 19″ low height tables. There have been no

[4] Clinician presenters included Barbara Ridley, RN, FNP, Cathy Ellis, PT, Medical Diagnostic Equipment; Michael Yochelson, MD, Medical Diagnostic Equipment; Lauren Snowden, PT, DPT, Practitioner Perspective on Transfers to Examination Services; Nuket Curran, PT, Diagnostic Equipment & Patient Accessibility: Closing the ''Gap''; Douglas Coldwell, MD, Medical Imaging; Theresa Branham, RT, ARRT, Technologist Perspective to Patient Access. MDE Advisory Committee Report, 141–142, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* Manufacturer presenters included Willa Crolius, Institute of Human Centered Design, No Formal Presentation, presented videos showing transfer; Michelle Lustrino, Mechanical Engineer, Hologic, Inc., Mammography Industry: Accessibility Standards; Glen Nygard, Senior Principal Engineer, Hologic, Inc., Dual-Energy X-ray Absorptiometry (DXA) for Osteoporosis Assessment; Elisabeth George, Vice President of Global Regulations & Standards Chair of Technical and Regulatory Affairs Committee, Phillips Healthcare, Medical Imaging; John Jaeckle, Chief Regulatory Affairs Strategist Chair of CT-Xray Committee, GE Healthcare, MITA, & John Metellus, Product Marketing Manager, Siemens Healthcare, Equipment with Bores and X-ray Devices Accessibility; Bob Menke & John Wells, Midmark Corporation, Examination Table Accessibility Standards; Jeff Baker, Brad Baker, & Darren Walters, Medical Technology Industries, Inc., Performance and Efficacy Considerations for Examination Chairs. Id.

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

[6] The Committee Members who submitted minority reports includes: Boston Center for Independent Living; The ADA National Network; Brewer Company; Duke University and Medical Center; Equal Rights Center; Harris Family Center for Disability and Health Policy at Western University of Health Sciences; Hausmann Industries, Inc.; Hologic, Inc.; Medical Technology Industries, Inc.; Midmark Corporation; National Council on Independent Living; Paralyzed Veterans of America; Phillips Healthcare; Siemens Medical Solutions USA, Inc.; United Spinal Association; University of the Sciences in Philadelphia. The Minority Reports are available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report/appendix-a-minority-reports.*

[7] Endorsed by Harris Family Center for Disability and Health Policy at Western University of Health Sciences, The ADA National Network, Equal Rights Center, National Council on Independent Living, Paralyzed Veterans of America, United Spinal Association, Duke University and Health System, and University of the Sciences in Philadelphia, Department of Occupational Therapy.

[8] Joint Report prepared by medical diagnostic imaging equipment industry members of the MDE Advisory committee, including GE Healthcare, Phillips Healthcare, Siemens Healthcare, and Hologic, Inc.

[9] Submitted by The Brewer Company, Hausmann Industries, Medical Technology Industries, Inc., and Midmark Corporation.

requests for a lower table. In addition, market growth of the adjustable height tables with 19 inch low heights provides further evidence that these tables are meeting the accessibility needs of patients requiring independent wheelchair transfer.

Minority Report from The Brewer Company, LLC (Oct. 1, 2013), available at *https://www.access-board/guidelines-and-standardshealth-/about-this-rulemaking/advisory-committee-final-report/appendix-a-minority-reports.* The exam table manufacturers asserted that they would incur costs to comply with a 17-inch low height, but would not incur costs to comply with a 19-inch low height requirement. *See* Recommendation of 19-inch Lower Adjustable Height as the Minimum Accessibility Standard (Joint Report) (Sept. 27, 2013), available at *https://www.access-board/guidelines-and-standardshealth-/about-this-rulemaking/advisory-committee-final-report/appendix-a-minority-reports* (characterizing a table with a 19-inch transfer height as a ''baseline 0%'' cost increase for ''accessible equipment as currently available on the market'').

In their joint minority report, examination table manufacturers asserted, ''Based on our analysis, we determined that transfer surface height requirements lower than 19 inches would increase the cost of designing and manufacturing examination tables, reduce the rate of adoption of accessible equipment, and increase the health provider's cost of purchasing accessible equipment.'' *Id.*

With respect to the cost of compliance for the tables on imaging equipment, some manufacturers noted the inherent difficulty of redesign, the potential cascading impacts of adopting a low height of 17 inches, and the difficulty in that imaging equipment undergoes many years of work before they become commercially available. *See* Minority Report of GE Healthcare, Phillips Healthcare, Siemens Healthcare, and Hologic, Inc., available at *https://www.access-board/guidelines-and-standardshealth-/about-this-rulemaking/advisory-committee-final-report/appendix-a-minority-reports.* Specifically, the imaging equipment manufacturers asserted that:

> given the integrated nature of the table to the system and its imaging performance, that a change of even a few inches in minimum transfer surface low height constitutes a significant engineering change to the device. Any such change must ensure there are no adverse effects to image quality, system performance, and patient safety. Complete scanner re-testing and re-certification under our formal FDA quality system and design controls are needed to verify overall system performance and safety.
>
> Moreover, the most significant of these design changes can result in cascading alterations to the scanner, potentially leading to unacceptable heating in the case of MR, impacts on image signal/quality, and changes in dose levels to ensure the same, effective, high quality images and increased examination times, that is, additional workflow steps.
>
> *Id.*

After carefully considering the totality of comments received and the MDE Advisory Committee materials, the Access Board has concluded that there is insufficient information to designate a single minimum low height requirement at this time. Specifically, there is insufficient data on the extent to which and how many individuals would benefit from a transfer height lower than 19 inches. Due to this lack of sufficient information, coupled with the lack of consensus among the MDE Advisory Committee and the commenters, the Access Board has decided to establish, for five years only, a range for the minimum low height requirement of 17 inches to 19 inches. During the five-year period following issuance of the final rule, any low transfer height between 17 and 19 inches will meet the MDE Standards. The Access Board acknowledges that this is a temporary solution, and has commissioned a study to quantify the portion of the population that would benefit from a low transfer height below 19 inches. A pilot study was completed prior to the publication of this final rule. A sunset provision has been included in the final rule that will repeal this low height range five years after the date of publication in the **Federal Register**, leaving only the requirements for the high transfer height and the additional transfer positions below the high transfer height. The Access Board intends to amend this portion of the final rule with a subsequent rulemaking to establish a minimum low transfer surface height once the study has been completed and before the sunset provision takes effect.

(3) Adjustability: Transfer Surface Intermediate Heights

In the MDE NPRM there was no requirement for the transfer surface to have intermediate transfer heights. Under the proposed rule, diagnostic equipment would be in compliance if it provided a low transfer height anywhere within the range of 17 inches minimum and 19 inches maximum. In addition to the matter of low transfer height, the Access Board sought public comment in question 14(c) on whether the final rule should require intermediate heights between a minimum low transfer height and a minimum high transfer height. NPRM, 77 FR at 6923. Three commenters responded (two accessibility consultants and a disability rights advocate) and supported the idea of requiring intermediate heights within a minimum low height and minimum high height of the transfer surface. One commenter, an accessibility consultant, recommended intervals of ½ to 1 inch, indicating that ½ inch increments would be more practical to match the varying heights of wheelchairs and mobility devices, which is critical for many patients in performing independent transfers. The MDE Advisory Committee recommended adjustable height in small, virtually continuous increments. To support this recommendation, the MDE Advisory Committee explained:

> that adjustability greatly increases the overall accessibility of equipment for all persons. Adjustable height MDE, such as exam tables, imaging tables and chairs, will make it possible to position the transfer surface near the height of the seat of the mobility device. For some, independent transfers are only possible when there is minimal or no change in vertical height between the seat of the mobility device and the transfer surface. People may prefer or, in some cases, require, transfer to a slightly lower surface moving the transfer surface lower than the seat of the mobility device; then adjusting the transfer surface to above the seat for the return transfer. MDE Advisory Committee Report, 68, available at *https://www.access-board/guidelines-and-standardshealth-/about-this-rulemaking/advisory-committee-final-report.*

The Access Board has decided to require that the height of the transfer surface be adjustable within the range for the minimum low and high heights in at least four unspecified intermediate heights, but has determined that the intermediate heights should be set a minimum of one inch apart. While the Access Board agrees that continuous adjustment is preferable, requiring such adjustability could preclude the use of certain types of lifting devices such as hydraulic systems that work in increments. The intent is to permit manufacturers flexibility in setting intermediate heights and not prohibitively restrict designs to those of particular manufacturers or equipment.

(4) Adjustability: Method of Measurement

The MDE NPRM proposed that the measurement of the height of the transfer surface for both diagnostic equipment used in the supine, prone, or side-lying position and diagnostic equipment used in the seated position, be taken from the floor to the top of the transfer surface (proposed M301.2.1 and M302.2.1, respectively). The Access

Board sought comment in question 13 in the MDE NPRM preamble, on whether the measurement should be taken with the upholstery in static (uncompressed) conditions, or with a certain amount of deflection. NPRM, 77 FR at 6922. The Access Board received eleven comments in response, most of which agreed with measuring the transfer surface in a static condition. A few commenters disagreed: One manufacturer recommended measuring in static conditions, but allowing a ¾ inch bolster in no more than 25 percent of the short side of the transfer surface to be permitted to be outside the height requirement; two commenters (medical association and manufacturer) asserted that the method of measurement should be dependent on the type of diagnostic equipment and left up to the manufacturers; and two commenters (state agency concerned with accessibility and accessibility consultant) recommended that the transfer surface meet the criteria in both dynamic and static conditions. The MDE Advisory Committee concurred with those comments recommending that the measurement be made with the upholstery in a static condition to ensure a consistent point of measurement. The MDE Advisory Committee explained that ''[s]ince many transfer surfaces are not perfectly flat, measuring to the highest point in an uncompressed state provides this consistent point of measurement.'' MDE Advisory Committee Report, 71, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* The Access Board agrees with the Advisory Committee's rationale and the final rule requires that the height be measured from the floor to the top of the uncompressed transfer surface. This method will ensure consistent measurement across all diagnostic equipment. Taking the measurement at the highest point on the transfer surface allows for small bolsters or contours and does not significantly increase the overall height of the transfer for people with disabilities.

b. Transfer Surface Location

The MDE NPRM proposed the same location and transfer sides of the transfer surface for diagnostic equipment used by patients in the supine, prone, or side-lying position (M301) and diagnostic equipment used by patients in the seated position (M302). This transfer surface was located at the end of the diagnostic equipment and provided options to transfer from a mobility device onto one short side and one long side of the transfer surface. (proposed M301.2.3 and M302.2.3, respectively). Numerous commenters objected on the basis that this type of transfer is not always possible for certain types of medical diagnostic equipment; the MDE Advisory Committee agreed with commenter concerns. The Access Board is persuaded by many of the concerns raised by commenters and the MDE Advisory Committee. In the final rule the structure and content of the transfer surface provision has been revised for diagnostic equipment used by patients in the supine, prone, or side-lying positions to provide two types of transfer surfaces; end transfer surfaces and side transfer surfaces. For diagnostic equipment used by patients in the seated position, the Access Board has decided to retain the proposed rule requirements for transfer surface location and transfer sides, but has added an exception to the transfer sides provision in the final rule to address the concerns raised by commenters and the MDE Advisory Committee.

(1) Transfer Surface Location for Diagnostic Equipment Used in the Supine, Prone, or Side-Lying Position

Multiple commenters expressed concerns that transfer cannot always occur at the end of the diagnostic equipment as contemplated by the requirements in the proposed rule. One commenter elaborated that stretchers and hospital beds are always entered from one or the other long side of the bed, not the foot end, due to obstructions at the head and foot ends that cannot be removed. Another commenter recommended allowing transfer space at both the center and the end of the transfer surface.

Evidence presented to the MDE Advisory Committee during its deliberations revealed that it is not always possible to transfer from adjoining sides at the end of the diagnostic equipment in the prone, supine, or side-lying position on certain types of equipment such as stretchers and imaging equipment with scanning beds. MDE Advisory Committee Report, 75–82, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* This is because many models of this equipment can be obstructed on the head or foot ends by necessary components such as emergency extraction handles, the gantry design, or integral patient positioning features. *Id.* For equipment with long patient examination surfaces such as stretchers and the scanning beds of many types of imaging machines, the foot end is not intended as a transfer point; patients transfer onto the surface on either of the long sides, approaching the equipment more towards the center. *Id.* Additionally, a transfer approach at the foot location may not be practical for many people with disabilities who would have to move themselves or be moved across a significant length of the surface to place their bodies into a position for effective imaging. *Id.* The MDE Advisory Committee recommended permitting an alternative transfer surface which was rotated in its orientation such that the width paralleled the examination surface's length and its depth spanned the examination surface's width, and was located near the center point of the diagnostic equipment surface. *Id.*

Based on the comments received and the MDE Advisory Committee recommendations, the Access Board has concluded that for diagnostic equipment used by patients in supine, prone, or side-lying positions two transfer surface orientations are possible depending on the intended location from which the transfer is to be made. These orientations are now identified as an end transfer surface and side transfer surface. This necessitated adding the definition of ''end transfer surface'' and ''side transfer surface'' to the defined terms (M102.1) in the final rule and resulted in the removal of the proposed M301.2.3 Transfer Sides, as that is now described within the two types of transfer surfaces provided. The end transfer surface accommodates the transfer method conceived of in the proposed rule; where the transfer occurs at one end of the examination surface and allows the patient the option to transfer at the end and on one adjoining side of the examination surface. The side transfer surface responds to the concerns raised by commenters and the MDE Advisory Committee to accommodate diagnostic equipment where transfer occurs within the length of the examination surface and allows patient transfer at the sides of the examination surface. Side transfer surfaces most typically will be imaging equipment, stretchers, hospital beds, and other equipment where the end is obstructed and cannot be used for transfer. Accordingly, the Access Board has reorganized the requirements regarding the transfer surface for M301 into two types based on where the transfer is to occur: ''End Transfer'' or ''Side Transfer.'' This revision to provide options for two types of transfer surfaces necessitated adding additional technical criteria addressing transfer surface size (M301.2.3) and transfer supports (M305.2), as well as adding the

definition of ''end transfer surface'' and ''side transfer surface'' to the defined terms (M102.1) in the final rule. These new requirements are addressed below in the applicable section in the Section-by-Section Analysis.

(2) Transfer Surface Location for Diagnostic Equipment Used in the Seated Position

Commenters also raised concerns with the provisions in the MDE NPRM related to transferring to medical diagnostic equipment used by patients in the seated position. Commenters stated that there is certain diagnostic equipment used by patients in the seated position where transfer at the end of the seat by two adjoining sides is not feasible. Specifically, commenters raised concerns about diagnostic equipment with fixed footrests, such as podiatry and dentistry chairs. Transfer onto these types of diagnostic equipment must be made from either long side, similar to the side transfer surface described above. One commenter explained that fixed footrest chairs are meant to treat patients with their legs extended parallel to the ground. If entered as suggested in the proposed rule the patient would have to enter the chair by positioning themselves onto this fixed footrest section that is at a downward angle and would require the patient to slide up an inclined surface to be properly positioned on the diagnostic equipment.

The MDE Advisory Committee agreed with a majority of the commenters that some examination chairs which have fixed footrests prevent transfer as conceived of in the proposed rule. The Committee noted that:

> the footrests obstruct access to the foot end of the chair. Examples of chairs that fit this category are most dental chairs and podiatry chairs. The current design allows only one long side for transfer, which limits some patient transfers where a patient can use only one side of the body due to paralysis on one side or other such conditions. To address this issue, the recommendation requires chairs with footrest obstructions to allow patient transfers from both [long] sides of the chair. The solution creates the option for either a left or right transfer. MDE Advisory Committee Report, 83, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.*

The Access Board agrees that diagnostic equipment used by patients in the seated position with fixed footrests requires a different transfer approach than those without fixed footrests. Therefore, the Access Board has added an exception to the transfer sides provision (M302.2.4) in the final rule to permit diagnostic equipment with fixed footrests to provide options to transfer from opposing sides of the transfer surface.

The American Dental Association proposed a complete exemption of dental chairs from the MDE Standards, asserting that the Access Board has not provided any evidence that dental offices are inaccessible, citing to the national survey in MDE NPRM ''that collected information on the types of medical equipment that are most difficult for individuals with disabilities to access and use. The American Dental Association urge[d] the Access Board to refrain from proposing costly new requirements based on examination chairs that are only 'moderately difficult' for disabled patients to use.'' The American Dental Association explains that ''dental chairs already have many accessibility features built in and manufacturers as well as health care providers have an economic incentive to produce and procure accessible medical diagnostic equipment and therefore, the American Dental Association does not believe that additional regulations are necessary, particularly with respect to dental examination chairs.'' Comment of American Dental Association, Notice of Proposed Rulemaking for Medical Diagnostic Equipment, (Apr. 4, 2012), available at *https://www.regulations.gov/document?D=ATBCB-2012-0003-0037.*

The Access Board does not concur with the comment urging that dental chairs should receive a blanket exemption. The record is replete with evidence that individuals with disabilities do encounter barriers to dental care as a result of inaccessible dental chairs. For example, one commenter, a disability rights organization representing 37,000 members, explained that it asked its members ''and others with disabilities about the barriers they encounter when seeking medical care and treatment. The most frequent responses involved access to examination chairs, dentist chairs, scales and mammography and colonoscopy equipment.'' Comment of United Spinal Association, Notice of Proposed Rulemaking for Medical Diagnostic Equipment, (June 4, 2012), available at *https://www.regulations.gov/document?D=ATBCB-2012-0003-0029.* Additionally, at the public hearing on May 8, 2012, a commenter raised concerns about the ability to obtain dental care when unable to transfer onto the dental chair. The public hearing transcript is available at *https://www.regulations.gov/docket?D=ATBCB-2012-0003.* Accordingly, the Access Board has concluded that dental chairs are appropriately covered by this rule.

c. Transfer Surface Size for Diagnostic Equipment Used by Patients in the Supine, Prone, or Side-Lying Position

The MDE NPRM proposed a transfer surface size for diagnostic equipment used in the supine, prone, or side-lying position of 30 inches wide and 15 inches deep minimum (proposed M301.2.2). These dimensions were based on the dimensions specified in the 2004 ADA and ABA Accessibility Guidelines for rectangular seats in roll-in showers (36 CFR part 1191, App. D 610.3.1) and the ANSI/AAMI HE 75 which notes that a standard examination table is 27 inches wide and a bariatric table is approximately 30 to 32 inches wide and recommends wider surfaces to make repositioning easier. ANSI/AAMI HE 75, section 16.4.7, available at *http://www.aami.org/he75.* The Access Board sought input in question 15 in the MDE NPRM preamble on whether this size transfer surface was sufficient to effectuate transfer. NPRM, 77 FR at 6923–6924. Of the 12 commenters who responded, only two supported the transfer surface size in the proposed rule. Four of the remaining commenters (manufacturers) felt that the transfer surface width should be decreased, while five (disability rights organizations, a medical association, and an individual) believed a larger surface was needed. The last commenter, recommended one size transfer surface for both seated and supine, prone, or side-lying diagnostic equipment. Commenter recommendations for transfer surface width ranged from 24 inches to 36 inches, while no commenters addressed the proposed depth of 15 inches. Those advocating for a larger width were concerned about the ability of the patient to reposition after transfer and about accommodating obese patients. Those commenters supporting a smaller transfer surface raised concerns about the ability to transfer with a large surface preventing the patient from reaching transfer supports on the opposite side of the transfer surface, while still seated in the wheeled mobility device. The commenters were also concerned that making existing tables comply would require entire base redesigns as product stability would have to be re-evaluated with a wider table. Commenters also raised concerns that a larger transfer surface would conflict with bore size limitations on imaging equipment and that it could limit the health care provider's access to the patient for proper exam. Finally, two commenters, in response to question

15(e), agreed that an adjustable feature such as an extendable platform, should be permitted to meet the transfer surface dimensions so long as it does not move when a load is applied and it is a permanent part of the device.

The MDE Advisory Committee discussions mirrored the comments to the MDE NPRM with recommendations ranging from 24 inches to 36 inches for the width of the transfer surface. The MDE Advisory Committee reviewed evidence about transfer surface size to include: Numerous video clips showing various transfers (both assisted and unassisted); industry exhibited tables to show current table and chair widths; and the findings of the Wheeled Mobility Anthropometry Project presented by Dr. Edward Steinfeld of the IDeA Center at the University of Buffalo. MDE Advisory Committee Report, 72–76, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* The Wheeled Mobility Anthropometry Project provided an analysis of transfer surface dimensions based on data collected from the study. The study is available at *http://www.udeworld.com/anthropometrics.html.* The data indicated that the minimum width of a table transfer surface could be as narrow as 28 inches and still accommodate 95 percent of the users sampled. *Id.* Some members of the MDE Advisory Committee noted that there was little gain in usability by increasing the transfer surface width from 28 inches to 30 inches, and that the significant gain in usability came from increasing the surface to 36 inches to accommodate very large or obese patients. MDE Advisory Committee Report, 72–76, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* While the committee members expressed concern about the need to provide accessibility criteria for obese patients, it decided that there is insufficient data to determine specific criteria at this time and recommended accessibility for bariatric patients be addressed in a subsequent rulemaking. *Id.* The Access Board concurs with the MDE Advisory Committee that while there is a need to address the accessibility needs of obese patients, more research is necessary before requirements can be developed. The MDE Advisory Committee also noted that if the surface is too wide it can become challenging for smaller sized persons to effectuate transfer, and thus by making all accessible equipment 36 inches wide, some patients would be unable to reach across the table to grasp the transfer support on the other side to utilize the support in the transfer process. *Id.* The MDE Advisory Committee recommended decreasing the required transfer surface width to 28 inches minimum for all diagnostic equipment used by patients in a supine, prone, or side-lying position. *Id.* at 73.

The MDE Advisory Committee made multiple recommendations for the transfer surface depth of diagnostic equipment used by patients in the supine, prone, or side-lying position. *Id.* at 74–76. The MDE Advisory Committee differentiated between equipment whose transfer surface was located on the end of the equipment with transfer sides on one short side and one long side of adjoining sides and stretchers and imaging equipment, which the MDE Advisory Committee noted transfer takes place in the center on either of the long sides. *Id.* For all diagnostic equipment used by patients in a supine, prone, or side-lying position, except imaging equipment, the MDE Advisory Committee recommended increasing the transfer surface depth to 17 inches, explaining that existing equipment already encompasses this dimension. *Id.* The MDE Advisory Committee included stretchers in this requirement, even though they have a transfer orientation akin to imaging equipment. *Id.* For imaging equipment, the MDE Advisory Committee recommended a transfer surface size of 28 inches long minimum by 28 inches deep minimum. The MDE Advisory Committee also recommended the addition of an exception for imaging equipment transfer surface size; to allow a decrease in depth to no less than 21 inches where it is technically infeasible to reach the 28 inches minimum. *Id.* at 75–76. The Committee explained that ''all x-ray tables meet the 28-inch table [depth] . . . because of physical design constraints such as bore size, not all tables used with equipment with bores meet the 28-inch-[deep] criteria, but all meet the 21-inch minimum.'' *Id.*

As discussed above in Section IV.B.1.b (Significant Changes—Transfer Surface Location) the restructure of the transfer surface to include two types of transfer surfaces; end transfer surface and side transfer surface, necessitates new technical requirements for the new side transfer surface. Accordingly, based on the comments received and the recommendations from the MDE Advisory Committee, the final rule establishes different sizes for each of the end and side transfer surfaces. The final rule requires that diagnostic equipment with an end transfer surface be a minimum size of 28 inches wide and 17 inches long. The Access Board has decreased the minimum width of the transfer surface from 30 inches to 28 inches based on the evidence presented to the advisory committee that 28 inches is sufficient to accommodate 95 percent of the users and will ensure that patients are able to utilize the transfer supports on the opposite side of the transfer surface. The Access Board has increased the length of the end transfer surface from 15 inches to 17 inches based on the evidence that diagnostic equipment currently on the market is already built to this dimension. In the final rule, the Access Board does not see a reason to prohibit an adjustable feature, such as a table with extendable sides, from meeting the size requirements of the transfer surface but believes it is unlikely that any diagnostic equipment would contain such a feature.

For diagnostic equipment with side transfer surfaces, the Access Board has decided to require a transfer surface size of 28 inches wide by 28 inches long, minimum. While the MDE Advisory Committee recommended only increasing the transfer surface size for imaging equipment to 28 inches deep by 28 inches wide minimum, the Access Board has concluded that diagnostic equipment used by patients in the supine, prone, or side-lying position with side transfer surfaces involve the same transfer dynamics whether they are imaging equipment, hospital beds, or stretchers and therefore should be subject to the same transfer surface size requirement.

Additionally, the Access Board concurs with the MDE Advisory Committee recommendation to provide an exception for the transfer surface size of imaging equipment in the final rule given the physical limitations affecting surface depth for imaging equipment with bores and the fact that it is unclear when technological advances in bore size may permit larger patient examination surfaces. However, the Access Board has narrowed the application of this exception only to imaging equipment with bores. The Access Board has determined that this exception, as recommended, was intended to account for the space constraints of imaging equipment with bores and wants to ensure the exception stays as narrow as possible. Therefore, in the final rule, the Access Board has provided an exception which permits the imaging bed of imaging equipment with bores' to be a minimum of 21 inches wide but requires the transfer surface to be the full width of the examination surface. As this exception applies regardless of whether the

imaging equipment has an end transfer surface or a side transfer surface, an exception has been added to each requirement (M301.2.3.1 and M301.2.3.2, respectively). Additionally, the Board has added two definitions to the final rule, ''imaging equipment with bores'' and ''imaging bed'' to assist with the application of this exception. (M102.1 final rule).

d. Unobstructed Transfer

The MDE NPRM proposed that each transfer side provide unobstructed access to the transfer surface, with an exception to permit temporary obstructions as long as they could be repositioned during transfer (proposed M301.2.3 and M302.2.3). As explained in the MDE NPRM preamble, the unobstructed access requirement was to ensure that armrests, side rails, stirrups, or other equipment parts attached to the diagnostic equipment did not impede the patient's ability to transfer. NPRM, 77 FR at 6923. The final rule retains the proposed requirements for unobstructed transfer for diagnostic equipment used in a supine, prone, or side-lying position, as well as diagnostic equipment used in the seated position, and has added a new exception described below.

In the preamble to the MDE NPRM the Access Board noted that it was considering permitting equipment parts to extend a maximum of three inches horizontally beyond the edge of the transfer side. The Access Board explained that ''[t]he 2004 ADA and ABA Accessibility Guidelines provide a gap of 3 inches between the edge of the shower seat and the shower compartment entry, and the gap does not appear to interfere with transferring onto and off of the shower seat.'' NPRM, 77 FR at 6924. The Access Board sought input from the public in the MDE NPRM preamble question 17, on whether equipment parts should be permitted to extend a maximum of three inches horizontally beyond the edge of the transfer sides, provided that they did not extend above the top of the transfer surface. *Id.* Six of the eleven commenters who responded to this question supported permitting equipment parts to extend up to three inches horizontally beyond the edge of the transfer surface. However, these commenters were primarily manufacturers who also expressed concerns about the cost of equipment redesign if a provision permitting the three-inch gap was not included in the final standards. The other five commenters, disability rights advocates and an accessibility consultant, did not support allowing equipment parts to extend up to three inches horizontally, unless they were removable. These commenters raised concerns that the equipment parts would impede transfer. Additionally, a manufacturer, responding to question 9 in the MDE NPRM, explained that all beds, stretchers, and cots have side rails that can be moved to allow unobstructed access for transfer.

The MDE Advisory Committee reviewed the comments. The Committee observed that transfer supports provide handholds that facilitate transfers onto and off of the equipment, and that some types of diagnostic equipment have components that create a gap between the transfer surface and the outer edge of the equipment on the side used for transfer. MDE Advisory Committee Report, 78–82, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* The MDE Advisory Committee reviewed the 2010 ADA Standards for shower compartment seat requirements, which allows a three-inch gap between the edge of a seat and the shower compartment entry, to determine if these gaps presented a problem to individuals attempting to transfer. The MDE Advisory Committee also considered anthropometric data from the Impact of Transfer Setup on the Performance of Independent Transfers study by the VA Pittsburgh Healthcare System in collaboration with the Human Engineering Research Laboratories at the University of Pittsburgh. *Id.* This study examined the transfer experience with an adjustable height transfer surface. This study is available at *http://herl.pitt.edu/ab/.* The MDE Advisory Committee explained that ''[t]he results showed that 95% of subjects could transfer when the seat and surface are at the same height with a 3.5-inch gap. This data helped inform the recommendation for the exception since the 3-inch criteria is less than that used in the research and should assure effective transfers for most.'' MDE Advisory Committee Report, 79, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* The MDE Advisory Committee recommended allowing a maximum three-inch obstruction protruding from the transfer sides, ''placing a limit on the size of the gap between the transfer surface and the outer edge of the equipment on the side used for transfer,'' that applies to both the long length (width) and short length (depth) transfer sides. *Id.* The Committee also recommended special consideration for stretchers, to incorporate the provision of IEC 60601–2–52 to establish a maximum vertical obstruction at no less than one inch below the top of the transfer surface. *Id.*

Based on the comments received and the MDE Advisory Committee recommendations, the Access Board is persuaded that a gap of up to three inches between the transfer side and the wheeled mobility device will not impede transfer given that accessible diagnostic equipment will be required to be adjustable. In addition, the Access Board is not persuaded that special consideration for stretchers is necessary in order to accommodate the IEC 60601–2–52 prohibition against vertical obstructions within one inch of the top of the patient surface. The final rule would not permit obstruction above the patient surface; consequently, by meeting the IEC requirements manufacturers will meet the MDE Standards.

Accordingly, the final rule includes an exception permitting obstructions of no more than three inches deep beyond the transfer side of the transfer surface provided that such obstructions do not protrude above the top of the transfer surface. A common example of this type of obstruction is articulating side rails on stretchers that move out of the way during transfer, but create a gap between the transfer surface and the mobility device. The exception allowing obstructions of up to three inches is included in each of the new provisions for unobstructed transfer for diagnostic equipment used in the supine, prone, or side-lying position (M301.2.4), and diagnostic equipment used in the seated position (M302.2.5), as Exception 1.

As noted above, the Access Board has retained the original exception from the MDE NPRM, permitting temporary obstructions provided that they can be repositioned out of the way during transfer. In the final rule, the Board moved this provision to Exception 2 to accommodate the new exception discussed above, and added language to specify that this exception may also apply to obstructions that qualify for Exception 1. For example, side rails that create a gap of three inches from the transfer side of the diagnostic equipment to the mobility device when moved out of the way for transfer, but also protrude above the top of the transfer surface when in place as a side rail.

2. Armrests Requirement

In the MDE NPRM, the Access Board required diagnostic equipment used by patients in the seated position to

provide armrests (proposed M302.3.2). The only commenter that addressed whether armrests should be required was a manufacturer who requested that beds, cots, and stretchers be excluded from the requirements as they are required to have side rails per IEC 60601–2–52. The MDE Advisory Committee addressed the armrest provision during their discussions of transfer supports and explained that ''armrests serve a similar function, and occupy the same physical space as the transfer supports as described in the MDE NPRM. The MDE NPRM requires transfer supports for all chairs, so the additional equipment for armrests for chairs was not only redundant, but could potentially create a physical conflict between the two devices.'' MDE Advisory Committee Report, 104, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* The MDE Advisory Committee recommended that armrests not be required, but if provided they cannot obstruct transfer supports. Additionally, the Committee noted that transfer supports meeting the final requirements, would provide support like that of armrests and enhance patient stability if left in place after a transfer from a mobility device. *Id.*

After review of the comment and the recommendations of the MDE Advisory Committee, the Access Board is persuaded that requiring armrests as well as transfer supports is redundant and has the potential to cause conflict between the two devices. Therefore, the Access Board has removed the provision requiring armrests from the final rule.

3. Lift Compatibility Exception

The MDE NPRM proposed that diagnostic equipment used by patients in the supine, prone or side-lying position and diagnostic equipment used by patients in the seated position be usable with portable patient lifts. The proposed rule specified base clearance requirements to ensure lift compatibility (M301.4 and M302.4, respectively). The preamble to the MDE NPRM sought comment on whether the final rule should exempt certain diagnostic equipment from these requirements if the equipment was specifically designed to be used with a fixed overhead lift. NPRM, 77 FR at 6927, question 27.

Eleven commenters responded to question 27. Six of the ten commenters (one manufacturer, three medical associations, and two government entities) concurred with the proposed scenario that if equipment was designed for use with overhead lifts then that equipment should be exempted from the proposed base clearance requirements. One commenter, a manufacturer, agreed that equipment designed for use with an overhead lift should be excepted, and also stated that portable floor lifts should be designed to be compatible with exam and procedure tables, not that the tables be redesigned to be compatible with floor lifts. Four of the commenters (three disability rights organizations and an accessibility consultant) were opposed to this exemption and expressed concern that the overhead lift would not be available when needed if the diagnostic equipment was moved to another room or the lift was not functioning. The final commenter, a manufacturer, opposed the exemption unless the overhead lift was included as part of the equipment when sold.

The MDE Advisory Committee reviewed this issue and recommended the use of overhead lifts as an alternative for imaging equipment where portable floor lifts are not feasible. Specifically, the MDE Advisory Committee explained:

> Overhead lifts can provide an alternate means of access instead of clearances around the bases of imaging equipment required for portable lifts. Table structural design and/or room layout may be such that providing the clearances in and around the base may be either technically difficult or impractical. In these cases, a ceiling-mounted lift may be a better method for some types of imaging equipment because the portable lift would need to access the diagnostic imaging table from the side or far end. Some imaging systems already use overhead lifts to assist patients . . . [Overhead lifts] may offer flexibility over a portable lift because it can transfer the patient from either side placing the patient in the desired imaging orientation, and the ability to move completely out of the way when not needed. MDE Advisory Committee Report, 107, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.*

After review of the comments received and the recommendations from the MDE Advisory Committee, the Access Board has concluded that fixed overhead lifts may be appropriate and even preferred in certain circumstances. However, the Access Board believes that the determination of the circumstances where an exception is warranted and the types of diagnostic equipment that should be excepted from the portable floor lift requirement is more appropriately left to the enforcing authority. Accordingly, the final rule provides a limited exception to the lift compatibility requirements for fixed overhead lifts in situations where: (1) A fixed overhead lift is provided; (2) the diagnostic equipment is clearly labeled as not compatible with portable floor lifts; and (3) the use of the overhead lift with that diagnostic equipment is specifically permitted by the enforcing authority. The exception applies only if all three conditions are met.

4. Exception From the Requirements of M301 for Certain Examination Chairs That Comply With M302

The Access Board proposed in M101.2 in the MDE NPRM to require diagnostic equipment to meet the standards for each patient position supported, meaning that if diagnostic equipment was designed to support a patient in multiple positions then the equipment would have to meet the technical criteria for each of those positions. The Access Board sought public input in question three in the preamble in the MDE NPRM, on whether organizing the technical criteria functionally by patient position was clear. 77 FR at 6919.

Fifteen commenters responded, with only two disability advocates and one medical association agreeing that the division of the MDE Standards was clear. The manufacturers raised concerns about applying the MDE Standards for multiple patient positions to a single piece of equipment. Multiple commenters recommended that when diagnostic equipment that fits in multiple categories, one category should take precedence. Medical Association and Accessibility Consultants recommended reorganizing the standards by types of facilities or by feature and one manufacturer recommended harmonizing M301 and M302 into one requirement. Additionally, commenters raised concerns about diagnostic chairs which could be reclined into a supine position after transfer; such as podiatry and dental chairs. These commenters argued that requiring the equipment to be designed to accommodate transfer in both positions would not achieve any objective benefit and would impose transfer surface width requirements that would not be appropriate and would be overly burdensome. The MDE Advisory Committee did not make a recommendation on this provision. However, the subcommittee for tables and chairs did explain that while the primary function of examination chairs is to support patients in a seated position, they are also capable of being reclined. The ability to recline is a secondary, rather than a primary purpose. The subcommittee asserted that these types of chairs should be covered by M302.

In response to the comments and Advisory Committee discussions, the Access Board acknowledges that one of the most important features of making diagnostic equipment used by patients in either the supine, prone, or side-lying position or the seated position accessible, is to ensure the patient has the opportunity to transfer independently to the maximum extent possible. The Access Board concurs with the commenters that there are certain examination chairs, such as dentistry and podiatry chairs, where the patient is only intended to transfer while the chair is in a seated position but is then reclined into a supine position while the diagnostic procedure is being performed. The Access Board concurs with commenters that in this limited situation it is unnecessary for the examination chair, which complies with the technical requirements in M302, to also have to comply with the technical requirements in M301. Therefore, in the final rule the Access Board has added an exception to M301.1 which states that examination chairs that comply with M302 and, after the patient transfers into the seat, reclines to facilitate diagnosis, do not have to comply with M301. Additionally, the Board has added a new definition for examination chair in M102.1 in the final rule to assist with the application of this exception. The other commenter concerns regarding the proposed application provision, M101.2, are addressed below in the Section-by-Section Analysis.

5. Exception From the Requirements of M302 for Weight Scales With Integral Seats

The MDE NPRM proposed that diagnostic equipment which could be used by patients in multiple positions must comply with the technical criteria for all positions in which it could be used (proposed M101.2). In the preamble in the MDE NPRM the Access Board proposed an exception to this requirement for folding seats on diagnostic equipment used by patients seated in a wheelchair. The MDE NPRM proposed that this type of diagnostic equipment would have to meet the technical requirements of M302 (diagnostic equipment used by patients in the seated position) and M303 (diagnostic equipment used by patients seated in a wheelchair), with the exception of the lift compatibility requirements in M302.4. NPRM, 77 FR at 6927. The Board explained that because the patients can use the equipment while seated in their wheelchairs, the seat does not have to provide the clearance necessary to be usable with a portable floor lift. *Id.*

In the MDE NPRM preamble the Access Board sought comment with two questions, 28 and 37. Question 37 asked whether a folding or removable seat should be required on weight scales for use in the standing position. NPRM, 77 FR at 6930. Four commenters responded: Three concurred (an accessibility consultant, disability rights organization, and a state agency concerned with accessibility); and one commenter (a manufacturer) agreed it should be an option, but not a requirement. Six commenters responded to question 28, which asked whether a folding seat provided on diagnostic equipment with a wheelchair space should be required to comply with the technical criteria in proposed M302 for transfer surfaces and supports. NPRM, 77 FR at 6927. Five of the commenters (three disability rights organizations, a state agency concerned with accessibility, and an accessibility consultant) asserted that if a seat is provided it should have to comply with the technical provisions for diagnostic equipment used by a patient in the seated position. One of these commenters explained that not all people with disabilities who need to transfer are wheelchair users and some wheelchair users may choose to transfer, even if the device is designed for use in a wheelchair. The remaining commenter, a medical association, noted that it was unaware of any diagnostic equipment with a folding seat, but asserted that if patients can use the equipment in wheelchairs, then they should not be transferred onto the folding seat, and the chair should not have to meet the requirements in proposed M302.

The MDE Advisory Committee discussed weight scales, noting the importance of obtaining a patient's weight for medical treatment and the difficulty patients in wheelchairs confront with obtaining an accurate weight. *See* MDE Advisory Committee Report, 66, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* However, the MDE Advisory Committee did not make specific recommendations for requiring a folding seat on diagnostic equipment used in the standing position, nor did it make any specific recommendations for an exception to M302 for seats on weight scales with wheelchair spaces. The Subcommittee on Weight Scales, in explaining its recommendations on size and ramp slope, recognized that ''space constraints are of consideration . . . as medical equipment and adequate space in the acute care or in the medical office setting are often competing. Scales that can be wall mounted or that are portable would facilitate where there are space constraints.'' Subcommittee Report—Weight Scales, 7, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report/appendix-b-supporting-documents.*

After reviewing the comments and the Subcommittee on Weight Scales Report, the Access Board has determined that weight scales that are designed to be used by patients seated in a wheelchair, but also provides a seat integral to the equipment, present a unique situation which warrants an exception to the general provision of M302.1 in the final rule. The primary purpose of the technical requirements for diagnostic equipment used by patients in the seated position is to facilitate independent transfer from a mobility device onto the diagnostic equipment. Some wheelchair accessible scales also provide a seat for patients who ambulate onto the scale, but due to stability or fatigue issues, may need to sit in order to be weighed. On many of these scales the seat folds down into the wheelchair space to accommodate the ambulatory patient who needs to sit. The MDE Advisory Committee notes that space is already at a premium for weight scales. To require a seat integral to the weight scale to meet the provisions of M302, when it already meets the requirements of M303 would require the weight scale platform to be significantly larger than a weight scale which just provides a wheelchairs space. To accommodate both a wheelchair space and seat permitting transfer from a mobility device, the platform would have to be large enough to accommodate individuals in their mobility devices and also provide enough space to allow for a side or perpendicular transfer from the mobility device onto the seat. Because weight scales with wheelchair spaces and seats are intended to be used by patients remaining in their wheelchairs or ambulating onto the scale, the Access Board has concluded that it is not necessary to require the weight scale to provide the wheelchair space for the patient to use the weight scale in a wheelchair and also provide the space for the patient to wheel onto the weight scale and then transfer onto the seat. Accordingly, the Access Board has excepted integral seats on weight scales that also contain wheelchair spaces meeting all the requirements of M303 from complying with M302. Due

to the addition of this exception from all of the M302 requirements, the exception in proposed M302.4, which exempted the folding seat from complying with the lift compatibility requirements, has been removed from the final rule as it is now encompassed under the new exception.

The Access Board acknowledges the comments recommending that accessible diagnostic equipment used in the standing position also provide a seat. However, the Access Board has declined to include such a provision in the final rule because of the potential space impact and because, it will ultimately be up to the enforcing authority to determine what types of diagnostic equipment and how many of each type must be provided in medical settings. However, if diagnostic equipment used in a standing position does provide a seat, but does not provide a wheelchair space, then it would have to comply with the requirements of M302 and M304 in the final rule.

C. M303 Diagnostic Equipment Used by Patients Seated in a Wheelchair

M303 contains the technical requirements for diagnostic equipment used by patients seated in wheelchairs. In the final rule the Access Board made four significant changes to this section: Two significant changes to accommodate the unique challenges of mammography equipment; one significant change to the ramped running slope requirement; and a final significant change to the width and depth of wheelchair spaces.

1. Width and Depth of Wheelchair Spaces

The MDE NPRM proposed to require diagnostic equipment to have a wheelchair space that is at least 36 inches wide (proposed M303.2.2). The MDE NPRM further proposed two alternative depth requirements: 48 inches for wheelchair spaces that are entered from the front or rear, and 60 inches for wheelchair spaces entered from the side (proposed 303.2.3). The MDE NPRM preamble also noted that the Access Board was considering adding exceptions in the final rule to the width and depth requirements for wheelchair spaces on raised platforms. NPRM, 77 FR at 6928–6929. The Access Board sought input in questions 31, 32, and 33, regarding the required size of wheelchair spaces on raised platforms, the use of scooters on raised platforms, and the associated costs. *Id.*

No commenters responded to questions 31 and 33; four commenters responded to question 32. Question 32 asked whether equipment with wheelchair spaces on raised platforms, such as weight scales, can accommodate patients who use scooters, and if they currently cannot, should the width and depth be changed so the equipment is usable by patients who use scooters. One commenter (a disability rights organization) asserted that if diagnostic equipment is accessible for wheelchairs it should also be accessible to scooters and recommended enlarging the space beyond 36 inches. Another disability rights organization opined that most weight scales in healthcare settings are inaccessible to wheelchair users, asserting that even the ''accessible'' weight scales are only 24 inches wide by 30 inches deep and are too small to accommodate manual wheelchairs and definitely would not accommodate the longer wheelbases of many power wheelchairs and scooters. This commenter recommended taking a ''universal design'' approach with a requirement of 34 inches wide by 58 inches deep for raised platforms on weight scales. The other two commenters (an academic and state agency concerned with accessibility) agreed that diagnostic equipment with wheelchair spaces on raised platforms should be usable by scooters, but did not provide any suggested dimensions.

The MDE Advisory Committee recommended a minimum platform size of 32 inches clear width and 40 inches clear length (depth). The Committee noted that their proposed recommendation sought to address the unique considerations of weight scales with raised platforms. The Committee stated that this size ''accommodates both manual and power wheeled mobility devices including small and mid-size scooters.'' MDE Advisory Committee Report, 109, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* The Committee relied on the Wheeled Mobility Anthropometry Project findings of wheelbase measurements and the Wheeled Mobility Anthropometry Project's recommendation of a minimum flat surface of 40 inches in length for platforms to accommodate wheeled mobility devices, including scooters. *Id.* at 110. The Committee explained that ''[t]o have an accurate weight, the entire wheelbase (either 3 or 4 wheels) of a mobility device must rest on and make contact with the platform. The foot pedals, footrests, scooter deck and tip wheels can overhang or extend beyond the platform and still get an accurate weight.'' *Id.*

In order to reconcile the public comments and the MDE Advisory Committee recommendations, the final rule retains the proposed M303.2.2 requirement for minimum width of 36 inches for wheelchair spaces, but provides an exception to permit wheelchair spaces on raised platforms to be a minimum of 32 inches wide. This width restriction assumes that the elbows and hands of persons using mobility devices would overhang the width of the platform and they would still be able to propel themselves. Because the final rule also requires raised platforms over 1½ inches in height to provide edge protection that is a minimum of 2 inches high from the surface of the platform (*See* M303.2.6 final rule), it was necessary to restrict the height of this edge protection for platforms using the exception of 32 inches wide to 4 inches. This height restriction is to ensure that a clear space is provided above any edge protection to allow the mobility device's casters and footrests or other components to extend over the edge protection.

For the depth of the wheelchair space, the final rule has retained both alternative depth requirements in proposed M303.2.3: 60 inches for wheelchair spaces entered from the side, and 48 inches for wheelchair spaces entered from the front or rear, discussed below in Section VI.10.c (Section-by-Section Analysis—M303.2.3). However, the Access Board has included an additional requirement for wheelchair spaces that are entered from the front or rear and permit pass-through from one end to the other. This provision requires wheelchair spaces that permit pass-through to have a minimum depth of 40 inches. Less space is required in these circumstances because the wheelchair user does not have to turn around or back out to exit the diagnostic equipment, but can enter and exit continuing on in one direction. Due to the addition of the new requirement, the Board reorganized this provision in the final rule to M303.2.3.1 (front or rear entry depth), M303.2.3.2 (Pass Through Entry), and M303.2.3.3 (side entry depth).

2. Equipment Clearances for Breast Platforms

The MDE NPRM proposed knee and toe clearance requirements for diagnostic equipment used by patients seated in wheelchairs that paralleled the knee and toe clearance requirements from the 2004 ADA and ABA Accessibility Guidelines. NPRM, 77 FR at 6929. The proposed rule included a requirement that 17 inches minimum and 25 inches maximum of the 48-inch

wheelchair space depth include knee and toe clearance. The knee and toe clearance would be permitted to be located beneath the diagnostic equipment, such as an optometrist diopter. The proposed rule contained a different requirement for breast platforms on mammography equipment, that of the 48-inch depth minimum of the wheelchair space, the knee and toe clearance under a breast platform would be 25 inches deep (proposed M303.2.4).

Two commenters, one manufacturer and one disability rights organization, commented on the knee and toe clearance under breast platforms. The disability rights organization raised concerns that existing machines do not provide deep enough clearance and that during the examination the breast platform will hit the patient's knees. The manufacturer also raised concerns with the size of the knee and toe clearance and recommended basing the requirements in relation to the height of the breast platform. Additionally, this commenter raised concerns that mammography equipment must have a stabilizing flange or foot at its base to prevent the equipment from tipping when the gantry is extended. This flange protrudes into the knee and toe clearance. Specifically, this commenter explained that the flange can be designed for optimal accessibility, but is necessary for the safety of the equipment.

The MDE Advisory Committee reviewed this provision and gave multiple recommendations regarding the necessary clearances for breast platforms. The Advisory Committee noted that mammography equipment presents a unique challenge for individuals seated in wheelchairs because the mammography exam requires the patient's breasts to be placed on top of the breast platform thereby requiring the knees and toes to go deeper beneath the equipment. The MDE Advisory Committee recommended changes to the proposed requirements for knee and toe clearance to create a deeper knee space under breast platforms. The MDE Advisory Committee did not suggest revisions to the proposed knee and toe clearances for diagnostic equipment used by patients seated in wheelchairs, other than for mammography equipment.

The knee and toe clearance requirements were adopted from the 2004 ADA and ABA Accessibility Guidelines and typically will allow a person seated in a wheelchair to pull underneath a work surface or equipment component or permit forward access to a control located above equipment overhanging the knee and toe space. We are persuaded by the MDE Advisory Committee report that mammography equipment presents a unique use and requires different specifications for the knee and toe clearance to ensure that the patient's breast can rest on top of the platform. The knee and toe clearance underneath mammography equipment must provide sufficient space to allow the patient to get close enough for their breast to be placed on the breast platform in order for the diagnostic procedure to be performed. Thus, the Access Board has reorganized the equipment clearances provision in the final rule into two separate requirements; breast platforms and other equipment. The requirements for breast platforms (M303.2.4.2 in the final rule) account for obstructions in the knee and toe clearance necessary to stabilize the mammography equipment and the location of the patient's body within the depth of the wheelchair space, such that more of the overall space is allocated to knees and toes. As discussed above, these factors result in an exception to allow equipment components of a low profile to extend into the toe end of the wheelchair space. The requirements for other equipment (M303.2.4.2 in the final rule) are substantively unchanged from the NPRM, and are discussed below in the Section VI.C.10.d (Section-by-Section Analysis—M303.2.4).

a. Knee and Toe Clearance

The proposed rule recommended a knee and toe clearance depth for breast platforms of 25 inches. There were no comments received on this requirement. The MDE Advisory Committee recommended increasing the overall knee and toe space to a minimum 28 inches deep. MDE Advisory Committee Report, 115–116, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* The MDE Advisory Committee asserted that a minimum of 28 inches in overall knee and toe clearance would accommodate 95 percent of the population. *Id.*

The Access Board concurs with the MDE Advisory Committee's conclusion that an increase in the overall knee and toe clearance under breast platforms is warranted. However, the Board is concerned that if the Advisory Committee's recommendation is adopted without change, it would significantly impact the requirement in the final rule for a 48-inch deep wheelchair space. Because at least 25 inches of the space must accommodate knees and toes, only 23 inches remains to accommodate that portion of the occupied wheelchair not including knees and toes. If the Access Board were to require 28 inches minimum knee and toe clearance, only 20 inches would remain. After reviewing all the evidence before the MDE Advisory Committee, the Access Board has decided to make a number of changes to the requirements for the knee and toe clearances for breast platforms. These new requirements are described in the Section VI.C.10.d (Section-by-Section Analysis—M303.2.4). The requirements are intended to ensure that there is adequate space for a patient seated in a wheelchair to position underneath the equipment and align themselves against the breast platform so that the diagnostic procedures can be performed.

b. Exception for Base Support Allowance and Unobstructed Knee and Toe Space

In the proposed rule, obstructions were not permitted within the knee and toe clearance space. This is consistent with the requirement in the existing accessibility guidelines and standards. One manufacturer commented on this provision, asserting that mammography equipment poses unique challenges and requires separate consideration. The commenter explained that the gantry of a mammography machine includes a base lip which is required for structural and seismic stability, and protrudes into the knee and toe clearance. This commenter recommended revisions to allow for a base lip on mammography equipment.

The MDE Advisory Committee recommended allowing obstructions into the knee and toe clear space, up to a height and depth that still permits the footrests of wheelchairs to pass over it. Specifically, the Committee recommended allowing base supports to be a maximum of 1½ inches high and allowing an additional sloped region above the base support at a depth of 25 inches from the front edge of the breast platform at 1½ inches above the floor, which can extend to a height of 4 inches above the floor at a depth of 28 inches. The MDE Advisory Committee explained its recommendation, noting that:

> The base support is of fundamental importance to mammography equipment and provides structural support, seismic stability, and installation safety. It does obstruct the floor space in front of the gantry and, thus, may limit how close a wheelchair can get to the equipment. To respond to this issue, industry proposed a configuration that would cause minimal obstruction to the floor space in front of the gantry and would allow footrests to ride over it.
>
> To discuss the maximum base support height, the sub-committee looked at anthropomorphic data regarding footrest

heights. The footrest height data measures the height from the floor to the top surface of the footrest at its proximal outside corner. To determine the necessary clearance for the footrests, the Committee used the footrest height data and subtracted the thickness of the footrests (~0.5 inch). Allowing a maximum base support height of 1.5 inches will provide room for the structural components necessary for an effective base support design and will also be accessible by around 92% of manual chair users and over 95% of power chair users. MDE Advisory Committee Report, 123–127, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.*

The Access Board concurs with the need for permitting base components in the knee and toe clear space for mammography equipment. While the Access Board recognizes that this is a deviation from existing accessibility guidelines and standards, the Board believes that mammography equipment presents special challenges due to the diagnostic, structural, and seismic requirements of the diagnostic equipment. In the final rule, the Access Board has created an exception to the height requirement for breast platforms. This exception permits the profile of base components to extend into the wheelchair space at a height of 1½ inches maximum between 17 inches minimum and 25 inches maximum in depth measured from the leading edge of the breast platform. In addition, the Access Board has found that the profile of the base components should increase toward the rear of the clearance space where a patient's foot and toes will be higher than the heel supporting portion of the footrest. Therefore, the final rule requires that from 25 inches to 28 inches measured from the leading edge of the breast platform, the height of the component above 1½ inches must be beveled at a rate of 2.5:3. This exception preserves a 17-inch minimum of unobstructed floor space measured from the leading edge of the breast platform.

3. Exception to Ramp Running Slope

The MDE NPRM proposed that where there is a change in level at the entry of a wheelchair space that is greater than 1½ inches, the entry shall be ramped and have a running slope not steeper than 1:12 (proposed M303.3). The Access Board explained in the MDE NPRM preamble that this provision is consistent with the 2004 ADA and ABA Accessibility Guidelines' technical criteria for changes in level. NPRM, 77 FR at 6929. No commenters addressed this provision. The MDE Advisory Committee, during its discussion of wheelchair spaces on weight scales, extensively addressed the permissible slopes of ramps on raised platforms. Specifically, the Committee noted:

[It] considered the needs of a ramped surface to access the platform on the accessible scale. Because there are different types of scales with different platform heights, the Committee developed a three tiered ramp slope proposal to fit different situations. The Committee reviewed and discussed the provisions on slopes for ramps as they apply to architectural elements in the built environment. The maximum slope for a ramp in the 2010 Standards is a rise of 1 vertical inch for each 12 inches of horizontal distance slope. Under very limited conditions in the built environment, the 2010 Standards allow a steeper ramp for a limited rise. A ramp in the built environment to which this exception applies may use a 1:2 grade slope on a short rise ramp.

Industry experts spoke to the concern for facility space often expressed by healthcare entities. The space constraints affect the desirability of accessible scales since space is often expensive and tight in many medical facilities. Scales that can be wall mounted or portable enhance the flexibility of scales and allow use in tight environments. Currently, these types of accessible scales use the short rise ramp to facilitate easy storage or mounting.

Existing technology for weight cell load allows for a platform profile to go as low as ¾ to 1½ inches. As the height of the platform lowers, the length of the ramp can decrease. The trend in the scale industry is to develop lower weight cell technology. However, industry currently does not know if lower profiles are possible. MDE Advisory Committee Report, 111–112, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.*

The MDE Advisory Committee recommended a three tiered approach for allowable ramp runs on raised platforms: Allowing a slope of 1:2 at 0 to 1½ inches, a slope of 1:8 at a height greater than 1½ inches to 2½ inches, and a slope of 1:12 at a height greater than 2½ inches. *Id.*

The Access Board agrees with the MDE Advisory Committee that additional allowances in the slope of ramp runs of diagnostic equipment used by patients seated in a wheelchair with raised platforms, primarily weight scales, is appropriate. However, for usability and safety reasons, the Access Board has determined that slopes of such ramp runs should not exceed the long standing maximum slope for accessible ramps of 1:8 that is allowable in certain circumstances in the 2004 ADA and ABA Accessibility Guidelines. The Board also notes that the Guidelines only permit changes in level up to ½ inch *e.g.,* thresholds to be steeper than 1:8.

Therefore, the Access Board has decided to add an exception in the final rule to the requirement that ramped entry wheelchair spaces have ramp runs with a running slope no steeper than 1:12 (M303.3.3.1). This exception permits a running slope not steeper than 1:8 for ramp runs with a maximum height of 2½ inches. Consistent with the MDE Advisory Committee recommendations, ramp runs over 2½ inches in height will have to comply with the general requirement of running slopes of not steeper than 1:12.

4. Breast Platform Adjustability

The MDE NPRM proposed to require diagnostic equipment used by patients seated in a wheelchair that have components which are used to examine specific body parts to be capable of examining the body parts of a patient while seated in a wheelchair (proposed M303.4). Additionally, the Access Board proposed specific technical requirements for breast platforms of mammography equipment. The MDE NPRM proposed a height range for breast platforms of 30 inches minimum and 42 inches maximum above the floor (proposed M303.4.1). In the preamble to the MDE NPRM, the Access Board sought input in question 36, on whether the breast platform height range proposed was sufficient to accommodate a patient seated in a wheelchair. NPRM, 77 FR at 6930.

Three commenters responded to this question. One commenter, a medical association, concurred with the proposed provisions. Two other commenters, a disability rights organization and a manufacturer disagreed. The disability rights organization recommended adopting a minimum height range of 24 to 26 inches. The manufacturer indicated that the proposed height range of 30 inches to 42 inches is sufficient, but also noted that several manufacturers lower the breast platform to 25 to 28 inches due to requests for accessibility. This manufacturer also recommended requiring a minimum range of travel for the breast platform instead of a specific minimum and maximum height.

The MDE Advisory Committee recommended changing the breast platform height requirement from a specified height range to a required minimum range bounded by a required high height of 42 inches and a required low height of 26 inches which

constitutes the minimum range of travel allowed. MDE Advisory Committee Report, 132, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* The MDE Advisory Committee Report noted that industry representatives explained that:

> equipment currently manufactured ranges anywhere between 25 and 28 inches for the lowest measurement of the breast platform. There were various reasons cited for each of the positions. Recommendations from accessibility experts who developed mammography protocols for women with disabilities identified a need for a breast platform height of 24 inches. Because this recommendation evolved from technologist experience on equipment with less knee space, disability advocates supported the rationale for 26 inches as the minimum. One member cited the diversity of body types and sizes for persons with disabilities as the rationale for the 26 inches. Another member emphasized the importance of considering patients of short stature in addition to considering patients seated in a wheelchair. Many industry organization members supported the 28-inch minimum. Reasons cited included providing more flexibility for manufacturers and concern that the lower minimum could result in more leg injuries as the technologist lowered the breast platform so close to the lap of the patient using a wheelchair.

The MDE Advisory Committee recommended, by strong majority, a minimum low height of 26 inches and a minimum high height of 42 inches. After review of the comments and the MDE Advisory Committee recommendations, the Access Board has accepted the MDE Advisory Committee's recommendation of low and high minimum heights. The Access Board believes that this requirement will ensure that the breast platform can be lowered or raised to the proper height for a patient seated in a wheelchair and is also within the range requested from manufacturers for patient accessibility. Therefore, the final rule requires at M303.4.1 that breast platforms have a minimum low height of 26 inches, a minimum high height of 42 inches, and be continually adjustable between the minimum low and high heights.

5. Edge Protection

The MDE NPRM proposed edge protection on the ramps leading up to the raised platform (proposed M303.3.3.4), but did not require edge protection on the raised platforms themselves. The Access Board sought public input with question 30 in the MDE NPRM preamble, on whether there is diagnostic equipment with wheelchair spaces on raised platforms that does not provide edge protection.

The Access Board received two comments from disability rights organizations. These commenters recommended requiring edge protection on platforms and one commenter suggested that the edge protection should not encroach into the wheelchair space on the platform and should be designed according to the edge protection requirements from the 2010 ADA Standards.

The Advisory Committee made two recommendations for requiring edge protection on raised platforms; for single ramped entry platforms, the Committee recommended requiring a minimum two-inch high edge protection on the back of the platform opposite the entry ramp and on the two sides of the platform, and for double ramped entry platforms, the Committee recommended a minimum two-inch high edge protection on both sides of the platform. The Advisory Committee explained that edge protection ''provides an additional safety feature and guides users of wheeled mobility devices onto the platform.'' The edge protection prevents the patient from over-shooting the platform, driving off either side, tipping, or falling. MDE Advisory Committee Report, 112–113, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.*

The Access Board concurs with the Advisory Committee that edge protection is necessary on raised platforms to provide a mechanism to ensure that wheelchair users do not fall off the platform. Therefore, the final rule requires in M303.2.6 that platforms with wheelchair spaces that are raised more than 1½ inches in height to provide a minimum 2-inch-high edge protection, measured from the surface of the platform, on each side of the platform not providing entry to or exit from the diagnostic equipment.

D. M304 Diagnostic Equipment Used by Patients in a Standing Position

M304 provides the technical requirements for diagnostic equipment used by patients in a standing position. There was only one significant change made to the requirement of standing supports on the diagnostic equipment.

1. Standing Supports

The proposed rule included a provision requiring standing supports on each side of the standing surface and compliance with the technical requirements for standing supports in proposed M305.3 (proposed M304.3). Question 38 in the MDE NPRM preamble requested input on the standing support configurations currently provided, their effectiveness for patients with disabilities, whether alternative criteria would be appropriate, whether angled standing supports are effective, and whether there are any industry standards for structural strength requirements. NPRM, 77 FR at 6931.

Two commenters responded to this question. One commenter, a medical association, indicated that standing supports for imaging equipment vary widely based on the type of environment and specific imaging equipment being used. For example, the standing support on a chest x-ray machine and mammography equipment is much different than a support on a fluoroscopic room table that can be moved from a recumbent to standing position. The second commenter, a manufacturer, expressed concerns that the proposed rule was treating supports on breast platforms as standing supports, explaining that this was not the supports' intended purpose. This commenter argued that these supports are actually arm supports intended to ensure proper patient positioning during the diagnostic exam, and were not intended as an accessibility feature to assist the patient in standing.

The MDE Advisory Committee addressed the issue of standing supports for mammography equipment as well as that of standing supports for wheelchair spaces with raised platforms. For mammography equipment, the MDE Advisory Committee came to a consensus agreeing with the commenter that the ''standing supports'' on mammography equipment were actually positioning supports and the ''primary use of these supports is for positioning of the arms during the imaging process to keep them out of the field of view of the image.'' MDE Advisory Committee Report, 135, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* The MDE Advisory Committee noted that ''[i]ndustry representatives posited that if a patient has limitations or balance issues severe enough to need standing assistance, then the healthcare provider should position her in a seated position for safe imaging.'' *Id.* The MDE Advisory Committee recommended removing the requirements for standing supports on mammography equipment and instead adding a requirement for positioning supports. Additionally, the MDE Advisory Committee noted that:

since the supports mount to the c-arm on many types of mammography equipment, they will move up and down with the breast platform. In these cases, they do not need to be as long as 18 inches to provide sufficient flexibility for patients to reach them. Industry representatives also indicated that there are controls in the area where these positioning supports are located. It is important that the patients' hands do not accidentally hit these controls when they are holding the positioning supports. For this reason, industry will sometimes intentionally shorten the length of these handholds to less than the 18-inch proposal. Considering these factors, the full Committee agreed that a 12-inch long positioning support would be sufficient if it moved with the movable breast platform. *Id.*

The MDE Advisory Committee made two recommendations for standing supports on raised platforms with wheelchair spaces: One for single-ramped entry raised platforms, and a second for dual-ramped entry raised platforms. These recommendations would apply when the diagnostic equipment is designed to accommodate both persons seated in wheelchairs and standing persons. For single-ramped entry raised platforms, the MDE Advisory Committee recommended maintaining the requirement for standing supports on both sides of the diagnostic equipment. To address concerns raised by industry representative on the MDE Advisory Committee regarding the space on the platform needed to attach two sets of standing supports which must be outside the minimum clear space required for a wheelchair, the Committee recommended that dual-ramped entry raised platforms require only one standing support on one side of the platform. The MDE Advisory Committee explained that patients may have a stronger side, right or left, and therefore with only one standing support provided, they would need to be able to use their preferred side to hold onto the standing support. With a single entry ramp, supports on both sides are necessary to allow patients to choose to use the right or left side of their body, but on a dual entry ramp the patient can enter or exit on opposing sides to allow them to use their preferred side of their body with only one support. *Id.*

The Access Board concurs with the commenters and the MDE Advisory Committee that the supports on mammography equipment were intended as positioning supports, not standing supports. However, the Board has determined that an exception is not necessary due to the restructuring of this requirement in the final rule. In the final rule, standing supports are only required on diagnostic equipment used by patients in a standing position that provide a surface on which a patient would stand. This is discussed in greater detail below in Section V.C. (Section-by-Section Analysis—M304.2). Additionally, as discussed below in Section IV.E.1. (Significant Changes—Positioning Supports), the Access Board has elected not to include positioning supports for mammography equipment in the final rule.

With regard to the MDE Advisory Committee recommendations regarding standing supports on diagnostic equipment with raised platforms, the Access Board has decided to include an exception in the final rule for diagnostic equipment with entry and exit that permit pass-through from one end to the other to provide a standing support on only one side of the standing surface, provided that the standing support complies with the requirements in M305.3 for standing supports in a horizontal position. This exception would not just apply to diagnostic equipment on a raised platform designed both for people seated in wheelchairs and in standing positions, it would also apply to equipment designed solely for patients in a standing position and would apply regardless of whether the standing surface is raised on a platform or combined with a wheelchair space. For all other standing surfaces, the Access Board has retained the original requirement of standing supports on two sides of the standing surface from the proposed rule. While the MDE Advisory Committee spoke in terms of raised platforms, the Access Board believes the exception should be permitted where entry and exit permits pass-through from one end to the other, regardless of whether the standing surface is raised. Accordingly, the Access Board has decided to apply this exception to all diagnostic equipment which permits this type of entry and exit in final rule (M304.2.2).

E. M305 Supports

M305 provides the technical requirements for supports on medical diagnostic equipment. There were multiple significant changes made to the transfer supports section, including the addition of new requirements as well as the removal of structural strength requirements from the final rule. Additionally, changes were made to the vertical and horizontal standing supports requirements.

1. Transfer Supports

The MDE NPRM proposed requirements for transfer supports that applied to all transfer surfaces (proposed M305.2). The requirements were the same for transfer surfaces on diagnostic equipment used by patients in the supine, prone, or side-lying position, as well as diagnostic equipment used by patients in the seated position. The proposed standards required transfer supports to be located within reach of the transfer surface and not obstruct transfer, be capable of resisting vertical and horizontal forces of 250 pounds applied to all points, and not rotate in their fittings. The latter two requirements were taken from the 2004 ADA and ABA Accessibility Guidelines for grab bars. 36 CFR part 1191, App. D. In the preamble to the MDE NPRM, the Access Board posed multiple questions about whether the final rule should include more specific requirements regarding location, length, size, height, and angle for transfer supports; and whether transfer supports should be allowed to rotate in their fittings. The Access Board received 31 comments to these questions and the MDE Advisory Committee made 10 recommendations regarding the transfer support section.

In response to the comments and the recommendations of the MDE Advisory Committee, and in consideration of the changes to the final rule regarding types of transfer surfaces, the Access Board has made multiple changes and additions to the transfer support requirements, located at M305.2. Specifically, the Access Board has added technical specifications to the requirements for location (M305.2.1) and length (M305.2.2) based on the type of transfer support required; has added new technical requirements for height (M305.2.3), cross section (M305.2.4), absence of surface hazards (M305.2.5), gripping surfaces (M305.2.6), and clearance (M305.2.7); and has made changes to the fittings provision (M305.2.8). These new and revised provisions are based on the 2004 ADA and ABA Accessibility Guidelines for grab bars and handrails, 36 CFR part 1191, App. D. Finally, the Access Board has removed the requirement for structural strength for transfer supports and has decided not to add any positioning support requirements in the final rule. Each requirement is discussed in detail in the Section-by-Section Analysis below.

a. Structural Strength

The MDE NPRM proposed to require transfer supports to be capable of resisting vertical and horizontal forces of 250 pounds at all points (proposed M305.2.2). The Access Board sought input in question 18, on whether current transfer supports are capable of

resisting vertical and horizontal forces of 250 pounds at all points. NPRM, 77 FR at 6925. Four commenters (three manufacturers and one accessibility consultant) addressed this requirement: The accessibility consultant concurred with the proposal and the other three commenters opposed this provision. Two of those opposing the 250-pound requirement asserted that very few supports would be able to withstand 250 pounds of force applied to all points in all directions and that the requirements should differ depending on the force vector or live load applied. The remaining opposing commenter supported compliance with the prevailing industry standard IEC 60601 instead of the proposed provision.

The MDE Advisory Committee recommended revising the language proposed in the MDE NPRM to require transfer supports to resist vertical and horizontal forces of 250 pounds at locations determined by the intended use of the equipment. The Committee indicated that ''during committee discussions manufacturers stated that industry is required to test the most vulnerable spots on the transfer support. Industry must follow testing parameters found in other standards.'' MDE Advisory Committee Report, 103, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.*

After reviewing the comments received and the recommendations from the MDE Advisory Committee, the Access Board has decided to remove this section in the final rule. The prevailing standard used by industry, IEC 60601 adopted under the ANSI/AAMI ES 60601 series in the U.S., contains provisions that address the structural strength of supports. ANSI/AAMI ES60601–1:2005/(R)2012, available at *http://my.aami.org.* The IEC 60601 Standard applies to a wide range of medical equipment including much of the diagnostic equipment covered by the MDE Standards and contains allowances for risk assessment not found in accessibility standards, such that support features on diagnostic equipment that will sustain transfers in a safe manner even without a specific provision in the MDE Standards. *Id.* Accordingly, it is not necessary for the Access Board to address the structural strength of transfer supports in the final rule as it is already covered by industry standards.

b. Positioning Supports

The Access Board noted in the MDE NPRM preamble that it was considering adding positioning supports to the final rule and sought public input with question 24 on whether positioning supports should be required in the final rule. NPRM, 77 FR at 6927. Six commenters responded: Two commenters (disability rights organizations) recommended adding positioning supports; two commenters (manufacturers) recommended providing positioning supports within reach of the patient; one commenter (an accessibility consultant) recommended flexibility to allow for design based on use; and the final commenter (a manufacturer) raised concerns about the technical impact for MRI machines. Additionally, as discussed above in Section IV.D.1 (Significant Changes—Standing Supports) and below in Section V.C.17 (Section-by-Section Analysis—M305.2), the MDE Advisory Committee made recommendations to add requirements for positioning supports on mammography equipment and imaging equipment with transfer surfaces having depths greater than 24 inches.

After review of the comments and the MDE Advisory Committee's recommendations, the Access Board has decided not to require positioning supports in the final rule. Although the Access Board considers positioning supports to be helpful, even necessary in some instances, given the wide range of diagnostic equipment addressed by the final rule, we have insufficient information on which to base a meaningful requirement that could apply to all types of equipment. Additionally, where transfer supports are provided, they can also serve to assist patients to position themselves.

2. Standing Supports

The proposed rule provided technical criteria for vertical and horizontal standing supports. For horizontal standing supports, the Access Board proposed a gripping surface of 4 inches long minimum, the top of which would be required to be located 34 inches minimum and 38 inches maximum above the standing surface (proposed M305.3.1). For vertical standing supports, the Access Board proposed a gripping surface of 18 inches long minimum, the bottom of which would be required to be located 34 inches minimum and 37 inches maximum above the standing surface (proposed M305.3.2). In the preamble to the MDE NPRM the Access Board sought input with question 38 on: (a) The current configurations of standing supports, and their effectiveness for persons with disabilities; (b) if there were any alternative technical criteria that would be appropriate; (c) whether angled supports are effective; and (d) whether there are industry standards for the structural strength of standing supports. NPRM, 77 FR at 6931. The Access Board received two comments, one of which addressed standing supports on mammography equipment (discussed above in Section IV.D.1 (Significant Changes—Standing Supports)) and one commenter (medical association) who noted that angled standing supports would be effective and that they are unaware of any industry standards regarding structural strength.

The MDE Advisory Committee reviewed the standing supports provision and while it supported the technical criteria in the proposed rule, the MDE Advisory Committee recommended adding additional criteria for standing supports on raised platforms with wheelchair spaces based on the recommended changes in requirements for standing supports for such diagnostic equipment (discussed above in Section IV.D.1 (Significant Changes—Standing Supports)). The Committee recommended that for single-ramped entry raised platforms with wheelchair spaces, the standing supports located on two sides of the platform have a minimum of 34 inches between supports, be integrated into the platform, and be a minimum of 32 inches in length (at least 80 percent of the platform length) at the platform entry edge. MDE Advisory Committee Report, 136–137, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* For standing supports on dual-ramped entry raised platforms with wheelchair spaces, the MDE Advisory Committee recommended the standing support, required on one side of the platform, be integrated into the platform and stretch the full length of the platform (40-inch minimum). *Id.*

The Access Board concurs with most of the MDE Advisory Committee's recommendations; however, although the Committee's recommendations pertained to diagnostic equipment with wheelchair spaces and standing spaces on raised platforms, the Access Board has decided to apply the recommended criteria to all diagnostic equipment for patients in a standing position that also contains a wheelchair space, regardless of whether the equipment standing surface is raised. In addition, the exception permitting only one standing support is conditioned on that support being positioned horizontally in relation to the standing surface, not vertically. Additionally, the Access Board has adopted the Committee's recommendation regarding the length of

these standing supports necessitating the Access Board to restructure the standing support provision, dividing it into length and height. In the final rule the Access Board permits diagnostic equipment that is required to have standing supports that also provides a wheelchair spaces with one entry to have standing supports with a gripping surface length equal to or greater than 80 percent of the overall length of the platform. For such diagnostic equipment with wheelchair spaces that permit pass-through from one end to the other, the final rule requires the length of the gripping surface of the standing support to be at least equal to the length of the platform.

V. Section-by-Section Analysis

A. Chapter 1: Application and Administration

In the final rule Chapter 1 establishes the purpose and the general requirements for the application of the MDE Standards. This chapter received 21 comments and no recommendations from the MDE Advisory Committee. The Access Board made a few editorial changes to some of the provisions, and added one provision M101.3 Existing Diagnostic Equipment, which is discussed below.

M101 General

This is an introductory section.

M101.1 Purpose

The MDE NPRM proposed that the purpose of the MDE Standards was to establish technical criteria for diagnostic equipment that is accessible to and usable by patients with disabilities and to provide patients with disabilities independent access to and use of diagnostic equipment to the maximum extent possible. One commenter, a manufacturer, responded to the proposed provision. The commenter asserted that this provision was unclear without a list of applicable disabilities and an explanation on how the maximum extent possible would be determined.

In response to the commenter, the Access Board notes that the term ''disability'' is defined in the Americans with Disabilities Act (ADA), 42 U.S.C. 12102. None of the Standards and Guidelines promulgated by the Access Board include a list of applicable disabilities. Rather, they rely on the definition of disability provided in the ADA. As for determining whether diagnostic equipment provides independent access and egress to the maximum extent possible, that is a decision left to the enforcing authorities that adopt and implement this standard. The Access Board, therefore, declines to implement the commenter's suggested changes. The Access Board has, however, made two editorial changes to this provision clarifying that ''medical diagnostic equipment'' is referred to as ''diagnostic equipment,'' and that these standards are referred to as ''MDE Standards'' throughout the rule text.

M101.2 Application

In the NPRM the Access Board proposed that the MDE Standards would be applied to diagnostic equipment based on the patient position the equipment is designed to support. Additionally, this provision stated that where the equipment was designed to support more than one patient position, the MDE Standards for each patient position supported would be applied to the equipment. Fifteen commenters responded to this provision asserting that some diagnostic equipment should not have to comply with more than one patient position requirement. These concerns have resulted in two added exceptions to the final rule. The first is to exempt examination chairs which comply with M302 and can be reclined to facilitate diagnosis after the patient transfers onto the seat from complying with M301. (M301.1, Exception). This exception is discussed above in Section IV.B.4 (Significant Changes—Exception from the Requirements of M301 for Certain Examination Chairs that Comply with M302). Additionally, the final rule also exempts weight scales which contain a wheelchair space complying with M303 and that have a seat integral to the equipment from complying with M302 (M302.1, Exception). This exception is discussed above in Section IV.B.5. (Significant Changes—Exception from the Requirements of M302 for Weight Scales with Integral Seats). In the final rule, the application provision was revised due to the addition of the exceptions and a few editorial changes were made for clarity. This provision now requires that sections M301 through M304 of the MDE Standards be applied to diagnostic equipment based on the patient position that the equipment supports during patient transfer and diagnostic use and sections M306 and M307 will be applied to diagnostic equipment that contains communication features or operable parts that are provided for patient use.

M101.3 Existing Diagnostic Equipment

The MDE NPRM did not address when or how the MDE Standards would be applied to existing medical diagnostic equipment. Commenters raised concerns about the cost of immediate compliance for the more expensive imaging equipment, noting the high cost and the concern that rooms are designed specifically for such equipment. Specifically, at the public hearing on March 14, 2012, two commenters recommended phasing in these requirements for imaging equipment based on when it is replaced. The public hearing transcript is available at *https://www.regulations.gov/docket?D=ATBCB-2012-0003.*

The MDE Standards are advisory and are not binding until adopted by an enforcing authority. The Access Board's mandate was to establish only the minimum technical criteria, however enforcing authorities may establish scoping requirements in the future. In response to the commenters' concerns regarding existing equipment, the Access Board has decided to add a new provision which clarifies that the MDE Standards do not address the accessibility of existing diagnostic equipment and that the enforcing authority will determine whether and how diagnostic equipment will be regulated.

M101.4 Equivalent Facilitation

The MDE NPRM proposed to permit the use of alternative designs or technologies that are substantially equivalent to or provide greater accessibility and usability than strict compliance with provisions in the MDE Standards. One commenter, a manufacturer, requested that the Access Board include examples of acceptable methods for providing equivalent facilitation.

The Access Board is unable to provide examples of acceptable methods of equivalent facilitation, as this section is intended to encompass those design solutions which the Access Board is unaware at the time that this rule is published. Additionally, the final determination of whether a particular design or technology meets this provision will be determined by the enforcing authorities. Therefore, the only change to this provision was to adjust the section number to allow for the addition of the new provision, M101.3 Existing Diagnostic Equipment.

M101.5 Dimensions

The MDE NPRM proposed that the MDE Standards be based on adult dimensions and anthropometrics. One commenter and the MDE Advisory Committee raised concerns about providing standards for obese patients and pediatric patients. While the Access Board acknowledges that these are additional issues of accessibility, the

final rule follows the MDE NPRM framework and provides technical requirements based on adult dimensions and anthropometrics, only. At this point in time the Access Board is focusing on adult dimensions and anthropometrics however, the Access Board may address potential expansions of the MDE Standards to other groups in future rulemakings. The only change to this provision was adjustment of the section number to allow for the addition of the new provision, M101.3 Existing Diagnostic Equipment.

M101.6 Dimensional Tolerances

The MDE NPRM proposed that dimensions were to be subject to conventional industry tolerances for manufacturing processes, material properties, and field conditions. In the preamble of the MDE NPRM, the Access Board sought public input in question five on available information or resources concerning conventional industry tolerances for medical diagnostic equipment. NPRM, 77 FR at 6920. Six commenters responded to the question. Three commenters (two manufacturers and one medical association) indicated that tolerances vary based on the manufacturer, product design, and manufacturing process and that they are unaware of any industry standard. One commenter, a manufacturer, referenced ASME Y14.5–1994 for dimensional tolerances. Another commenter, a medical association, asserted that tolerances are in operator manuals. The final commenter, a manufacturer, recommended providing tolerances when dimensions are specified and recommended defining a specific tolerance, such as +/− 0.5 inch for linear dimensions.

After considering the comments received, the Access Board has decided to retain the original provision. The Access Board was persuaded by arguments from the commenters that there is not one industry-wide standard that can be applied to all MDE and concurs that the Access Board should not attempt to establish manufacturing tolerances. Where available, tolerances are best addressed by industry standards for the specific materials and methods employed in the manufacturing process. The only change to this provision was to adjust the section number to allow for the addition of a new section, M101.3 Existing Diagnostic Equipment.

M101.7 Units of Measurement

In the MDE NPRM there was no explanation of the units of measurement used throughout the rule text. In order to avoid confusion and to align this final rule with the other accessibility guidelines and standards promulgated by the Access Board; this provision has been added to explain that the values stated in each system (U.S. customary and metric units) may not be exact equivalents, and each system must be used independently of the other.

M102 Definitions

This is an introductory section.

M102.1 Defined Terms

The MDE NPRM proposed definitions for enforcing authority, medical diagnostic equipment, operable parts, and transfer surface. The Access Board sought input in question six in the preamble of the MDE NPRM, on whether there were other terms in the proposed standards that should be defined. NPRM, 77 FR at 6920. Ten commenters responded to this question. One commenter, a medical association, did not offer other terms that should be defined, but stated that there were many instances where the Board used acronyms without a definition. However, this commenter failed to provide any examples. Another commenter, a disability rights organization, suggested modifying the definition of medical diagnostic equipment to clarify that the standard is intended for all medical equipment in which any part of the equipment is used for diagnostic purposes for any amount of time. Another commenter, a manufacturer, recommended changing the term ''operable part'' to ''applied part'' and adding a new definition of operable part as ''caregiver operated parts,'' asserting that this aligns with IEC 60601. Other commenters (manufacturers, medical associations, disability rights organizations, and an individual) suggested the following terms be defined: health care provider, breast platform, patient support surface, transfer supports, positioning supports, prone position, supine position, examination tables, diagnostic purposes, maximum extent possible, landing area, exam table, procedure table, and procedure chair.

After review of the comments, the Access Board declines to add any of the suggested terms to the defined terms section. The definition of medical diagnostic equipment was taken directly from Section 510 of the Rehabilitation Act and thus for consistency has not been altered. 29 U.S.C. 794f. Some of the definitions proposed by commenters are not terms used in the MDE final rule and, therefore, providing the requested definitions would serve no purpose. The definitions for other proposed terms used in the final rule are the same as the ordinarily accepted meanings in the context that applies, and the Access Board does not believe that the reader would be significantly aided in understanding the final rule by adding the requested definitions. However, the Access Board has decided to add six additional terms to this section; end transfer surface, examination chair, imagining equipment with bores, imagining bed, side transfer surface, and wheelchair space. As described above in Section IV.B.1.b. (Significant Changes—Transfer Surface Location), the Access Board has added definitions for ''end transfer surface'' and ''side transfer surface'' to this provision to describe the two types of transfer surfaces for diagnostic equipment used by patients in the supine, prone, or side-lying position. The ''wheelchair space'' definition was taken from the 2004 ADA and ABA Accessibility Guidelines and adopted in the MDE final rule to provide consistency across Access Board rulemakings. Examination chair, imagining equipment with bores, and imagining bed were added to help clarify application of exceptions added in the final rule. (*See* M301.1, M301.2.3, and M305.2.2.2). Finally, the Access Board also made a minor editorial change to the title of ''operable part'' so that all components and parts are referred to in the plural.

M102.2 Undefined Terms

The MDE NPRM proposed that the meaning of terms not defined in proposed M102.1 or in regulations or policies issued by an enforcing authority, be defined by collegiate dictionaries in the sense that the context implies. There were no comments and no MDE Advisory Committee recommendations on this provision. In the final rule, the Access Board has changed this provision to indicate that the meaning of terms not defined in M102.1 will be given their ordinarily accepted meaning in the context that applies.

M102.3 Interchangeability

The MDE NPRM proposed that singular and plural words, terms, and phrases are used interchangeably. There were no comments on this requirement and no changes have been made.

B. Chapter 2: Scoping

In the final rule, Chapter 2 establishes that the enforcing authority will determine the number and types of diagnostic equipment to which the MDE Standards will apply. The Access Board did not receive any comments regarding Chapter 2 as written; however, several commenters expressed concern

regarding the ability of certain types of diagnostic equipment to comply with the MDE Standards. These concerns, discussed above in Section IV.A.1. (Significant Changes—General Exception), resulted in the addition of the M201.2 General Exception, described below. In addition, the Access Board made one editorial change to M201.1.

M201 General

This is an introductory section.

M201.1 Enforcing Authority

The MDE NPRM proposed to explain that the enforcing authority would specify the minimum number of types of accessible diagnostic equipment that would be required to comply with the MDE Standards. There were no public comments regarding this provision. The Access Board has decided to make an editorial change to this section to clarify that the enforcing authority will specify the minimum number and types of accessible diagnostic equipment that will be required to comply with the MDE Standards.

M201.2 General Exception

The MDE NPRM did not propose a general exception for diagnostic equipment that was not capable of meeting the MDE Standards. As described in Section IV.A.1. (Significant Changes—General Exception), the Access Board received public comments and MDE Advisory Committee recommendations regarding certain types of diagnostic equipment that are unable to meet all of the requirements in the MDE Standards. In response, the Access Board has added a new provision excepting diagnostic equipment from compliance with an applicable requirement in the MDE Standards in the rare circumstance where compliance would alter diagnostically required structural or operational characteristics of the equipment, and would prevent the use of the equipment for its intended diagnostic purpose. Any equipment falling under this exception must comply with the provision(s) in question to the maximum extent practicable, and must fully comply with all other provisions not utilizing this exception.

C. Chapter 3: Technical Requirements

In the final rule, Chapter 3 establishes the technical requirements for accessible medical diagnostic equipment based on how the diagnostic equipment is used by the patients, including: Diagnostic equipment used by patients in a supine prone, or side-lying position (M301); diagnostic equipment used by patients in a seated position (M302); diagnostic equipment used by patients seated in a wheelchair (M303); and diagnostic equipment used by patients in a standing position (M304). Chapter 3 also provides technical criteria for supports (M305), communication (M306), and operable parts (M307). This chapter underwent significant reorganization and changes as described in Section IV.B through IV.E (Significant Changes—M301 through M305). Additionally, the Access Board made editorial changes which are described below in the applicable Section-by-Section Analysis.

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

M301 in the final rule establishes the technical criteria for diagnostic equipment used by patients in a supine, prone, or side-lying position such as, examination tables, imaging tables, hospital beds, and stretchers.

M301.1 General

The MDE NPRM proposed that all diagnostic equipment used by patients in a supine, prone, or side-lying position must comply with the technical requirements of proposed section M301. As discussed in Section IV.B.4. (Significant Changes—Exception from the Requirements of M301 for Certain Examination Chairs that Comply with M302), in response to public comment and recommendations from the MDE Advisory Committee, in the final rule the Access Board has added an exception to this requirement for examination chairs that can be reclined to facilitate diagnosis after the patient transfers. This new exception exempts these diagnostic chairs from compliance with M301's requirements, as long as the examination chairs comply with the requirements in M302.

M301.2 Transfer Surface

This is an introductory section.

M301.2.1 Adjustability

The MDE NPRM proposed a transfer surface height range for diagnostic equipment used by patients in the supine, prone, or side-lying position of 17 inches minimum and 19 inches maximum. The Access Board received multiple comments on this provision and the MDE Advisory Committee provided four recommendations. As discussed in Section IV.B.1.a. (Significant Changes—Transfer Surface Adjustability), in the final rule the Access Board has renamed this provision and now requires the transfer surface height to be adjustable to: (1) A low transfer height of 17 inches minimum and 19 inches maximum; (2) a high transfer height of 25 inches; (3) at least four additional transfer heights located between the low and high transfer heights, separated by one inch minimum increments; and (4) the transfer surface height will be measured from the floor to the top of the uncompressed transfer surface.

M301.2.2 Sunset Provision

As discussed in Section IV.B.1.a. (Significant Changes—Transfer Surface Adjustability), this is a new provision that was added to the final rule in conjunction with the new requirement of a low height range in M301.2.1. It provides a sunset for the low transfer height provision of five years from the date of publication of this rule in the **Federal Register**. The Access Board intends to complete the necessary research to determine an appropriate minimum low transfer height prior to the effective date of the sunset, and will update this provision in a subsequent rulemaking.

M301.2.3 Size

The MDE NPRM proposed a transfer surface size for diagnostic equipment used in the supine, prone, or side-lying position of 30 inches wide and 15 inches deep minimum. (proposed M301.2.2). The Access Board received multiple comments on this provision as well as multiple recommendations from the MDE Advisory Committee. As discussed in Section IV.B.1.c (Significant Changes—Transfer Surface Size), in the final rule the Access Board has revised this provision to account for the two types of transfer surfaces (end and side), requiring end transfer surfaces to be a minimum of 28 inches wide and 17 inches long and side transfer surfaces to be a minimum of 28 inches wide and 28 inches long and has added an exception for transfer surfaces for imagining equipment with bores.

M301.2.4 Unobstructed Transfer

In the MDE NPRM the Access Board proposed that each transfer side provide unobstructed access to the transfer surface, with an exception to permit temporary obstructions as long as they could be repositioned during transfer. Examples of temporary obstructions include folding armrests, removable side rails, retractable footrests, and stirrups. NPRM, 77 FR at 6924. There were no comments received on the proposed provision and the MDE Advisory Committee did not make any recommendations. The final rule retains the requirement for unobstructed

transfer, but has reworded the requirement to specify that each transfer surface must provide two unobstructed sides for the patient to transfer.

Additionally, the Access Board sought public input on whether an additional exception to the requirement of unobstructed transfer should be added. NPRM, 77 FR at 6924. Specifically, the Access Board asked whether equipment parts should be permitted to extend a maximum of three inches horizontally beyond the edge of the transfer sides, provided they do not extend above the top of the transfer surface. The Access Board received multiple comments and recommendations from the MDE Advisory Committee on this topic. As discussed above in the Section IV.B.1.d. (Significant Changes—Unobstructed Transfer), the final rule includes a second exception to the unobstructed transfer provision which permits obstructions of no more than three inches to extend beyond the transfer side of the transfer surface, provided that such obstructions do not protrude above the top of the transfer surface.

M301.3 Supports

This is an introductory section. An editorial change was made to this section as a result of the change in M301.3.2, described below, to replace the word ''stirrups'' with the term ''leg supports.''

M301.3.1 Transfer Supports

The MDE NPRM proposed to require transfer supports to be provided for use with transfer sides on diagnostic equipment used by patients in the supine, prone, or side-lying position, and that these transfer supports comply with the technical requirements for transfer support in M305.2. There were no public comments and no recommendations by the MDE Advisory Committee on this provision. The only change in the final rule was to update the cross reference to applicable transfer surfaces to accommodate the changes made to transfer surfaces, described above in Section IV.B.1. (Significant Changes—Transfer Surface).

M301.3.2 Leg Supports

In the MDE NPRM, the Access Board proposed to place the requirements for stirrups on diagnostic equipment used by patients in the supine, prone, or side-lying position in M301. In the final rule the Access Board has decided to move the technical requirements for stirrups to M305, which includes all of the technical requirements for supports. Therefore, in the final rule, this provision instructs that when stirrups are provided on diagnostic equipment used in the supine, prone, or side-lying position leg supports must also be provided and comply with the technical requirements in M305.4. Additionally, in the final rule, the Access Board has made an editorial change in terminology, from stirrups to leg supports, in response to an MDE Advisory Committee recommendation to draw a distinction between stirrups which often only support the feet and leg supports which would support the legs when the patient's feet are in the stirrups and to provide consistency with the headings of other support provisions which are based on the body part supported.

M301.3.3 Head and Back Support

In the MDE NPRM the Access Board proposed to place the requirements for head and back support for diagnostic equipment used by patients in the supine, prone, or side-lying position in M301. In the final rule, the Access Board has decided to move the technical requirements for head and back support to M305, which includes all of the technical requirements for supports. Therefore, in the final rule, this provision instructs that where diagnostic equipment is used in a reclined position it must provide head and back support that complies with the technical requirements in M305.5.

M301.4 Lift Compatibility

The MDE NPRM proposed to require that diagnostic equipment used by patients in the supine, prone, or side-lying position be usable with a patient lift and comply with either the proposed clearance in base (proposed M301.4.1) or clearance around base (proposed M301.4.2) technical requirements. One manufacturer commented on this provision, asserting that the proposed requirement was unclear and should clearly state that the diagnostic equipment only has to be compatible with either the clearance around base or the clearance in base provisions. The Access Board considered this comment, but finds that the language is clear as written. This provision clearly states that diagnostic equipment shall comply with clearance in base or clearance around base. In the final rule the Access Board has made an editorial change to clarify the type of lift; namely portable patient lift, and a change to clarify that the clearance provisions only apply when the diagnostic equipment is being used with the portable patient lift.

Additionally, question 27 in the MDE NPRM preamble requested input on whether the final rule should provide an exception from the lift compatibility requirements where the diagnostic equipment is designed for use with overhead lifts. As discussed above in Section IV.B.3. (Significant Changes—Lift Compatibility Exception), the Access Board has decided to add this exception for diagnostic equipment that meets the following three criteria: Fixed overhead patient lifts are provided for use with the diagnostic equipment; the use with the fixed overhead patient lift with the diagnostic equipment is permitted by an enforcing authority; and the diagnostic equipment is clearly labeled as not compatible with portable patient lifts.

M301.4.1 Clearance in Base

The MDE NPRM proposed certain clearance requirements beneath the diagnostic equipment to allow sufficient space for the legs of a portable patient lift to fit underneath the equipment so that the patient could be raised out of their mobility device, moved over to the medical diagnostic equipment, and then be lowered onto the transfer surface. The proposed requirement could be met by providing an open area beneath the equipment, or by configuring the equipment with a wide slot recessed into the base enclosure. NPRM, 77 FR at 6927. The MDE NPRM proposed a clearance in the base of 44 inches wide minimum, 6 inches high minimum measured from the floor, and 36 inches deep minimum measured from the edge of the examination surface. Where the width of the equipment is less than 36 inches wide, the proposed rule required the clearance to extend the full width of the equipment. *Id.* Additionally, the Access Board proposed to permit equipment components to be located within 8 inches maximum of the centerline of the clearance width. *Id.* The Access Board sought input in question 25 in the MDE NPRM preamble, on whether the proposed dimensions for the clearance in base requirement is sufficient to allow for the use of portable floor lifts. *Id.*

Six commenters responded to the question. One commenter, a manufacturer, concurred with the proposed provision. Another commenter, a medical association, explained that portable lifts are a problem in older outpatient facilities due to limited space. Another commenter, a manufacturer, raised concerns about requiring floor based patient lifts with MRI systems, explaining the concern about the significant structural support required in the patient bed which makes the under bed clearance impractical and the concern about requiring non-ferrous materials in the MRI room. This commenter explained a preference for

fixed overhead lifts. Three commenters (two manufacturers and one medical association) raised concerns with the six-inch vertical clearance measured from the floor requirement. One manufacturer explained that the proposed six-inch vertical clearance requirement would encompass 100 percent of all portable patient lifts on the market, and that several portable patient lifts only require 2.5 inches clearance, such as those designed to be used with stretchers. This commenter asserted that the proposed six-inch vertical clearance would require redesign of every medical bed and stretcher on the market, and recommended reducing the required clearance. One commenter (medical association) noted that it would be difficult to meet the six-inch clearance from the floor when the table is lowered to 17 inches to allow for transfer. The final commenter explained that a standard that only required either compliance with clearance in the base or clearance around the base, was attainable, but warned that if both were required it would impose significant redesign costs and would increase product costs. This commenter further posited that it would be more cost effective to redesign the lift than the diagnostic equipment. These three commenters also raised concerns that this provision was in conflict with the prevailing standard used by manufacturers for medical beds and stretchers, IEC 60601–2–52, which contains requirements for lift clearance under the equipment.

The MDE Advisory Committee recommended reducing the equipment base clearance for stretchers from 44 inches wide minimum to 39 inches wide minimum. The Committee noted that this was to harmonize the MDE Standards with IEC 60601–2–52, which provides requirements for stretchers and includes lift clearance at the 39-inch width. MDE Advisory Committee Report, 106–107, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.*

The Access Board has reviewed the comments and the recommendations from the MDE Advisory Committee and is persuaded by the arguments in favor of harmonizing the lift clearance requirements with the IEC 60601–2–52. Accordingly, the Access Board has adopted the recommendation from the MDE Advisory Committee, but has decided to apply the reduction in lift clearance width to all medical diagnostic equipment that complies with the clearance in base provision because a lift that deploys effectively under a stretcher should also function properly under other less constrained diagnostic equipment. Secondly, the Access Board has decided to retain the six-inch height clearance requirement but agrees with the commenters that the diagnostic equipment should not have to meet the six-inch height clearance requirement when in position for independent transfer. Therefore, the final rule clarifies that the lift compatibility requirements only apply when the diagnostic equipment is being used with the portable lift, as a lift will only be used when independent transfer is not possible.

M301.4.2 Clearance Around Base

The MDE NPRM proposed certain requirements to provide clearance around the base of the diagnostic equipment to allow the legs of the portable floor lift to straddle the base of the diagnostic equipment with a solid base that sits on or close to the floor. The proposed rule required a minimum clearance of 6 inches high measured from the floor and 36 inches deep measured from the edge of the examination surface. NPRM, 77 FR at 6927. The width of the base permitted within this clearance would be 26 inches maximum at the edge of the examination surface and was permitted to increase at a rate of 1 inch in width for every 3 inches in depth. *Id.* In addition, where the width of the examination surface is less than 26 inches, the clearance depth would be the full width of the examination surface. *Id.* The Access Board sought public input in question 26 in the MDE NPRM, on whether the proposed dimensions for clearance around the base of the equipment was sufficient to allow for the use of portable floor lifts. *Id.*

Two commenters, both manufacturers, responded to this question. One commenter recommended clarifying that the exam table must be compatible with a patient lift and meet the six-inch clearance, but not when the table is at its lowest level for independent transfer. This manufacturer indicated that its adjustable table does not have a six-inch minimum clearance when at its lowest position, but does meet the standard when the table is raised. The other commenter asserted that the proposed dimensions are not sufficient to accommodate the various portable floor lifts and recommended that the Access Board instead provide technical criteria for the portable patient lift to be usable with diagnostic equipment since it is more cost effective to change the floor lift, than to change the diagnostic equipment. Additionally, this manufacturer reported that all but one of its examination and procedure tables currently meet the clearance around base provision, but opined that if the proposed increase in width of the transfer surface of examination tables and chairs to 30 inches by 15 inches is adopted then it would be required to redesign the examination tables and chairs to have a larger base which would interfere with the ability to meet this clearance around base provision. The MDE Advisory Committee did not address this provision, and thus provided no recommendations on the clearance around the base requirements.

The Access Board has reviewed the comments and has decided to retain the provision from the proposed rule. In the final rule, the Access Board has decided to decrease the size of the transfer surface (See final M301.2.3) and thus the commenter's concern regarding an increase in base size is not applicable. As described above, M301.4 does not require the 6-inch height clearance to be maintained when the equipment is lowered to the minimum low height for independent transfer as required by M301.2.1, because portable patient lifts will only be used when independent transfer is not possible. Finally, a portable patient lift is not medical diagnostic equipment and, therefore, not within the purview of the Access Board's regulatory jurisdiction. However, portable patient lifts are integral to ensuring that patients with disabilities who are unable to independently transfer are otherwise able to use the medical diagnostic equipment. Therefore, the Access Board has provided the technical criteria necessary for the portable floor lift to be usable with medical diagnostic equipment.

M302 Diagnostic Equipment Used by Patients in a Seated Position

M302 in the final rule establishes the technical criteria for diagnostic equipment used by patients in a seated position such as examination chairs.

M302.1 General

The MDE NPRM proposed that all diagnostic equipment used by patients in a seated position must comply with the technical requirements of proposed section M302. As discussed in Section IV.B.5. (Significant Changes—Exception from the Requirements of M302 for Weight Scales with Integral Seats), in response to public comment and evidence presented to the MDE Advisory Committee, in the final rule the Access Board has added an exception to this requirement for weight

scales that contain wheelchair spaces and also provide a seat integral to the equipment. This new exception exempts these weight scales from compliance with M302's requirements for the seat, as long as the wheelchair space complies with the requirements in M303.

M302.2 Transfer Surface

This is an introductory section.

M302.2.1 Adjustability

The MDE NPRM proposed a transfer surface height range for diagnostic equipment used by patients in a seated position of 17 inches minimum and 19 inches maximum. The Access Board received multiple comments on this provision and the MDE Advisory Committee provided four recommendations. As discussed in Section IV.B.1.a. (Significant Changes—Transfer Surface Adjustability) in the final rule the Access Board has renamed this provision and now requires the transfer surface to be adjustable to: (1) A low transfer position height at or between 17 inches and 19 inches; (2) a high transfer position of 25 inches; (3) at least four additional transfer positions located between the low and high transfer positions and separated by one inch minimum increments; (4) measured from the floor to the top of the uncompressed transfer surface.

M302.2.2 Sunset Provision

As discussed in Section IV.B.1.a. (Significant Changes—Transfer Surface Adjustability), this is a new provision added to the final rule in conjunction with the new requirement of a low height range in M302.2.1. It provides a sunset for the low transfer height provision of five years from the date of publication of this rule in the **Federal Register.** The Access Board intends to complete the necessary research to determine an appropriate minimum low transfer height prior to the effective date of the sunset, and will update this provision in a subsequent rulemaking.

M302.2.3 Size

The MDE NPRM proposed a transfer surface size for diagnostic equipment used by patients in the seated position of 21 inches wide and 15 inches deep (proposed M302.2.2). The Access Board also solicited comment in question 16 on whether the transfer surface size proposed for seated position diagnostic equipment was sufficient to facilitate independent transfer. NPRM, 77 FR at 6924. Two of the seven commenters who responded supported the proposed requirements. One commenter, a manufacturer, although in agreement with the 21-inch width, stated that the 15 inches deep requirement should be increased to 17 inches, a disability advocate recommended increasing the width to 23 inches, two of the commenters, accessibility consultant and disability advocate, stated that the proposed dimensions were insufficient citing concerns for persons of larger stature or who are obese and may be unable to safely transfer to a surface of that size. One commenter, a manufacturer, recommended harmonizing with the requirements for the seated position with those of the supine, prone, or side-lying position transfer surface size.

The MDE Advisory Committee considered the dimensions for rectangular seats in roll-in showers from the 2010 ADA Standards for Accessible Design and the ''ideal'' chair width recommended in Architectural Graphic Standards for auditorium seating. MDE Advisory Committee Report, 77, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* The Committee also reviewed anthropometric data from a variety of sources. *Id.* Many Committee members expressed concern about the adequacy of the transfer surface depth. *Id.* The Committee recommended increasing the minimum depth of the transfer surface from 15 inches to 17 inches, noting that existing equipment already meets or exceeds this dimension. *Id.* The Committee recommended retaining the 21-inch width requirement, noting that it was sufficient to facilitate independent transfer. *Id.*

Based on the commenters' responses and the MDE Advisory Committee recommendations, the Access Board has decided to increase the transfer surface size for equipment used by patients in a seated position to 17 inches deep and retain the 21-inch-wide requirement from the proposed rule.

M302.2.4 Transfer Sides

In the MDE NPRM, the transfer side provision for diagnostic equipment used by patients in the seated position required transfer surfaces to have the option to transfer from a mobility device onto one short side (depth) and one long side (width) of the surface, and provide unobstructed transfer to the surface. The Access Board received multiple comments and recommendations from the MDE Advisory Committee, which are discussed above in Section IV.B.1.b. (Significant Changes—Transfer Surface Location). In the final rule, the Access Board retained this provision, but made editorial changes to clarify the location of the transfer sides and to relocate the language concerning unobstructed transfer into a new section M302.2.5. The transfer sides are still intended to allow a patient to choose to transfer onto either of two adjoining sides of the transfer surface. Additionally, based on comments and recommendations from the MDE Advisory Committee, the Access Board has decided to add an exception to this provision to accommodate chairs with fixed footrests which prevent transfer onto the adjoining sides. This is discussed in Section IV.B.1.b. (Significant Changes—Transfer Surface Location). As explained above, in order to provide patients with the ability to choose what side of their body they use to transfer, chairs with fixed footrests will provide the ability to transfer from either opposing side of the transfer surface. This allows the patient to choose to transfer from their right or left side and prevents the patient from having to transfer onto a fixed footrest.

M302.2.5 Unobstructed Transfer

In the MDE NPRM the Access Board proposed that each transfer side provide unobstructed access to the transfer surface, with an exception to permit temporary obstructions as long as they could be repositioned during transfer. This requirement is identical to the unobstructed transfer requirement in M301.2.4, and this provision is discussed in the Section V.C.2.d. (Section-by-Section Analysis—M301.2.4). The final rule retains the requirement for unobstructed transfer, but has been reworded to specify that each transfer surface must provide two unobstructed sides for the patient to transfer.

Additionally, as discussed above in the Section IV.B.1.d. (Significant Changes—Unobstructed Transfer), the final rule includes a second exception to the unobstructed transfer provision which permits obstructions of no more than three inches to extend beyond the transfer side of the transfer surface, provided that such obstructions do not protrude above the top of the transfer surface.

M302.3 Supports

This is an introductory section. An editorial change was made to this section as a result of the change in M302.3.2, described below, to replace the word ''stirrups'' with the term ''leg supports.''

M302.3.1 Transfer Supports

In the MDE NPRM the Access Board proposed that transfer supports must be provided for use with transfer sides on

diagnostic equipment used by patients in the seated position, and that these transfer supports must comply with the technical requirements in M305.2 of the proposed rule. There were no comments on this provision and no recommendations by the MDE Advisory Committee. Based on the restructure of the transfer surface provisions, described above in Section IV.B.1.b. (Significant Changes—Transfer Surface Location), and the additional technical criteria added to the transfer supports provisions, discussed above in Section IV.E.1 (Significant Changes—Transfer Supports), the Access Board has made editorial changes to this section. The technical requirements for transfer supports is in M305.2 of the final rule and has been reorganized to mirror the two types of transfer surfaces (end and side) in the final rule for diagnostic equipment used by the patient in the supine, prone, or side-lying position. The transfer surface required for diagnostic equipment used by patients in the seated position is similar to the new end transfer surface and therefore, diagnostic equipment used by patients in the seated position is required to comply with the transfer support provisions for end transfer supports. Additionally, the Access Board has included cross-references to the new transfer support requirements in M305.2.

M302.3.2 Leg Supports

The MDE NPRM did not propose to require stirrups to provide a method of supporting, positioning, and securing the patient's legs for diagnostic equipment used by patients in the seated position. However, in response to question 23, on whether diagnostic equipment used by patients in a seated position that provide stirrups should have to provide such support, the Board received six comments. NPRM, 77 FR at 6926. All six commenters concurred that when stirrups are provided for use with diagnostic equipment used by patients in the seated position, a method must be provided for supporting, positioning, and securing the patient's legs. The MDE Advisory Committee did not address this provision.

The Access Board concurs with the commenters, and the final rule requires that where stirrups are provided on seated diagnostic equipment, leg supports must also be provided and must comply with the technical requirements for leg supports in M305.4. This will ensure that patients with limited leg strength and control will be able to keep their legs in the appropriate position for examination.

M302.3.3 Head and Back Support

In the MDE NPRM the Access Board proposed to place the requirements for head and back support for diagnostic equipment used by patients in the seated position in M302. In the final rule the Access Board has decided to move the technical requirements for head and back support to M305 which includes all of the technical requirements for supports. Therefore, in the final rule, this provision instructs that where diagnostic equipment is used in a reclined position it must provide head and back support that complies with the technical requirements in M305.5.

M302.4 Lift Compatibility

The MDE NPRM proposed to require that diagnostic equipment used by patients in the seated position be usable with a patient lift and comply with either the proposed clearance in base (proposed M302.4.1) or clearance around base (proposed M302.4.2) technical requirements. This requirement is identical to the lift compatibility requirement for diagnostic equipment used by patients in the supine, prone, or side-lying position, and is discussed in the Section-by Section Analysis for M301.4. In the final rule the Access Board has made an editorial change to clarify the type of lift; namely portable patient lift, reduced the lift clearance to 39 inches and clarified that the clearance provisions only apply when the diagnostic equipment is being used with the portable patient lift. *See* Section V.C.4. (Section-by-Section Analysis—M301.4.) Additionally, as discussed above in Section IV.B.3. (Significant Changes—Lift Compatibility Exception), the Access Board has added an exception for diagnostic equipment that meets the following three criteria: Fixed overhead patient lifts are provided for use with the diagnostic equipment; the use with the fixed overhead patient lift with the diagnostic equipment is permitted by an enforcing authority; and the diagnostic equipment is clearly labeled as not compatible with portable patient lifts.

M303 Diagnostic Equipment Used by Patients in a Wheelchair

M303 in the final rule establishes the technical requirements for diagnostic equipment used by patients seated in a wheelchair, such as weight scales with wheelchair spaces and mammography equipment.

M303.1 General

This is an introductory section.

M303.2 Wheelchair spaces

This is an introductory section.

M303.2.1 Orientation

The MDE NPRM proposed to require wheelchair spaces to be designed so that a patient in a wheelchair using diagnostic equipment would be oriented in the same direction that other non-wheelchair using patients using the equipment are typically oriented. NPRM, 77 FR at 6927. The Access Board received one comment about this requirement. The commenter, an accessibility consultant, recommended that patient positioning be addressed along with orientation of the wheelchair, noting that there are many cases where it is insufficient to simply position the user facing the same direction as a non-wheelchair user. The commenter asserted that body positioning is key for obtaining accurate results when using diagnostic devices, such as x-ray equipment, and recommends amending the rule text to require wheelchair spaces to be designed so that the patient orients and positions their body in the same position as someone who is not in a wheelchair. There was no recommendation from the MDE Advisory Committee on this requirement. The Access Board has retained the original requirement in the final rule. The Board did not include requirements for patient body positioning because the diagnostic equipment cannot override the position in which an individual is seated in his or her wheelchair. Wheelchairs often are contoured to fit the specific and unique needs of the user and to provide support where it is needed. However, the design of a wheelchair space often influences whether a wheelchair user can orient with respect to diagnostic components. For example, without knee and toe space beneath an optometrist diopter, the patient cannot look into the lens.

M303.2.2 Width

The MDE NPRM proposed to require that diagnostic equipment used by patients seated in a wheelchair provide a wheelchair space that was at least 36 inches wide. There were no public comments and no MDE Advisory Committee recommendations regarding this requirement. Thus, the final rule retains the 36-inch wheelchair space width requirement. However, the Board added a new exception for wheelchair spaces on raised platforms, as discussed in Section IV.C.1. (Significant Changes—Width and Depth of Wheelchair Spaces), and discussed briefly below.

In the preamble to the MDE NPRM, the Access Board sought input on whether an exception to the width requirement was needed for wheelchair spaces on raised platforms. Multiple commenters responded to this provision and the MDE Advisory Committee recommended reducing the width requirement for wheelchair spaces on raised platforms. The Access Board has added an exception in the final rule that permits wheelchair spaces on raised platforms to be 32 inches wide minimum with edge protection no higher than 4 inches, measured from the platform surface.

M303.2.3 Depth

The MDE NPRM proposed two wheelchair space depth requirements based on how the wheelchair user enters the space: For spaces entered from the front or rear, 48 inches deep minimum; and for spaces that can only be entered from the side, 60 inches deep minimum. In the preamble in the MDE NPRM, the Access Board noted it was considering increasing the minimum depth for wheelchair spaces entered from the front or rear to 58 inches and sought input in question 29 on whether the Access Board should increase this minimum depth requirement. NPRM, 77 FR at 6928.

The Access Board received eight comments in response to this question. Three commenters (two disability rights organizations and a state agency concerned with accessibility) recommended increasing the depth of front or rear entered spaces to 58 inches. The other five commenters (manufacturers, medical associations and accessibility consultants) recommended retaining the proposed requirement in the MDE NPRM of 48 inches minimum, raising concerns that the size of the rooms in which the diagnostic equipment are located are insufficient to provide additional space. The MDE Advisory Committee did not make recommendations regarding the general requirement for depth for wheelchair spaces, but did make recommendations regarding the depth of wheelchair spaces on raised platforms, which is discussed in above in Section IV.C.1. (Significant Changes—Width and Depth of Wheelchair Spaces).

First, the Access Board clarifies that this provision is not a clear space requirement for wheelchair approach, but is instead the wheelchair space integral to diagnostic equipment for a patient seated in a wheelchair, such as mammography equipment or wheelchair accessible scales. Second, based on the comments received and the absence of recommendations from the MDE Advisory Committee to change the proposed requirement, the Access Board has retained the MDE NPRM's requirements for a minimum depth of 48 inches for wheelchair spaces entered from the front or rear, and a minimum depth of 60 inches for wheelchair spaces entered from the side. However, the Access Board has reorganized this provision into three separate requirements based on how the wheelchair space is entered, made an editorial change to clarify that front or rear entry is where the wheelchair space entry and exit is provided at only one end, and as discussed in Section IV.C.1. (Significant Changes—Width and Depth of Wheelchair Spaces), added an additional requirement to the depth provision for wheelchair spaces entered from the front or rear to permit a minimum of 40 inches if the wheelchair space provides pass-through from one end to the other.

M303.2.4 Equipment Clearances

The MDE NPRM proposed knee and toe clearance for diagnostic equipment used by patients seated in wheelchairs to allow for components in the wheelchair space which the patient could approach successfully to use for its intended diagnostic purpose. The proposed requirements for equipment clearances paralleled the knee and toe clearance requirements from the 2004 ADA and ABA Accessibility Guidelines. The proposed rule provided one additional requirement for breast platforms on mammography equipment, proposing the knee and toe clearance under a breast platform to be 25 inches deep (proposed M303.2.4). The MDE NPRM preamble sought input with question 34 on whether the dimensions recommended by the Wheeled Mobility Anthropometry Project should be adopted.[10] Three commenters responded. A manufacturer asserted that adopting a different requirement than what is already required under existing accessibility guidelines and standards would cause confusion and increase costs. A medical association asserted that to the best of their knowledge, imaging equipment already meets the Wheeled Mobility Anthropometry Project recommendations. The final commenter, a state agency concerned with accessibility, recommended adopting the new Wheeled Mobility Anthropometry Project recommendations. The MDE Advisory Committee only provided recommendations pertaining to the knee and toe clearance for mammography equipment.

The Access Board has determined that mammography equipment presents a unique challenge. Mammography equipment contains breast platforms which patients seated in wheelchairs must approach, and successfully maneuver their lower body under the platform enough to allow their chest to be flush with the leading edge of the platform. A separate set of equipment clearance requirements is necessary to address the unique positioning at mammography equipment. Therefore, in the final rule the Access Board has separated out the knee and toe clearance requirements into two provisions; breast platforms and other equipment. Breast platform requirements address the knee and toe clearance requirements for mammography equipment which is usable by patients seated in a wheelchair and is discussed in Section IV.C.2. (Significant Changes—Equipment Clearances for Breast Platforms). All other diagnostic equipment used by patients seated in a wheelchair must comply with the other equipment clearances requirements.

For all other equipment, the Access Board has decided to retain the original requirements in the proposed rule for knee and toe clearance. The Access Board is not persuaded to adopt the Wheeled Mobility Anthropometry Project recommendations for knee and toe clearances at this time. These recommendations represent a significant departure from the 2004 ADA and ABA Accessibility Guidelines. Therefore, the Board has elected in the final rule to retain the proposed provisions in the NPRM for knee and toe clearance for other equipment (M303.2.4.2). Due to the reorganization of the equipment clearances provision in the final rule, the knee and toe clearance requirements for the other equipment section have been renamed depth and height and relocated to M303.2.4.2. In addition, the Access Board has made an editorial change to the toe height requirement to clarify that the measurement is taken from the toe end of the wheelchair space.

M303.2.5 Surfaces

The MDE NPRM proposed to require diagnostic equipment used by patients seated in a wheelchair to provide a wheelchair space with a surface that does not slope more than 1:48 in any direction. This provision is consistent with the 2004 ADA and ABA Accessibility Guidelines. There were no comments on this section and it was not addressed by the MDE Advisory

[10] The Wheeled Mobility Anthropometry Project recommended a toe clearance that is 5 inches deep maximum at 14 inches above the floor and a knee clearance that is 12 inches deep minimum at 28 inches above the floor.

Committee. There have been no changes made to this provision.

M303.2.6 Edge Protection

The MDE NPRM proposed edge protection on the ramps leading up to the raised platform (proposed M303.3.3.4), but did not require edge protection on the raised platforms themselves. The Access Board received two comments and two recommendations from the MDE Advisory Committee regarding edge protection on raised platforms. As discussed in Section IV.C.5. (Significant Changes—Edge Protection), the final rule requires platforms with wheelchair spaces that are raised more than 1½ inches in height to provide a minimum 2-inch-high edge protection, measured from the surface of the platform, on each side of the platform not providing entry to or exit from the diagnostic equipment.

M303.3 Entry

This is an introductory section.

M303.3.1 Vertical

The MDE NPRM proposed that for equipment with a change in level at the entry to the wheelchair space, level changes of up to ¼ inch high are permitted to be vertical. This provision is consistent with the 2004 ADA and ABA Accessibility Guidelines. There were no comments on this section and it was not addressed by the MDE Advisory Committee. There have been no changes made to this provision.

M303.3.2 Beveled

The MDE NPRM proposed that for equipment with a change in level at the entry to the wheelchair space, level changes greater than ¼ inch but not greater than ½ inch would be required to be beveled with a slope not steeper than 1:2. This provision is consistent with the 2004 ADA and ABA Accessibility Guidelines. There were no comments on this section and it was not addressed by the MDE Advisory Committee. There have been no changes made to this provision.

M303.3.3 Ramped

The MDE NPRM proposed that for equipment with a change in level at the entry of a wheelchair space, level changes greater than ½ inch high would be required to be ramped and comply with technical requirements for running slope, cross slope, clear width, edge protection, and handrails. The Access Board received one comment on this provision. The commenter, a medical association, concurred with the requirement for handrails on diagnostic equipment with ramps over six inches in height. The MDE Advisory Committee only reviewed and gave recommendations on the portion of the provision addressing running slope. Therefore, the Access Board has retained the proposed requirements for cross slope, clear width, edge protection, and handrails in the final rule.

Regarding running slope, the MDE NPRM proposed that ramp runs have a running slope not steeper than 1:12. There were no comments on this section; however, as discussed in Section IV.C.3. (Significant Changes—Exception to Ramp Running Slope), the MDE Advisory Committee made a three-tiered recommendation for the allowable running slope. After careful consideration of the Advisory Committee's recommendations, the Access Board has retained in the final rule the original requirement for running slope, but has added an exception that permits a running slope not steeper than 1:8 for ramp runs with a maximum height of 2½ inches. See Section IV.C.3. (Significant Changes—Exception to Ramp Running Slope) for a full discussion of the rationale for this exception.

M303.4 Components

The MDE NPRM proposed to require diagnostic equipment used by patients seated in a wheelchair which has components that are used to examine specific body parts, be capable of examining those body parts of the patient while the patient is seated in a wheelchair. For example, an x-ray platform on which a patient places an arm or hand would have to be capable of examining the arm or hand of the patient while seated in a wheelchair. NPRM, 77 FR at 6930. There were no comments on this requirement and it was not addressed by the MDE Advisory Committee. There have been no changes made to this requirement.

M303.4.1 Breast Platform Adjustability

The MDE NPRM proposed a mammography breast platform height range of 30 inches high minimum and 42 inches high maximum above the floor. The Access Board received three comments on this provision, and the MDE Advisory Committee made several recommendations for changes. As discussed above in the Section IV.C.4. (Significant Changes—Breast Platform Adjustability), the Access Board has revised this provision to require the breast platform to be continually adjustable from a low height of 26 inches to a high height of 42 inches above the floor and made an editorial change to the provision title changing it from height to adjustability.

M304 Diagnostic Equipment Used by Patients in Standing Position

M304 in the final rule establishes the technical criteria for diagnostic equipment used by patients in a standing position such as a weight scale or x-ray equipment that is used in a standing position for certain diagnostic procedures.

M304.1 General

This is an introductory section.

M304.2 Standing Surface

The MDE NPRM proposed to require that the standing surface on which patients stand be slip resistant. In preparing the final rule, the Board has determined that as previously drafted this provision unintentionally placed requirements on the facility floor, as opposed to restricting the requirements to the diagnostic equipment itself. While the Access Board may choose to promulgate requirements for the building under its other rulemaking authority at a later date, this type of requirement is outside the scope of the MDE Standards and therefore M304 in the final rule has been restructured. The requirement for slip resistant and standing supports has been moved under this new requirement applying to standing surfaces. This reorganization ensures that only diagnostic equipment used by patients in a standing position that provides a surface for the patient to stand on must be slip resistant (M304.2.1) and provide standing supports (M304.2.2) in the final rule. Both of these requirements are discussed below.

M304.2.1 Slip Resistant

The MDE NPRM proposed to require that the standing surface on which patients stand be slip resistant. One manufacturer commented on this requirement, requesting that the rule provide clarification on how to define or measure a standing surface as ''slip resistant.'' This provision was not addressed by the MDE Advisory Committee. The Access Board has decided to retain the original requirement in the final rule as it is the Board's understanding that various industries employ different testing methods, there is no universally adopted or specified test for slip resistance, and the assessed level varies according to the measuring method used. Other than the change to clarify that the provision applies only to standing surfaces that are part of the

diagnostic equipment, there have been no changes to this provision.

M304.2.2 Standing Supports

The MDE NPRM proposed requiring standing supports on each side of the standing surface of diagnostic equipment used by patients in the standing position, and compliance with the technical requirements for standing supports in proposed M305.3. The Access Board received multiple comments and two recommendations from the MDE Advisory Committee. As discussed above in the Section IV.D.1. (Significant Changes—Standing Supports) and IV.E.2. (Significant Changes—Standing Supports), the final rule retains the general requirement that standing supports be provided on two sides of the standing surface. In addition, the Access Board has added a new exception for diagnostic equipment with entry and exit that permits pass-through from one end to another to provide one standing support provided it complies with the requirements for standing supports in the horizontal position in M305.3 in the final rule.

M305 Supports

M305 in the final rule provides the technical requirements for transfer supports, standing supports, leg supports, and head and back supports. Transfer supports are required for diagnostic equipment complying with M301 and M302 and standing supports are required for diagnostic equipment complying with M304. Leg supports and head and back supports apply, where provided, to diagnostic equipment complying with M301 and M302.

M305.1 General

This is an introductory section.

M305.2 Transfer Supports

This is an introductory section. As discussed above in Section IV.E.1. (Significant Changes—Transfer Supports), the Access Board strengthened the transfer support requirements and added additional requirements in the final rule to ensure that supports are capable of assisting with independent transfer onto and off of the diagnostic equipment. With the changes to the final rule, the Board sought to harmonize as much as possible, these requirements with the 2004 ADA and ABA Accessibility Guidelines for grab bars.

M305.2.1 Location

The MDE NPRM proposed that transfer supports be located within reach of the transfer surface and not obstruct transfer onto or off of the surface when in position (proposed M305.2.1). In the preamble to the MDE NPRM, the Access Board noted it was considering requiring transfer supports to be located no further than 1½ inches from the transfer surface, when measured horizontally, and requiring the transfer support to be located on the side of the transfer surface opposite the transfer side. NPRM, 77 FR at 6925. The Access Board sought public comment with question 19, which asked for input on multiple proposed changes to the transfer support provision, including whether the proposed location of the transfer support, and the requirement that it be located 1½ inches from the transfer surface, would be sufficient to facilitate transfers. *Id.*

Eight commenters responded to question 19, but only six of the commenters addressed the location of transfer supports. Two commenters, a manufacturer and a state agency concerned with accessibility, concurred with the technical requirements proposed in question 19 for the transfer support location. Another commenter, a disability rights organization, stated that transfer supports should be required on both sides of the equipment. A manufacturer noted that if the proposed transfer surface size of 30 inches wide is adopted, then a transfer support opposite the transfer side would be useless as the patient would be unable to reach the support until nearly fully on the diagnostic equipment. This commenter noted that an adjacent transfer support would be more effective, but would conflict with the provider expectations of bed and stretcher side rails. The final two commenters, a manufacturer and a medical association, raised concerns about requiring any transfer supports on imaging equipment, specifically MRI and CT machines, asserting that the supports may interfere with the image quality.

The MDE Advisory Committee made three separate recommendations for the location of transfer supports: A general requirement, a requirement for stretchers, and a requirement for imaging equipment. For the general provision, the MDE Advisory Committee recommended requiring transfer supports on both sides of the transfer surface that can be removed or repositioned during transfer and are located at a maximum distance of 1½ inches from the transfer surface. The Committee explained that ''transfer supports or handholds on adjustable medical equipment facilitate transfers onto a transfer surface by giving the individual something to hold or grab onto while transferring. This recommendation for placement of supports on both sides of the equipment will increase the options during patient transfers.'' MDE Advisory Committee Report, 86, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.*

For stretchers, the MDE Advisory Committee noted that patients enter from either of the long sides, rather than on one long side and one short side, and this change in orientation necessitated a different location for the transfer supports so that the support would be reachable during transfer. The MDE Advisory Committee recommended locating the transfer support ''along the long side of the transfer surface on the opposite side of the transfer.'' MDE Advisory Committee Report, 87–88, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* Additionally, the Committee recommended a horizontal distance from the transfer surface of no more than 3 inches from the edge of the patient support surface, indicating that stretcher transfer supports are part of a rail system that needs to fold and store out of the way and therefore require more space to articulate. *Id.* at 96.

For imaging equipment, the MDE Advisory Committee recommended requiring transfer supports when the transfer surface was 24 inches deep or less, and requiring positioning supports for transfer surface depths of greater than 24 inches. *Id.* at 88–89. The Committee recommended requiring one support on the opposite side of the transfer side regardless of whether it was a transfer support or positioning support. The Committee noted that:

> Because of the size, diversity, and use of diagnostic imaging tables, this support will carry out different functions on different tables . . . This two-part recommendation recognizes the different use of the supports based on the table width. The Committee used a 24-inch dividing point for table width to accommodate the dimensions for the maximum reach range. For transfer surface depths on tables less than 24 inches wide, a transfer support must be available on the side opposite the entry of the transfer surface . . . For transfer surface depths on tables greater than 24 inches wide, a positioning support must be available on the side opposite the entry to the transfer surface. *Id.*

After review of the public comments and the MDE Advisory Committee recommendations, the Access Board has determined that there is a need for two types of transfer supports, based on the orientation of the transfer surface. As

described in Section IV.B.1.b.(Significant Changes—Transfer Surface Location), the Access Board has designated two types of transfer surfaces based on orientation for diagnostic equipment used by patients in the supine, prone, or side-lying position: End and side transfer surfaces, either of which can be employed depending on the configuration and use of the particular equipment. Here, a similar dual approach is warranted for transfer supports. While the MDE Advisory Committee recommended separate requirements based on the type of diagnostic equipment, stretchers and imaging equipment, the Access Board believes that the type of support should be based on where the transfer surface is located on the examination surface. Therefore, the Access Board has separated the location provision into end transfer supports and side transfer supports. End transfer supports cover diagnostic equipment used by patients in the supine, prone, or side-lying position with end transfer surfaces, M301.2.3.1 in the final rule, and all diagnostic equipment with transfer surfaces used by patients in the seated position, M302.2 in the final rule. Side transfer supports cover diagnostic equipment used by patients in the supine, prone, or side-lying position with side transfer surfaces, this includes stretchers and most imaging equipment, M301.2.3.2.

In the final rule the Access Board has decided for end transfer supports to require at least one support located on the long side of the transfer surface, opposite the transfer side. For side transfer supports, the Access Board has decided to require a transfer support which is capable of supporting transfer on each side of the transfer surface. A side transfer surface could contain one transfer support which is capable of being repositioned from one side to the other side depending on which side the patient chooses to transfer or it is acceptable to have two transfer supports, one on each long side, which are both capable of being removed or repositioned on the side the patient chooses to transfer. Additionally, the final rule requires both end and side transfer supports to be located a maximum of 1½ inches measured horizontally from the nearest edge of the transfer surface to the transfer support. In reviewing the MDE Advisory Committee's recommendations, the Access Board agrees that transfer supports that fold, collapse, or articulate need more space, but disagrees with the MDE Advisory Committee that an allowance for more space should apply only to stretchers and imaging equipment. The Access Board finds that other types of diagnostic equipment, such as hospital beds, also have transfer supports that collapse on either side to allow transfer. Therefore, the Access Board has provided an exception to the general provision which permits supports that fold, collapse, or articulate to be located three inches maximum from the nearest edge of the transfer surface to the transfer support. Additionally, as discussed in Section IV.E.1.b (Significant Changes—Positioning Supports), the Access Board has decided not to include positioning supports in the final rule.

M305.2.2 Length

In the MDE NPRM there was no requirement for length of the transfer support; however, the MDE NPRM preamble noted that the Access Board was considering requiring the transfer supports to extend the entire depth of the transfer surface and be a minimum of 15 inches in length. NPRM, 77 FR at 6925. The Access Board specifically sought public input with question 19, asking if the proposed length of the transfer supports would be sufficient to facilitate transfer and maintain position on the diagnostic equipment. *Id.*

Three commenters responded to this issue, two manufacturers and a state agency concerned with accessibility. The state agency concurred with the 15-inch requirement. One commenter did not support a 15-inch length transfer support. This commenter (a manufacturer) stated that a transfer support that is a minimum of 15 inches in length would make it even more difficult to comply with load bearing requirements and recommended that this length requirement be reduced. The second commenter, a manufacturer, recommended revising the proposed provision from requiring the transfer support to extend horizontally the entire depth of the transfer surface, to extend horizontally along the transfer surface to within three inches, to allow for manufacturing tolerances.

The MDE Advisory Committee made three transfer support length recommendations, one for each type of transfer support recommended by the Committee, described above. For the general provision, the MDE Advisory Committee recommended a transfer support with a length of 15 inches minimum, that overlaps the minimum depth of the transfer surface by 80 percent. The Committee explained that the transfer support length provides the gripping surface for the patient to grasp or maintain balance while transferring. MDE Advisory Committee Report, 90, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* For stretchers, the MDE Advisory Committee also recommended 15 inches in length stating that this would provide continuous support for patients and still accommodate the articulation that is necessary for the head and back support on stretchers. *Id.* For imaging equipment with transfer surfaces less than or equal to 24 inches deep, the Committee recommended requiring a transfer support to extend horizontally along the side of the patient table at the designated transfer location for at least the minimum width of the transfer surface, with a minimum length of 28 inches. For transfer surfaces greater than 24 inches deep, the MDE Advisory Committee recommended requiring a positioning support instead of a transfer support, which extends horizontally along the side of the patient table 12 to 16 inches and is located at a position to accommodate clinical use. *Id.* at 91–92.

The Access Board agrees with the MDE Advisory Committee that the addition of a requirement for a transfer support length provision is necessary and has adopted many of the MDE Advisory Committee's recommendations for transfer support length in the final rule. The Board restructured the Committee's recommendations to fit within the end and side transfer supports discussed above. For end transfer supports the Access Board has adopted the general provision recommended by the MDE Advisory Committee and determined that the required length will be 15 inches minimum. Additionally, the Access Board acknowledges that manufacturers need some flexibility with respect to the location of the support to account for clearances with other equipment components that may articulate or move. Therefore, the final rule requires that the 15-inch minimum length transfer support be positioned along 13½ inches minimum of the depth of the transfer surface.

For side transfer supports the Access Board adopted the MDE Advisory Committee recommendation for imaging equipment, that this support be a minimum of 28 inches long positioned along the width of the transfer surface. In addition, the Board has added two exceptions to the requirements for side transfer supports to address the concerns raised by the MDE Advisory Committee. The first exception addresses articulating patient surfaces, primarily stretchers, where a continuous 28-inch transfer support may conflict with other supports or railings as the

equipment is adjusted. In such cases, the support may be reduced to no less than 15 inches in length. The second exception applies to transfer supports on imaging bed surfaces of more than 24 inches in width, such as large x-ray tables, where the support is likely to be used in the latter stages of a transfer from a prone or side-lying position. In these cases, the Access Board finds that permitting the transfer support to be no less than 12 inches long is appropriate. While the exception is based on an Advisory Committee recommendation using the term ''positioning support,'' this is still transfer support, that can assist with transfer onto the transfer surface and will likely be used to reposition in the later stages of a transfer.

In question 19 part (e) the Access Board sought input on whether angled or vertical transfer supports should be permitted. 77 FR at 6925. Three commenters, a manufacturer, an accessibility consultant, and a disability rights organization, responded and all concurred with the proposal. The MDE Advisory Committee did not specifically address this proposal, however, in its recommendations for the length of transfer supports on imaging equipment, it did recommend that the transfer support should extend horizontally along the side of the patient table. MDE Advisory Committee Report, 90–91, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* The Access Board considered the public comments and the MDE Advisory Committee's recommendation, and has decided not to require that transfer supports be horizontal, allowing manufacturers flexibility to contour supports appropriate for the diagnostic purpose of the equipment.

M305.2.3 Height

In the MDE NPRM there was no specific requirement regarding the height of the transfer support, only that it be ''within reach'' of the patient (proposed M305.2.1). The Access Board sought input from the public in question 20 of the MDE NPRM preamble, on whether a transfer support height requirement of 6 inches minimum and 19 inches maximum above the transfer surface would be usable by patients with disabilities. NPRM, 77 FR at 6925. Six commenters responded to question 20. Four commenters (two manufacturers, one disability rights organization, and a state agency concerned with accessibility) supported the proposed height range. Three commenters (a manufacturer, a medical association, and a disability rights organization) did not support the proposal. The manufacturer opposing the proposed range raised concerns with its ability to attain a 19-inch height on its diagnostic equipment. The medical association asserted that radiography exam tables are not equipped with transfer bars, and if required should retract fully into the surface of the table and the disability rights organization expressed concern that 19 inches was too high to facilitate safe transfer.

The MDE Advisory Committee supported adding a requirement setting the height of transfer supports within the range described in question 20 in the MDE NPRM preamble, of 6 inches minimum and 19 inches maximum. The MDE Advisory Committee explained that the manufacturers on the Committee determined that this recommendation did not conflict with the IEC 60601–2–52, which provides requirements for side rails to prevent entrapment hazards, and would allow the equipment to be designed to provide accessibility and safety from entrapment hazards. MDE Advisory Committee Report, 94, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* Additionally, for transfer surfaces that are greater than 24 inches deep, the MDE Advisory Committee recommended requiring a positioning support instead of a transfer support, with a height of three to six inches above the transfer surface. *Id.*

The Access Board considered the public comments and the MDE Advisory Committee's recommendations, and has decided to include a new provision, M305.2.3 in the final rule, that requires the tops of transfer support gripping surfaces to be located 6 inches minimum and 19 inches maximum higher than the top of the associated uncompressed transfer surface during use. This range allows the manufacturer to choose a height between 6 inches and 19 inches to place their transfer supports; it does not require that the transfer supports be 19 inches high. The transfer support is permitted to be horizontal, angled, curved, or a combination of these as long as the top of any point along the gripping surface is located at or between 6 inches and 19 inches. Thus, the commenter's concern about reaching the 19-inch height is not warranted. Secondly, as discussed above in Section IV.E.1.b (Significant Changes —Positioning Supports), the Access Board has declined to include the MDE Advisory Committee's recommended positioning supports in the final rule; however, the Access Board does concur with the MDE Advisory Committee that for imaging equipment with transfer surfaces that exceed 24 inches in width, a lower transfer support is warranted. Therefore, in the final rule, the Access Board has provided an exception that permits transfer supports to be located three inches minimum and six inches maximum higher than the tops of the transfer surfaces for imagining beds that are greater than 24 inches wide.

M305.2.4 Cross Section

The proposed rule did not provide specific requirements for the cross section of transfer supports. However, in the MDE NPRM preamble, the Access Board noted that it was considering adopting the cross sectional dimensions for grab bars from the 2004 ADA and ABA Accessibility Guidelines for transfer supports. NPRM, 77 FR at 6925–6926. Specifically, the Access Board indicated it was considering requiring circular cross sections to have an outside diameter of 1¼ inches minimum and 2 inches maximum, and transfer supports with non-circular cross sections to have a cross section dimension of 2 inches maximum, and a perimeter dimension of 4 inches minimum and 4.8 inches maximum. *Id.* The Access Board sought input in MDE NPRM preamble question 21, on whether the gripping surfaces of current transfer supports on different types of equipment meet the cross sectional dimensions specified above and whether handholds that meet the above cross section dimensions could be integrated into armrests that are also cushioned to support arms and elbows. *Id.*

Five commenters responded to question 21. Two commenters (one manufacturer and one accessibility consultant) were opposed to permitting non-rounded cross sections, noting concern that harsh edges or angles may not allow users to comfortably and adequately grasp the support. One commenter (a manufacturer) asserted that because currently there are no standards, existing products would likely not meet the proposed provision. Another commenter (a manufacturer) was concerned that the requirement could preclude the use of cushioned arm pads.

The MDE Advisory Committee expressed confidence ''in reliance on the cross section dimensions in the 2010 Standards.'' MDE Advisory Committee Report, 99, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* The Committee further opined:

Allowing both noncircular cross sections and circular cross sections gives manufacturers flexibility to employ the best configuration for use of the equipment, hand, grip strength, and power grab functions. While a majority of the Committee members supported a recommendation allowing both noncircular and circular cross sections, some members noted ergonomic considerations support the better functionality of circular cross section gripping surface. *Id.*

After review of the comments and the MDE Advisory Committee's recommendations, the Access Board has decided to apply the 2004 ADA and ABA Accessibility Guidelines for grab bar cross sections to transfer supports in the final rule. Accordingly, the final rule includes a new provision, M305.2.4, requiring transfer supports to have one of two cross sections: circular cross sections, with an outside diameter of 1¼ inches minimum and 2 inches maximum; or non-circular cross sections, a cross section dimension of 2 inches maximum and a perimeter dimension of 4 inches minimum and 4.8 inches maximum.

M305.2.5 Surface Hazards

The proposed rule did not provide any specific restrictions regarding surface hazards around the transfer supports. No public comments were submitted on this issue, but the MDE Advisory Committee voiced concern about surface hazards stating, ''gripping surface configurations must provide an effective and safe surface for patients to hold onto. Sharp edges or abrasive elements may injure and cause the patient to lose their grip during positioning or transfer.'' The MDE Advisory Committee recommended that a provision be added to the final rule requiring ''gripping surfaces to be free of sharp or abrasive elements and have rounded edges.'' The Committee based this recommendation on related provisions in the 2004 ADA and ABA Accessibility Guidelines for handrails and grab bars. MDE Advisory Committee Report, 101, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.*

The Access Board concurs with the MDE Advisory Committee's recommendation and views the proposed provision as beneficial and consistent with the cross section requirements of M305.2.4, above. Therefore, the Access Board has added a new provision to the final rule, M305.2.5 Surface Hazards, to ensure that transfer supports and surfaces adjacent to transfer supports are free of sharp or abrasive components and have eased edges.

M305.2.6 Gripping Surfaces

The proposed rule did not provide any specific requirements regarding gripping surfaces on transfer supports. However, in the MDE NPRM preamble the Access Board repeatedly noted that it was considering applying many of the provisions from the 2004 ABA and ADA Accessibility Guidelines for grab bars and handrails to transfer supports. NPRM, 77 FR at 6924–6926. The MDE Advisory Committee explained that:

[t]ransfer supports may contain elements to provide structural support or prevent patient entrapment. The elements, bars, pickets, spacers, panels, and similar features, connect to the transfer support and may interrupt the gripping surface. At the point of connection, these features impede the ability to grasp completely around the cross section of the gripping surface. MDE Advisory Committee Report, 102, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report. The Committee recommended requiring the bottom of the transfer support to have no obstructions affecting more than 20 percent of the transfer support's length. Id.*

The Access Board concurs with the recommendation of the MDE Advisory Committee and views the proposed provision as beneficial and consistent with the existing accessibility guidelines. Therefore, the Access Board has added this new provision to the final rule, M305.2.6, which ensures that an adequate surface area for gripping is provided to the patient.

M305.2.7 Clearance

In the MDE NPRM, the Access Board did not provide any specific requirements for clearances around the transfer support. However, in the preamble to the MDE NPRM the Access Board noted that it was considering applying the 2004 ADA and ABA Accessibility Guidelines for clearance around grab bars to the transfer support provision in the final rule. NPRM, 77 FR at 6926. Specifically, the Access Board sought input from the public in question 22, on whether transfer supports on diagnostic equipment could provide 1½ inches minimum clearance around the gripping surface. *Id.* Two commenters responded, both manufacturers, and indicated that transfer supports could provide 1½ inches minimum clearance around the transfer support. The MDE Advisory Committee concurred with the commenters and expressed support for the use of the 2010 ADA Standards and International Building Code Requirements (ICC/ANSI A117.1–2009), and recommended adding the requirements to the final rule. MDE Advisory Committee Report, 100, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.*

Based on public commenter responses and MDE Advisory Committee recommendations, the Access Board has added a new provision to the final rule, M305.2.7, requiring a 1½ inch minimum clearance between the transfer support gripping surface and adjacent surfaces or obstructions.

M305.2.8 Fittings

The MDE NPRM proposed to require that transfer supports not rotate in their fittings (proposed M305.2.3). Five commenters addressed this provision. Four of the commenters disagreed with this requirement and explained the need for transfer supports to be able to rotate in their fittings. Specifically, one commenter (manufacturer) asserted that the technical criteria from the 2004 ADA and ABA Accessibility Guidelines for grab bars in bathrooms should not be applied to exam tables as they would restrict the ability for the transfer supports to be moved out of the way after transfer. Further, this commenter noted that the requirement conflicts with proposed M302.2.3, which allows for temporary obstructions such as armrests, footrests, and side rails that can be repositioned to allow for transfer. Another commenter (manufacturer) pointed out that bed rails, which are common on hospital beds, require a latched position and an unlatched position, which allows them to rotate in their fittings when not latched. A different manufacturer stated that its seated diagnostic equipment uses armrests as transfer supports, which can be pushed back toward the rear of the equipment to allow entry. An accessibility consultant recommended swing-away or removable armrests for chairs to allow for transfer on either side. The only commenter (accessibility consultant) opposed to allowing transfer supports to rotate in their fittings, expressed concern for the potential for injury if transfer supports rotated unexpectedly during transfer.

The MDE Advisory Committee recommended amending this provision to allow transfer supports to rotate in their fittings, but to require that they not rotate when they are locked into place for transfer. The Committee noted that it is advantageous to allow supports to perform the needed movement, but they should not do so when locked. MDE Advisory Committee Report, 102–103, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.*

The Access Board concurs with the majority of the commenters and the MDE Advisory Committee. As noted in proposed M302.2.3, the Access Board intended to allow manufacturers to provide temporary obstructions such as armrests and bedrails that can be repositioned, or rotate in their fittings, and then be locked into place when needed as a transfer support. Therefore, the Access Board has revised this provision in the final rule to require that transfer supports do not rotate in their fittings when in place for transfer (M305.2.8).

M305.3 Standing Supports

M305.3 provides the technical requirements for standing supports which are required on diagnostic equipment covered by M304. This provision has been reorganized in the final rule into requirements for length and height, as opposed to vertical and horizontal.

In the MDE NPRM preamble, the Access Board noted that it was considering adopting the cross section dimensions for grab bars from the 2004 ADA and ABA Accessibility Guidelines and applying them to standing supports. The Access Board sought public input in questions 39 and 40 in the MDE NPRM preamble on whether the cross section dimensions for gripping surfaces should be applied to standing supports and whether standing supports can provide a 1½ inch minimum clearance around the gripping surface. Three commenters responded to question 39 (a medical association, accessibility consultant, and a state agency concerned with accessibility). All three concurred with adding cross section dimension requirements to standing supports. Two commenters responded to question 40 (one medical association and a state agency concerned with accessibility), and both concurred that diagnostic equipment could provide a 1½ inch minimum clearance around the gripping surface of standing supports. The MDE Advisory Committee did not address the cross section and clearance proposal for standing supports. Unlike transfer supports, standing supports can be horizontal or vertical and thus there will be variations in the configuration of standing supports dependent on the equipment configuration. Due to this wide variety of allowable standing supports and the significant difference in the nature of how a standing support is used versus a transfer support, the Access Board has decided not to adopt cross section dimensions or require a minimum clearance around the gripping surface for standing supports in the final rule.

Additionally, one commenter (manufacturer) requested that requirements for structural strength be added to the standing support provision. For the same reasons the Access Board has removed the requirement of structural strength for transfer supports (See Section IV.E.1.a. (Significant Changes—Structural Strength) the Access Board declines to adopt such a requirement for standing supports in the final rule.

M305.3.1 Length

In the MDE NPRM, the Access Board proposed a gripping surface length of four inches minimum for horizontal standing supports. No public comments were submitted on this requirement. The MDE Advisory Committee supported the proposed technical provisions, but recommended adding additional criteria for standing supports on raised platforms with wheelchair spaces. As discussed above in the Section IV.E.2. (Significant Changes—Standing Supports), the final rule requires that horizontal standing supports be positioned horizontally in relation to standing surfaces and retains the proposed requirement of four inches minimum length. The Access Board added a new provision applying to diagnostic equipment containing a wheelchair space that also requires standing supports. This provision, M305.3.1.2 in the final rule, has added two new requirements for this type of equipment. First, for diagnostic equipment containing wheelchair spaces with one entry that also serves as the exit, the length of the gripping surface for horizontal standing supports must be equal to or greater than 80 percent of the overall length of the platform. Second, for diagnostic equipment with wheelchair spaces that permit pass-through from one end to the other, the length of the gripping surface for the horizontal standing support must be at least equal to the length of the platform. In the final rule these requirements are located in M305.3.1.1 Horizontal Position and M305.3.1.2 Diagnostic Equipment Containing a Wheelchair Space.

For vertical standing supports, the MDE NPRM proposed a gripping surface length of 18 inches minimum. There were no public comments submitted on this requirement, and the MDE Advisory Committee supported the proposed technical provisions. In the final rule, the Access Board retained the original requirement for gripping surface length and clarified that the vertical standing supports must be positioned vertically in relation to the standing surface. Both requirements are included in the new M305.3.1.3 Vertical Position provision in the final rule.

M305.3.2 Height

For horizontal supports, the MDE NPRM proposed a gripping surface height of 34 inches minimum and 38 inches maximum above the standing surface. There were no public comments on this requirement, and the MDE Advisory Committee supported the proposed technical provisions. In the final rule the Access Board retains the original requirement. This requirement has been relocated to M305.3.2.1 in the final rule.

For vertical supports, the MDE NPRM proposed that the bottom end of the support be 34 inches high minimum and 37 inches high maximum above the standing surface. There were no public comments on this requirement, and the MDE Advisory Committee supported the proposed technical provisions. In the final rule the Access Board retains the original requirement, but made a few minor editorial changes to the text. This requirement has been relocated to M305.3.2.2 in the final rule.

M305.3.3 Fittings

The MDE NPRM proposed to prohibit standing supports from rotating in their fittings. There were no comments on this section and it was not addressed by the MDE Advisory Committee. The Access Board made no changes to this provision.

M305.4 Leg Supports

As discussed above in Section V.C.3.b (Section-by-Section Analysis—M301.3.2) and Section V.C.7.b (Section-by-Section Analysis—M302.3.2), the technical requirements for leg supports from M301 and M302 have been relocated to M305 Supports. The MDE NPRM proposed that where stirrups are provided, they must provide a method to support, position, and secure the patients legs. Four commenters (medical association, accessibility consultant, disability rights organization, and a state agency) agreed with requiring leg supports when stirrups are provided.

The MDE Advisory Committee agreed that, for procedures that use stirrups and require the leg to be stable, there must be a method to support the patient's legs. The Committee referenced ANSI/AAMI HE75 which recommends that ''[f]or patients with limited leg strength and control, instead of stirrups that support only the foot and require active user leg strength, leg supports that support both the foot and the leg should be used to assist patients in keeping their legs in the appropriate position.'' MDE Advisory Committee

Report, 105, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* The MDE Advisory Committee recommended adding additional language to this provision to clarify that ''where the equipment provides stirrups, it must also provide an alternate method to support, position, and secure the patients legs (specifically including sufficient support of the patient's thigh, knee, and calf to stabilize the leg). This method will either supplement or serve as a substitute for the stirrups.'' *Id.*

After reviewing the MDE Advisory Committee recommendations, the Access Board has decided that the proposed provision is sufficient to require the leg support advocated by the MDE Advisory Committee and has therefore not adopted the MDE Advisory Committee recommendation to require an alternate method of leg supports. However, in the final rule the Access Board has made an editorial change in terminology, from stirrups to leg supports, in response to the MDE Advisory Committee recommendation and to provide consistency with the headings of other support provisions that are based on the body part supported.

M305.4 Head and Back Support

As discussed above in Section V.C.3.c (Section-by-Section Analysis—M301.3.3) and Section V.C.7.c. (Section-by-Section Analysis—M302.3.3), the technical requirements for head and back supports from M301 and M302 have been relocated to M305 Supports. The MDE NPRM proposed to require diagnostic equipment used by patients in the supine, prone, or side-lying position and the seated position that can be adjusted to a reclined position to provide head and back support throughout the entire range of the incline. Three manufacturers commented on this provision. One manufacturer asserted that this requirement was ambiguous and that he had to read it multiple times to understand it; however, this commenter also indicated that the tables it currently manufactures meet the proposed requirement. Another manufacturer noted that existing MRI equipment meets this requirement. The final manufacturer asserted that a reclining backrest necessarily provides head and back support, unless the Access Board intended a different meaning for ''support.'' The MDE Advisory Committee did not review the proposed requirement for head and back support, and thus provided no recommendations on this requirement.

After review of the comments, the Access Board has decided not to make any changes to this provision in the final rule. All of the commenters on this topic agree that current diagnostic equipment meets the proposed requirement and the Access Board believes that this requirement is clearly articulated. Therefore, the final rule requires that where diagnostic equipment can be adjusted to a reclined position, head and back support must be provided.

M306 Communication

M306 in the final rule provides the technical criteria for communication from the diagnostic equipment to the patient.

M306.1 General

The MDE NPRM proposed that, where diagnostic equipment communicates instructions or other information to the patient, the instructions or information must be provided in at least two of the following methods: Audible, visible, or tactile (proposed M306.1). The Access Board sought public input in question 41 in the preamble to the MDE NPRM, on whether diagnostic equipment that communicates instructions or other information to the patient should provide information in all three methods of communication, and what the cost to provide all three methods would be. NPRM, 77 FR at 6931. Seven commenters responded. Three commenters (a manufacturer, a medical association, and a state agency concerned with accessibility) concurred with the proposed requirement to provide two methods of communication. Three commenters (two disability rights organizations and one medical association) supported requiring all three modes of communication, and the final commenter (a manufacturer) recommended requiring one mode of communication if the medical provider is present and three modes of communication for home use devices. The MDE Advisory Committee did not address this provision.

The Access Board carefully considered the public comments; however, it has decided to retain the provision from the proposed rule, requiring diagnostic equipment that communicates instructions or other information to the patient to provide the communication in two methods. The commenters were split in their support of two or three methods of communication and the commenters supporting the increase to three methods of communication provided no additional information to warrant the increase. The commenter that recommended different requirements for home-use equipment is not dispositive as this rule does not cover any home use equipment. The Access Board has concluded that providing two means of communication will serve the majority of people and that there was not enough information provided to warrant an increase in this requirement in the final rule.

M307 Operable Parts

M307 in the final rule provides the technical criteria for operable parts used by patients to activate, deactivate, or adjust the diagnostic equipment. For example, equipment used for an auditory examination may require the patient to press a button when sounds are heard. M307 does not apply to controls used only by health care personnel or others who are not patients. There were no comments received on the proposed provisions, and as discussed below, the provisions from the proposed rule have been retained in the final rule.

The Access Board did receive comments in response to question 43, which sought public input on whether the final rule should include reach range requirements such as those in the 2004 ADA and ABA Accessibility Guidelines for an unobstructed forward reach or side reach for the operable parts provision. Five commenters responded, one commenter (state agency concerned with accessibility) recommended adopting the reach ranges and four commenters (one medical association, one academic, and two disability rights organizations) recommended against adding reach ranges for operable parts to the final rule. One of these commenters (disability rights organization) explained that the 2004 ADA and ABA requirements are not appropriate for application to operable parts of medical diagnostic equipment. The MDE Advisory Committee did not address this provision. Based on the majority of the commenters response, the Access Board has decided not to add reach ranges to the operable parts section at this time.

M307.1 General

This is an introductory section.

M307.2 Tactilely Discernible

The MDE NPRM proposed that operable parts intended for patient use be tactilely discernible without activation. Patients who are blind or have low vision have difficulty

distinguishing a flat membrane button or similar control unless it is tactilely discernible from the surrounding surface and any adjacent controls. The most common method to ensure that buttons and similar controls are tactilely discernible is to raise part or all of the control surface above the surrounding surface and at a distance from any adjacent controls such that a relief of each individual control can be determined by touch. There were no public comments on this section and it was not addressed by the MDE Advisory Committee. There have been no changes made to this provision.

M307.3 Operation

The MDE NPRM proposed to require operable parts to be operable with one hand and not require tight grasping, pinching, or twisting of the wrist. There were no public comments on this section and it was not addressed by the MDE Advisory Committee. There have been no changes made to this provision.

M307.4 Operating Force

The MDE NPRM proposed to restrict the force required to activate operable parts to 5 pounds. The Access Board sought public input on this provision in question 42 on whether the operating force should be reduced to 2 pounds. NPRM, 77 FR at 6932. One commenter, a state agency concerned with accessibility, responded and concurred with the suggested reduction. The MDE Advisory Committee did not address this requirement. Although the Access Board initially considered a reduction in the force required to activate operable parts, upon further consideration, the Board found no reason to deviate from the long-established maximum of 5 pounds in the 2004 ADA and ABA Accessibility Guidelines. 36 CFR part 1191, App. D 309.4. Therefore, there have been no changes made to this provision.

VI. Regulatory Process Matters

A. Final Regulatory Assessment (E.O. 13563 and E.O. 12866)

Executive Orders 13563 and 12866 direct agencies to propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs; tailor the regulation to impose the least burden on society, consistent with obtaining the regulatory objectives; and, in choosing among alternative regulatory approaches, select those approaches that maximize net benefits. Important goals of regulatory analysis are to (1) establish whether federal regulation is necessary and justified to achieve a market failure or other social goal and (2) demonstrate that a range of reasonably feasible regulatory alternatives have been considered and that the most efficient and effective alternative has been selected. Executive Order 13563 also recognizes that some benefits are difficult to quantify and provides that, where appropriate and permitted by law, agencies may consider and discuss qualitatively those values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts.

The final rule, which sets forth the MDE Standards, is a significant regulatory action within the meaning of Executive Order 12866. *See* E.O. 12866 § 3(f)(4), 58 FR 51735 (Oct. 4, 1993) (defining ''significant regulatory action'' as, among other things, regulatory action that raises novel legal or policy issues). Accordingly, we prepared a final regulatory assessment (Final RA) to accompany the MDE Standards. The Final RA is available on the Access Board's Web site (*www.access-board.gov*), as well the federal government's online rulemaking portal (*www.regulations.gov*). Summarized below are some of the key findings of this regulatory assessment.

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. Examples of such diagnostic equipment include examination tables and chairs, weight scales, mammography equipment, and other imaging equipment. The Access Board is now issuing the final rule pursuant to this authority.

The MDE Standards set forth minimum technical criteria for medical diagnostic equipment to facilitate access and use of medical diagnostic equipment by persons with disabilities, most particularly those with mobility- or communication-related impairments. However, under Section 510, the Access Board is statutorily tasked only with promulgation (and revision) of these Standards. Although the MDE Standards do not have legal effect until adopted (in whole or in part) by an enforcing authority, they can advance accessibility to medical services for persons with disabilities by providing specific guidance concerning accessible medical diagnostic equipment that can be used by service providers in a voluntary manner.

At this point, the 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 Board cannot estimate the incremental monetary or quantitative impacts of the final rule.

Nevertheless, the Board is able to characterize qualitatively some of the potential impacts of these Standards. If enforcing agencies adopt the MDE Standards 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. Consequently, they may be able to receive health care comparable to that received by their non-disabled counterparts.

In addition, the Standards could yield some 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 reflects the input from a diverse set of stakeholders and provide solid groundwork for any future rulemaking pertaining to the accessibility of 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 Board thus concludes that the potential benefits of the MDE Standards justify the 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.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires federal agencies to analyze the impact of regulatory actions on small entities, unless an agency certifies that the rule will not have a significant impact on a substantial number of small entities. 5 U.S.C. 604, 605(b). The MDE Standards do not impose any mandatory requirements on any entity, including small entities. Therefore, we did not prepare a final regulatory flexibility analysis for the final rule.

C. Executive Order 13132: Federalism

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

D. Unfunded Mandates Reform Act

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

E. Paperwork Reduction Act

Under the Paperwork Reduction Act (PRA), federal agencies are generally prohibited from conducting or sponsoring a ''collection of information'' as defined by the PRA, absent OMB approval. *See* 44 U.S.C. 3507 *et seq.* The MDE Standards do not impose any new or revised collections of information within the meaning of the PRA.

List of Subjects in 36 CFR Part 1195

Health care, Individuals with disabilities, Medical devices.

Approved by vote of the Board on September 14, 2016.

David M. Capozzi,

Executive Director.

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

PART 1195—STANDARDS FOR ACCESSIBILE MEDICAL DIAGNOSTIC EQUIPMENT

Sec.

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

§ 1195.1 Standards.

The standards for accessible medical diagnostic equipment are set forth in the appendix to this part. Other agencies, referred to as an enforcing authority in the standards, may adopt the standards as mandatory requirements for entities subject to their jurisdiction. Advisory sections and figures that illustrate the technical requirements in the appendix to part 1195 are available on the Internet at: *www.access-board.gov.* These advisory materials provide guidance only and do not contain mandatory requirements.

Appendix to Part 1195—Standards for Accessible Medical Diagnostic Equipment

Table of Contents

Chapter 1: Application and Administration

M101 General

M101.1 Purpose. These Standards (MDE Standards) contain scoping and technical requirements for medical diagnostic equipment (diagnostic equipment) to ensure accessibility to, and usability of the diagnostic equipment by patients with disabilities. The MDE Standards provide for independent access to, and use of, diagnostic equipment by patients with disabilities to the maximum extent possible.

M101.2 Application. Sections M301 through M304 shall be applied to diagnostic equipment, based on the patient positions that the equipment supports, during patient transfer and diagnostic use. Sections M306 and M307 shall be applied to diagnostic equipment where communication features or operable parts are provided for patient use.

M101.3 Existing Diagnostic Equipment. The MDE Standards do not address the applicability of scoping or technical requirements to existing diagnostic equipment. Enforcing authorities, such as the Department of Justice or the Department of Health and Human Services, have authority over the accessibility of existing equipment and any regulation of that equipment will be effective only to the extent required by such enforcing authorities.

M101.4 Equivalent Facilitation. The use of alternative designs or technologies that result in substantially equivalent or greater accessibility and usability than specified in the MDE Standards is permitted.

M101.5 Dimensions. The MDE Standards are based on adult dimensions and anthropometrics. Dimensions that are not stated as ''maximum'' or ''minimum'' are absolute.

M101.6 Dimensional Tolerances. Dimensions are subject to conventional industry tolerances for manufacturing processes, material properties, and field conditions.

M101.7 Units of Measurement. Measurements are stated in U.S. customary and metric units. The values stated in each system (U.S. customary and metric units) may not be exact equivalents, and each system shall be used independently of the other.

M102 Definitions

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

End Transfer Surface. A transfer surface located at one end of an examination surface that allows patient transfer at the end and one adjoining side of the examination surface.

Enforcing Authority. An agency or other governmental entity that adopts the MDE Standards as mandatory requirements for entities subject to its jurisdiction. Enforcing authorities may include, but are not limited to the United States Departments of Justice and Health and Human Services.

Examination Chair. Diagnostic equipment with a seat in which a patient typically is positioned with buttocks approximately parallel to the ground and shins approximately perpendicular to the ground. Examination chairs typically have back support and may recline to properly position the patient during examination. Such chairs may also have footrests or stirrups. Examination chairs include, but are not limited to, equipment used for dental, ophthalmic, podiatric, gynecological,

urological, and ear, nose, and throat examinations.

Imaging bed. A component of diagnostic scanning equipment that accommodates patients in supine, prone, or side-lying positions.

Imaging equipment with bores. Diagnostic scanning equipment using magnets, x-rays, or detectors into which a patient and the table on which the patient lies is inserted into the equipment through a cylindrical opening (bore) in order to achieve the positioning accuracy needed during the scan. Such equipment includes, but is not limited to, computerized axial tomography (CT or CAT), positron emission tomography (PET), and nuclear medicine (NM) scanning equipment or a combination thereof.

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

Operable Parts. Components of diagnostic equipment that are used by the patient to activate, deactivate, or adjust the equipment.

Side Transfer Surface. A transfer surface located within the length of the examination surface that allows patient transfer on two opposing sides of the examination surface.

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

Wheelchair Space. Space for a single wheelchair and its occupant.

M102.2 Undefined Terms. Terms not defined in M102.1 or in regulations or policies issued by an enforcing authority shall be given their ordinarily accepted meaning in the sense that the context implies.

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

Chapter 2: Scoping

M201 General

M201.1 Application by Enforcing Authority. The enforcing authority shall specify the number and type of diagnostic equipment that are required to comply with the MDE Standards.

M201.2 General Exception. Medical diagnostic equipment shall not be required to comply with one or more applicable requirements in the MDE Standards in the rare circumstances where compliance would alter diagnostically required structural or operational characteristics of the equipment and would prevent the use of the equipment for its intended diagnostic purpose. Diagnostic equipment subject to M201.2 shall comply to the maximum extent practicable.

Chapter 3: Technical Requirements

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

M301.1 General. Diagnostic equipment that supports patients in a supine, prone, or side-lying position shall comply with M301.

Exception: Examination chairs complying with M302 that recline to facilitate diagnosis after patients transfer onto the chair shall not be required to comply with M301.

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

M301.2.1 Adjustability. Transfer surfaces shall be adjustable in height measured from the floor to the top of the uncompressed transfer surface and shall provide the following:

A. A low transfer position at a height of 17 inches (430 mm) minimum and 19 inches (485 mm) maximum;

B. A high transfer position at 25 inches (635 mm); and

C. At least 4 additional transfer positions located between the low and high transfer positions and separated by 1 inch (25 mm) minimum.

M301.2.2 Sunset. The low transfer position height, Item A of M301.2.1, shall cease to have effect on January 10, 2022.

M301.2.3 Size. The size of the transfer surface shall comply with M301.2.3.1 or M301.2.3.2. The size of transfer surfaces shall be measured from center points of their opposing sides.

M301.2.3.1 End Transfer Surface. End transfer surfaces shall be 28 inches (710 mm) wide minimum and 17 inches (430 mm) long minimum.

Exception: Transfer surfaces for imaging equipment with bores shall be permitted to be 21 inches (535 mm) wide minimum but shall not be permitted to be less than the full width of the examination surface provided for the patient.

M301.2.3.2 Side Transfer Surface. Side transfer surfaces shall be 28 inches (710 mm) wide minimum and 28 inches (710 mm) long minimum.

Exception: Transfer surfaces for imaging equipment with bores shall be permitted to be 21 inches (535 mm) wide minimum but shall not be permitted to be less than the full width of the examination surface provided for the patient.

M301.2.4 Unobstructed Transfer. Each transfer surface shall provide two unobstructed sides for patient transfer.

Exceptions: 1. Obstructions no more than 3 inches (75 mm) deep shall be permitted to extend beyond transfer sides of transfer surfaces provided that such obstructions do not protrude above the tops of transfer surfaces.

2. Temporary obstructions shall be permitted provided that they can be repositioned during transfer to comply with M301.2.4, including Exception 1.

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

M301.3.1 Transfer Supports. Transfer surfaces required by M301.2 shall provide transfer supports and shall comply with M305.2.

M301.3.2 Leg Supports. Where stirrups are provided, leg supports shall also be provided and shall comply with M305.4.

M301.3.3 Head and Back Support. Where the diagnostic equipment is used in a reclined position, head and back support shall be provided and shall comply with M305.5.

M301.4 Lift Compatibility. Diagnostic equipment shall be usable with portable patient lifts and, when in use with such lifts, shall comply with M301.4.1 or M301.4.2.

Exception: Where fixed overhead patient lifts are provided, and when their use with diagnostic equipment is permitted by an enforcing authority, diagnostic equipment shall not be required to meet the lift compatibility requirements of this section provided that such equipment is clearly labeled as not compatible with portable floor lifts.

M301.4.1 Clearance in Base. The base of diagnostic equipment shall provide a clearance 39 inches (990 mm) wide minimum, 6 inches (150 mm) high minimum measured from the floor, and 36 inches (915 mm) deep minimum measured from the edge of the examination surface. Where the width of examination surfaces is less than 36 inches (915 mm), the clearance depth shall extend the full width of the equipment. Components of diagnostic equipment are permitted to be located within 8 inches (205 mm) maximum of the centerline of the clearance width.

M301.4.2 Clearance Around Base. The base of diagnostic equipment shall provide a clearance 6 inches (150 mm) high minimum measured from the floor and 36 inches (915 mm) deep minimum measured from the edge of the examination surface. The width of the base permitted within this clearance shall be 26 inches (660 mm) wide maximum at the edge of the examination surface and shall be permitted to increase at a rate of 1 inch (25 mm) in width for each 3 inches (75 mm) in depth.

M302 Diagnostic Equipment Used by Patients in Seated Position

M302.1 General. Diagnostic equipment that supports patients in a seated position shall comply with M302.

Exception: Where weight scales contain wheelchair spaces complying with M303 and also provide a seat integral to the equipment, the scales shall not be required to comply with M302.

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

M302.2.1 Adjustability. Transfer surfaces shall be adjustable in height measured from the floor to the top of the uncompressed transfer surface and shall provide the following:

A. A low transfer position at a height of 17 inches (430 mm) minimum and 19 inches (485 mm) maximum;

B. A high transfer position at 25 inches (635 mm); and

C. At least 4 additional transfer positions located between the low and high transfer positions and separated by 1 inch (25 mm) minimum.

M302.2.2 Sunset. The low transfer position height, Item A of M302.2.1, shall cease to have effect on January 10, 2022.

M302.2.3 Size. Transfer surfaces shall be 21 inches (610 mm) wide minimum and 17 inches (430 mm) deep minimum. The size of transfer surfaces shall be measured from center points of their opposing sides.

M302.2.4 Transfer Sides. Options to transfer from a mobility device shall be provided on two adjoining sides of transfer surfaces.

Exception: Options to transfer to or from a mobility device onto opposing sides of

transfer surfaces shall be permitted where the transfer surface is obstructed by fixed footrests.

M302.2.5 Unobstructed Transfer. Each transfer side complying with M302.2.4 shall provide unobstructed access to transfer surfaces.

Exceptions: 1. Obstructions no more than 3 inches (75 mm) deep shall be permitted to extend beyond transfer sides of transfer surfaces provided that such obstructions do not protrude above the tops of transfer surfaces.

2. Temporary obstructions shall be permitted provided that they can be repositioned during transfer to comply with M302.2.5, including Exception 1.

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

M302.3.1 Transfer Supports. Transfer supports shall be provided for use with transfer sides required by M302.2.4 and shall comply with M305.2.1.1, M305.2.2.1, and M305.2.3 through M305.2.8.

M302.3.2 Leg Supports. Where stirrups are provided, leg supports shall also be provided and comply with M305.4.

M302.3.3 Head and Back Support. Where the diagnostic equipment is used in a reclined position, head and back support shall be provided and shall comply with M305.5.

M302.4 Lift Compatibility. Diagnostic equipment shall be usable with portable patient lifts and, when in use with such lifts, shall comply with M302.4.1 or M302.4.2.

Exception: Where fixed overhead patient lifts are provided, and when their use with diagnostic equipment is permitted by an enforcing authority, diagnostic equipment shall not be required to meet the lift compatibility requirements of this section provided that such equipment is clearly labeled as not compatible with portable floor lifts.

M302.4.1 Clearance in Base. The base of the diagnostic equipment shall provide a clearance 39 inches (990 mm) wide minimum, 6 inches (150 mm) high minimum measured from the floor, and 36 inches (915 mm) deep minimum measured from the edge of the examination surface. Where the width of the examination surface is less than 36 inches (915 mm), the clearance depth shall extend the full width of the equipment. Equipment components are permitted to be located within 8 inches (205 mm) maximum of the centerline of the clearance width.

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

M303 Diagnostic Equipment Used by Patients Seated in a Wheelchair

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

M303.2 Wheelchair Spaces. Wheelchair spaces complying with M303.2 shall be provided at diagnostic equipment.

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

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

Exception: Wheelchair spaces located on raised platforms shall be permitted to be 32 inches (815 mm) wide minimum to a height of 4 inches (100 mm) measured from the platform surface.

M303.2.3 Depth. The depth of wheelchair spaces shall comply with M303.2.3.

M303.2.3.1 Front or Rear Entry. Where wheelchair space entry and exit is provided at only one end (front or rear) the wheelchair space shall be 48 inches (1220 mm) deep minimum.

M303.2.3.2 Pass Through Entry. Where wheelchair space entry and exit permits pass through from one end to the other, the wheelchair space shall be 40 inches deep (1015 mm) minimum.

M303.2.3.3 Side Entry. Where wheelchair space entry is only from the side, the wheelchair space shall be 60 inches (1525 mm) deep minimum.

M303.2.4 Equipment Clearances. Where wheelchair spaces are entered from the rear and includes space beneath components, wheelchair spaces shall include knee and toe clearances complying with M303.2.4.1 for breast platforms and M303.2.4.2 for all other equipment.

M303.2.4.1 Breast Platforms. Wheelchair spaces beneath breast platforms shall comply with M303.2.4.1.

M303.2.4.1.1 Depth. Wheelchair spaces shall include knee and toe clearance 25 inches (635 mm) deep minimum and 28 inches (710 mm) deep maximum.

M303.2.4.1.2 Height. Wheelchair spaces shall include toe clearance 9 inches (230 mm) high minimum above the floor measured to a depth of 6 inches (150 mm) maximum from the toe end of the wheelchair space. Knee clearance shall be provided at a depth of 19 inches (485 mm) minimum and 22 inches (560 mm) maximum at 9 inches (230 mm) above the floor and at a depth of 16 inches (405 mm) minimum at 27 inches (685 mm) above the floor measured from the leading edge of the breast platform. Between 9 inches (230 mm) and 27 inches (685 mm) above the floor, the knee clearance shall be permitted to reduce at a rate of 1 inch (25 mm) in depth for every 6 inches (150 mm) in height.

Exception: Components shall be permitted to extend into the wheelchair space at a height of 1½ inches (38 mm) maximum between 17 inches (430 mm) minimum and 25 inches (635 mm) maximum in depth measured from the leading edge of the breast platform. From 25 inches (635 mm) to 28 inches (710 mm) in depth the height of a component above 1½ inches (38 mm) shall be beveled at a rate of 2.5:3 maximum.

M303.2.4.2 Other Equipment. Wheelchair spaces beneath diagnostic equipment other than breast platforms shall comply with M303.2.4.2.

M303.2.4.2.1 Depth. Wheelchair spaces shall include knee and toe clearance 17 inches (430 mm) deep minimum and 25 inches (635 mm) deep maximum.

M303.2.4.2.2 Height. Wheelchair spaces shall include toe clearance 9 inches (230 mm) high minimum above the floor measured to a depth of 6 inches (150 mm) maximum measured from the toe end of the wheelchair space. Knee clearance shall be provided at a depth of 11 inches (280 mm) minimum and 25 inches (635 mm) maximum at 9 inches (230 mm) above the floor and at a depth of 8 inches (205 mm) minimum at 27 inches (685 mm) above the floor measured from the leading edge of the equipment. Between 9 inches (230 mm) and 27 inches (685 mm) above the floor, the knee clearance shall be permitted to reduce at a rate of 1 inch (25 mm) in depth for every 6 inches (150 mm) in height.

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

M303.2.6 Edge Protection. Where wheelchair spaces are provided on a platform raised more than 1½ inches (38 mm) in height, edge protection 2 inches (51 mm) high minimum measured from the surface of the platform shall be provided on each side not providing entry to or exit from the equipment.

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

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

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

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

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

Exception: A running slope not steeper than 1:8 shall be permitted for ramp runs with a maximum height of 2½ inches (64 mm).

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

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

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

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

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

M303.4.1 Breast Platform Adjustability. Breast platforms shall be continuously adjustable from a low height of 26 inches (660 mm) to a high height of 42 inches (1065 mm) above the floor.

M304 Diagnostic Equipment Used by Patients in Standing Position

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

M304.2 Standing Surface. Equipment surfaces on which patients stand must comply with M304.2

M304.2.1 Slip Resistant. The surface on which the patient stands shall be slip resistant.

M304.2.2 Standing Supports. Standing supports shall be provided on two sides of the standing surface and shall comply with M305.3.

Exception: Diagnostic equipment with entry and exit permitting pass-through from one end to the other shall be permitted to provide one standing support on one side of the standing surface provided that the standing support complies with the requirements for standing supports in a horizontal position in M305.3.

M305 Supports

M305.1 General. Supports shall comply with M305.

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

M305.2.1 Location. Transfer supports shall comply with M305.2.1.1 or M305.2.1.2 and shall be located 1½ inches (38 mm) maximum measured horizontally from the plane defined by the nearest edge of the transfer surface.

Exception: Where the support folds, collapses, or articulates, the transfer support shall be permitted to be located 3 inches (75 mm) maximum from the plane defined by the nearest edge of the transfer surface.

M305.2.1.1 End Transfer Supports. Transfer supports for transfer surfaces complying with M301.2.3.1 and M302.2 shall be located on the short side (length) opposite the transfer side.

M305.2.1.2 Side Transfer Supports. Transfer supports for transfer surfaces complying with M301.2.3.2 shall be capable of supporting transfer on each side of the transfer surface.

M305.2.2 Length. The length of transfer supports shall comply with M305.2.2.1 or M305.2.2.2.

M305.2.2.1 End Transfer Supports. Transfer supports for transfer surfaces complying with M301.2.3.1 and M305.2.2.1 shall be 15 inches (380 mm) long minimum. Transfer supports shall be positioned along 13½ inches (345 mm) minimum of the depth of the transfer surface.

M305.2.2.2 Side Transfer Supports. Transfer supports for transfer surfaces complying with M301.2.3.2 shall be 28 inches (710 mm) long minimum and shall be positioned along the width of transfer surfaces.

Exceptions: 1. Where transfer surfaces are part of an articulating surface, the support shall be permitted to be 15 inches (380 mm) long minimum.

2. Where the width of an imaging bed is more than 24 inches (533 mm), transfer supports shall be permitted to be 12 inches (305 mm) long minimum.

M305.2.3 Height. During use, the tops of transfer support gripping surfaces shall be 6 inches (150 mm) minimum and 19 inches (485 mm) maximum higher than the top of the associated uncompressed transfer surface.

Exception: Where the width of the transfer surface for imaging beds exceed 24 inches (610 mm), the tops of the gripping surfaces shall be permitted to be 3 inches (75 mm) minimum and 6 inches (150 mm) maximum higher than the top of the associated uncompressed transfer surface.

M305.2.4 Cross Section. Transfer supports shall have a cross section complying with 305.2.4.1 or 305.2.4.2.

M305.2.4.1 Circular Cross Section. Transfer supports with circular cross sections shall have an outside diameter of 1¼ inches (32 mm) minimum and 2 inches (51 mm) maximum.

M305.2.4.2 Non-Circular Cross Section. Transfer supports with non-circular cross sections shall have a cross-section dimension of 2 inches (51 mm) maximum and a perimeter dimension of 4 inches (100 mm) minimum and 4.8 inches (120 mm) maximum.

M305.2.5 Surface Hazards. Transfer supports and surfaces adjacent to transfer supports shall be free of sharp or abrasive components and shall have eased edges.

M305.2.6 Gripping Surface. Transfer support gripping surfaces shall be continuous along their length and shall not be obstructed along their tops or sides. The bottoms of transfer support gripping surfaces shall not be obstructed for more than 20 percent of their length.

M305.2.7 Clearance. Clearance between the transfer support gripping surface and adjacent surfaces or obstructions shall be 1½ inches (38 mm) minimum.

M305.2.8 Fittings. Transfer supports shall not rotate within their fittings when in place for transfer.

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

M305.3.1 Length. The length of gripping surfaces for standing supports shall be based on the position of the standing supports in relation to the standing surfaces they serve. Horizontal standing support gripping surfaces shall comply with M305.3.1.1, horizontal standing support gripping surfaces on diagnostic equipment containing a wheelchair space shall comply with M305.3.1.2 and, vertical standing support gripping surfaces shall comply with M305.3.1.3.

M305.3.1.1 Horizontal Position. The length of gripping surfaces on horizontal standing supports shall be 4 inches (100 mm) minimum except for diagnostic equipment containing a wheelchair space which shall comply with M305.3.1.2.

M305.3.1.2 Diagnostic Equipment Containing a Wheelchair Space. On diagnostic equipment containing wheelchair spaces with one entry that also serves as the exit, the length of the gripping surface of horizontal standing supports shall be equal to or greater than 80 percent of the overall length of the platform. On diagnostic equipment containing a wheelchair space and permitting pass-through from one end to the other, the length of the gripping surface on horizontal standing supports shall be at least equal to the length of the platform.

M305.3.1.3 Vertical Position. The length of the gripping surface on vertical standing supports shall be 18 inches (455 mm) minimum.

M305.3.2 Height. The height of gripping surfaces for standing supports shall be based on the position of the standing supports in relation to the standing surfaces they serve. Horizontal standing support gripping surfaces shall comply with M305.3.2.1 and vertical standing support gripping surfaces shall comply with M305.3.2.2.

M305.3.2.1 Horizontal Position. The height of the top of the gripping surface on horizontal standing supports shall be 34 inches (865 mm) minimum and 38 inches (965 mm) maximum above the standing surface.

M305.3.2.2 Vertical Position. The height of the lowest end of the gripping surface on vertical standing supports shall be 34 inches (865 mm) minimum and 37 inches (940 mm) maximum above the standing surface.

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

M305.4 Leg Supports. Leg supports shall provide a method of supporting, positioning, and securing the patient's legs.

M305.5 Head and Back Support. Where the diagnostic equipment is used in a reclined position, head and back support shall be provided. Where the incline of the back support can be modified while in use, head and back support shall be provided throughout the entire range of the incline.

M306 Communication

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

M307 Operable Parts

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

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

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

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

[FR Doc. 2016–31186 Filed 1–6–17; 8:45 am]

BILLING CODE 8150–01–P