message can be received without jeopardizing the safety or security of people, places, or vessels.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

Submitting comments. We encourage you to submit comments through the Federal Decision-Making Portal at *https://www.regulations.gov.* To do so, go to *https://www.regulations.gov,* type USCG–2023–0286 in the search box and click ''Search.'' Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If you cannot submit your material by using *https://www.regulations.gov,* call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule for alternate instructions.

Viewing material in docket. To view documents mentioned in this proposed rule as being available in the docket, find the docket as described in the previous paragraph, and then select ''Supporting & Related Material'' in the Document Type column. Public comments will also be placed in our online docket and can be viewed by following instructions on the *https://www.regulations.gov* Frequently Asked Questions web page. Also, if you click on the Dockets tab and then the proposed rule, you should see a ''Subscribe'' option for email alerts. The option will notify you when comments are posted, or a final rule is published.

We review all comments received, but we will only post comments that address the topic of the proposed rule. We may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

Personal information. We accept anonymous comments. Comments we post to *https://www.regulations.gov* will include any personal information you have provided. For more about privacy and submissions to the docket in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

List of Subjects in 33 CFR Part 165

Harbors, Marine Safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard is proposing to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 165.T01–0286 to read as follows:

§ 165.T01–0286 Safety Zone; Shrewsbury River, S–32 Bridge, Boroughs of Rumson and Sea Bright, NJ.

(a) *Location.* The following area is a safety zone: All navigable waters of the Shrewsbury River, within a 100-yard radius of the center point of the S–32 Bridge, County Route 520 (Rumson Road) in the boroughs of Rumson and Sea Bright, New Jersey.

(b) *Definitions.* As used in this section, *Designated Representative* means a Coast Guard Officer, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port New York (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, no person or vessel may enter the safety zone described in paragraph (a) of this section unless authorized by the Captain of the Port (COTP) or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative via VHF channel 16 or by phone at (718) 354–4353 (Sector New York Command Center). Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This section is effective from September 25, 2023, through December 31, 2024, but will only be enforced during periods when heavy lift operations at the new bridge are in progress.

Dated: May 4, 2023.

Z. Merchant,

Captain, U.S. Coast Guard, Captain of the Port New York.

[FR Doc. 2023–10942 Filed 5–22–23; 8:45 am]

BILLING CODE 9110–04–P

ARCHITECTURAL AND TRANSPORTATION BARRIERS COMPLIANCE BOARD

36 CFR Part 1195

[Docket No. ATBCB–2023–0001]

RIN 3014–AA45

Standards for Accessible Medical Diagnostic Equipment

AGENCY: Architectural and Transportation Barriers Compliance Board.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Architectural and Transportation Barriers Compliance Board (hereafter, ''Access Board'' or ''Board''), is issuing this notice of proposed rulemaking to remove the sunset provisions in the Board's existing accessibility standards for medical diagnostic equipment related to the low-height specifications for transfer surfaces, and replace them with a final specification for the low-transfer-height of medical diagnostic equipment used in the supine, prone, side-lying position and the seated position.

DATES: Send comments on or before July 24, 2023.

ADDRESSES: You may submit comments by any one of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: docket@access-board.gov.* Include docket number ATBCB–2023–0001 in the subject line of the message.
- *Mail:* Office of General Counsel, U.S. Access Board, 1331 F Street NW, Suite 1000, Washington, DC 20004–1111.

Instructions: All submissions must include the docket number (ATBCB–2023–0001) for this regulatory action. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov/docket/ATBCB-2023-0001.*

FOR FURTHER INFORMATION CONTACT: Accessibility Specialist Bobby Stinnette, (202) 272–0021, *stinnette@access-board.gov;* or Attorney Advisor Wendy Marshall, (202) 272–0043, *marshall@access-board.gov.*

SUPPLEMENTARY INFORMATION:

I. Legal Authority

Section 510 of the Rehabilitation Act charges the Access Board with developing and maintaining minimum

technical criteria to ensure that ''medical diagnostic equipment used in or in conjunction with physician's offices, dental 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 Access Board's minimum technical criteria do not impose any mandatory requirements on health care providers or medical device manufacturers. Agencies or entities may choose to issue regulations or adopt policies requiring health care providers to acquire accessible medical diagnostic equipment that complies with the technical criteria set forth by the Access Board, however, these agencies or entities would have to develop the appropriate scoping provisions to determine how to apply these technical criteria and would be free to strengthen or lessen the requirements as they so determine.

II. Rulemaking History

In January 2017, the Board issued a final rule establishing technical criteria for medical diagnostic equipment. 82 FR 2810 (codified at 36 CFR part 1195). The Accessibility Standards for Medical Diagnostic Equipment (MDE Standards) set forth technical criteria to ensure that medical diagnostic equipment used by health care providers (such as examination tables, weight scales, and imaging equipment) is accessible to, and usable by, individuals with disabilities. One of the areas covered by the MDE Standards is the adjustability of transfer surfaces for certain types of medical diagnostic equipment. Specifically, for diagnostic equipment used by patients in a supine, prone, side-lying, or seated position. The MDE Standards currently specify the following adjustability requirements for transfer-height positions: a high height of 25 inches, a low height of 17–19 inches, and four unspecified intermediate heights between the high and low transfer height, which are separated by a minimum of one inch. 36 CFR part 1195, appendix, M301.2.1 & M302.2.2. Unlike the other transfer height specifications, the low transfer height was set as a temporary range with a five-year sunset provision. *Id.*

As explained in the preamble to the final rule, the Board took this approach because ''there was insufficient information to designate a single minimum low height requirement at [that] time. Specifically, there [was] insufficient data on the extent to which and how many individuals would benefit from a transfer height lower than 19 inches.'' 82 FR at 2816. The Board explained that the MDE Advisory Committee was unable to come to an agreement on a single low height transfer position. In the MDE Advisory Committee Report, minority reports submitted by disability advocates and academics supported a minimum low height of 17 inches. *See* Minority Reports from Boston Center for Living Inc., National Network for ADA Centers, and Medical Diagnostic Equipment Advisory Committee, available at *https://www.regulations.gov/docket/ATBCB-2013-0009/document* (last visited April 5, 2023). These reports strongly supported a 17-inch low height, referencing the importance of accessible care, ensuring as many independent transfers as possible, and minimizing the risk of injury to both patient and provider if an assisted transfer is necessary. The reports asserted that the 17-inch low height provides ''the greatest number of individuals the opportunity to transfer independently.'' 82 FR 2810, 2815 (Jan. 9, 2017). 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, and Recommendation of 19-inch Lower Adjustable Height as the Minimum Accessibility Standard (Joint Report), available at *https://www.regulations.gov/docket/ATBCB-2013-0009/document* (last visited April 5, 2023) The exam table manufacturers asserted that they would incur costs to comply with the 17-inch low height, but not similarly for the 19-inch low height. The manufactures asserted that, at that time, there were no accessible diagnostic tables on the market that met a 17-inch low height requirement. *Id.*

Thus, the Board decided to specify a five-year sunset period to afford time for needed research and subsequent promulgation of a final specification for the low transfer height position. *Id.* On February 3, 2022, the Board issued a direct final rule extending the sunset provision until January 10, 2025. 87 FR 21089 (Apr. 11, 2022).

III. Research on Transfer Height

The Access Board has supported multiple research projects over the years regarding the height of wheelchairs, independent transfer, and the height of the transfer surface. In 2010, the Board commissioned a research study, the *Anthropometry of Wheeled Mobility Project,* which was conducted by the University of Buffalo's Center for Inclusive Design and Environmental Access (IDeA). This research study focused on the anthropometry of 500 wheeled mobility device users in the United States and analyzed the seat height of manual chairs, power chairs, and scooters. The study explained that ''keeping the height of a transfer surface close to the height of a wheelchair seat reduces the effort necessary to transfer and provides a safer environment, especially in bathing and toilet rooms.'' pg. 89 *available at http://idea.ap.buffalo.edu/projects/anthropometry.* The study analyzed wheelchair seat heights and found that for manual chair users, the ''5th—95th percentile range of wheelchair seat heights was 430mm–566mm (17 in–22.3 in).'' *Id.* at 85. The study also opined that in applying these findings, if the purpose is to accommodate the 5th percentile occupied manual chair user seat height and the 95th percentile scooter user height, a range of 430 mm–635 mm (17 in.–25 in.) is needed. *Id.*

In November 2015, a final report was issued for a study commissioned by the Access Board on *Independent Wheelchair Transfers in the Built Environment: How Transfers Setup Impacts Performance* conducted by Human Engineering Research Laboratories (HERL). While this study focused on transfers in the built environment, including clear floor space dimensions, impact of grab bars, and finding a fixed height that can accommodate the largest percentage of users, it provides some information that is pertinent to the issue of an appropriate adjustable height range for independent transfers in a medical setting. In this study, the researchers explained that for wheelchair users, ''transfers are required to perform essential tasks of daily living such as bathing, toileting, and driving. On average, transfers are performed between 11 and 20 times per day. Independent transfers are ranked among the most strenuous tasks of daily living because of the high mechanical demands they place on upper limbs. The built environment can either increase or decrease the effort required to perform independent transfers. Environments that require more effort to transfer ultimately limit the number of WMD users who can access them.'' *Independent Wheelchair Transfers in the Built Environment: How Transfer Setup Impacts Performance Phase 2: Final Report,* pg. 8, *available at https://www.herl.pitt.edu/ab/ABTransferSetupReportPhaseII.pdf (last accessed April 5, 2023).* In this study, all participants were able to complete a level transfer, meaning they successfully transferred

from their wheeled mobility device to a transfer surface that was level with the seat of their chair. *Id.* at 49. The researchers noted that ''transfers are easiest and safest to obtain when they are as close to level as possible''. *Id.* The participants of this study had wheelchair seat heights which ranged from 19 inches minimum to 27.5 inches maximum. Based on the study participants, this study recommended an adjustable platform height from 19 to 27.5 inches as ''all participants can make a level transfer.'' *Id.* at 49.

In 2021, the Access Board commissioned a secondary analysis of occupied seat heights based on the 2010 *Anthropometry of Wheeled Mobility Project* to address some of the concerns raised about the original study, specifically that the participants were not statistically representative of the wheelchair-user community. This new analysis took the ''data on occupied seat heights for manual and powered wheelchair users (N= 466 of 500 users in the AWM database) [and] statistically resampled to create virtual samples that were proportionally representative of the total population of wheelchair users in the U.S. in terms of device type (manual vs. powered), gender (men vs. women) and age category (younger 18–64 vs. older 65+). *Analysis of Low Wheelchair Seat Heights and Transfer surfaces for Medical Diagnostic Equipment Final Report,* Clive D'Souza, *available at https://www.access-board.gov/research/human/wheelchair-seat-height/.* The proportions were obtained from the 1994–97 National Health Interview Survey on Disability (NHIS–D) study findings presented by LaPlante and Kay (2010).'' [1] In the Final Report, Dr. D'Souza explains that the ''occupied seat height of wheeled mobility devices is important for determining the necessary height ranges for adjustable transfer surfaces of MDE. Generally, maintaining a transfer surface at the same height as the wheelchair seat reduces the effort needed to transfer, since occupants would not have to lift their body weight to make up the difference between the two surface heights, in one direction or the other.'' *Id.*

In his final report, Dr. D'Souza used demographically representative virtual samples to determine the proportion of manual and power wheelchair users who would be excluded from a level transfer if the lower height limit of the MDE transfer surfaces were set to 17 inches, 18 inches, or 19 inches. Dr. D'Souza's analysis found that at a 17-inch low transfer height, 4.5 percent of wheelchair users would be excluded; at an 18-inch low transfer height, 21 percent of wheelchair users would be excluded; and at a 19-inch low transfer height, 43 percent of wheelchair users would be excluded. *Id.* Additionally, Dr. D'Souza conducted further analysis to account for the predictable increase in power wheelchair users since the last available survey of the total population of wheelchair users in the United States in terms of device type, gender, and age was last conducted in 1994–1997. *Id.* Dr. D'Souza accounted for a 10 percent increase and a 20 percent increase in power wheelchair use. This increase in power wheelchair proportions indicated ''that the percent excluded would show a small decrease (*i.e.,* increased accommodation) at intermediate values (*e.g.,* at 19 inches, a 10% increase in powered wheelchair proportions decreased the percent excluded from 42% to 39%). However, at lower heights such as 17 inches, there is no substantial change in percentiles, since most wheelchair users, regardless of device type, are already accommodated (*i.e.,* at 17 in., a 10% increase in powered wheelchair proportions decreased the percent excluded from about 4.5% to 4%).'' Dr. D'Souza opined that setting the low transfer height requirement ''closer to the tails of the distribution (*e.g.,* 17 or 17.5 in.)'' would continue to ensure a level transfer despite future changes in population demographics. *Id.*

IV. Public Meeting and Comments on Research Study

On May 12, 2022, after the publication of the final report *Analysis of Low Wheelchair Seat Heights and Transfer Surfaces for Medical Diagnostic Equipment,* the Access Board held a public meeting to obtain further information on the appropriate low-height specification of transfer surfaces for medical diagnostic equipment. The Access Board also invited public comment on the findings in Dr. D'Souza's final report and any new information regarding the low transfer height provision, since the issuance of the MDE Final Rule in 2017.[2] The Access Board had disability rights organizations, members of the public, and a manufacturer attend the public meeting and provide comment. Most of those commenters also provided written comments. In all, the Access Board received 107 comments in response to its request. *Available at https://www.regulations.gov/docket/ATBCB-2022-0002/comments.*

Of those comments, 12 were from disability rights organizations. These organizations unanimously support adoption of 17 inches as the low transfer height specification. Specifically, multiple organizations point out the importance of ensuring that the greatest number of people with disabilities can access medical services by being able to transfer onto the exam table. Additionally, one organization in the state of Mississippi asserts that it disagrees with the premise that more people are moving to power wheelchairs. The organization claims that the majority of users it encounters use manual wheelchairs and that a significant number of the population would require the 17-inch low height to be able to transfer to MDE. *See* Comment ATBCB–2022–0002–0028, *available at https://www.regulations.gov/comment/ATBCB-2022-0002-0028.*

The Access Board received approximately 90 comments from members of the public, who almost unanimously supported a low height of 17 inches. Many commenters explained the continued struggle to obtain proper medical care and diagnosis as a result of inaccessible medical diagnostic equipment. A few commenters explained their preference for higher height MDE between 18 to 25 inches to allow level transfer with their specific wheelchair, but most of those commenters also highlighted the importance of the lower specification of 17 inches to accommodate those in wheelchairs that sit lower to the ground. The Board also received two comments from medical professionals, one recommending 17 inches to accommodate patients with specific medical conditions and the other recommending a low height of 18 inches.

Finally, the Board received two comments from manufactures of exam tables, both supporting a 19-inch low height for MDE transfer surfaces. Both of these manufacturers also served on the MDE Advisory Committee and filed minority reports to the Advisory Committee Report supporting a 19-inch low height specification. In its public comment, one manufacturer explains that in the U.S. ''approximately 62 percent of physicians, hospitals, and other health care providers use examination and procedures tables with a 32-inch fixed height. Industry commonly refers to these tables as 'box tables.' These tables provide an often-

[1] The 1994–97 National Health Interview Survey on disability is the most recent survey on wheelchair use within the United States.

[2] Comments in response to the public meeting are available on Docket ATBCB–2022–0002, available at *https://www.regulations.gov/docket/ATBCB-2022-0002/comments.*

insurmountable barrier to health care for people with accessibility needs. Since 2001, the number of adjustable-height tables has steadily increased from 5% but continues to represent a minority of examination and procedure tables in the United States with cost being one of the factors that limits full adoption.'' *See* Comment ATBCB–2022–0002–0073, *available at https://www.regulations.gov/comment/ATBCB-2022-0002-0073.* This manufacturer goes on to explain that while it makes an accessible exam table that has a low transfer height of 15.5 inches, it still supports a low-height specification for MDE of 19 inches, as it considers the lower exam table to be cost prohibitive. Additionally, if a specification lower than 19 inches is adopted, then the adjustable tables in exam rooms currently would be deemed inaccessible. *Id.* Concerning the latter point, the effect of the proposed change in this NPRM on existing MDE will depend on if and in what manner enforcement authorities decide to adopt them. For example, agencies may decide to delay the effective date or implementation date of any rules they adopt, they may deem MDE acquired prior to their rulemaking or this rulemaking to be ''accessible'' if it complied with the low transfer height range currently provided for, or it may make changes to the Access board's technical criteria during adoption, such as by continuing to allow for a range of low transfer heights between 17 and 19 inches.

Another manufacturer that also strongly supports a low-height-specification of 19 inches asserts that lowering the height to 17 inches would be cost prohibitive, would prevent the table from raising to a level comfortable for the medical professional examining the patient, and would cause a reduction in length of the table once reclined into a supine position. The commenter also raises concerns about the methodology behind our low height specification determination, asserting that the Board should be conducting a study to determine the heights to which people in wheelchairs can transfer, instead of attempting to provide for a level transfer by requiring MDE that aligns with the patient's wheeled mobility device. This manufacturer also raises concerns with the methodology of the original 2010 Study, in measuring to the seat of the wheelchair at the back, instead of measuring to the front of the wheelchair. Finally, the comment includes an opinion from Don Wardell, a professor of operations management from the University of Utah. Dr. Wardell raises three concerns about Dr. D'Souza's statistical resampling: (1) that the data set used to derive the proportions of people using powered vs. manual wheelchairs is old; (2) that there is not sufficient evidence to assert that a percentage of the population would be excluded if not provided a level transfer, since the ability to transfer from one surface height to another involves many assumptions regarding individual abilities and methods as well as equipment characteristics; and (3) that the sensitivity analysis is inaccurate as there is no date or new information to suggest that the height of manual wheelchairs today are the same as they were in 1994.

As to Dr. Wardell's first and third concerns, the 1994–97 data from the National Health Interview Survey on Disability (NHIS–D) was only used to determine the proportions of the wheelchair user population by gender, use of powered vs. manual wheelchairs, and age. The heights of wheelchairs were from data collected in the *Anthropometry of Wheeled Mobility Project* from 2010. While we do understand the concern with using the statistics of wheelchair users in the United States from 1994–97, this is the most recent collection of data by the Center for Disease Control (CDC), and the most recent sufficient data the Board and Dr. D'Souza were able to obtain.

Question 1. The Board seeks additional information about more recent available studies regarding the population of wheelchair users in the United States, by gender, age, and device type.

Regarding the second assertion about level transfer, much of the research conducted on transfer to and from a mobility device has found that a level transfer requires less effort or upper body strength and has the highest success rate. In the *Independent Wheelchair Transfers in the Built Environment: How Transfers Setup Impacts Performance* study mentioned above, 100 percent of the participants that were capable of independent transfer could effectuate a transfer to a surface that is level with the height of their wheelchair. *Available at https://www.herl.pitt.edu/ab/ABTransferSetupReportPhaseII.pdf. (last visited April 5, 2023).* The ability to transfer vertically, on the other hand, is difficult to determine, as it differs among individuals depending on factors such as their disability, upper body strength, physical body make up, weight, etc. *Id.* Additionally, the same study references multiple journal articles which explain that most individuals in a wheelchair transfer many times per day, and their capabilities may be different depending on the number of times they have transferred on a particular day. *Id.*

Patient and provider safety during transfer is another reason the Board believes that an independent level transfer is imperative. A level transfer provides less risk of injury to both the patient and provider by preventing the need for the patient to transfer vertically. Wheelchair related trip and falls are a yearly occurrence in the United States and can result in injury, decreased independence and affect the quality of life of someone who uses a wheelchair. D. Gavin-Dreschnack, A. Nelson, S. Fitzgerald, J. Harrow, A. Sanchez-Anguiano, S. Ahmed, and G. Powell-Cope, ''Wheelchair-related Falls: Current Evidence and Directors for Improved Quality Care'', *Journal of Nursing Care Quality* 20, no. 2 (2005) 119. It is estimated that in the U.S. there is an average of 36, 559 nonfatal wheelchair related accidents each year that require emergency room visits. *Id.* Transfers to and from a wheelchair are one of five hazardous conditions that give rise to trips, falls, and fall-related injuries. *Id.* Specifically, this study showed that injuries can occur to the patient and the caregiver when an independent transfer is not possible and the caregiver is assisting with the transfer. *Id.* at 122. ''Tripping and falling are the most common form of incidents, accounting for 68.5% of fatal accidents and 73.2% of nonfatal accidents. . .among elderly long-term care residents, the majority of wheelchair-related injuries appeared to be connected with failed attempts to independently transfer into or out of a wheelchair and leaning forward.'' *Id. at* 123.

Additionally, in a recent report by the National Council on Disability (NCD) entitled *Enforceable Accessible Medical Equipment Standards* NCD explains that a ''growing body of research has demonstrated a relationship between musculoskeletal injuries, workers compensation claims, and safe patient handling, due in part to the overreliance on manual transfers to inaccessible equipment. Inaccessible equipment leads health care workers to use awkward body posture and poor ergonomics that heighten the risk of injury. In a vicious cycle, musculoskeletal injuries among healthcare workers can also create a greater risk of injury to patients'' during transfer. National Council on Disability, *Enforceable Accessible Medical Equipment Standards: A Necessary Means to Address the Health Care Needs of People with Mobility Disabilities, available at https://ncd.gov/*

sites/default/files/Documents/NCD_Medical_Equipment_Report_508.pdf (last visited Apr. 5, 2023). Based on the risk of falls, injuries to patients and providers, the success of transfer at a level transfer, and the exertion needed for vertical transfer, the Board has determined that providing for a level transfer height for medical diagnostic equipment whenever possible ensures that almost everyone, if not everyone, who is capable of an independent transfer would be able to transfer to this adjustable height surface.

V. Current Status of Accessible Medical Diagnostic Equipment

The Access Board informally reviewed publicly available information on current medical diagnostic equipment, specifically examination tables and chairs, to discern the current low transfer height and cost of adjustable MDE. The Board reviewed information on individual products to determine what low height the product could achieve, it did not undertake a systematic review of every feature of each product to assess potential compliance with the MDE Standards. The level of specificity of publicly available information regarding each product varies by manufacturer and product line, and it would have been impossible to compare every feature of every product. Further, such a robust, systematic study would be inappropriate at this point, given that the MDE Standards have no mandatory application. For most of the products, the Board was able to find publicly available price information. A number of online MDE suppliers listed both a manufacturer suggested retail price (MSRP) and discounted prices. As the actual price paid for a certain piece of medical equipment can vary widely depending on the supplier from which it is purchased and the type of contract a purchaser may have, the Access Board is focusing on the MSRP. The prices reported here are likely higher than the actual prices the MDE purchasers would pay, because purchases typically pay less than MSRP, due to special sale, volume discount, or other reasons. The information the Board collected, including links to the public websites where the Access Board obtained the product and price information is available in the *2022 Review of MDE Low Heights and MSRP. See Access Board Review of MDE Low Height and MSRP,* dated Dec. 5, 2022, *available at https://www.regulations.gov/docket/ATBCB-2023-0001.*

The Board relied on the suppliers' and manufactures' websites for its information collection, including photographs, schematics, and other specification lists and descriptions provided by the manufacturer or supplier online. The Board did not directly contact any manufacturers or suppliers to discuss their products.

Adjustable Height Exam Tables

The Access Board reviewed 28 adjustable exam tables currently on the market, 21 of which meet the current requirement with low heights within the 17-to-19-inch range. Of these 21 exam tables, five have a low height of 19 inches and an MSRP range of $5,923.01 to $12,74 2.00, or an average cost of $8,290.40; 16 exam tables have a low height of 18 inches and a MSRP range of $2,127.08 to $14,144, or an average cost of $4,635.11; and one exam table has a low height of 15.5 inches and a MSRP of $10,644. The other seven exam tables have low heights between 20 to 27 inches, falling outside of the current low transfer height requirement and have a MSRP range of $3,114.82 to $6,699.42, or an average cost of $4,173.33. The Board also reviewed 18 fixed heights exam tables with a height range of 27 to 33 inches and a MSRP range of $548.90 to $3,966.38, with an average cost of $1,505.07.

In comparing the average MSRP of these adjustable exam tables, we found the difference between the one exam table that currently reaches below 17 inches and the average cost of exam tables in the 18-to-19- inch range to be a $5,138.58 difference. It would be an additional $1,332 if comparing the 15.5-inch exam table, to exam tables that were adjustable but outside of the current MDE Standard low height range.

In comparing the costs of these exam tables it is important to note that the Board did not evaluate the exam tables to determine if they comply with the other provisions of the MDE Standards, and given the large range of cost for exam tables within the 18-to-19-inch range ($2,127.08 to $14,144), it is difficult to ascertain the actual specific cost of moving from a low height range of 17 to 19 inches to a single specification of 17 inches. Additionally, the Board believes that with this NPRM, other manufacturers will produce tables that reach a low height of 17 inches, which will cause the cost to decrease, as we saw an increase in lower exam table transfer heights since the promulgation of the original MDE Standards in 2017.

Adjustable Height Exam Chairs

The Board also reviewed specialized adjustable height exam chairs. Specifically, Obstetrics and Gynecological (OB–GYN) chairs, phlebotomy chairs, podiatry chairs, optometry/ophthalmology chairs, and dental chairs. None of the chairs other than the dental chairs met the requirement for a 17-inch low transfer height. Consequently, for those chairs, we were not able to determine the approximate additional cost per unit that would be required to comply with this proposed rule.

The Access Board reviewed three OB/GYN chairs, one of which has a low height of 22 inches and a MSRP of $3,450, and two which have a low height of 18 inches and 18.5 inches and a MSRP range of $3,972.67 to $5,470, with an average cost of $4,721.34. The Board also reviewed six fixed height OB–GYN chairs, finding a height range of 31 to 33 inches and a MSRP range of $543.82 to $2,624.08, with an average cost of $1,554.54.

The Board reviewed 12 phlebotomy chairs, two of which have low heights of 18 and 18.5 inches with a MSRP range of $1,199 to $2,249, and an average cost of $1,724. The other ten phlebotomy chairs have low heights from 20.25 inches to 22 inches and a MSRP range of $1,474 to $2,959, with an average cost of $2,05.64. The Board also reviewed 16 fixed height phlebotomy chairs, finding a height range from 18 to 26 inches with a MSRP range of $500 to $3,015.49, with an average cost of $1,432.98.

All 16 dental chairs that the Access Board reviewed have a low height at 19 inches or lower. Three of the chairs have a low height from 18 to 19 inches; however the Board was only able to obtain the cost for one of these chairs, which is a refurbished price at $3,568. The other 13 chairs have a low height from 13.5 inches to 17 inches, with five having a low height below 14 inches. The Board was only able to ascertain an MSRP for six of these 13 chairs, which have an MSRP range from $5,598.00 to $9,490, with an average cost of $7,492.95. It is difficult to compare costs between these sets of dental chairs, as the only cost information the Board was able to obtain for a chair at 18 inches was a refurbished cost. However, based on the fact that the vast majority of dental chairs low height was well below 17 inches and the other differences in these chairs, low height doesn't appear to be a significant driver of cost difference for dental chairs.

The Access Board reviewed five podiatry chairs, four of which have a low height between 18 and 19 inches. For three of these podiatry chairs the Board was able to ascertain a MSRP range of $8,063 to $15,241.38,[3] and an

[3] The Board was unable to obtain a MSRP for the UMF Power Podiatry Chair, Model number 5015.

average cost of $11,534.49. The other podiatry chair has a low height of 24 inches and a MSRP of $4,995.

Finally, the Board reviewed 11 optometry/ophthalmology chairs, all of which fall outside the current low height range. The seat height of these chairs ranged from 19.75 to 23 inches; the MSRP range was from $4,200 to $10,352; and the average cost was $6,073. However, the Board notes that since the original rulemaking a new type of optometry/ophthalmology chair has entered the market, which allows the examination chair to spin out of the way to permit patients in wheelchairs to move up to and use the equipment while remaining in their personal chairs. This examination chair with the accompanying stand for the equipment is $8,900, the chair alone is $4,650. This specific chair also provides a headrest, movable armrests and a chair the moves up and down and reclines, but the Board was unable to determine the low height. The Board acknowledges that for examinations where transfer is not necessary for a complete and accurate examination, such as an eye examination, there is a benefit to allowing patients to remain in their wheelchairs and avoid any potential for injury that accompanies transfer. In this situation the equipment would also need to meet M303, the requirements for diagnostic equipment used by patients seated in a wheelchair. Enforcement authorities would need to address applicable specifications in the scoping of an enforceable rule for dual use equipment that allows patients either to remain in their wheelchairs or to transfer to the examination chair. However, one possibility is to exempt MDE from the low transfer height requirement where transfer is not required for examination.

VI. Low Transfer Height

Obtaining medical diagnostic care is imperative for everyone, including people with disabilities, and the first step of obtaining adequate medical care is being able to transfer onto the MDE for examination. Historically, MDE has been, and continues to be, inaccessible to the vast majority of people in wheelchairs, as commenters have noted throughout the original MDE rulemaking, inaccessible equipment can lead to misdiagnosis and inability to access care or even basic exams. In response to the Board's call for comments on Dr. D'Souza's Report, a manufacturer of examination tables explained that over 60 percent of the examination tables in exam rooms today still have a fixed height of 32-inches. The Board determined early on in the original MDE rulemaking process that specifying an adjustable height transfer surface with at least six different height options (high height, low height, and 4 intermediate heights) would best be able to encompass the largest percentage of wheelchair users that are able to independently transfer. While we know some users are unable to independently transfer, those who are able should not be hindered by the height of the MDE. In this NPRM, the Board has determined that the low height of this adjustable height transfer surface should be 17 inches.

Multiple commenters, supportive of both 17 and 19 inches as a low transfer height, reference the transfer heights for fixtures in the built environment in the Board's Americans with Disabilities Act Accessibility Guidelines (36 CFR part 1191). However, the low transfer height specification for MDE is uniquely different from the specifications for transfer heights that the Access Board has instituted for the built environment. In the built environment, the Board has required that fixtures such as water closets (toilets), shower and bathtub seats be installed within a range of 17 to 19 inches for the height of these fixed elements to provide access for transfer to people with disabilities. *See* 36 CFR part 1191, appendix D, 604. This is not comparable to MDE, as these fixed elements only provide one height for transfer, so in determining that height, the Board had to specify a range for a static height that would effectuate transfer for the majority of users. With MDE and the ability to have 6 different transfer points, the goal is to accommodate all people with disabilities who are able to effectuate an independent transfer. As explained above in Dr. D'Souza's Report, if the Board was to adopt a low height of 19 inches, then between 39 to 42 percent of wheelchair users would not be able to effectuate a level transfer. However, by providing a low height of 17 inches, with at least five other heights between 17 and 25 inches, the adjustable height transfer surface should be able to accommodate at least 95 percent of wheelchair users who can independently transfer.

When the Board initially undertook this rulemaking, there was no MDE on the market with a height lower than 19 inches, and most of what was on the market was well above 19 inches. *See* Final Regulatory Assessment, (December 2016) *available at https://www.access-board.gov/files/mde/mde-assessment.pdf.* Since 2016, the market has changed. More examination tables and chairs provide a low-height within the current range of 17 to 19 inches, many in the 18-to-19-inch range. There is also an examination table currently on the market that provides a 15.5-inch low transfer height. Finally, the vast majority of dental chairs on the market have a low transfer height at or below 17 inches.

Based on the findings of Dr. D'Souza's report and the other research discussed herein, as well as the changes to the market since the issuance of the MDE Standards in 2017, the Board has decided to propose a low transfer height of 17 inches. The Board expects that the market will continue to progress to low transfer heights and believes that at the time of any adoption by any enforcement authorities if a specific exception is needed for a specific regulated party, that enforcement authority could do so at that time. Additionally, enforcement authorities could address any lack of available equipment on the market by utilizing the exception already provided within the MDE Standards (M201.2) or could propose a delayed or phased-in effective date for the low height transfer position.

VII. Regulatory Process Matters

A. Regulatory Planning and Review (Executive Orders 12866 and 13563)

The Access Board has examined the impact of this notice of proposed rulemaking under Executive Orders 12866 and 13563. These Executive Orders direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). This NPRM is a significant regulatory action as it raises a novel legal or policy issue within the meaning of Executive Order 12866. *See* E.O. 12866 § 3(f), 58 FR 51735 (Oct. 4, 1993) (defining ''significant regulatory action'' as, among other things, regulatory actions that has an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities, or raise novel legal or policy issues).

This proposed rule does not impose any incremental costs. Unlike many of the Access Board's other rulemakings that provide minimum guidelines which enforcement agencies must adopt as minimum standards for accessibility, Section 510 of the Rehabilitation Act does not require any enforcement

agency to adopt these technical criteria as minimum standards or at all. Additionally, the Access Board has not provided any scoping provisions, as the Board does not have the authority to determine who should comply with these provisions or how many of each particular type of medical diagnostic equipment would need to comply in any given facility. Therefore, because the MDE Standards are more akin to technical guidance, even if they are subsequently adopted by another Federal agency, that agency would have the ability to make changes to any part of the technical criteria as deemed necessary or appropriate (*e.g.,* as the result of conducting a cost/benefit analysis) and would be required to undertake its own regulatory assessment before issuing enforceable Standards. Finally, this NPRM is restricted to one provision regarding the low transfer height, which was already set at the range of 17 to 19 inches, in this NPRM we are proposing to change that to a single specification of 17 inches. In the final regulatory impact analysis (FRIA 2017) for the MDE Standards issued in 2017, the Board explained that it was unable to estimate what costs (if any) manufacturers, providers, or others would incur as a result of the rule, or what level of social benefits would be accrued. *Available at https://www.access-board.gov/files/mde/mde-assessment.pdf.* Instead, that FRIA provided a brief overview of commonly used MDE in the current U.S. market to give a sense of how the technical requirements in the MDE Standards were or were not met among products being sold. *Id.* The FRIA 2017 analyzed the potential costs and benefits of the MDE Standards from a qualitative perspective. The change from a range of 17 to 19 inches to one specification would not have changed the analysis in the original FRIA, nor does the Access Board believe that finalizing this provision with a specification within the already proposed range would have an annual effect on the economy of $100 million.

The benefits of providing accessible MDE were well documented throughout the original MDE rulemaking process, including the extensive explanation in the Final Regulatory Analysis (December 2016). *Available at https://www.access-board.gov/files/mde/mde-assessment.pdf.* These arguments continue to be valid in 2022, as noted above, 60 percent of examination rooms still provide only a fixed-height table which is completely inaccessible to a person in a wheelchair.

In 2020, the National Council on Disability (NCD) issued a report titled Enforceable Accessible Medical Equipment Standards—A Necessary Means to Address the Health Care Needs of People with Mobility Disabilities. *Available at https://ncd.gov/publications/2021/enforceable-accessible-medical-equipment-standards.* In this Report, NCD describes the difficulty people with mobility disabilities still face in trying to access medical care. NCD explains that ''[a]dults with physical disabilities are at higher risk of foregoing or delaying necessary care and having unmet medical, dental, and prescription needs compared to adults without disabilities. Lack of timely access to primary and preventive care can result in the development of chronic and secondary conditions as well as exacerbation of the original disability condition itself, resulting in poorer health outcomes. Of the 61 million people with disabilities in the United States, more than 20 million people over the age of 18 years of age have a disability that limits their functional mobility; this can pose challenges to accessing standard medical diagnostic equipment.'' Id. at 13. Further, NCD explains that ''[i]f patients are not transferred to an examination table, when it is clinically appropriate, it may be difficult if not impossible to conduct a comprehensive examination, which may lead to missed or delayed diagnosis.'' Id. at 17. NCD explains, and the Access Board concurs, that accessible MDE not only benefits the quality of care of patients with disabilities, but also impacts ''the occupational health and safety of health care workers, especially nurses and nursing assistants.'' Id. at 19. NCD notes that research is showing a relationship between musculoskeletal injuries and workers' compensation claims for health care professionals and safe patient handling, ''due in part to the overreliance on manual transfers to inaccessible equipment.'' Id.

While there are many provisions within the MDE Standards which address all aspects of the equipment, including the requirement for the ability to use a lift with the MDE (M301.4), to ensure that a person is able to be examined on the diagnostic equipment, it is imperative that the low transfer height selected provide access to independent transfers to the largest percentage of people who use wheeled mobility devices that are capable of such a transfer. Independent transfer is safer for the patient and provides a safer environment for the health care provider in reducing the risk of injury during an assisted transfer.

As explained above in Dr. D'Souza's Report, if the Board was to adopt a low transfer height of 19-inches, then between 39 to 42 percent of wheelchair users would not be able to effectuate a level transfer. However, by requiring a low height of 17 inches and high height of 25 inches and at least four other intermediate heights in between, the adjustable height transfer surface should be accessible to and usable by almost all (95 percent) of wheelchair users that can independently transfer.

The MDE FRIA 2017 reviewed the overall cost of MDE on the market but did not address the incremental cost of each provision. During our information collection for this NPRM, we again looked at the overall cost of the MDE and also assessed the low transfer heights of the respective MDE; however there were other differences in the MDE, beyond just a lower transfer height, so we are unable to attribute all of the cost difference to simply a lower transfer height. For examination tables, we saw a wide range in the adjustable table market, for tables with a low height of 18 to 19 inches, we saw a MSRP range of $2,127 to $14,144. Currently, on the market there is one examination table which reaches a low transfer height below 17 inches, the Midmark 626 Barrier-Free examination chair, which reaches a low height of 15.5 inches and has an MSRP of $10,644. Over 75 percent of the adjustable examination tables the Access Board reviewed have a low height of 18 to 19 inches, and 50 percent of those are at 18 inches. Currently, the Board is unable to determine the incremental cost for these manufacturers to lower the low height of the transfer surface from 18 to 17 inches or from 19 to 17 inches.

Question 2. The Board seeks additional information regarding the estimated cost of modifying current examination tables that have a low transfer height of 18 or 19 inches in order to comply with the 17-inch low transfer height requirement, or, if it is not possible to modify existing MDE, the difference in the cost of manufacturing MDE with a low transfer height of 18 or 19 inches and the cost of manufacturing MDE that meets the 17-inch low transfer height.

Question 3. The Board seeks additional information regarding the estimated cost of modifying current examination chairs, specifically phlebotomy, OB–GYN, podiatry, and optometry/ophthalmology chairs, that have a low transfer height of 18 or 19 inches in order to comply with the 17-inch low transfer height requirement, or, if it is not possible to modify existing MDE, the difference in the cost of manufacturing MDE with a low transfer height of 18 or 19 inches and the cost

of manufacturing MDE that meets the 17-inch low transfer height. The Board also seeks information about whether transfer to a phlebotomy chair would be necessary, or whether procedures can be performed on patients while they remain in their wheelchairs.

Question 4. How much time would manufacturers need to be able to develop a sufficient number of examination chairs (other than dental chairs) and tables with a minimum low transfer height of 17 inches to meet market demand? How long will it take the market to adjust so that prices for examination tables and chairs with a minimum low transfer height of 17 inches are comparable to those that are 18 and 19 inches? Does this length of time, if any, vary depending on the specialty in which the equipment is used?

Question 5. Are there other resources, data, or information the Board should consider with respect to its proposed minimum low transfer height requirement of 17 inches?

The Board asserts that the benefits provided to the millions of Americans that use mobility devices and medical professionals and caregivers assisting those individuals transfer outweighs the potential costs of requiring a low transfer height of 17 inches for medical diagnostic equipment. Specifically, the Board finds that there is a significant need for accessible medical diagnostic equipment and that the safety of both the patient and caregiver are affected by ensuring as many individuals as possible that are capable of independent transfer are provided the opportunity to effectuate that transfer with a height of medical diagnostic equipment that is level to their current mobility device. These benefits, which include the health care cost savings from preventing injuries to the patient and health care worker outweigh the costs to comply with the proposed 17-inch low height provision, especially considering the significant increase of MDE that currently attains a lower transfer height than even five years ago; However, as noted above, the Access Board is unaware of who would incur these potential costs and to what extent, based on the structure of this rulemaking. Additionally, the Access Board expects that when rulemaking agencies propose to enforce the MDE Standards, they will carry out regulatory assessments that provide specific cost and benefit estimates relevant to their rules.

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.

C. Federalism (Executive Order 13132)

The Access Board has evaluated this notice of proposed rulemaking in accordance with the principles and criteria set forth in Executive Order 13132. We have determined that this action will not have a substantial direct effect on the States, the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government, and, therefore, does not have federalism implications.

D. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (codified at 2 U.S.C. 1531 *et seq.*) (''UMRA'') generally requires that Federal agencies assess the effects of their discretionary regulatory actions that may result in the expenditure of $100 million (adjusted for inflation) or more in any one year by the private sector, or by state, local, and tribal governments in the aggregate. The MDE 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.

F. Congressional Review Act

This notice of proposed rulemaking is not a major rule within the meaning of the Congressional Review Act (5 U.S.C. 801 *et seq.*)

List of Subjects in 36 CFR Part 1195

Health care, Individuals with disabilities, Medical devices.

For the reasons stated in the preamble, and under the authority of 29 U.S.C. 794f, the Board proposes to amend 36 CFR part 1195 as follows:

PART 1195—STANDARDS FOR ACCESSIBLE MEDICAL DIAGNOSTIC EQUIPMENT

■ 1. The authority citation for part 1195 continues to read as follows:

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

■ 2. Amend appendix to part 1195 by:
■ a. Revising M301.2.1;
■ b. Removing M301.2.2;
■ c. Revising M302.2.1; and
■ d. Removing M302.2.2.

The revisions read as follows:

Appendix to Part 1195—Standards for Accessible Medical Diagnostic Equipment

* * * * *

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

* * * * *

M301.2.1 * * *

A. A low transfer position at a height of 17 inches (430 mm);

* * * * *

M302 Diagnostic Equipment Used by Patients in Seated Position

M302.2.1 * * *

A. A low transfer position at a height of 17 inches (430 mm);

* * * * *

Approved by vote of the Access Board.

Christopher Kuczynski,

General Counsel.

[FR Doc. 2023–10827 Filed 5–22–23; 8:45 am]

BILLING CODE 8150–01–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 42

[Docket No.: PTO–P–2023–0024]

Request for Comments Regarding the Motion To Amend Pilot Program and Rules of Practice To Allocate the Burdens of Persuasion on Motions To Amend in Trial Proceedings Before the Patent Trial and Appeal Board

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Request for comments.

SUMMARY: The United States Patent and Trademark Office (USPTO or Office) currently implements a pilot program for motion to amend (MTA) practice and procedures in trial proceedings under the America Invents Act (AIA) before the Patent Trial and Appeal Board (PTAB or Board). The USPTO seeks public comments on whether the MTA Pilot Program's procedures should be