American College of Radiology

July 24, 2023

Submitted electronically via regulations.gov

Office of General Counsel
U.S. Access Board
1331 F Street, NW, Suite 1000
Washington, DC 20004-1111

Re: Docket No. ATBCB-2023-0001; 88 FR 33056 -- Standards for Accessible Medical Diagnostic Equipment; Comments of the American College of Radiology

The American College of Radiology (ACR)—a professional organization representing more than 41,000 radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists — appreciates the opportunity to comment on the Architectural and Transportation Barriers Compliance Board's notice of proposed rulemaking (NPRM) on standards for accessible medical diagnostic equipment related to the low-height specifications for transfer surfaces. As an organization with a longstanding commitment to quality and safety in medical imaging, and as vigorous advocates of access to imaging services, we recognize the importance of ensuring appropriate access to diagnostic equipment for all patients. We are concerned, however, that the proposed standard represents a 'one size fits all' approach to diagnostic equipment table height that does not reflect the diversity in design and purpose, engineering complexities, or clinical practices applicable to diagnostic imaging equipment. We believe the proposed table height standard as applied to advanced diagnostic imaging (ADI) equipment could impede, rather than improve, access to quality imaging services for all patients. We therefore urge the Access Board to exempt from the proposed table height standards ADI equipment that meets already-developed usability standards specific to medical diagnostic equipment.

Importance of Diagnostic Imaging

Although the work of the Board presumes the importance of medical imaging, it is worth emphasizing that medical imaging is a critical component of medical care. Advances in medical imaging have improved disease screening and diagnosis for a range of acute and chronic conditions, allowing many diseases to be identified early, when they can more readily be treated successfully and with less morbidity. Medical imaging can improve health care outcomes, reduce the use of more invasive or unnecessary procedures, diminish patient recovery times, and save significant resources within the health care system.

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Independent Access to Diagnostic Imaging Equipment

While we understand that the Affordable Care Act's charge to the Board was the development of standards that would allow "independent entry to, use of, and exit from the equipment by individuals with disabilities to the maximum extent possible", we note that medical imaging equipment is not intended to be accessed independently by patients, regardless of whether the patient has a disability. For every diagnostic imaging procedure, a trained technologist(s) and if necessary, physicians, assist the patient in safely accessing the equipment and helps to place and position the patient to ensure a diagnostic quality image. While maximizing patient comfort is always a key consideration, safety, and the ability to achieve a diagnostic quality image for all patients, must not be sacrificed.

As an example, MRI equipment provides unique challenges with respect to direct transfer from a patient's personal wheelchair. MR scanners use extremely powerful magnets. Metal that is ferromagnetic – including ferromagnetic metal-containing wheelchairs, gurneys, etc. – are actually dangerous to patients and staff in proximity to these magnets and are not allowed in the exam room at any time. Therefore, for safety reasons, the standard of practice for patient access to MRI equipment involves sequential transfer utilizing MR-compatible gurneys (see ACR Manual on MR Safety Version 1.0 (2020). Use of adjustable gurneys that elevate to the height of the actual imaging device is a far more reasonable approach to ensuring access to ADI equipment than redesign of the equipment itself, especially when sequential transfer aligns with safety-driven standards of practice.

As the Board considers comments submitted in response to this NRPM, and as implementing bodies contemplate enforcement of the Board's standards, we urge recognition of the fact that independent access is not the equivalent of "full and equal access" to health care services and facilities. We also note that based on the diversity of patient needs, there is no single standard that will be ideal for every patient. Indeed, transcripts of the deliberations preceding this rulemaking show variability in patient preferences and/or needs with respect to exam table height.

Complexities in the Design of ADI Equipment Warranting Special Consideration

ACR acknowledges the tremendous amount of work the Board undertook in developing its medical diagnostic equipment standards and we appreciate the Board's willingness to engage stakeholders in its processes. ACR was very involved in the various forums and committee meetings more than a decade ago that led to the development of the draft standard. Among the repeating themes of those meetings was the variety, complexity, engineering challenges and the unique considerations involving medical imaging devices, particularly with respect to computed tomography (CT), MRI, and diagnostic nuclear medicine equipment. Testimony and statements from manufacturers of this imaging equipment highlighted the technological constraints of lowering the table height without impairing functionality. We are disappointed that the NPRM does not acknowledge the multitude of variables that go into the design of advanced diagnostic medical equipment or make distinctions between complex medical imaging equipment and basic patient examination tables/gurneys. Seemingly simple changes to table heights, even when technologically possible, would almost certainly generate additional quality and safety concerns not envisioned by the Board. Given the complexity of advanced diagnostic imaging equipment, any new standards must be carefully vetted by the various stakeholders (such as manufacturers, physicians, medical physicists, technologists, medical suite architects, hospital administrators, and regulatory agencies, including the Food and Drug Administration and the Occupational Safety and Health

Administration) to avoid conflicting standards and requirements that could jeopardize the industry and ultimately patient safety and access to imaging.

We respectfully request reconsideration of the input provided by medical imaging equipment manufacturers on this topic and request that the slides and transcripts of the public meetings associated with this rulemaking be incorporated into the public docket for future consideration by any potential enforcement agency or entity.

Regulatory and Standardization Considerations Specific to Diagnostic Imaging Devices

As noted, medical imaging devices, and the clinical imaging suites in which they are housed, are highly complex and subject to a plethora of state, federal and international standards and regulations. Although we recognize the Board has no independent authority to enforce the proposed table height standards, we believe it should ensure that any accessibility standards it adopts fully account for the structural, functional, fiscal, and regulatory constraints that contribute to the design characteristics of the equipment, and consider quality and safety for patients in addition to independent access.

As the Board heard in oral testimony during each of the public meetings, significant effort has been undertaken and great strides have been made in meeting accessibility needs of the full range of patients who rely on diagnostic imaging equipment. In response to feedback from clinicians, technologists, and patients, much of the equipment used in medical imaging today has been designed with patient accessibility in mind and includes features to accommodate individuals with disabilities or other unique attributes that present accessibility challenges. These usability standards have evolved over time through an ongoing feedback loop involving real world clinical experience that manufacturers seek to address, utilizing the expertise of biomedical engineers and other content experts.

When considering how best to accommodate the needs of the full gamut of patients that rely on diagnostic imaging, it is important to recognize the diversity of the patients we serve, and the clinical environment in which we serve them. In most cases, imaging equipment must accommodate patients of all ages and sizes from very small children to extremely large adults. Likewise, there is great variability in the nature and level of assistance needed, even among individuals who are not differently abled. This is especially true considering the variety of situations in which patients are subjected to medical imaging studies. This includes sedated, unconscious and seriously ill patients; critical care, emergency room and trauma cases; patients experiencing extreme acute or chronic pain, and patients with temporary or permanent disabling or debilitating conditions. Technologists undergo extensive training to maximize accessibility and comfort for patients with a variety of disabilities and under a variety of conditions.

Overlaying the need to ensure accessibility for all patients who require imaging, and the variety of situations in which imaging is required, are a myriad of similarly critical priorities, standards, and regulatory requirements that equipment manufacturers must meet. Additional (sometimes competing) priorities include the safety and effectiveness of the device; the ability of the operator/technologist to use and access the device and assist the patient; ergonomic, health and safety considerations of the operator/technologist; and, most importantly, the ability of the equipment to produce diagnostic quality images, to name a few. In certain circumstances of critical care/injury, speed in access is essential and changing equipment specifications could impact that care.

Standards that manufacturers must meet include requirements for structural strength; material choice; radiation safety for the patient, operator, and the public; electrical safety; positional accuracy requirements; usability and human factor standards; and risk mitigation, among others. Apparently simple adjustments to table height requirements could implicate other seemingly unrelated standards for complex ADI systems. As such, ACR believes that already-developed and evolving usability standards specific to medical diagnostic equipment will better ensure access for all patients than will table height standards developed outside this real-world context and feed-back loop.

Incremental Cost Considerations

Notwithstanding the NPRM's statement that the proposed rule does not impose any incremental costs, as enforcement agencies would need to adopt the proposed standards before costs would be incurred, we believe the potential fiscal impact needs to be addressed if the proposed rule is adopted. An important part of accessibility to certain patient care services is ensuring the economic feasibility of accommodating, upgrading/purchasing, and maintaining equipment that meets the specified standards.

It is important to appreciate that all costs are ultimately passed down to facilities and patients in need of imaging with these medical devices. Concern over costs could also be a major factor in the selection of medical equipment by providers of imaging services, as well as a consideration as to whether or not providers choose to offer modalities for which the cost of providing the services are not recoverable. As noted during prior testimony to the Board, it is important to ensure that those facilities that have already expended significant resources in an effort to maximize user-accessibility are not unduly disadvantaged for having done so.

We note that most facilities that provide imaging services offer multiple imaging modalities and thus would incur a cumulative cost far greater than the cost of acquiring any single piece of imaging equipment. Moreover, in many cases, the medical facilities that house the imaging devices would need to undergo substantial renovation to accommodate different design configurations. The cost of such updates would undoubtedly be substantial, particularly to update rooms and architectural structures that have been built around specific equipment, and those requiring costly shielding to address radiation protection or radiofrequency issues.

Thank you in advance for your consideration of these comments. Please contact Gloria Romanelli, Esq., ACR Senior Director of Government Relations, at gromanelli@acr.org, if you have questions concerning this submission or if we can otherwise be of assistance.

Sincerely,

Jacqueline A. Bello, MD, FACR
Chair, Board of Chancellors
American College of Radiology