

December 15, 2022

Submitted via Regulations.gov

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

**Re: (Docket No. FDA-2022-D-1061; 87 FR 64057) Select Updates for the Breakthrough Devices Program
Guidance: Reducing Disparities in Health and Healthcare; Comments of the American College of Radiology**

The American College of Radiology (ACR)— a professional association representing more than 41,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists— appreciates the opportunity to respond to the draft guidance from the U.S. Food and Drug Administration (FDA) addressing “Select Updates for the Breakthrough Devices Program Guidance: Reducing Disparities in Health and Healthcare” (Docket No. FDA-2022-D-1061), published in the *Federal Register* on October 21, 2022 (87 FR 64057). The American College of Radiology strongly supports technological innovation and FDA’s key role in providing reasonable assurance of the safety and effectiveness of medical devices used in radiology patient care.

The FDA’s Breakthrough Devices Program enables prioritization of agency resources for expediting the existing pathways to market for certain medical device and device-led combination products while preserving the statutory standards for premarket approval, 510(k) clearance, and De Novo marketing authorization. Recently, the program has been referenced within certain technology payment concepts, including the rescinded Centers for Medicare and Medicaid Services’ final rule regarding “Medicare Coverage of Innovative Technology and Definition of ‘Reasonable and Necessary.’” It is understood that a reworked CMS proposed rule addressing coverage of innovative medical devices is planned for the near future. Consequently, we anticipate the possibility of enhanced public interest in the Breakthrough Devices Program as it relates to artificial intelligence/machine learning (AI/ML)-enabled software as a medical device (SaMD).

FDA proposal on reducing healthcare disparities and promote health equity: The FDA proposed to update the “Introduction” section of the Breakthrough Devices Program guidance to state that the program may *expedite the availability of certain devices that meet the statutory designation criteria and benefit populations impacted by health and/or health care disparities, thereby promoting and advancing health equity*. The FDA also proposed to update guidance Section III.B.3 “Additional Considerations” that FDA intends to *consider technologies and device features that could allow for improved accessibility when evaluating if there is a reasonable expectation that the device may provide for more effective treatment or diagnosis as compared to the current standard of care*.

ACR response: The ACR supports the FDA proposal to consider the device’s impact on reducing healthcare disparities and promoting health equity. The ACR previously recommended that FDA consider prioritizing Breakthrough Device designations for radiology AI/ML SaMD intended for use with pediatric patient populations. Our understanding is that children are likely underserved by radiology AI/ML SaMD in the current marketplace, and that further innovation and transparency in this area is desirable to facilitate equitable radiology care across age groups. We recommend that the FDA’s Breakthrough Devices Program be leveraged, in part, to help address this issue.

FDA proposal to share breakthrough device designation already made public by the sponsor: Breakthrough Device designations are generally non-public unless disclosed by the sponsor, or until the device benefitting from the program has completed FDA’s premarket process. In the proposed guidance update for Section III.C “Designation Review Process,” FDA proposed to *publicly disclose a Breakthrough Device designation that has been previously publicly disclosed or acknowledged by the sponsor of the Breakthrough Device designation request. Additionally, once a designated Breakthrough Device obtains marketing authorization for an indication consistent with its Breakthrough Device designation, FDA intends to publicly disclose its Breakthrough Device designation status for that indication for use.* However, FDA will continue to decline to publicly disclose Breakthrough Device designations of products under review that have not been voluntarily publicized by sponsors.

ACR response: As CMS considers establishing coverage of “new and emerging technology in a parallel review program” with the FDA¹, the Breakthrough Device designation may have immediate post-market public health and payment policy implications. As such, the ACR supports enabling any and all appropriate public transparency allowed by the statute as early as possible in FDA’s review processes. We believe it is crucial for provider and patient stakeholders to be apprised of Breakthrough Device designations if such designations will be used by CMS or other payers to help determine coverage/payment for medical use of innovative devices.

To that end, the ACR recommends that FDA ask sponsors to voluntarily disclose Breakthrough Device designations at the earliest opportunity. We further recommend that FDA consider the public notification plans of sponsors when vetting requests for Breakthrough Device designations—i.e., proactive transparency by sponsors should be appropriately incentivized.

As always, the ACR welcomes continued communications with the FDA on all issues related to radiology devices, including AI/ML SaMD. Please contact Gloria Romanelli, JD, ACR Senior Director of Legislative and Regulatory Relations and Legal Counsel, Quality and Safety, at gromanelli@acr.org; or Michael Peters, ACR Senior Government Affairs Director, Regulatory Policy, at mpeters@acr.org, for follow-up information.

Sincerely,



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

1. Fleisher LA, Blum JD. A Vision of Medicare Coverage for New and Emerging Technologies—A Consistent Process to Foster Innovation and Promote Value. *JAMA Internal Medicine*. 2022 Oct 12.