American College of Radiology

July 31, 2023

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

Re: (FDA-2022-D-2628) Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions; Comments of the American College of Radiology

The American College of Radiology (ACR)—a professional association representing over 41,000 diagnostic radiologists, interventional radiologists, nuclear medicine physicians, radiation oncologists, and medical physicists—appreciates the opportunity to comment on the draft guidance, "Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions," published by the Food and Drug Administration (FDA) in the April 3, 2023, *Federal Register* (FDA-2022-D-2628; 88 FR 19648). The ACR supports FDA's ongoing efforts to advance safe and effective AI/ML innovations in radiology patient care pursuant to the agency's 2021 "AI/ML-Based Software as a Medical Device (SaMD) Action Plan."

Background

The draft Predetermined Change Control Plan (PCCP) concept would apply to an AI/ML-enabled device software function (ML-DSF) intended to be modified in a manner that would otherwise require a PMA supplement, De Novo submission, or new 510(k) notification. The PCCP would consist of additional documentation included and reviewed by FDA staff in the initial marketing submission. The purpose is to enable limited ML-DSF modifications to be implemented without additional marketing submissions to FDA, provided such ML-DSF modifications adhere to the PCCP. The PCCP would describe (1) planned future ML-DSF modifications; (2) development, validation, and implementation methodologies for those modifications; and (3) associated benefits, risks, and risk mitigations.

The types of modifications appropriate for PCCP flexibility would be limited in scope. FDA noted these would include (1) modifications related to quantitative measures of ML-DSF performance specifications; (2) modifications related to device inputs to the ML-DSF (e.g., updated input device models/versions); and (3) limited modifications related to the device's use and performance (e.g., for use within a specific subpopulation, such as with pediatric patients). FDA noted that modifications made to an ML-DSF that are not specified in, or implemented in accordance with, the FDA-vetted PCCP will likely require new marketing submissions.

ACR Recommendations

The ACR generally agrees that FDA-authorized PCCPs, as detailed in the draft guidance, would provide developers flexibility to make planned changes to their ML-DSF solutions. This would allow pre-authorized improvements to expeditiously benefit radiologist end-users and their patients, such as enhancing pediatric access to safe and effective AI/ML innovations. We believe the recommendations

detailed below would provide appropriate safeguards and enable successful provider adoption of modified ML-DSF versions.

Recommendation 1 – Qualified End-Users and Feedback Loops for Local Risk Mitigation
Intended end-users of modified ML-DSFs should be qualified to review input data and algorithm recommendations independently. Therefore, the PCCP should not suggest reductions in the qualifications of the end-user, such as non-expert use of a ML-DSF previously intended for physician-expert use. Feedback loops between end-users and device manufacturers help ensure unintended local performance changes are identified and evaluated in a timely, comprehensive manner. Such feedback should include low-risk issues that do not meet 21 CFR §803 (Medical Device Report) criteria.

Recommendation 2 – Monitor Trends and Real-World Performance
Beyond local feedback mechanisms, manufacturers and regulators should have adequate systems in place for monitoring real-world performance changes and trends, both positive and unintended. For example, this approach could include participation in the ACR Data Science Institute (DSI) Assess-AI program (https://www.acrdsi.org/DSI-Services/Assess-AI). Such monitoring data should be accessible to health care facilities and end-users for informing version adoption and patient care decision-making.

Recommendation 3 – Enhance AI Transparency, Including PCCP Local Condition Information
FDA should leverage the PCCP mechanism to enhance AI/ML transparency to ensure that health care facilities and end-users have ready access to actionable information they need to make informed AI/ML acquisition, implementation, and medical use decisions. For the PCCP final guidance, this could include participation in a centralized repository/registry of "local conditions" necessary for provider implementation of improved ML-DSF versions. Local condition data could be publicly accessible via FDA's existing device databases and/or compiled for end-users by medical societies, such as via the ACR DSI's AI Central database (https://aicentral.acrdsi.org/).

The ACR filed comments in Nov. 2021 for the public record of the Oct. 14, 2021, FDA workshop on transparency of AI-enabled medical devices (https://www.acr.org/-/media/ACR/Files/Advocacy/Regulatory-Issues/acr-comments_fda-ai-transparency.pdf). The submission included recommendations to support the availability of data necessary to inform decisions on AI/ML-enabled radiology software devices. Implementation of the ACR's recommendations would help broadly advance AI innovation by empowering radiology providers to seek, acquire, and adopt tools that best suit their patient populations, clinical environments, and input devices/technologies.

The ACR welcomes further communication with FDA staff regarding the advancement of safe and effective radiology AI innovation. Please contact Michael Peters, ACR Senior Government Affairs Director, at mpeters@acr.org with questions.

Sincerely,

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