September 21, 2022

Attn: Afrouz A. Anderson, Ph.D. and Aaron C. Pawlyk, Ph.D.
NIH-NIBIB and NIH-NICHD
9000 Rockville Pike
Bethesda, Maryland 20892

Re: (NOT-EB-22-008) RFI: Inviting comments and suggestions from stakeholders on Pediatric Medical Devices Public-Private Partnership; comments of the American College of Radiology (ACR)

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 comment on the request for information from the National Institutes of Health (NIH) National Institute of Child Health and Human Development (NICHD) and National Institute of Biomedical Imaging and Bioengineering (NIBIB) regarding the future Pediatric Medical Devices (PMD) Public-Private Partnership (PPP). We understand PMD to broadly include various medical technologies and pediatric subspecialty domains; however, **the following comments are specific to artificial intelligence (AI)-enabled software as a medical device (SaMD) for pediatric radiology patients**.

The ACR strongly supports innovation in safe and effective radiology AI SaMD meeting the PMD definition. Despite significant private sector investments in the radiology AI SaMD domain, only a small number of commercially available tools with pediatric-applicable use cases have been designed, tested, and validated for use on pediatric patients (see https://aicentral.acrdsi.org/). The radiology AI SaMD that are commercially available for under-18 age groups are mostly limited to non-interpretive use cases, such as image processing/quantification. Even fewer radiology AI SaMD are primarily or exclusively intended to address pediatric radiology-specific use cases.

Unfortunately, clinical use of radiology AI SaMD for triage, detection, or diagnoses designed for *adult* patients that have not been trained, tested, and validated with *pediatric* datasets could negatively impact pediatric care. For example, medical imaging providers in multi-age practice settings could unwittingly use adult-designed algorithms "off-label" on pediatric patients due to lack of understanding of this shortcoming. Related workflow engine or tool configuration issues are also unlikely to have been configured to avoid this unintended use (e.g., exam code based DICOM routing does not consider/filter by patient age). Additionally, as radiology AI SaMD triage ("CADt") tools currently on the market have yet to be tested and cleared for use on pediatric patients, their exclusive routine use on adult patients could lead to selective case prioritization of the adult cases for interpretation, which may indirectly cause health care inequities between adult and pediatric patient populations.

To that end, the PMD PPP could help address the following pediatric radiology AI areas of need:

- **Enable pediatric imaging data availability** – NIH or PPP partners should support privacy-preserving access to representative pediatric radiology datasets (e.g., via federated data access or similar methods) that can be used for training, testing, and validation of radiology AI PMD.

- **Support validation or re-training of existing (adult) AI SaMD for use on pediatric patients** – NIH or PPP partners should fund third-party validation and testing of radiology AI SaMD previously cleared by the Food and Drug Administration (FDA) to determine the safety and effectiveness of expanded

HEADQUARTERS
1891 Preston White Drive
Reston, VA 20191
703-648-8900

GOVERNMENT RELATIONS
505 Ninth St. N.W.
Suite 910
Washington, DC 20004-2173
202-223-1670

CLINICAL RESEARCH
1818 Market Street
Suite 1600
Philadelphia, PA 19103-3609
215-574-3150

AMERICAN INSTITUTE FOR RADIOLOGIC PATHOLOGY
1010 Wayne Ave., Suite 320
Silver Spring, MD 20910
703-648-8900

applicability to pediatric patients. Many commercially available radiology AI SaMD cover pediatric-applicable use cases but are not yet tested/validated for real-world use on younger patients.

- **Fund new AI PMD research and development** – NIH or PPP partners should support research of radiology AI in general, prioritizing funding of pediatric-inclusive and pediatric-specific innovations. Innovators and private investors are generally disincentivized by the perceived suboptimal return on investment (ROI) for PMD. Radiology AI PMD innovation is similarly stifled by this ROI problem despite significant investment and growth in the AI SaMD industry more broadly. It is important for federal research and regulatory agencies become aware of this reality and prioritize support for new radiology AI PMD research, development, and commercialization.

- **Identify AI PMD payment models and financial incentives** – Centers for Medicare and Medicaid Services and private payer representatives in the PPP should consider appropriate Medicaid payment models and other financial incentives for acquisition of and use of radiology AI PMDs. Doing so may incentivize innovators and investors to pursue development and commercialization of radiology AI PMD.

- **Prioritize regulatory agency review and resources for AI PMDs** – FDA and other relevant PPP regulatory agency collaborators should prioritize internal resources for PMD to expedite review while ensuring safety and effectiveness. One example could be to automatically designate as a breakthrough device in the FDA's Breakthrough Devices Program any submission of an AI SaMD intended for use on pediatric patients.

- **Promote AI transparency** – PPP and regulatory agency participants should promote public AI transparency improvements to provide information about patient data used in the development and testing of FDA-authorized AI SaMD. PPP participants could also explore use of decision support alerts or other types of automatic fail-safes that effectively prevent adult AI SaMD from being used unwittingly by providers on pediatric patients due to radiology workflow, workstation, or platform configurations.

The ACR Data Science Institute (DSI) is comprised of physician and medical physicist leaders as well as other stakeholders who wish to further the development of radiology AI. The DSI includes a Pediatric AI Workgroup focused on advancing innovation in safe and effective pediatric radiology AI. In addition, a separate Pediatrics Panel of the ACR DSI has developed, and is in the process of developing, AI clinical use cases that are especially relevant in the care of pediatric patients with the hope these algorithms will be developed for clinical use. The ACR DSI welcomes further collaboration and communication with the NIH and other PMD PPP participants.

For additional information on ACR's assorted AI-related programs, including its library of interpretive and non-interpretive radiology AI use cases, please visit the ACR DSI website at https://www.acrdsi.org/. For questions about this comment submission, please contact Gloria Romanelli, JD, ACR Senior Director of Government Relations, at gromanelli@acr.ogr; or Michael Peters, ACR Senior Government Affairs Director, Regulatory Policy, at mpeters@acr.org.

Sincerely,

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