March 27, 2020

Don Rucker, MD
National Coordinator for Health Information Technology
Office of the National Coordinator for Health IT (ONC)
U.S. Department of Health and Human Services
330 C Street SW, Floor 7
Washington, DC 20201

Re: Draft 2020-2025 Federal Health IT Strategic Plan; Comments of the American College of Radiology

Dear Dr. Rucker:

The American College of Radiology (ACR)—a professional association representing nearly 40,000 diagnostic radiologists, interventional radiologists, nuclear medicine physicians, radiation oncologists, and medical physicists—appreciates the opportunity to comment on the draft *2020-2025 Federal Health IT Strategic Plan* (the draft plan). The ACR generally supports the goals and objectives described in the draft plan, and we urge federal agencies to consider the following three recommendations during development and implementation of the final iteration of the strategic plan.

Federal agencies should facilitate modernization of medical image exchange

The ACR, Radiological Society for North America (RSNA), and other major organizations and companies have been working collaboratively on a "ditch the disk" initiative to modernize medical image-sharing capabilities across the nation using open application programming interfaces (APIs). Access to medical images can improve quality, reduce radiation exposure, and lower costs by enhancing available information and eliminating duplicative imaging.

The ACR urges federal agencies to work with the private sector to modernize and promote image exchange. Federal agencies can enable the radiology community's work in this area in several ways, such as through the development of a national image-sharing strategy covering provider-to-provider exchange and enabling patient access to medical images via open APIs, incorporation of medical images into the U.S. Core Data for Interoperability (USCDI), requiring image exchange facilitation of health information networks participating in the Trusted Exchange Framework and Common Agreement (TEFCA), and federal funding of research and standards initiatives intended to accomplish the "ditch the disk" objective.

Federal agencies should partner with national physician associations and other trusted third parties to ensure clinical utility, safety, and performance of AI/ML tools

Objective 2a of the draft plan calls for ensuring safe and high-quality care through the use of health IT, and notes that achieving this objective will require the application of technologies such as machine

learning, improved patient matching, patient safety solutions, and mechanisms for data governance and provenance.

Due to the brittle nature of artificial intelligence (AI) algorithms, we feel the deployment of all AI for medical imaging needs to have comprehensive processes to ensure patient safety. There is an urgent need for trusted third party validation and real world performance monitoring of AI-enabled tools, including solutions regulated by the Food and Drug Administration (FDA). Prior to clinical deployment, heterogeneous and large datasets for performance and reader testing are required. Once a model has been deployed in a clinical setting, it must be continuously monitored to detect the effect of any changes in the clinical environment including patient demographics, scanner types, acquisition parameters, and patient comorbidities. To that end, the ACR established its Data Science Institute (DSI) in 2017 to define publicly accessible use cases and corresponding standards for imaging AI, validate and certify algorithms, use connectivity with imaging facilities and advanced clinical data registries to monitor real world performance, and promote safe innovation of imaging AI/ML tools.

We recommend that federal regulatory and research agencies require that AI algorithms deployed in a clinical setting be validated and continually monitored. We recommend collaborations with trusted third party organizations, such as medical specialty societies, that are capable of providing validation and monitoring services to help ensure the clinical utility, safety, trustworthiness, and performance of AI/ML-enabled software.

Federal research agencies should prioritize secure movement of AI/ML models to the data for R&D

The ACR applauds HHS' important progress via implementation of the 21st Century Cures Act of 2016 toward data interoperability and information exchange for patient care uses. However, federal research agencies should also seek to promote and prioritize funding for collaborative partnerships between healthcare providers and the many innovators/developers that need to have patient data made available for AI/ML research and development purposes (i.e., secondary or nonclinical uses of data).

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule and corresponding guidance from the HHS Office for Civil Rights (OCR) define standard requirements for de-identification. These de-identification methodologies have the inherent trade-off of limiting the R&D usefulness of the data. However, the ability to permanently anonymize imaging data and other datasets for secondary uses may become an impossibility in the near future due to advances in AI/ML, reconstruction, and predictive modeling in combination with the ubiquity of voluntarily shared social data. Additionally, due to the commoditization of data useful for AI/ML R&D, developers with fewer resources often must rely on openly published datasets derived from legacy technologies that have been stripped of potentially useful elements. Instead, the most efficient, cost effective, and secure practice may be to move the AI/ML models for R&D purposes to the data, allowing for optimal access to health information while addressing various privacy/security risks.

To that end, the ACR DSI has been working to create a standard interface for moving imaging-related AI/ML to data locally managed by healthcare institutions. This level of access and security would improve algorithm performance, alleviate researchers/developers' financial burden of purchasing and processing data, and ultimately help address the privacy/security risks described in the draft plan. Standard interfaces for moving AI/ML models to the data could also provide a foundation for real world performance monitoring by third party validators and federal regulatory agencies.

As always, the ACR welcomes further dialog with ONC regarding the draft plan and related topics. Please contact Michael Peters, ACR Director of Legislative and Regulatory Affairs, at (202) 223-1670 / mpeters@acr.org with questions.

Sincerely,

Geraldine B. McGinty, MD, MBA, FACR
Chair, Board of Chancellors
American College of Radiology