March 12, 2020

Submitted via Regulations.gov

Russell T. Vought
Acting Director
The Office of Management and Budget (OMB)
725 17th Street, NW
Washington, DC 20503

Re: Guidance for Regulation of Artificial Intelligence Applications

Dear Acting Director Vought:

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 OMB's draft memorandum for the heads of executive departments and agencies titled, *Guidance for Regulation of Artificial Intelligence Applications* (FR Doc. 2020-00261). The ACR and the ACR Data Science Institute (DSI) has collaborated with public health service agencies for the past few years on oversight considerations for artificial intelligence (AI) in medical imaging, and we applaud the U.S. Government's efforts to promote useful, safe, and effective AI innovation.

ACR Comments on Principles for Stewardship of AI Applications

Principle 1: Public Trust in AI

The ACR agrees with OMB that regulatory and non-regulatory approaches must contribute to public trust in AI, and that continued adoption and acceptance will depend on appropriate risk mitigations and performance validation. To that end, we encourage the U.S. government to collaborate with trusted third parties—e.g., national professional associations representing end-users of AI—to establish algorithm validation services, certification statuses, and real world performance monitoring capabilities. These third parties could supplement and inform regulatory agencies while also aiding developers by building public trust in AI applications.

Principle 2: Public Participation

The ACR supports public participation in government processes and transparency/accountability of regulatory agencies, and we agree with OMB that these ideals will continue to be critical for establishing stakeholder trust in the government's oversight of AI applications.

Principle 3: Scientific Integrity and Information Quality

The ACR supports scientific integrity in the federal rulemaking and guidance processes. We agree with OMB regarding best practices for regulatory agencies including "*transparently articulating the strengths,*

weaknesses, intended optimizations or outcomes, bias mitigations, and appropriate uses of the regulated AI applications." "Risks and risk mitigations" should also be added to this list.

Principle 4: Risk Assessment and Management

The ACR agrees with the OMB's general statement that oversight "*approaches to AI should be based on a consistent application of risk assessment and risk management across various agencies and various technologies*;" however, it is important to consider sector- or agency-specific jurisdictional differences and gaps in oversight. For example, in healthcare, only those AI applications that meet the statutory definition of a "medical device" per Section 201(h) of the Food, Drug, and Cosmetic Act are subject to regulation by the U.S. Food and Drug Administration (FDA), while certain types of AI-enabled electronic health record (EHR) technologies and clinical decision support functionalities may be excluded from the medical device definition pursuant to Section 520(o).

In cases where regulatory agencies do not have jurisdiction, voluntary participation in trusted third party validation and certification services could potentially stand in for regulatory oversight. In other cases where AI applications are subject to FDA oversight (or oversight by some other regulatory agency), third party validation/certification or monitoring services could help mitigate or manage risk, and thus supplement the capabilities and alleviate the burdens of pre-market approval/clearance/authorization.

Principle 5: Benefits and Costs

The draft memorandum notes that federal agencies should consider various benefits, costs, and distributional effects before considering regulations for AI applications, and indeed the same principle could be applied to the development of specific AI applications. A major component of the government's regulatory considerations related to AI should include the utility of the AI applications for the intended end-user communities. For example, the ACR DSI has worked with the radiologist community and other stakeholders to define publicly accessible imaging AI use cases for algorithm developers to create marketable solutions of high value to radiologist end-users. The U.S. Government should consider this program and strive to support similar collaborations across healthcare and in other sectors.

To that end, federal agencies should partner with national professional associations representing end-users to determine AI use cases and identify standards and implementation specifications that would enable the development and adoption of in-demand AI innovations. This collaborative approach would ensure that edge cases are not missed, appropriate considerations are made to ensure all relevant data elements are factored, and that regulatory agencies' resources are focused on enabling AI innovations most likely to be adopted and implemented in the real world.

Principle 6: Flexibility

The ACR supports the concept of regulatory agencies implementing performance-based and flexible approaches that can adapt to rapid changes and updates to AI applications while also protecting health and safety. However, such flexibility must not come at the expense of transparency, accountability, public participation in rulemakings and other policy-setting initiatives, or any of the other principles described in OMB's draft memorandum.

Principle 7: Fairness and Non-Discrimination

The ACR agrees that limited training data can introduce unintended bias and decrease the performance of AI models, and we believe it is essential for regulatory agencies to ensure that algorithms intended for a variety of sites, populations, and/or input technologies are trained and/or optimized using appropriately

diverse datasets to ensure model generalizability. It is also important for AI algorithms to be rigorously validated by trusted third parties using validation datasets that are not subsets of the training data. As AI models can evolve in unexpected ways even if developed using robustly diverse datasets, it is also important to monitor AI implementations to ensure that as additional populations of data are introduced, performance is not adversely affected.

Principle 8: Disclosure and Transparency

Principle 8, *Disclosure and Transparency*, should also be applied to premarket review of AI applications. For instance, premarket regulatory approaches should ensure a high level of data traceability and visibility into training data to document the origins and processing of any data used in AI model development. Without a formal documentation process, it may be impossible to reproduce models built from large and unstructured datasets, or to correct future issues by augmenting the data. Moreover, a lack of documentation would hamper regulatory agency oversight and retrospective investigations of AI output errors.

Principle 9: Safety and Security

The ACR strong supports Principle 9, *Safety and Security*, as stated in the draft memorandum. Patient and public safety should be the foremost consideration for AI applications used in healthcare settings. We agree with OMB that regulatory agencies should also consider and anticipate potential cybersecurity risks of AI deployed in the clinical setting, and should work closely with developers to ensure appropriate controls and mitigations are made available to end-users.

Principle 10: Interagency Coordination

The OMB should ensure that interagency coordination is appropriately transparent to public stakeholders, including AI developers and end-users.

ACR Comments on Non-Regulatory Approaches to AI

In addition to the examples described in the draft memorandum of sector-specific policy guidance/frameworks, pilot programs, and voluntary consensus standards, the ACR recommends that federal agencies collaborate with trusted third party organizations to define AI use cases and establish validation/certification and real world performance monitoring capabilities. The example of the ACR DSI program could be followed by other healthcare professional societies and associations representing end-users of AI applications in other sectors.

ACR Comments on Reducing Barriers to the Deployment and Use of AI

Access to Federal Data and Models for AI R&D

The ACR agrees with the example of federal government agencies appropriately releasing datasets and models for AI R&D. However, in certain sectors and domains, the most efficient, cost effective, and secure practice may be to move the AI 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 models to data that is 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 mitigate certain privacy/security risks.

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

Sincerely,

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Chair, Board of Chancellors
American College of Radiology