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David A. Myklegard
Deputy Federal Chief Information Officer.

Christine J. Harada
Senior Advisor, Office of Federal Procurement Policy, Performing, by delegation, the duties of the Administrator for Federal Procurement Policy.

Submitted electronically through regulations.gov.

Re: *Docket ID OMB-2024-0004, "RFI for Responsible Procurement of Artificial Intelligence in Government"*

Dear Mr. Myklegard and Ms. Harada,

On behalf of the AdvaMed Medical Imaging Division and AdvaMed Digital Health Tech, we provide these comments in response to Docket ID OMB-2024-0004, "RFI for Responsible Procurement of Artificial Intelligence in Government."

The AdvaMed Medical Imaging Division represents the manufacturers of medical imaging equipment, including, magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, and imaging information systems. Our members have introduced innovative medical imaging technologies for use by healthcare providers, and they play an essential role in our nation's health care infrastructure and the care pathways of screening, staging, evaluating, managing, and effectively treating patients with cancer, heart disease, neurological degeneration, COVID-19, and numerous other medical conditions.

AdvaMed Digital Health Tech members represent the leading companies that are driving digital health innovation across healthcare, including AI-enabled health products and solutions, digital therapeutics, remote monitoring, connected care, wearables and provider care management.

We applaud the administration's efforts to advance responsible AI innovation while protecting patients' rights and safety. We agree that bias and discrimination need to be proactively addressed in the development and deployment of AI-enabled medical devices and solutions. We encourage OMB to recognize the effective work done by medical device manufacturers and verified Food and Drug Administration (FDA) to achieve those aims in the medical device industry.

4. How might metrics be developed and communicated to enable performance-based procurement of AI? What questions should agencies be asking vendors to determine whether AI is already being used in performance-based services contracts?

We believe the existing FDA review process, which evaluates devices for safety, efficacy, and fairness, should be seen as sufficient proof that an AI medical device meets the performance needs of agencies which look to procure medical devices. Additional AI procurement requirements would be duplicative. In addition, questions about a medical device's intended use, safety, and efficacy are highly specialized. It would be very difficult to replicate the expertise already provided by FDA and would not provide any additional safety or value to patients. Therefore, the only question an agency needs to ask medical device vendors is whether the AI-enabled medical device has FDA market authorization.

5. What access to documentation, data, code, models, software, and other technical components might vendors provide to agencies to demonstrate compliance with the requirements established in the AI M-memo? What contract language would best effectuate this access, and is this best envisioned as a standard clause, or requirements-specific elements in a statement of work?

When an agency seeks to procure an AI-enabled medical device, they should defer to FDA oversight, which already requires medical device manufacturers to submit all necessary technical information to perform a thorough evaluation for safety and effectiveness, including performance.

We do not believe that any contractual language should mandate access to intellectual property and proprietary information such as data, code, models, software and other technical components, since compliance to requirements established by the AI M-memo are already achieved by FDA review and approval of AI-enabled medical devices and conformity to international voluntary consensus standards.

6. Which elements of testing, evaluation, and impact assessments are best conducted by the vendor, and which responsibilities should remain with the agencies?

Medical device manufacturers conduct rigorous testing, evaluation, and impact assessments, including generation of all necessary objective evidence to demonstrate the safety and effectiveness of their AI-enabled medical devices. The FDA further reviews this data as part of the premarket

review process to assess whether a given device meets the robust regulatory requirements for clearance or approval. Agencies looking to procure an AI-enabled medical device should accept the evaluation, and assessments conducted by FDA as part of their review process. No additional testing, evaluation, or assessments should be necessary or required for medical devices already reviewed by FDA.

8. What if any terms, including terms governing information-sharing among agencies, vendors, and the public, should be included in contracts for AI systems or services to implement the AI M-memo's provisions regarding notice and appeal (sections 5(c)(v)(D) and (E))?

Transparency is vital when it comes to the procurement and use of AI tools by government agencies like HHS and FDA. This is particularly important in the context of healthcare and drug regulation, where AI-assisted decisions can have far-reaching consequences for public health.

Information on AI procured and deployed by agencies should identify how the systems will be used in their operations and how it was evaluated for that use. If an AI system influences an administrative or regulatory decision that affects an individual or organization, they should be notified and provided with a clear explanation of the basis for that decision. There should also be a straightforward process for appealing the decision and having it reviewed by a human expert.

Contracts for AI systems or services should include these transparency and appeal provisions to ensure that the public retains trust in the use of these powerful technologies for the administrative and regulatory functions performed by agencies like HHS and FDA.

9. How might agencies structure their procurements to reduce the risk that an AI system or service they acquire may produce harmful or illegal content, such as fraudulent or deceptive content, or content that includes child sex abuse material or non-consensual intimate imagery?

OMB should be careful to avoid conflating the risks associated with generative AI (e.g., LLMs) with the risks posed by other AI technologies. The FDA has performed oversight for numerous AI technologies for many decades, which ensures that those devices that receive market authorization avoid the risks like those indicated by this question. Additional procurement language addressing risks associated with generative AI are not needed on top of existing FDA requirements for AI-enabled medical devices.

We thank you for your attention to these comments and look forward to engaging further as the rulemaking process continues. If you have any questions, our contact information is available below.

Sincerely,

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