Federation of American Hospitals®

Charles N. Kahn III
President and CEO

February 2, 2024

Dr. Laurie E. Locascio
Under Secretary of Commerce and Technology
Director of the National Institute of Standards and Technology
100 Bureau Drive
Gaithersburg, MD 20899

Via electronic submission at: *hhtp://www.regulations.gov*

RE: NIST–2023–0309, Request for Information (RFI) Related to NIST's Assignments Under Sections 4.1, 4.5 and 11 of the Executive Order Concerning Artificial Intelligence; 88 Fed. Reg. 88,368 (December 21, 2023)

Dear Dr. Locascio:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, DC, and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services. The FAH appreciates the opportunity to submit comments to the National Institute of Standards and Technology (NIST) regarding its *Request for Information (RFI) Related to NIST's Assignments Under Sections 4.1, 4.5 and 11 of the Executive Order Concerning Artificial Intelligence* (AI).

The FAH greatly appreciates the willingness of NIST to work with private sector stakeholders to ensure that the United States can realize the promise of AI technology while avoiding and mitigating harms. Under Executive Order 14110 – *Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence* – NIST will have a key role in establishing guidelines and best practices in order to promote consensus industry standards in the development and deployment of safe, secure, and trustworthy AI systems. NIST may also offer guidance to a wide range of federal agencies on how best to deploy and regulate AI within their respective sectors.

As NIST develops its guidelines and best practices related to AI, the FAH recommends that it keep in mind the unique attributes of health care (e.g., size of the industry; impact on health and safety) and the needs of the multiple health sector actors that will interact with AI technologies, such as AI developers, health care technologists, health care organizations, health care providers, and patients/consumers.

Developing Guidelines, Standards, Best Practices for AI Safety and Security

The FAH makes the following recommendations to NIST as it undertakes efforts to develop guidelines and standards for AI safety and security, both generally and with specific consideration of the health care sector.

1. **Use a Risk Management Approach**

   Risk management is a key aspect of ensuring that both generative and rules-based AI solutions are appropriately developed, disseminated, and monitored over time. Risk management approaches also would support trustworthy, safe, appropriate, and equitable design. This is particularly true in health care, where decisions can literally be life or death. **As with other technologies, the FAH recommends that NIST use a risk-based, patient-centered approach to any guidance it develops for the health care sector on the use of AI solutions (both generative and rules-based).**

   Within the health care system, some hospitals and health systems deploy and develop AI solutions for use within their own organizations. Health care providers are already familiar with risk management processes and would welcome additional guidance from NIST on how best to manage the risks posed by generative and other AI tools that they deploy, develop, and use.

   The FAH shares general concerns about the potential risks of AI tools that may inadvertently embed bias or lead to poor patient outcomes and encourages NIST to provide guidance in this area. Commercial AI tool developers must evaluate the risk of bias in their tools, take appropriate steps to mitigate bias, and communicate the results of testing and any needed cautions to their customers. These and other risks that are embedded in the original model by a tool developer cannot be refined and remedied by an end user, so it is critical to ensure these risks are evaluated and addressed at the outset.

2. **Create Standard Definitions and Benchmarking Tools**

   NIST has a long history of working across the public and private sectors to develop consensus-based, workable standards and tools to advance the use of technologies that improve the lives of individuals. **The FAH recommends that NIST invest in creating a single set of definitions within the area of AI that can be leveraged by others.** Without standard definitions, the FAH is concerned that individual federal agencies and

states will create their own definitions, leading to inefficiencies and confusion, as well as contradictory legal and regulatory approaches. One important example of a term to be defined is "high-risk algorithm," as those are the tools that may likely be referenced in regulations.

The FAH also believes that NIST has the appropriate technical knowledge and experience to develop benchmarking metrics and other tools that both AI developers and deployers would be able to leverage as they seek to ensure that AI solutions are safe, secure, trustworthy, and fit to purpose. One example of a successful NIST testing tool is the Face Recognition Vendor Test (FRVT) | NIST. A key area where NIST could create testing tools is to validate, benchmark, or even certify synthetic data. For example, it would be helpful to have access to tools that could assess whether a dataset is representative, or how it might compare to the population for which it will be used.

3. **Focus on Transparency and Explainability**

As with medications, procedures, or other health care interventions, transparency regarding the action, expected use, and possible cautions about an AI solution will inform appropriate use. Similarly, health care providers need commercial developers of AI tools to explain how their tools work.

As health care embraces artificial intelligence and other analytic tools, it will be important for clinicians to have access to reliable information about AI tools. Users should in turn be able to explain the role of algorithms to individuals (including patients) affected by AI-assisted decisions. Explanations should be meaningful and useful, material and tailored to the specific audience, and calibrated to the level of risk.

For example, the types of information a health system needs to make a decision about purchasing a given AI-enabled technology may be different from the information that a clinician needs to determine how best to use it in making care decisions, which will be different from the information that a patient needs to understand the use of AI in their care. As AI tools become more routine, those who deploy and use them will need guidance on whether and how to inform consumers about the use of AI in health care, including attributes of uses that are sufficiently consequential to merit disclosure.
It is important, however, to balance these transparency and risk management approaches with innovation and the risk of unnecessary burden. For example, a health care practitioner will not realistically be able to individually evaluate AI tools and their output in the midst of patient treatment.

Finally, it will be important to have public facing websites, sponsored or certified by relevant federal agencies, where individuals can access, based on their level of skill, reliable and valid information concerning AI uses.

4. **Collaborate with Health Care Experts to Ensure Guidance Will Be Applicable**

   The FAH recommends that NIST specifically seek input from health care organizations and providers who are deploying and using AI solutions today to ensure that its guidance will be appropriate to the unique needs of those who provide care to patients.

5. **Educate All Parties, Including Consumers, on NIST Guidance**

   AI has the potential to change many aspects of society, including how health care is provided and consumed. NIST has an important role to play in creating a common understanding across developers, deployers, users, and consumers about the benefits and risks of AI, and how to determine whether a given tool is safe, secure, and trustworthy. **The FAH urges that as NIST creates guidelines and standards, that NIST engage in and expand educational efforts beyond tool developers to all stakeholders, including consumers.**

Advancing Responsible Global Technical Standards for AI Development

The FAH urges a national and global approach as NIST undertakes efforts to ensure that approaches to AI are consistent across the United States and to create a global paradigm of safe, secure, and trustworthy technologies.

The FAH urges NIST to work with other federal agencies and Congress to ensure that any regulatory frameworks for AI application are developed and applied at the federal level. A single, national standard that preempts state laws is crucial to facilitating compliance while enhancing innovation. The health care sector already faces a complex matrix of federal and state health information privacy laws that create confusion and inefficiencies, while increasing costs. It would be unfortunate and unnecessary to repeat the same problem in the AI space.

Further, the United States should be a leader in advancing global standards for AI development and promoting global standards that ensure that technologies can be used across borders in a manner that is safe, valid, and effective. This also means that the United States should ensure that health care providers that deploy and/or use AI solutions are represented in the global standards development processes. And, as the United States learns from other countries, it should share with the private sector best practices for AI risk management and governance, including managing potential risk and harms in health care.

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The FAH appreciates the opportunity to submit these comments on these important issues to patients and providers. If you have any questions, please contact me or any member of my staff at (202) 624-1500.

Sincerely,