AMERICAN CLINICAL LABORATORY ASSOCIATION

March 15, 2025

Faisal D'Souza
Networking and Information Technology Research and Development
National Coordination Office
National Science Foundation
2415 Eisenhower Avenue
Alexandria, VA 22314

Submitted electronically

Re: Development of an Artificial Intelligence (AI) Action Plan

Dear Mr. D'Souza,

The American Clinical Laboratory Association (ACLA) appreciates the opportunity to respond to the request for information on the Development of an Artificial Intelligence (AI) Action Plan, as directed by President Trump's January 23, 2025 Executive Order 14179 (Removing Barriers to American Leadership in Artificial Intelligence).

ACLA is the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers by advocating for policies that expand access to the highest quality clinical laboratory services, improve patient outcomes, and advance the next generation of personalized care. We appreciate the Administration's efforts to curb unnecessarily burdensome requirements that may hamper innovation. These efforts are critical to ACLA's patient-centered mission as well as our shared priorities around promoting a healthier America. As clinical laboratories strive to empower patients with actionable information about their health, AI tools can bolster the ability to detect the onset of diseases and changes in chronic conditions. One such example is transforming women's healthcare by leveraging digital cytology utilizing AI to detect cervical cancer – saving lives, improving care delivery, and ameliorating persistent shortages in the field.

In clinical laboratories, where precision, efficiency, and quality are paramount, AI innovations, including machine learning models, are emerging as promising tools to help address workforce shortages and manage the increasing demand for healthcare services. AI is one of many ways that ACLA member laboratories are utilizing innovative technology to streamline business processes, prioritize and increase the efficiency of workflows, and combine and summarize data from multiple sources to reduce employee burnout, all to ensure the highest quality services for patients. Additionally, while the diagnosis and decision-making process is still determined by the review and expertise of trained healthcare professionals, AI-generated insights that take into account patient history, diagnostic test results, and medical records may assist clinicians with making a comprehensive diagnosis and formulating a

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personalized treatment plan for each patient.

As the Administration works to develop its AI Action Plan, ACLA urges relevant departments and agencies to adhere to the following the principles to maximize the benefits of AI tools, minimize risks, and foster innovation:

- **Regulatory Clarity:** The scope of regulatory and congressional oversight over AI tools should be clear and transparent, as predictability in oversight will help guide the development of AI tools and encourage deployment of emerging technologies that will ultimately benefit patients.
- **Flexibility:** The rapid development of AI underscores the need for policies to be flexible enough to keep pace with technological advancements. Where appropriate, AI regulation should consider the evolving benchmarks and standards developed by the AI research community to ensure that AI models are able to reach the full scope of their potential and are not hindered by potentially outdated approaches.
- **Risk-Based Approach:** Regulation of AI tools should be sector-specific, balance risks and benefits to patients, and avoid overregulation that could stifle innovation and delay adoption. Specifically, AI regulation should consider the risk presented by a particular use case and the context in which the tool is used, and tailor requirements accordingly. Where appropriate, existing regulatory frameworks should be leveraged, and any new oversight should work with existing frameworks. Any new authorities also should avoid unnecessarily overlapping or duplicative requirements that could slow the adoption of innovative AI technologies. Additionally, any regulatory requirements should be agile and adaptable to an increasingly evolving technology.
- **Transparency:** AI systems should provide transparency that enables users to understand the validity, reliability, and trustworthiness of the system. ACLA members are committed to designing trustworthy AI tools, identifying any limitations of data, and clearly communicating such limitations.
    - **Guardrails for Use of AI in Coverage Decisions:** ACLA is concerned with the application of AI and other automation that currently negatively impacts patient coverage and laboratory reimbursement. For example, third-party organizations such as laboratory benefit managers (LBMs) that health plans contract with apply front-end proprietary coding edits that lead to automatic denials before the plans have the opportunity to review the claim for coverage based on medical necessity. Front-end edits result in a significant number of inappropriate claim denials and are a tremendous source of administrative burden on the laboratory and the ordering provider when claims must be re-submitted despite each of the laboratory testing services being medically necessary based on medical policy. AI and automated systems should not be used to deny or impede

patient access to services automatically. There must be a human evaluation to ensure patients are not being denied care that is medically necessary to address their health conditions.

- **Federal Preemption:** Explicit and strong federal preemption is necessary for national uniformity and to prevent a continually growing patchwork of inconsistent and burdensome state laws that are infeasible for clinical laboratories to adhere to and that will stifle innovation.
- **Privacy:** Safeguarding patient data and privacy is paramount to maintain trust and uphold ethical standards in healthcare. Simultaneously, utilizing deidentified data for AI innovation enables advancements in diagnosis, treatment, and personalized medicine, ultimately improving patient outcomes. It is important to strike a thoughtful balance between protecting sensitive health information and permitting the use of deidentified data for research and development purposes to further innovation.
- **Reimbursement:** As laboratories seek to adopt and invest in new technologies, like AI, they must have stable and predictable reimbursement, reflective of the value of diagnostics to patient care. Implementation of the Protecting Access to Medicare Act (PAMA) in 2014 resulted in significant payment cuts to the Medicare Clinical Laboratory Fee Schedule, which has not seen a payment adjustment since 2020, following three years of up to 10% payment cuts to laboratories. ACLA is working closely with key congressional leaders in the House and Senate to advance PAMA reform that would prevent further payment reductions and enact a long-term solution that would enable sustainable reimbursement rates to provide laboratories the stability needed for investments into advanced diagnostic tools, such as AI. Further, beneficial uses of AI in health care procedures, including laboratory services that incorporate AI, should be appropriately reimbursed to reflect their value.

Thank you for your consideration of ACLA's comments.

Sincerely,

Susan Van Meter
President, ACLA

Enclosure: ACLA Artificial Intelligence Policy Paper

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