August 19, 2025

The Honorable Dr. Akilah Weber Pierson
California State Senate
1021 O Street, Room 8740
Sacramento, California 95814

Dear Senator Weber Pierson,

Representing a diverse coalition of stakeholders that are deeply committed to improving healthcare outcomes through safe, effective, and responsible use of artificial intelligence (AI), we write to express our strong concerns with an amendment recently added to California Senate Bill 503 that would require developers of AI technologies used in healthcare to submit their systems to third-party auditors to assess compliance with bias mitigation requirements.

 A well-established and growing evidence base continues to demonstrate that the responsible use of safe and effective digital health solutions produces better patient outcomes, reduces costs, augments population health management, and improves the healthcare workforce experience (the Quadruple Aim[1]). Digital health tools, increasingly powered by AI, leverage patient-generated health data (PGHD) and include cloud-enabled solutions to reduce administrative burden, support medical and clinical decision-making, and chronic and acute care management. The use of these tools is also vital in supporting unserved and underserved Californians' access to prevention, diagnosis, and treatment for both acute and chronic conditions.

Your attention to healthcare's use of AI comes at a critical time. Tapping into the tremendous potential of AI is critical to empowering Californians with personalized solutions; equipping healthcare providers with better and timely data about the patients they serve and improving health outcomes; and shifting the paradigm for health care to a system that fosters prevention, wellness, and chronic disease management. Many AI use cases, ranging from solving administrative/backend efficiencies to supportive clinical decisions, have already demonstrated their capacity to advance the Quadruple Aim.

We support the overall goal of SB 503 to promote equity and accountability in the development and deployment of AI. However, mandating third-party audits to verify bias mitigation takes a fundamentally flawed approach that threatens to undermine the bill's intended objectives. Specifically:

1. **Lack of Standards or Infrastructure for Compliance:** While newly-amended SB 503 would require certification for AI models used in healthcare, there are currently no established groups or standards to perform such certifications, making compliance uncertain and implementation unclear. This amendment would particularly impact under-resourced frontline providers that focus on California's populations with the most need. In addition, start-ups will lack the guidance needed to align to these currently non-existent standards.

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[1] Bodenheimer, T., & Sinsky, C. (2014). "From Triple to Quadruple Aim: Care of the Patient Requires Care of the Provider." *Annals of Family Medicine*, 12(6), 573-576.

2. **Costly and Burdensome:** Third-party auditors for health AI tools do not yet exist, and therefore many unanswered questions remain that could affect the cost and burden of bringing new AI-based tools to market. For example, how many resources will each auditor require per test? Relatedly, will AI developers need to submit every update of their technology to an auditor? Many AI tools are updated on a frequent basis; even as infrequent as quarterly updates could require four reviews per year—both delaying access and increasing costs. Until these issues are addressed for healthcare using widely adopted standards, it is premature to consider mandatory third-party audits.

3. **Misaligned Accountability in the AI Value Chain:** A cornerstone of effective AI governance must be ensuring that responsibility to mitigate demonstrated harms is assigned to the actors that are most appropriately positioned to address them based on their knowledge and ability. Mandating third party audits across all entities that fall within the scope of SB 503 departs from this foundation, distorting healthcare AI value chains and discouraging participation from those best positioned to innovate responsibly. We strongly encourage California to employ a risk-based approach that scales requirements based on the intended uses and reasonably expected harm of a given tool, in alignment with international standards (e.g., ISO/IEC 42001, 'Information technology — Artificial intelligence — Management system').

4. **Intervention Post-Deployment is More Effective for Addressing Bias**: The auditor language would require a review prior to AI tool deployment. An analysis on bias prior to deployment may not effectively address the nuances on AI adoption in deployed settings—including diversity among patient populations, unique workflows, and other sociotechnical factors. Instead, to provide more accurate and actionable information, responsible AI approaches should prioritize a review of AI-based tools in the intended setting with the intended population.

The uncertainties and costs noted above would compound to make the deployment of vital healthcare AI tools unworkable, effectively restricting access to countless Californians seeking timely and necessary healthcare. We are particularly concerned about the impact on California's state-funded frontline providers that focus on California's most underserved populations.

We therefore respectfully recommend that SB 503 be revised to remove the new auditor language, and reflect a more collaborative, stakeholder-driven process. A successful legislative framework must balance bias mitigation with innovation, ensure appropriate responsibility across the AI supply chain, and support the deployment of trustworthy AI that improves clinical outcomes and reduces disparities.

We stand ready to assist in crafting language that both protects patients and fosters the safe development and use of AI in healthcare. We urge you to reject the current amendment and instead engage healthcare providers, AI developers, and patient advocates to build a workable path forward.

Thank you for your leadership and your commitment to advancing equitable healthcare innovation in California.

Sincerely,

ATA Action

ATLASense Biomed

Bayesian Health

Blue Spark Technologies

Connected Health Initiative

Dogtown Media

Epic Reach, LLC

Fool Me Once, LLC

Global Ultrasound Institute

Health Innovation Alliance

HealthFlow Inc

Hyfe, Inc

Johns Hopkins

Klarity Health

MiCare Path

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