

December 10, 2025

The Honorable Joe Ciresi Chair, House Communications & Technology Committee P.O. Box 202146 Harrisburg, PA 17120-2146

The Honorable Jason Ortitay Republican Chair, House Communications & Technology Committee P.O. Box 202046 Harrisburg, PA 17120-2146

RE: ATA ACTION COMMENTS ON HOUSE BILL 1925

Dear Chairs Ciresi and Ortitay and members of the House Communications & Technology Committee,

On behalf of ATA Action, I am writing to provide comments for your consideration as you evaluate House Bill 1925 regarding the use of artificial intelligence (AI) in healthcare.

ATA Action, the American Telemedicine Association's affiliated trade association focused on advocacy, advances policy to ensure all individuals have permanent access to telehealth services across the care continuum. ATA Action supports the enactment of state and federal telehealth policies to secure telehealth access for all Americans, including those in rural and underserved communities. ATA Action recognizes that telehealth and virtual care have the potential to truly transform the health care delivery system – by improving patient outcomes, enhancing safety and effectiveness of care, addressing health disparities, and reducing costs – if only allowed to flourish.

As artificial intelligence has continued to become more refined, healthcare entities have begun to utilize this technology in many aspects of care delivery due to its potential to improve quality and service capacity at every state of the care journey. AI-powered technologies are being deployed to analyze data quickly and accurately to assist providers in making better informed decisions and identifying diseases earlier. AI is also helping healthcare entities streamline administrative tasks-- such as improving patient scheduling or medication refill requests--which frees up more time for patient care. Accordingly, legislators and regulators have begun to consider the proper guardrails for the use of AI in healthcare, allowing for increased innovation and efficiency while ensuring patient care is not compromised. With this in mind, in 2023 the ATA adopted AI Principles to help guide policies that enhance patient and provider trust, safety, and efficacy of AI adoption as a tool in healthcare, including in telehealth. We are currently in the process of updating these principles and would be happy to share the updated version with the committee when finalized.

We are grateful for the opportunity to testify before the committee and also want to thank Representative Venkat and the other sponsors for their openness to collaboration and consideration of our feedback, both before and after this bill was introduced. Our organization stands in support of the intent behind this legislation and believes this is one of the best state bills introduced around the country regarding the use of AI in healthcare. While the intent and introduced version of this legislation are strong, we believe that some amendments are necessary to provide further clarity for entities and providers, ensure that reporting requirements are not onerous or stifle innovation and to avoid unintended consequences. We look forward



to working with the sponsors, committee and other stakeholders to refine this bill into its best form and we are grateful for your consideration of our comments.

Consideration of FDA Cleared Devices

As currently drafted, HB 1925 does not take into account FDA-cleared products, treating all products the same, which we believe is harmful to patient care. FDA-regulated digital therapeutics and AI tools are held to rigorous standards, including quality management systems, cybersecurity requirements and mandatory adverse event reporting, ensuring both safety and efficacy. Our organization represents Digital Therapeutics, which are clinically validated and FDA regulated Software as a Medical Device products that incorporate artificial intelligence and other technologies into treatments delivered to patients through phones, tablets, computers, and VR headsets. The FDA approved its first prescription digital therapeutic in 2017 and has since approved more than 20 through this rigorous review process under both the Biden and Trump administrations.

These products undergo clinical validation, are subject to pre- and post-market oversight and involve regulated healthcare practitioners as gatekeepers, protecting patients throughout the care process. In contrast, unregulated mobile health apps operate without these safeguards, rely only on general consumer protections, and may compromise patient data while making unproven health claims. Maintaining the distinction between regulated and unregulated products is essential to protect patients while allowing safe, evidence-based digital interventions to thrive. Indeed, given the existing federal oversight, Colorado's AI Act -- the country's first comprehensive AI law -- exempts high-risk AI systems already approved, authorized, or certified by the Food and Drug Administration (FDA).

To address this issue, we suggest adding the following language to § 3509. Exemption:

This chapter shall not apply to any artificial intelligence deployed in facilities that has been reviewed and cleared for use by the Federal Food and Drug Administration, or another federal agency tasked with approving artificial intelligence and artificial intelligence algorithms for use in health care.

Allow Patients to Consent to the Use of Their Data

Our organization firmly believes in the importance of patient data privacy, and has published <u>Health Data Privacy Principles</u> accordingly. We are concerned that the current drafting of § 3503(b)(6) is too restrictive and neglects patient control over their own data. Patients should be able to provide affirmative and informed consent to the use of their data for research, development and improvement, as is currently allowed by prevailing health data privacy frameworks such as HIPAA. We suggest amending § 3503(b)(6) as outlined below to allow for patient control, through informed consent, over the disposition of patient information that they own.

(6) Patient data must not be used beyond the intended and stated purpose of the artificial intelligence-based algorithms, except as permitted by the patient through informed consent or as otherwise authorized under applicable Federal or State law. Use of deidentified or aggregate patient data for research, development, or improvement of artificial intelligence-based algorithms shall be consistent with the laws of this



Commonwealth and 42 U.S.C. Ch. 7 Subch. XI Part C (relating to administrative simplification), as applicable.

Clarifying Provisions Regarding Third-Party Vendors and Entities

ATA Action understands that the General Assembly's intent is to ensure that third party entities who sell, license, partner with or are contracted by healthcare facilities to develop or deploy AI systems meet the same standards and requirements as facilities. We believe this intent could still be captured, without creating entirely new jurisdiction for the DOH, by replacing § 3508 in its entirety and replacing it with the language below.

A facility utilizing, contracting or subcontracting a third-party vendor for the development or deployment of artificial intelligence-based algorithms or services based on artificial intelligence-based algorithms shall ensure that the third-party vendor complies with this chapter and shall include evidence of compliance in the compliance statement required by § 3504.

This ensures that vendor products and services in facilities will still meet the requirements of responsible use and compliance, wherein the facilities will require sub-certification or contractual requirements.

At a minimum, it is crucial that the term "third-party vendor" be defined in the bill as it us currently undefined. We submit the definition below for your consideration.

<u>"Third-party vendor." A person or entity that makes an artificial intelligence system</u> commercially available, whether by sale, license or other offering, for use by a facility."

Amending Reporting Requirements to Avoid Onerous Compliance Regimes

While we understand the intent behind the requirement to file annual reports to the Department of Health to ensure facilities are compliant with the provisions of this legislation, our organization believes that this annual requirement is overly onerous and instead would be better served through a compliance statement or attestation. This would require facilities to document their compliance program and have this information readily available for audit by the Department, without the tall task of an annual report. The annual report requirement would be particularly onerous for small provider groups or digital entities serving small, but crucial, client populations such as patients receiving treatment for opioid use disorder, reproductive health or mental health. These companies have small compliance teams and could opt against using innovative and beneficial AI systems in the healthcare setting, to the detriment of patients, in order to avoid expensive and onerous compliance regimes created by an annual reporting requirement. We have included suggested language below to amend § 3504 accordingly. Subsequently we suggest striking § 3505, Reports in its entirety as the affirmation in a compliance statement required in the amended § 3504(a) replaces the mandatory annual reporting requirement.

(a) Compliance statement required.--A facility using artificial intelligence-based algorithms for clinical decision making shall annually file with the department in the form and manner prescribed by the department an artificial intelligence compliance statement.' shall establish and maintain an artificial intelligence compliance statement in



the form and manner prescribed in this section, which shall be produced to the Department within 30 business days upon request.

There are other details regarding the compliance statements that we also believe need to be amended for further clarity and to provide for intellectual property protection. § 3504(b)(2) should be tweaked to add "where applicable" to the end of the clause as not all artificial intelligence-based algorithms use logic or decisions trees. Furthermore, we believe common sense protections for facilities filing compliance statement should be put in place. This will ensure that facilities will not be placed at a competitive disadvantage from public release of proprietary information or from requirements of information release that may create a security risk. Below is proposed language amending § 3504(b)(2) regarding logic tress and a proposed new § 3504(b)(6) to address intellectual property protection respectively.

(2) Provide a logic or decision tree of artificial intelligence-based algorithms used for clinical decision making, where applicable.

(6) Nothing in this section shall require a facility to disclose any trade secret, information that could create a security risk, or any confidential or proprietary information.

Necessity for Further Clarity in the Definition of Clinical Decision Making

As currently drafted our organization believes the definition of the phrase "clinical decision making" is overly broad and undefined in § 3502(a). The inclusion of the language "other similar tasks" at the end of the definition will cause significant confusion and uncertainty for facilities. Either a task is clinical decision making or it is not. We encourage the committee to strike this undefined catch-all as outlined in the redline below.

(a) Duty to disclose.--A facility shall disclose to patients of the facility if artificial intelligence-based algorithms are or will be used for clinical decision making or similar tasks.

Thank you again for your consideration of our proposed changes and for your commitment to a collaborative and robust legislative process. We reaffirm our support for the intent of this legislation and looking forward to continuing to work with the sponsor and the committee to improve it.

Thank you for the opportunity to comment and for your consideration of these important issues. As your committee considers this legislation the implications of AI regulations on healthcare entities, we are happy to serve as a resource. If you have any questions or would like to further discuss ATA Action's perspective on this critical issue, please contact me at hyoung@ataaction.org.

Kind regards,

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ATA Action

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CC:

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