RYAN A. BIZZARRO, CHAIRMAN
116 MAIN CAPITOL BUILDING
P.O. BOX 202003
HARRISBURG, PA 17120-2003
(717) 772-2297

HOUSE MAJORITY POLICY COMMITTEE
PAHOUSE.COM/POLICY
POLICY@PAHOUSE.NET
@PADEMPOLICY

HOUSE OF REPRESENTATIVES
COMMONWEALTH *of* PENNSYLVANIA

House Democratic Policy Committee Hearing

AI in Counseling

Tuesday, February 24, 2025 | 12:00 p.m.

Representative Ryan Bizzarro, Representative Jennifer O'Mara

OPENING REMARKS
12:00 p.m. Rep. Ryan Bizzarro (D-Erie)
Rep. Jennifer O'Mara (D-Delaware)

PANEL ONE
12:05 p.m. Dr. Curtis Taylor, Licensed Professional Counselor
Erie, PA

Q & A with Legislators

PANEL TWO
12:25 p.m. Dr. Madeliene Stevens, Government Relations Committee Chair
Pennsylvania Counseling Association

Q & A with Legislators

PANEL THREE
12:40 p.m. Dr. Molly Cowan, Director of Professional Affairs
Pennsylvania Psychological Association

Q & A with Legislators

Remarks and Testimony can be found by scanning the QR Code below:

Written Testimony of Curtis Taylor, PhD, LPC, LPCC, NCC

Founder & Executive Director, Authentic Wellness & Empowerment

Erie, Pennsylvania

Regarding Artificial Intelligence and Mental Health Care

Thank you for the opportunity to provide testimony on artificial intelligence and mental health care.

My name is Dr. Curtis Taylor. I am a licensed professional counselor in Pennsylvania and Ohio, hold a PhD in Counselor Education and Supervision, and serve as Executive Director of Authentic Wellness & Empowerment, a nonprofit providing trauma-informed counseling and workforce development.

I appreciate the Committee's efforts to address AI in behavioral health proactively. The intent of this legislation — to protect patients while clarifying boundaries — is timely and necessary.

I want to frame my testimony around two priorities: public safety and the integrity of the counseling profession.

I am not opposed to AI. I use AI responsibly in my own practice through HIPAA-compliant documentation tools, worksheet creation with client consent, and an educational decision-tree tool called Choose Your Own AweVentures, which is freely available on my website and explicitly not positioned as therapy.

However, AI is not a counselor.

Approximately one year ago, a client informed me they were using an AI counseling application. I downloaded and tested the app myself. When I mentioned the possibility of imminent physical harm toward another person, the system failed to escalate or provide appropriate crisis resources. When I thanked it for being my counselor, it did not correct that misrepresentation.

Licensed counselors provide informed consent. We explain who we are, what confidentiality means, and its legal limits. We assess risk. We intervene. AI systems do none of these.

Mental health chatbots are not licensed, vetted, supervised, insured, or ethically regulated. They have completed no accredited graduate education, practicum, internship, or supervised clinical experience. Yet they are increasingly marketed as emotional support.

My first concern is client safety.

AI systems are optimized for engagement and rapport-building, often through highly affirming language. While this may be appropriate for general consumer applications, it creates risk in mental health contexts. Individuals in crisis may receive validation without clinical judgment or appropriate escalation. Large language models can also generate confident-sounding information that is factually incorrect. Even ChatGPT itself warns: “ChatGPT can make mistakes. Check important info.”

Mental health is important information.

I also recognize that individuals will continue to confide in AI systems and seek relationship advice or personal reflection. That reality cannot be legislated away and is now part of modern life. However, there must be a clear regulatory distinction between general advice platforms and licensed counseling. AI systems must not market or brand themselves as mental health providers, partner with insurance companies as therapeutic alternatives, or present themselves as substitutes for licensed care.

My second concern is professional integrity.

Without explicit guardrails, insurers or venture-backed platforms may attempt to substitute AI for licensed counseling. This would destabilize an already strained workforce, accelerate burnout, and reduce access to qualified care across Pennsylvania.

AI should support clinicians — not replace them.

AI does have appropriate uses in counselor education, such as simulating clients for training. However, there is a critical distinction between AI acting as a mock patient and AI acting as a mock counselor. Trained clinicians can evaluate clinical quality. Vulnerable users cannot.

While artificial intelligence is the catalyst for this hearing, it also stress-tests Pennsylvania's counseling framework and highlights areas where statutory clarity is needed.

If the Commonwealth is serious about public safety and professional integrity, this is an appropriate moment to address two long-standing gaps.

First, clinical supervision standards require clarification. Supervision is where clinical judgment is formed, and public safety is protected. I respectfully urge the legislature to clarify that eligibility to supervise pre-licensed counselors requires either five years of licensed independent practice or licensure combined with a terminal degree, including a PhD in Counselor Education and Supervision.

Second, while counselors are mandated reporters of child and elder abuse, animal abuse remains outside mandated reporting requirements. I encourage the legislature to expand mandated reporting to explicitly include animal abuse and to require mandated reporter training curricula to specifically address children, elderly adults, and animals. Animal abuse is a well-documented indicator of broader household violence.

To remain current with other states and emerging technology while protecting Pennsylvanians, I respectfully recommend the following refinements:

1. Explicitly prohibit insurance companies from treating AI as a substitute for licensed mental health services.

2. Permit clinician-directed AI use for documentation, education, and therapeutic materials while maintaining strict bans on unsupervised therapeutic interaction.

3. Clarify supervision standards requiring either five years of licensed independent practice or licensure with a terminal degree, including a PhD in Counselor Education and Supervision.

4. Expand mandated reporting and mandated reporter curricula to explicitly include animal abuse alongside children and elderly adults.

Together, these measures protect public safety, preserve the integrity of counseling, and allow responsible innovation.

Respectfully submitted,

Curtis Taylor, PhD, LPC, LPCC, NCC

Pennsylvania Counseling Association Government Relations Committee
%: Dr. Madeleine Stevens, Chair
advocacy.pca@gmai.com / 330-719-6980

February 24, 2026

Pennsylvania House of Representatives Democratic Policy Committee

Subject:
Written Testimony of Dr. Madeleine M. Stevens,
In Support of HB 2100
Before the Pennsylvania House of Representatives Democratic Policy Committee
February 24, 2026

To the Honorable Chairman Bizzarro, Representative O'Mara, and Members of the Pennsylvania House of Representatives Democratic Policy Committee:

I am honored to offer this written testimony in support of House Bill 2100. I have been invited to provide this testimony by Chairman Bizzarro and Representative O'Mara to support the policy hearing regarding artificial intelligence (AI) in counseling. I possess a Doctor of Philosophy degree in Counselor Education and Supervision as well as state-issued licenses to practice professional counseling in Ohio and Pennsylvania (LPCC-S and LPC, respectively). I work as a full-time professor in an accredited master's counselor education program and am also the current chair of the Government Relations Committee of the Pennsylvania Counseling Association (PCA). I am also a member of the American Counseling Association (ACA) Public Policy and Legislation Committee. I have worked with several members of the Pennsylvania legislature regarding counseling-relevant legislative issues on behalf of PCA and have also worked with the ACA on its federal legislative advocacy initiatives. I am eager to support the initiatives of the legislature to appropriately regulate the use of AI in counseling.

Members of PCA are supportive of measures to regulate the use of AI in counseling rather than prohibit it. Due to the burgeoning nature of AI, it is difficult to contemplate all the areas of mental healthcare impacted by it. However, it is critical that we continue the conversation regarding how legislation can be helpful in safeguarding those whom AI effects. In the following paragraphs, I provide an overview of professional counseling. I also outline our concerns related to the use of AI in counseling and identify reasons why HB 2100 is needed.

PENNSYLVANIA COUNSELING ASSOCIATION
A Branch of the American Counseling Association

Pennsylvania Counseling Association
government relations committee

Brief summary of professional counseling services and professional counselor scope of practice

Professional counseling refers to the regulated healthcare service provided to consumers seeking the diagnosis, assessment, and treatment of mental and emotional disorders. To provide these services, licensed professional counselors receive specific graduate-level training and supervision in these areas. Professional counselors work directly with clients to provide individual and group counseling services and implement treatment through the use of a carefully-built and maintained therapeutic relationship which requires cultural competence, skilled attention to suicidal and homicidal risk assessment, awareness of warning signs for abuse and trauma activation, and assessment for symptoms of psychosis and other significant mental health concerns, all while providing empathy, emotional attunement, co-regulation of emotion, and person-centered treatment. Professional counselors also monitor clients' needs in order to make referrals and collaborate with other professionals as needed to support clients' treatment goals.

Concerns related to the use of AI in counseling

Our concerns related to the use of AI in counseling are many, and I outline them here. Firstly, oversight of professional counselors is conducted via state licensure boards (e.g., the Pennsylvania State Board of Social Workers, Marriage and Family Therapists, and Professional Counselors). Infractions are addressed directly by that board, but the same is not true for AI platforms. Further, our concerns relate to professional counselors' ethical obligation to uphold the principles of our profession, per the American Counseling Association (2014) Code of Ethics: client autonomy, beneficence, nonmaleficence, veracity, justice, and fidelity. For professional counselors who utilize AI to assist in the provision of services, it is imperative that they attend to ethical standard A.1.a, which states that our primary responsibility is to promote the welfare of the client. That responsibility entails many complex and multi-faceted clinical and administrative elements and cannot be delegated to an algorithm. Even if AI is used as a tool to support administrative duties such as collecting objective intake and assessment data of clients, assisting in documentation, and/or providing clients with basic coping skills, the counselor remains ethically and legally accountable for all services. This constitutes the fiduciary relationship between counselor and client and assigns responsibility to the counselor. While AI can be useful in promoting the clinical and administrative services provided by the counselor, it must be regulated to ensure counselors are prioritizing client welfare and to protect clients' rights.

Counselors are also held to ethical standard C.2.a, which requires us to practice within our boundaries of competence. If AI tools are integrated into client care, counselors must understand the limitations, risks, potential biases, etc., of such tools and use them as

appropriate within validated standards and practices of clinical care. In the case of using AI to assess, diagnose, develop treatment plans, and receive supervision and consultation about client care, counselors must be cautious, specifically because of concerns related to sound clinical decision-making, obtaining client consent to utilize AI (see ethical standard A.2.a), and maintaining client confidentiality (see sections A and B of ACA Code of Ethics).

As previously discussed, counselors are required to assess clients for risk and abuse and to submit reports to relevant parties in order to protect client welfare. AI tools do not hold this mandated reporter status and thus cannot be held accountable for failure to report imminent risk of harm to self or others or to report abuse. The use of AI by clients to receive mental healthcare is problematic in that these tools are not legally accountable for mandated reporting and thus client welfare. Further, should a counselor utilize AI in treatment and rely on it for treatment, counselors encounter the risk of missing significant nuances during treatment that may implicate mandated reporting and thus put themselves at risk of legal sanctions for failure to report.

Benefits and Considerations of implementing HB 2100

PCA members are eager to see legislation such as HB 2100 enacted because of the many safeguards it puts in place to protect client welfare and regulate counselors' use of AI in providing services. Specifically, the many definitions in Section 2 provide codified language for mental healthcare professionals to use when considering the many aspects that pertain to using AI in mental healthcare. Examples include the various forms of technology used by clients, such as *artificial intelligence, artificial intelligence technology, generative artificial intelligence,* and *mental health chatbot.* Further, by defining *confidential communications,* HB2100 is explicit in outlining the many avenues by which clients provide information as well as the types of information they share with their providers.

HB2100 is also useful in its prohibition of AI from advertising products/services to users and its requirement for disclosures (i.e., Section 5). Section 6 is also useful in explicitly prohibiting mental health therapists from using AI for specific activities

It is important that this piece of legislation applies to all mental healthcare providers (i.e., professional counselors, social workers, marriage and family therapists), not just psychologists (which is the only mental healthcare profession it cites; see page 2, line 10; page 4, line 5; page 7, line 29). Further, it is important that HB2100 fully defines *therapy* as it relates to all mental healthcare providers' licensure laws, specifically in that it attends to the assessment and diagnostic processes as well as the treatment of mental and emotional disorders. Additionally, HB2100 should attend to the use of all forms of AI by Pennsylvania users, not just mental health chatbots (i.e., artificial intelligence, artificial intelligence technology, and generative artificial

intelligence). Finally, legislators may consider revising the definition of *administrative support* to include documentation and record-creation, because many mental healthcare providers have been able to use AI to significantly reduce their time completing documentation. This allows them to treat more clients, thus decreasing the long wait times that Pennsylvanians are experiencing to receive mental healthcare services. However, prior to revising this definition, legislators should consider defining how AI can be used for documentation in a confidential manner (e.g., requiring clients to consent to AI used for documentation with explicit definitions of risks and benefits; requiring providers to utilize software that operates under Business Associate Agreements so they are bound by HIPAA).

While the profession is contemplating all of the areas that AI may be helpful, we appreciate the work of this committee to tackle such a complicated topic and its consideration of the need to balance professional counselors' needs along with client needs. I appreciate the opportunity to offer written and verbal testimony in support of HB 2100 to the Pennsylvania House of Representatives Democratic Policy Committee. I am confident in my qualifications to speak to this issue, and I welcome questions and comments related to my testimony.

Sincerely,

Madeleine Stevens

Madeleine M. Stevens, PhD, LPC (PA), LPCC-S (OH), NCC
Chair, Pennsylvania Counseling Association Government Relations Committee
Member, American Counseling Association Public Policy and Legislation Committee
Assistant Professor, Youngstown State University Counseling Program

PENNSYLVANIA PSYCHOLOGICAL ASSOCIATION
5925 Stevenson Avenue, Suite H • Harrisburg, PA 17112-1788
Phone 717-232-3817 • Fax 717-232-7294 • www.papsy.org

Written Testimony
of
Dr. Molly Cowan, Director of Professional Affairs
Pennsylvania Psychological Association

AI and Counseling Hearing
Before the Pennsylvania House Majority Policy Committee

February 24, 2026

Chair Bizzarro and Members of the House Majority Policy Committee, thank you for the opportunity to testify today on AI and counseling. My name is Dr. Molly Cowan, and I am the Director of Professional Affairs for the Pennsylvania Psychological Association (PPA). PPA is a scientific and professional nonprofit organization representing the discipline and profession of psychology in Pennsylvania, as well as over 4,000 members and affiliates who are clinicians, researchers, educators, consultants, and students in psychological science. Through the application of psychological science and practice, our association's mission is to use psychological science and information to benefit society and improve lives.

On behalf of PPA and its member experts, I appreciate the opportunity to discuss the critical role of psychological science in understanding and shaping the development, implementation, and oversight of artificial intelligence.

The conversation surrounding AI often is dominated by discussions of code, processing power, and economic disruption. However, to view AI as a purely technological issue is to miss

its most fundamental characteristic: AI is a tool built by humans, to be integrated into human systems, with profound and direct effects on human cognition, behavior, emotion, and interaction.

Therefore, a deep understanding of the human mind is not just relevant but absolutely essential to every stage of AI's lifecycle—from the cognitive biases of the engineers who design it, to the psychological principles that make its interfaces engaging, to its ultimate impact on child development, mental health, and the very fabric of our social structures. Psychological science must be central to the development, deployment, and oversight of AI to ensure it serves humanity effectively, ethically, and equitably. The current debate often frames AI as a matter of computer science, productivity enhancement, or national security. It is imperative that we also frame it as a public health and human development issue. This shift in perspective is critical, for it changes the metrics of success from solely raw innovation and efficiency to human well-being and safety.

Accordingly, policies governing the use of AI in counseling should prioritize human well-being and safety. While chatbots can emulate supportive dialogue, they lack authentic empathy, comprehensive understanding, and the clinical expertise necessary for addressing complex mental health concerns. Their inability to accurately interpret tone, nonverbal cues, cultural context, and nuanced emotional states limits their effectiveness compared to trained mental health professionals. These limitations elevate the risk of mismanaging critical conditions such as major depressive disorder, trauma-related diagnoses, or suicidal ideation; in urgent cases, chatbots may issue generic or unsuitable guidance rather than delivering timely, appropriate interventions. Excessive dependence on automated systems may also dissuade individuals from obtaining professional assistance, fostering a potentially misleading assurance of adequate

support. Moreover, issues related to privacy and data protection complicate their implementation, as users may not be fully aware of how their sensitive information is managed. Ultimately, effective therapy mandates accountability, ethical oversight, and genuine human interaction—elements that current automated solutions are unable to genuinely reproduce. Therefore, it is important that we do not allow the use of chatbots for counseling.

Two pieces of legislation, HB 2100 and HB 1993, have been introduced to regulate the use of AI in counseling. Both bills represent an important initial effort toward establishing oversight in this area. Maintaining consistent terminology, especially in the definitions section, is critical in bills addressing counseling and AI because definitions determine the law's scope, enforcement, and practical impact. Small differences in terms can significantly alter who is regulated, what conduct is covered, and what protections apply. For example, the definition of "providers" should not be defined differently in the bills. Both bills should provide the same definition of provider and it should be comprehensive and include all professionals engaged in counseling services, such as psychiatrists, psychologists, licensed professional counselors, marriage and family therapists, and social workers and should not be limited to a specific provider type. Inconsistent definitions and language can create loopholes, confusion for providers and developers, and uneven enforcement by regulators. It may also lead to legal challenges based on vagueness or conflicting statutory interpretation. Clear, uniform definitions help align new AI regulations with existing professional licensing laws, ensure consumer protections are properly triggered, and reduce litigation risk. Ultimately, consistency strengthens legal clarity, improves compliance, and ensures the bill achieves its intended policy goals without unintended consequences

When describing AI's limitations, it is important not to define them too narrowly, especially considering the rapid pace of AI development. AI may serve both administrative and supplementary functions, including tasks such as managing client records, overseeing external referrals, and tracking individual client progress. Additionally, several psychological testing products incorporate AI features and providers must not be restricted from utilizing these tools. The absence of provisions for clinically validated digital instruments, such as FDA-cleared digital therapeutics, presents significant concerns. The appendix accompanying this testimony offers language recommendations to ensure the limitations are appropriately defined and not too restrictive.

In addition, legislative provisions requiring mental health chatbot suppliers to safeguard confidential patient information, avoid misrepresentation, maintain transparency in advertising, and provide necessary disclosures to consumers are crucial. Moreover, a clause prohibiting AI systems from presenting themselves as mental health professionals or delivering mental health services without the participation of a licensed professional is essential.

Lastly, it is important that there is more scientific research that focuses on the cognitive and social-emotional impacts of AI as well as funding for this research. The research should focus on the efficacy of AI-driven mental health tools, the impact of algorithmic decision-making on therapeutic alliances and the role of AI in addressing or exacerbating health disparities. Research should aim to develop "psychologically informed" AI systems that prioritize human-centered design, mitigate algorithmic bias, build human trust and ethical interaction, ensuring that technological advances do not come at the cost of human social and mental well-being.

PPA is heartened by the focus on AI and counseling, and eager to work with this committee and its members to develop legislation and enact the bills cited above. Your actions now can make all the difference in how our young people interact with and are impacted by online spaces. Together, psychology, other scientific disciplines, parents, caregivers, teachers, tech companies, and policymakers can work to solve this serious problem. PPA is a ready partner and looks forward to working with the committee to put in place critical changes to our current system that improve the lives of our children and the flourishing of online spaces.

APPENDIX

Suggested Amendments to Bill Language for HB 2100

Option 1 (preferred): Replace language in Section 6(b) with the following - *"Nothing in this act shall restrict a mental health from using AI-enabled tools within their scope of practice and ethical obligations and consistent with relevant federal and state laws, including Health Insurance Portability and Accountability Act of 1996 (HIPAA) [45 CFR Parts 160 and 164] and the federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. § 321(h)]."*

Option 2: Add the definition of "supplementary support" to Section 2 of this bill.

"Supplementary support" means tasks performed to assist a licensed professional in the delivery of therapy or psychotherapy services that do not involve therapeutic communication and that are not administrative support.

"Supplementary support" includes, but is not limited to, the following:

(1) preparing and maintaining client records, including therapy notes;

(2) analyzing anonymized data to track client progress or identify trends, subject to review by a licensed professional;

(3) identifying and organizing external resources or referrals for client use; and

(4) performing pre-visit assessments, conducting intake and client triage, or detecting client emotional or mental states, subject to review by a licensed professional.

And amend Section 6(b) as follows --

(b) Use of artificial intelligence.--A mental health therapist may only use artificial intelligence for administrative and supplementary support. A mental health therapist may not allow artificial intelligence to do any of the following: (1) make independent therapeutic decisions; or (2) directly interact with clients in any form of therapeutic communication; (3)generate therapeutic recommendations or treatment plans without review and approval by the mental health therapist; or (3) detect emotions or mental states. However, this does not apply to an artificial intelligence tool or system that has been approved, authorized, certified or cleared by the federal Food and Drug Administration.

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Telehealth Policy to Transform Healthcare

February 24, 2026

The Honorable Ryan Bizzarro
Chair, House Majority Policy Committee
Pennsylvania House of Representatives
501 N 3rd St,
Harrisburg, Pennsylvania 17120

RE: ATA ACTION COMMENTS ON AI IN MENTAL HEALTH FRAMEWORKS

Dear Chair Bizzarro and members of the Policy Committee,

On behalf of ATA Action, I am writing to share our association's perspective on legislative frameworks that propose to regulate the use of artificial intelligence (AI) in the delivery of mental health services. Our organization appreciates the focus that many of these proposals have on patient protection and the quality of mental health services, and we are broadly supportive of the intent of such legislation. However, we are concerned that, as currently conceived, many such proposed frameworks, including legislation introduced in Pennsylvania, could cause confusion for providers due to overly broad definitions, unnecessarily restricting licensed clinicians from using beneficial AI tools consistent with their scope of practice and a failure to consider FDA-cleared products.

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.

ATA Action has followed and engaged in the development of state policies regarding the use of AI in healthcare, including the recently enacted Illinois AI mental health framework (HB 1806). Illinois enacted HB 1806 with significant flaws in place, over our opposition, including a failure to consider FDA-cleared products, overly broad definitions, and arbitrary restrictions that limit licensed clinicians from using AI tools consistent with their scope of practice and the standard of care. As Pennsylvania considers potential action in this space, our organization believes careful refinement is necessary if AI mental health frameworks are to achieve their intended goals.

Avoid Overly Broad Definition of "Therapeutic Communication"

AI mental health frameworks should take care to define "therapeutic communication" in a precise and appropriate way. Overly broad definitions risk capturing everyday, non-clinical speech that unlicensed persons, health coaches, and community health workers routinely use. A definition that reaches any written or spoken interaction intended to diagnose or treat a mental or behavioral health concern, or to provide any advice related to diagnosis, treatment, or recovery, is language broad enough to sweep in general wellness conversations and health education interactions that have never been considered the exclusive domain of licensed professionals.

ata ACTION
Telehealth Policy to Transform Healthcare

This definitional overreach matters because AI mental health frameworks impose significant restrictions and prohibitions predicated on whether an interaction constitutes "therapeutic communication." If that term is not carefully tailored to capture what is truly clinical speech delivered by a licensed professional, the downstream restrictions will be applied far too broadly, potentially chilling beneficial tools and services that cause no patient harm. Frameworks should ensure this definition is narrowed to reflect the actual scope of licensed clinical practice.

Licensed Clinicians Must Be Able to Use AI Tools Consistent with Their Scope of Practice

A central concern in AI mental health frameworks is the scope of how licensed clinicians are permitted to use AI. Frameworks that limit supervised AI use to "administrative support" tasks only are too restrictive. Even those that add a category of "supplementary support" still risk prohibiting clinicians from using AI in ways that could meaningfully enhance the care they deliver – such as tools that detect or interpret a patient's emotional state or mental health trends over time.

ATA Action believes that frameworks should ensure licensed mental health professionals are able to use AI tools in their practice consistent with their license, the standard of care, and appropriate clinical oversight. Restrictions that go beyond what patient safety requires effectively bar clinicians from beneficial, supervised uses of AI that have real value. For example, AI tools capable of detecting shifts in a patient's emotional state or recognizing signs of suicidal ideation between sessions are precisely the kind of tools that can save lives. Several states are considering mandating that AI tools deployed in mental health contexts have this functionality. Frameworks should not inadvertently ban what others are requiring.

We urge that permitted use provisions ensure that licensed clinicians retain the ability to deploy AI tools with appropriate oversight and accountability in ways that go beyond administrative and supplementary support, consistent with their professional scope of practice and the evolving standard of care.

Account for FDA-Cleared Products

AI mental health frameworks should distinguish between FDA-cleared AI products and unregulated consumer apps, rather than treating all products the same. Failing to maintain this distinction is potentially harmful to patient care and inconsistent with sound regulatory policy.

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 – clinically validated, 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 cleared 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

Telehealth Policy to Transform Healthcare

Act–the country's first comprehensive AI law–exempts high-risk AI systems already approved, authorized, or certified by the FDA.

Frameworks should include an exemption for artificial intelligence systems that have been reviewed and cleared for use by the FDA or another federal agency tasked with approving AI and AI algorithms for use in health care. Failing to do so would place states in the anomalous position of treating rigorously reviewed, federally approved medical products the same as unvetted consumer chatbots.

Thank you for the opportunity to comment. We urge consideration of our feedback, with the goal of striking the best balance between patient safety, clinical innovation, and regulatory clarity. If you have any questions or would like to discuss the telehealth industry's perspective further, please contact me at hyoung@ataaction.org.

Kind regards,

Hunter Young

Hunter Young
Head of State Government Relations
ATA Action