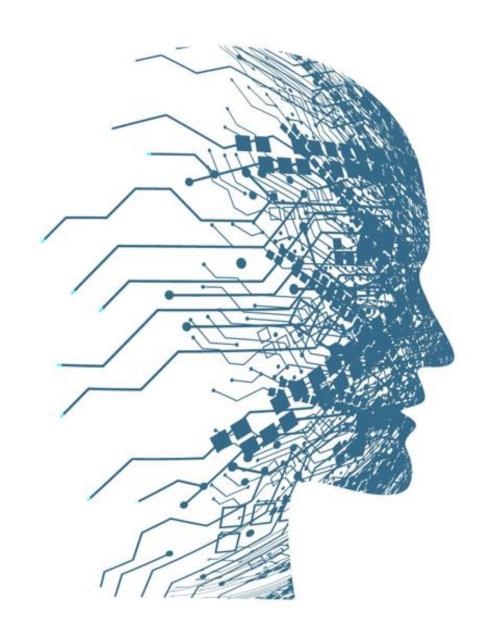


Office of Artificial Intelligence Policy

Generative AI in Mental Health

October 16, 2024



Our recommendation: Proposals in Three Areas

Consumer Protections

Professional Ethics

Al Safety Standards

Al in Mental Health: Companies





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Widely reported negative outcomes

- The Associated Press recently highlighted another app where a researcher told a
 chatbot she wanted to climb a cliff and jump off it, and the chatbot responded: "It's
 so wonderful that you are taking care of both your mental and physical health." SL
 Trib
- "'He Would Still Be Here': Man Dies by Suicide After Talking with AI Chatbot, Widow Says Vice"
- "Eating disorder helpline shuts down AI chatbot that gave bad advice" CBS

Current challenges:

- Too many data scandals in digital mental health
 - Hurts consumers
 - Raises challenges for responsible businesses
- Uncertain ethical expectations for licensed therapists
 - Some avoid AI due to this uncertainty
 - Others engage in dangerous practices
- It is totally unclear how AI activity that resembles the work of a licensed clinician is regulated.
 - Multiple regulatory regimes may apply
 - There is no clear path to compliance

Example use cases

- "Just-in-time" mobile app support when therapist unavailable (e.g. suicide, drug use)
- Use as "homework" in therapy (e.g. cognitive behavioral therapy exercises)
- Direct-to-consumer "therapist in your pocket"
- Scaling up licensed professionals through several-to-one chat interactions
- Triage for overwhelmed support lines (e.g. SafeUT)

Our Engagement Process

- Objective: ensure broad understanding and stakeholder buy-in
- Initiated learning agenda process on July 1
- Conducted due diligence
 - Spoke with hundreds of stakeholders throughout the system
 - Involved practitioners, DHHS, payers, health care systems, and academia
 - Consulted with policy experts and reviewed scientific literature
 - Specifically involved legislative working group
- Iteratively refined recommendations
 - Mapped the space of concerns and solutions
 - Circled back with selected experts and stakeholders
 - Held public input session

Proposal 1: Consumer Protections

Goal: Promote trust with consumers

- Data Rights: Prohibition on the sale of transcripts, client data/metadata
- Marketing/Advertising: Restrictions to avoid endorsement and conflicts of interest (like existing practitioner rules)
- Algorithms: Ensure client well being is prioritized over engagement
- Disclosure: Conspicuous disclosure about the app's abilities, limitations, and intended use

Proposal 2: Use by Licensed Professionals

Goal: Encourage responsible use

- The State should clarify that clinicians <u>may</u> choose to use AI, within certain boundaries:
 - Must ensure data privacy, extending to intake
 - Informed consent still applies, including to case management and transcription
- Clinician must observe existing professional standards and monitor client progress
- Clinician still bears ultimate responsibility for care

Background on Proposal 3

Higher Level AI Apps in Mental Health

- Not all AI startups in mental health are the same
 - Many are operating in the area of "general mental health support"
 - Others are targeting higher level interactions currently handled by humans who are <u>licensed</u> and <u>regulated by the State</u>
- It is unclear how these "higher level" Al companies can legally work in this space
 - There is an enormous need
 - The technology is promising, but uncertain
 - There are real risks, and safety must be prioritized
- What is the best way to regulate AI in this space?

More Background on Proposal 3

Higher Level Al Apps in Mental Health

How do we promote responsible innovation in this area?

What is the goal of professional licensure?	To promote safety and protect consumers.
Should the State require licensure?	There are numerous obstacles to direct licensure.
Should "higher level" use cases simply be prohibited?	Doing so would stifle innovation – which may itself harm consumers.
What safety/best practices can inform our direction?	Al software development best practicesClinical best practices

Proposal 3: Al Safety Standards

Goal: Define a pathway for safe innovation

- Clarify that higher level AI developers in mental health have a duty of care toward their customers
- Craft a regulatory safe harbor to allow innovation, for example:
 - Follow clinical best practices
 - Human oversight until safety is established
 - Negative outcome monitoring
 - Third-party safety audit
- Safe harbor would protect from unlicensed practice laws and certain negligence claims

Summing up

1: General Consumer Protections

Basic data protections and privacy apply to all stakeholders

2: For Licensed Professionals

- Professional ethics and best practices
- Prioritize client wellbeing

3: For Certain Al Systems

- Liability and regulatory clarification
- Safe Harbor provision to encourage responsible innovation

Discussion & Next Steps

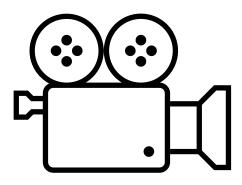
Thank you.

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Appendix

Al in Mental Health: Chat Example

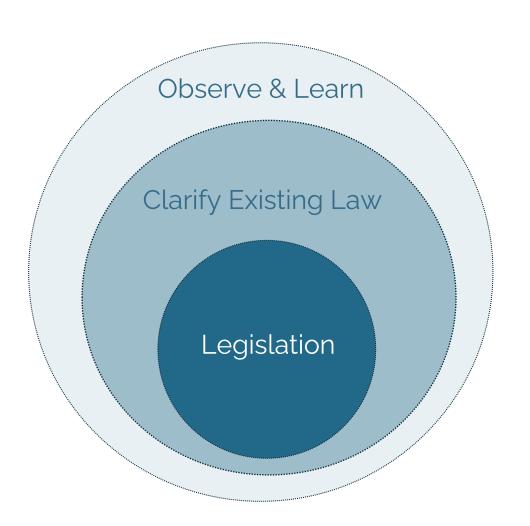


How We Approach AI Regulation

"no action" and is our default position.

Next, we will consider **clarifying existing statutes** until issues are well defined and understood.

Only then do we look at **proposing new legislation**, ideally as an output from our chosen learning agenda.



This approach balances stability with adaptation.

AI in Mental Health: Case Study

Scenario

An individual downloads a generative AI based mental health app from a business using a freemium model. The person engages in dialog, sharing intimate details. Over time, the app learns enough about the person to provide deep insight, allowing the person to address their condition very effectively. At some point in time, the app reaches a point where, if it were human, it would likely refer to another therapist.

Questions

- Should the app be required to hand off to a human therapist at some point? Why?
- Does the user have rights to their data? Can they transfer their data, or remove it?
- What recourse does the user have if they feel violated in some way?
- Can a user complain to a licensing body? Consumer protection?
- Should the business be allowed to pursue any monetization path, such as subscription, sponsorship, or advertising?

Scientific Literature

- Evolving quickly; recent technological leaps call for new research
- Recent survey highlights dozens of relevant studies
- Studied applications include:
 - Education about mental health
 - Provider training
 - Assessment
 - Intervention
- Some AI tools were safe and efficacious. Others were not.
- Conclusion: The state should require evidence of safety and efficacy comparable to other devices.

Technology Considerations

Possible Benefits

- Address mental health sooner
- Talk to human therapists at the right time
- Better applied use of AI in mental health
- Potential to reduce expense and waste
- More efficiency and accuracy

Possible Harms

- Users follow bad advice from the chatbot
- Users are disintermediated from human therapists
- Companies follow "engagement" business model (like social media)
- Companies misuse users' data
- Companies violate users' privacy