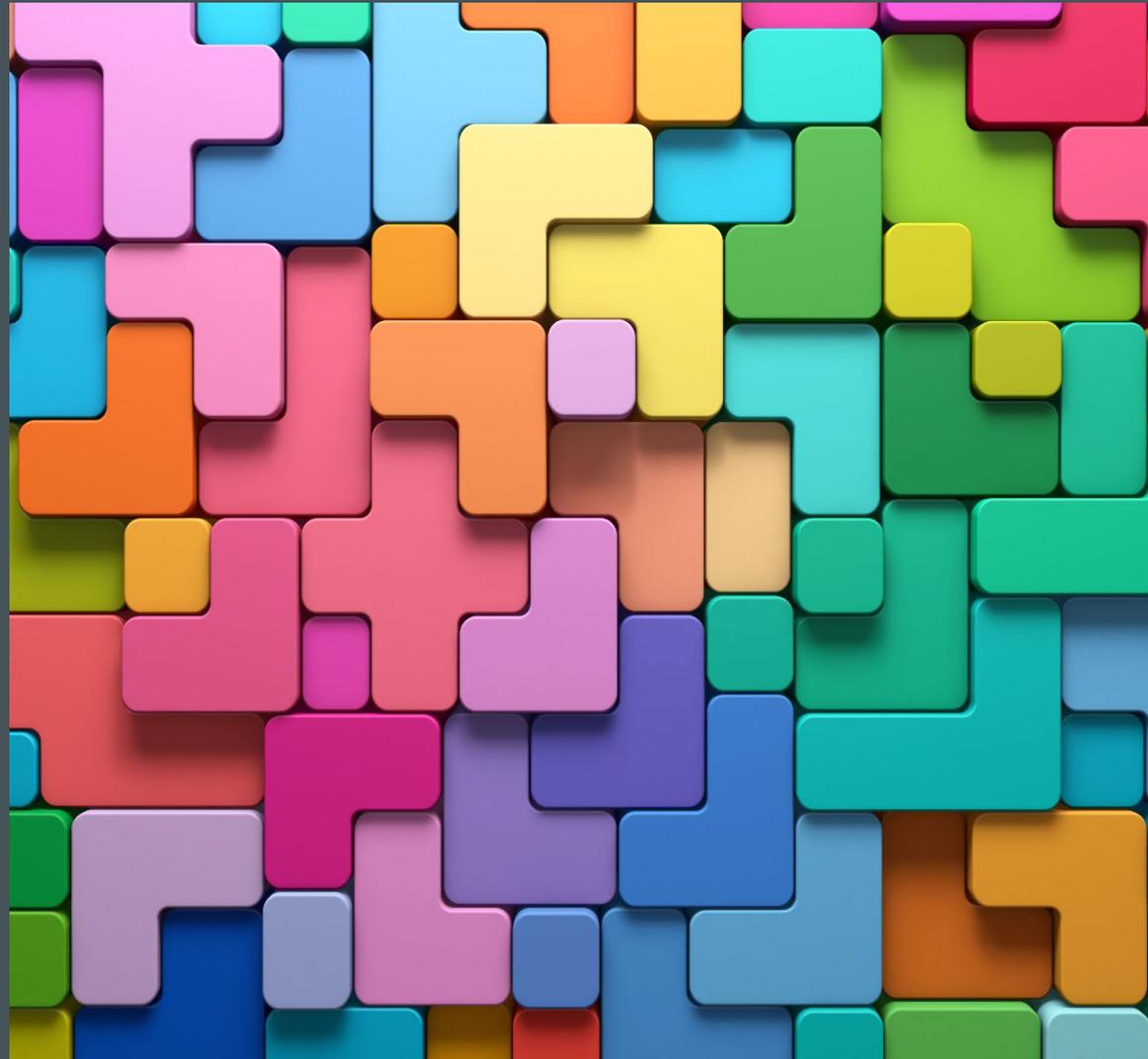

FDA Digital Health Advisory Committee Meeting
November 6, 2025

Payor Perspectives on Digital Mental Health Technologies

Bradley E. Karlin, PhD, ABPP, MSCP, MBA
Advanced Research Projects Agency for Health
(ARPA-H)

Bradley.Karlin@arpa-h.gov

Views expressed are my own and do not necessarily reflect
those of ARPA-H, HHS, or the federal government



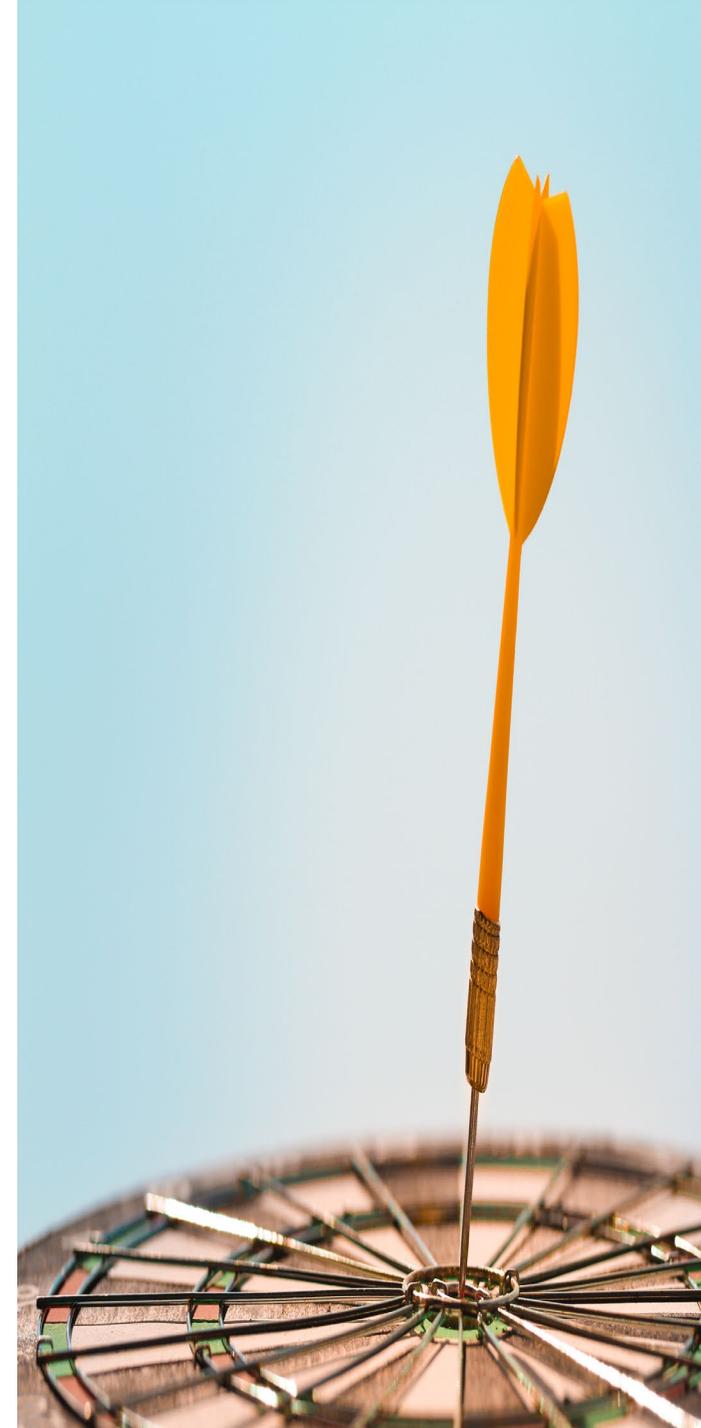
Payor Priorities and Considerations: “What” Factors Clinical and Engagement Outcomes

■ Clinical efficacy/effectiveness

- Access vs. quality
- RCTs, *RWE
- Evaluation frameworks available (e.g., Evidence DEFINED [Silberman et al., 2023])

■ Engagement outcomes

Type	Solutions without GenAI	Solutions with GenAI
Primary Interaction	<ul style="list-style-type: none">• Static content, pre-set modules, rules-based chatbots	<ul style="list-style-type: none">• Personalized, human-like conversational agents• Dynamic content creation
Initial Engagement	<ul style="list-style-type: none">• Low to moderate	<ul style="list-style-type: none">• High• Personalization capabilities can attract and hold interest early on
Ongoing Engagement	<ul style="list-style-type: none">• Very low retention, with most users dropping off within 2 weeks• “Inverted hockey stick” graph	<ul style="list-style-type: none">• Significantly higher, especially with more sophisticated personalization, adaptive capabilities, and multimodality
Key Differentiator	<ul style="list-style-type: none">• Requires self-motivation and novelty; engagement suffers as content becomes repetitive	<ul style="list-style-type: none">• Interactivity, novelty, and contextual awareness provide a more dynamic and engaging user experience



Payor Priorities and Considerations: “What” Factors Financial Impact and Value

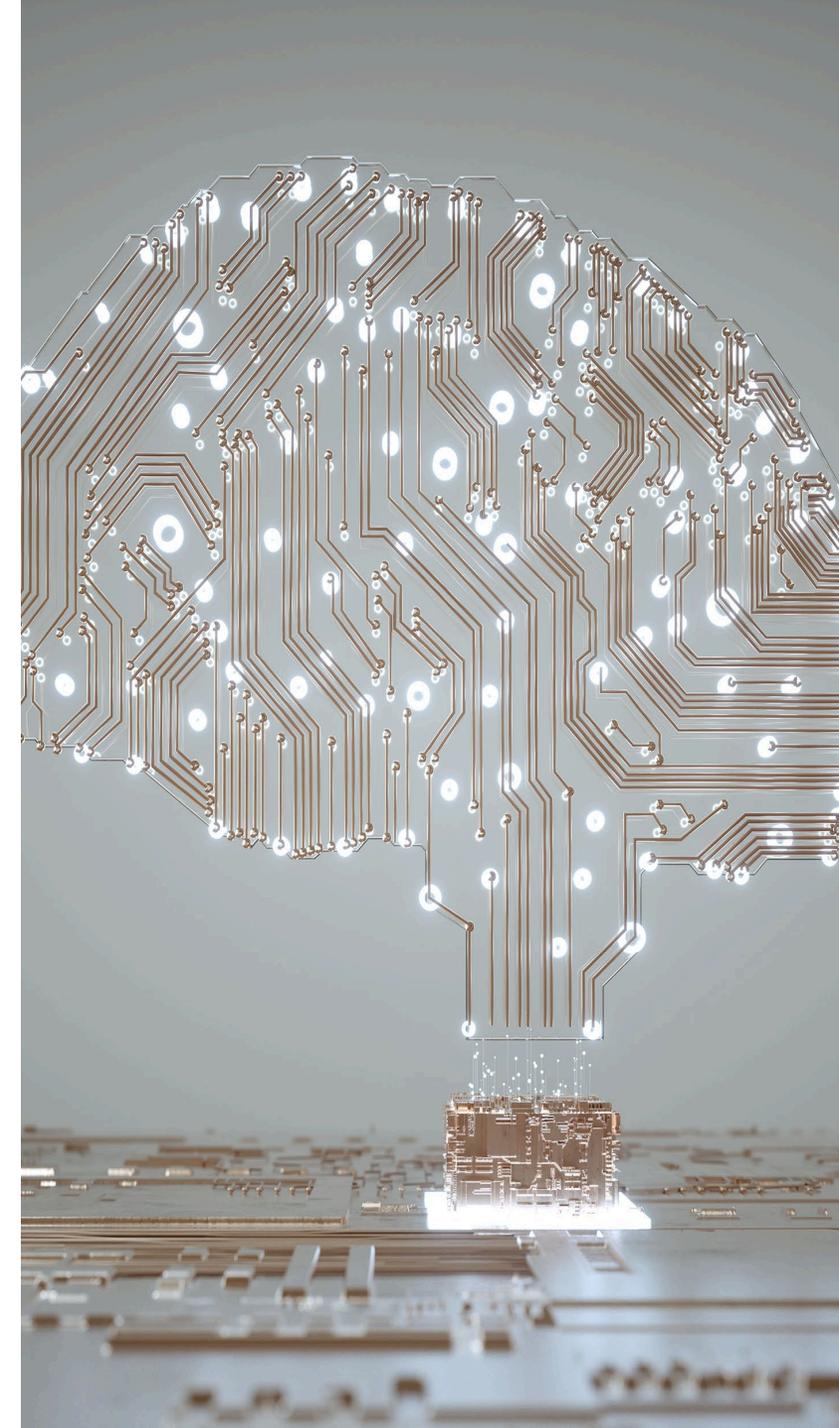
- **Financial impact/ROI**
 - Members with a BH condition have 3-6x higher annual total health care costs than those without (Davenport et al., 2020)
 - Health service offset (PH visits, BH visits, ED visits, inpatient), total cost of care reduction
 - Longer ROI time horizon for BH (months → years)
- **Value potential**
 - Innovative payment models
 - Pay for performance (P4P)
 - Pay for measurement (P4M)
 - Risk-based value-based models
 - Upside risk vs. downside risk
- Limited by **lack of measurement** and data provision!



Payor Priorities and Considerations: “How” Factors

Member Experience, Integration, and Scalability

- **Member experience and satisfaction**
 - Design, ease of use, perceived utility, customizability
- **Technical interoperability and integration**
 - EHR compatibility
 - Fragmented point solution vs. SSO vs. full integration
 - Low friction → higher adoption
- **Clinical integration and scalability**
 - Clinical workflow, added burden
 - Driver of adoption and engagement
 - Standalone vs. blended models
 - Commercial payors and CMS coverage initiation of digital therapeutics/formulary models
 - PDT with FDA clearance, broader definition of “prescriber”
 - Fully automated, standalone AI chatbots not covered (but may be used outside of FFS models)
 - Some state laws prohibit providers from using AI for direct patient care (non-admin tasks)



Payor Priorities and Considerations: “How” Factors

Data Privacy and Ethical Considerations



OPT-IN/CONSENT & CUSTOMIZABILITY

- Consent for (minimized) data collection and sharing
- Customizability/opt-in/out rights



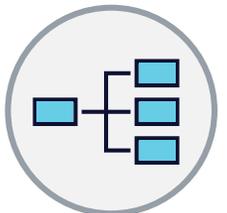
DATA SECURITY & PRIVACY

- Privacy-preserving methods
- Protections for data use, collection, and sharing
- Use of federated learning
- HIPAA-compliance



ACCOUNTABILITY

Review by independent interdisciplinary experts



SAFETY

- Specially-trained and tested models
- Escalation capabilities
- Notification of trusted others



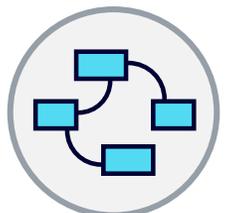
APPROPRIATENESS OF USE

Used for intended application



FAIRNESS

Collaborative research partnerships, model refinement and explainability that minimize bias



TRANSPARENCY

- Clear disclosure on how information will be used and disseminated
- Use of explainable AI models
- Communication of processes and results



EVIDENCE OF PERFORMANCE

Ensure accuracy and validity



DEMONSTRATE VALUE PROPOSITION

Clear communication of benefits and limitations

Payor Priorities and Considerations: “When” Factors Personalization and Population Health Utility

Personalization (3 R's)

- Right-fit
- Right-timed
- Right-sized

Population Health

- Proactive ID and risk stratification
- Upstream (vs. downstream) utility
 - Depression severity changes (\uparrow/\downarrow) associated with \pm changes in TCC (Popkov et al., 2025)
- Pop health-oriented payment models
 - PMPM > FFS/reimbursement-based
 - Commonly with full-stack digital/virtual BH companies



Additional Priorities and Considerations – GenAI-Based Solutions

- Escalation protocols/risk management
 - <2 in 10 include even basic standard crisis line (988) information; many include incorrect or nonfunctional resources (Dwyer et al., in press)
 - “Black box” models/explainability
- Regulatory ambiguity
 - Solution pre-market review (wellness vs. disease-focused)
 - Evidence and privacy/security thresholds
- Post-market surveillance and continuous monitoring
- Consistent labeling and disclaimers
 - Intended use, limits, origin of content, scope/clinician involvement
 - Great variability in marketplace among solutions
 - Many key stakeholders and decisionmakers are not BH experts!
- Solution proliferation vs. market consolidation and payor partnerships





THANK YOU.
