HB5003

LRB10418445AAS31887b

104TH GENERAL ASSEMBLY

State of Illinois

2025 and 2026

HB5003

Introduced 2/10/2026, by Rep. Bob Morgan

SYNOPSIS AS INTRODUCED:

225 ILCS 155/20.1 new

Amends the Wellness and Oversight for Psychological Resources Act. Defines "qualified research program". Provides that the prohibitions on unauthorized therapy services under the Act shall not apply to artificial intelligence-assisted therapy or psychotherapy services provided exclusively within a qualified research program. Sets forth requirements for qualified research programs. Requires a licensed professional participating in a qualified research program to perform certain actions. Provides that academic medical centers shall register existing research programs that meet the criteria for qualified research programs within 90 days after the effective date of the amendatory Act. Provides that the exemption shall apply only to services provided within the context of an approved research protocol and shall not extend to certain services. Sets forth requirements for academic medical centers conducting qualified research programs. Provides that research participants shall not be denied access to standard care as a condition of participating in research involving artificial intelligence-assisted therapy. Sets forth requirements for the Department of Financial and Professional Regulation. Provides penalties for any academic medical center or licensed professional found to have misrepresented a commercial service as qualifying for the research exemption, or to have otherwise violated the requirements of the amendatory Act. Requires the Department to submit a report to the General Assembly evaluating aspects of the qualified research programs. Repeals the provisions on January 1, 2030. Makes other changes.

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A BILL FOR

AN ACT concerning regulation.

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

Section 1. Findings. The General Assembly finds that:

(1) responsible scientific research into artificial intelligence applications for mental health care serves the public interest by potentially expanding access to evidence-based treatment for underserved populations;

(2) academic research conducted under rigorous institutional oversight, with appropriate safeguards and ethical review, is categorically distinct from unregulated commercial artificial intelligence therapy services marketed directly to consumers;

(3) Illinois has a compelling interest in maintaining its position as a leader in responsible health care innovation while protecting patients from harm; and

(4) research exemptions with appropriate safeguards can advance scientific knowledge without compromising the consumer protection objectives of the original Act.

Section 2. Purpose. The purpose of this Act is to amend the Wellness and Oversight for Psychological Resources Act to establish a limited exemption for bona fide clinical research conducted at academic medical centers, while maintaining the

Act's core consumer protections against unregulated artificial intelligence therapy services.

Section 5. The Wellness and Oversight for Psychological Resources Act is amended by adding Section 20.1 as follows:

(225 ILCS 155/20.1 new)

Sec. 20.1. Artificial intelligence-assisted therapy; qualified research programs.

(a) As used in this Section, "qualified research program" means a program of clinical research that satisfies all the following criteria:

(1) The research is conducted by or under the supervision of an academic medical center that:

(A) is affiliated with an accredited medical school or university;

(B) operates under a valid hospital license issued by the Department of Public Health; and

(C) maintains accreditation by the Joint Commission or an equivalent national accrediting body.

(2) The research protocol has received approval from an Institutional Review Board (IRB) registered with the United States Department of Health and Human Services Office for Human Research Protections and the IRB:

(A) has determined that the research satisfies federal regulations for the protection of human

subjects under 45 CFR Part 46;

(B) conducts a continuing review of the research at intervals appropriate to the degree of risk, but no less than annually; and

(C) has specific expertise or consultation in mental health research, artificial intelligence applications, and research ethics.

(3) All artificial intelligence systems used in the research:

(A) are designed and operated in compliance with the Health Insurance Portability and Accountability Act (HIPAA) and all applicable federal and State privacy regulations;

(B) undergo documented safety testing to identify and mitigate potential harms before use with human research participants;

(C) include real-time monitoring mechanisms to detect and respond to crisis situations, harmful content, or therapeutic errors; and

(D) are used only as adjuncts to, and not replacements for, services provided by licensed mental health professionals.

(4) All research participants:

(A) must provide informed consent that specifically describes the use of artificial intelligence, the experimental nature of the

intervention, potential risks and benefits, and alternatives to participation;

(B) are informed in writing of the participants' right to withdraw from the research at any time without penalty;

(C) receive information about how to access licensed mental health professionals outside the research context; and

(D) have access to licensed mental health professionals who can intervene if safety concerns arise during the research.

(5) The research program maintains:

(A) a data safety monitoring plan appropriate to the level of risk;

(B) procedures for reporting adverse events to the IRB and, where applicable, to federal oversight agencies;

(C) documentation of all protocol modifications and safety incidents; and

(D) plans for dissemination of research findings through peer-reviewed scientific publications or presentations.

(6) The primary purpose of the research program is to generate generalizable scientific knowledge about the safety, efficacy, or implementation of artificial intelligence applications in mental health care, rather

than to provide routine clinical services or to market commercial products.

(b) The prohibitions under Section 20 of this Act shall not apply to artificial intelligence-assisted therapy or psychotherapy services provided exclusively within a qualified research program, subject to the requirements and limitations specified in this Section.

(c) A licensed professional participating in a qualified research program shall:

(1) maintain an active, unrestricted license in good standing as required under Illinois law;

(2) receive training specific to the artificial intelligence systems used in the research, including the artificial intelligence systems' capabilities, limitations, and potential risks;

(3) maintain ultimate clinical responsibility for all care provided to research participants;

(4) be available to intervene when safety concerns arise or when the artificial intelligence system's performance is inadequate; and

(5) document the licensed professional's supervision and oversight activities in accordance with the research protocol.

(d) Academic medical centers shall register qualified research programs in existence on the effective date of this amendatory Act of the 104th General Assembly within 90 days

after the effective date of this amendatory Act of the 104th General Assembly.

(e) The exemption under this Section shall apply only to services provided within the context of an approved research protocol and shall not extend to:

(1) clinical services marketed or provided outside a research context;

(2) services provided primarily for revenue generation rather than scientific inquiry; and

(3) services provided without active IRB approval and oversight.

(f) An academic medical center shall not:

(1) advertise artificial intelligence therapy services to the general public as routine clinical services;

(2) use the exemption under this Section to circumvent licensing requirements for commercial therapy services; and

(3) charge research participants fees beyond those disclosed in and permitted by the IRB-approved research protocol.

(g) An academic medical center conducting a qualified research program shall:

(1) register such programs with the Department within 30 days after IRB approval;

(2) provide annual reports to the Department summarizing the number of research participants, any

serious adverse events, any protocol modifications, and any scientific findings; and

(3) notify the Department within 10 business days of any IRB suspension or termination of a research protocol.

(h) Research participants shall not be denied access to standard care as a condition of participating in research involving artificial intelligence-assisted therapy.

(i) The Department shall comply with the following requirements:

(1) maintain a public registry of qualified research programs operating under this Section;

(2) develop forms and procedures for registration and annual reporting; and

(3) coordinate with relevant professional licensing boards to ensure compliance with this Section.

(j) Any academic medical center or licensed professional found to have misrepresented a commercial service as qualifying for the exemption under this Section, or to have otherwise violated the requirements of this Section, is subject to the following:

(1) immediate loss of exemption status for the program in question;

(2) civil penalties under Section 30;

(3) referral to the appropriate licensing boards for professional discipline; and

(4) prohibition from seeking exemption status for new

research programs for a period of not less than 2 years.

(k) No later than July 1, 2029, the Department shall submit a report to the General Assembly evaluating the following:

(1) the number and nature of research programs that have operated under the exemption under this Section;

(2) any reported adverse events or safety concerns;

(3) scientific findings regarding the safety and efficacy of artificial intelligence applications in mental health care; and

(4) recommendations regarding whether the exemption under this Section should be continued, modified, or allowed to expire.

(l) Nothing in this Section shall limit the authority of professional licensing boards to discipline licensed professionals for violations of professional standards of care.

(m) The provisions of this Section are severable under Section 1.31 of the Statute on Statutes.

(n) This Section is repealed on January 1, 2030.