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ARTIFICIAL INTELLIGENCE IN MENTAL HEALTH LANDSCAPE – LEGAL AND REGULATORY CHALLENGES[1]

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***Summary**: Mental health diseases are increasingly prevalent in contemporary society, affecting millions of individuals globally in the post-industrial era. In addition, post-COVID-19 impact, lack of interpersonal contact, and economic concern have caused new cases of major depression and anxiety disorders and other stress-related disorders. Artificial intelligence (AI) offers new perspectives in the mental healthcare sector, ranging from clinical decision support tools to new treatment strategies or alternative patient remote monitoring, accurate prognostic assessments, and self-managed support systems, all of which can significantly improve the efficiency and structure of mental health services. However, while the introduction of AI in mental healthcare presents certain advantages, it also introduces specific challenges. As an innovative technology, artificial intelligence is associated with certain barriers, limitations, and challenges for appropriate integration in medical practice. To avoid potential risks and harms to patient safety, and ensure their well-being, it is necessary to establish a comprehensive legal and regulatory framework to guide healthcare professionals in their AI adoption in clinical practice. By adopting the Artificial Intelligence Act, the European Union offers a new legal framework for the development and application of AI systems. However, these new regulatory concepts may be obscure for healthcare professionals. Therefore, the aim of this paper is to examine the legal and regulatory framework governing the AI application in mental health, with a particular focus on recently enacted legal documents, primarily adopted in some US states, AI Act, and other relevant international legal documents, as well as to consider the potential risks associated with the implementation of artificial intelligence in relation to patient safety.*

***Key words**: Mental Healthcare; Artificial Intelligence; Federal regulation of AI in the US; AI Act; Patient Protection; Legal and Regulatory Framework.*

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1. INTRODUCTION

With the onset of the fourth industrial revolution, technological progress, driven by the development and utilization of artificial intelligence (AI), has achieved unprecedented levels, providing humanity with substantial advantages.[3] As an innovative technology, artificial intelligence is also associated with certain barriers, limitations, and challenges for appropriate integration in medical (clinical) practice.

Mental health deceases are becoming increasingly predominant in contemporary society, affecting millions of individuals globally in the post-industrial era.[4] Mental deceases, also called mental health disorders, are highly prevalent globally, and have been one of the most serious public health concerns.[5] Additionally, the impact of the COVID-19 pandemic, combined with the reduction in interpersonal contact, and growing economic uncertainties, has led to a rise in cases of major depression and anxiety disorders and other stress-related disorders.[6] Artificial Intelligence is emerging as a promising tool in the mental healthcare sector, offering new perspectives on treatment and care. AI applications range from clinical decision support systems to innovative treatment strategies, remote patient monitoring, accurate prognostic assessments, and self-managed support systems.[7] These AI-driven solutions have the potential to significantly enhance the efficiency, accessibility, and structure of mental health services. However, the integration of AI into mental health also presents a set of unique challenges. While the advantages are undeniable, careful consideration is needed to address the potential risks, ethical concerns, and limitations associated with AI implementation in this sensitive field.[8]

The integration of artificial intelligence in the prevention and protection of mental health represents a significant advance in the provision and improvement of patient healthcare. Therefore, the paper will first investigate and analyze the potential of artificial intelligence in transforming current clinical practice related to preservation of mental health. The aim of this paper is to examine the legal and regulatory framework governing the application of artificial intelligence in mental health, with a particular focus on recently enacted legal documents, primarily adopted in some US states, Artificial Intelligence Act, and other relevant international legal documents, and to address key questions commonly raised by healthcare professionals in relation to these technologies. In that sense, the aim of this research is to offer a concise guide outlining the principal legal considerations, providing healthcare professionals with the basic information necessary for the properly use new AI applications, while also addressing the potential risks to patient safety.

3 Igor Milinković, „The Moral and Legal Status of Artificial Intelligence (Present Dilemmas and Future Challenges)". *Law and Business* (2021), 29.

4 Researchers assess that more than 38% of Europeans suffer from a mental disorder each year. See: Patricia Gual-Montolio, Irene Jaen, Veronica Martínez-Borba, Diana Castilla & Carlos Suso-Ribera, "Using Artificial Intelligence to Enhance Ongoing Psychological Interventions for Emotional Problems in Real- or Close to Real-Time: A Systematic Review". *International Journal of Environmental Research and Public Health* 19 (13) (2022) 7737, 1.

5 Tianlin Zhang, Annika M. Schoene, Shaoxiong Ji & Sophia Ananiadou, "Natural language processing applied to mental illness detection: a narrative review". *NPJ Digital Medicine* 5 (2022), 1.

6 David B. Olawade, Ojima Z. Wada, Aderonke Odetayo *et al*., „Enhancing mental health with Artificial Intelligence: Current trends and future prospects". *Journal of Medicine, Surgery and Public Health* 3 (2024):100099, 1.

7 Shuroug A. Alowais, Sahar S. Alghamdi, Nada Alsuhebany, Tariq Alqahtani, Abdulrahman I. Alshaya, *et al*. "Revolutionizing healthcare: the role of artificial intelligence in clinical practice". *BMC Medical Education* (2023), 23:689.

8 Allison Gilbert, Emanuela Pizzolla, Sofia Palmieri & Giovanni Briganti, "Artificial Intelligence in Healthcare and Regulation Challenges: A Mini Guide for (Mental) Health Professionals". *Psychiatria Danubina*, 36 (2) (2024), 348.

2. THE EVOLUTION OF ARTIFICIAL INTELLIGENCE INTEGRATION IN THE ADVANCEMENT OF MENTAL HEALTH PROTECTION

The evolution of artificial intelligence integration in the protection of mental healthcare dates back to the 1950s, with the appearance of the first computers, which provided the foundation for scientists to initiate efforts aimed at creating machines capable of replicating cognitive processes.[9] During this period, pioneers in the field of artificial intelligence, Allen Newell and Herbert Simon, initiated groundbreaking research aimed at constructing AI models designed to address complex human challenges. Although their research may be regarded as foundationally rudimentary by contemporary standards, they established the foundational framework for symbolic artificial intelligence, which subsequently proved to be vital in simulating cognitive functions and contributing to the preservation of mental healthcare.[10] In the early 1970s, Josef Weisenbaum was among the first to create AI tools in psychology. His program, Eliza, can be considered a precursor to contemporary chatbots, as it simulated a psychotherapeutic dialogue. Despite the relatively simple nature of the responses generated by Eliza, they effectively engaged users in text-based interactions, thereby demonstrating the potential of technology to enhance user engagement within the context of mental healthcare services.[11] Although the initial tools of artificial intelligence systems were limited compared to modern AI tools, they certainly represented significant progress in the integration of technology and mental healthcare.

During the 1980s and 1990s, researches in artificial intelligence experienced a significant paradigm shift toward machine learning and neural network methodologies. These approaches enabled computational systems to learn from data inputs and progressively enhance their performance. Notably, this era witnessed the creation of advanced systems such as IBM's *Deep Blue*, which famously defeated the reigning world chess champion, Garry Kasparov, in 1997 - a landmark achievement in AI capabilities.[12]

In the 2000s, AI research continued to advance, with increased emphasis on natural language processing and computer vision. These developments facilitated the emergence of intelligent virtual assistants, including Apple's Siri and Amazon's Alexa, which are capable of comprehending and responding to human language with increasing sophistication.[13] These innovations marked a pivotal step in the integration of AI technologies into consumer applications and everyday digital interactions.[14]

As technology progressed, so did the complexity of AI models. Over time, AI applications in mental healthcare began to range from chatbots and virtual therapists (e.g. Woebot or Wysa) to more complex systems used for diagnostic support, personalized treatment plans, and even

9 Paul Uwa, „Unleashing the Potential of Artificial Intelligence: Revolutionizing Industries and Shaping the Future". Medium (2023). Available at: https://medium.com/@paulnodfield/unleashing-the-potential-of-artificial-intelligence-revolutionizing-industries-and-shaping-the-74a668f9712e (Accessed: 17.08.2025)

10 James Moor, „The Dartmouth College Artificial Intelligence Conference: The Next Fifty Years". *AI Magazine* 27 (4) (2006), 87.

11 Caroline Bassett, "The computational therapeutic: exploring Weizenbaum's ELIZA as a history of the present". *AI & Society* 34 (4) (2019), 803-812.

12 Shuroug A. Alowais, *et al*., "Revolutionizing healthcare: the role of artificial intelligence in clinical practice", 2.

13 Paul Uwa, „Unleashing the Potential of Artificial Intelligence: Revolutionizing Industries and Shaping the Future".

14 Shuroug A. Alowais, *et al*., "Revolutionizing healthcare: the role of artificial intelligence in clinical practice", 2.

monitoring mental health symptoms in real-time via mobile apps and wearable's. Today, artificial intelligence is widely used to diagnose mental health conditions, manage treatment plans, provide therapeutic interventions, and even identify early indicators of mental health crises (such as depression, anxiety, or suicidal ideation) utilizing natural language processing (NLP) and machine learning algorithms.[15]

3. THE IMPLEMENTATION AND IMPACT OF ARTIFICIAL INTELLIGENCE IN CONTEMPORARY MENTAL HEALTHCARE SYSTEMS

AI-enabled clinical decision-support systems have the potential to mitigate diagnostic errors, enhance decision-making processes, and assist healthcare professionals in tasks such as electronic health record data extraction and documentation. Advancements in computational techniques, including natural language processing, pattern recognition, efficient search, predictive analytics, and bias-free reasoning, are expected to expand the functionalities of AI, thereby addressing challenges that are currently deemed intractable.[16]

Artificial intelligence is used in the early detection and prediction of mental health disorders. By analyzing speech, facial expressions, text or electronic health records, artificial intelligence transforms the current way of diagnosing and treating diseases. For example, voice analysis can reveal changes in speech patterns, including variations in pitch, tone, and rhythm.[17] These changes can serve as valuable indicators of emotional or psychological states, such as anxiety or depression. For instance, the AI-driven mental health application Woebot utilizes sentiment analysis to assess user text input. In instances where a user continuously expresses emotions such as sadness, hopelessness, or despair during chat interactions, Woebot is designed to identify these patterns and, provide guidance or recommend referral to professional mental health services.[18] Another example of similar technology is the AI platform Cogito, which is used in telemedicine to monitor patients' speech patterns during therapy sessions. When Cogito detects alterations in speech characteristics like pitch, rhythm, or tone, it may signal underlying emotional conditions, prompting a notification to the psychotherapist for further investigation and possible intervention.[19] Similarly, facial expression analysis uses AI to detect subtle shifts in facial features or mimicry, which can provide additional insights into a patient's emotional or psychological state. By observing the expressions, AI tools can identify potential signs of distress or emotional struggle, helping healthcare providers to better understand the patient's condition and respond accordingly.[20] In both instances, the inte-

15 David B. Olawade, Ojima Z. Wada, Aderonke Odetayo *et al*., „Enhancing mental health with Artificial Intelligence: Current trends and future prospects". 2.

16 Kevin B. Johnson, Wei-Qi Wei, Dilhan Weeraratne *et al*., "Precision Medicine, AI, and the Future of Personalized Health Care". *Clin Transl Sci* 14 (1) (2021). 87.

17 Olivia Flanagan, Amy Chan, Partha Roop & Frederick Sundram, "Using Acoustic Speech Patterns From Smartphones to Investigate Mood Disorders: Scoping Review". *JMIR mHealth and uHealth* 9 (9) (2021), 1-11.

18 David B. Olawade, Ojima Z. Wada, Aderonke Odetayo *et al*., „Enhancing mental health with Artificial Intelligence: Current trends and future prospects". 4.

19 Ibid.

20 Ibid.

gration of AI in these analyses allows for a more comprehensive approach to monitoring mental health, offering valuable data to guide timely and targeted interventions.

AI has demonstrated significant potential in improving the early diagnosis of mental health disorders by analyzing electronic health records (EHRs). Specifically, machine learning algorithms possess the capability to carefully review and analyze vast amounts of patient data stored in electronic health records, including medical histories, diagnosis tests, medications, and clinical notes, to identify patterns that indicate a mental health condition. Additionally, most EHRs related to mental deceases cover clinical notes written in narrative form. Consequently, the application of natural language processing techniques is deemed appropriate for supporting disease diagnosis within EHR datasets, including but not limited to suicide risk assessment, identification of depressive disorders, and mental condition prediction.[21] By doing so, AI tools can flag patients who may be at risk, prompting healthcare professionals to pay closer attention to their mental well-being during routine care and screenings. The use of AI in early detection enhances personalized care by considering each individual's unique medical history, alongside other crucial factors such as genetic predispositions, environmental influences, and lifestyle choices.[22] This early identification enables timely interventions, ultimately fostering a more targeted and proactive approach to mental health. Furthermore, artificial intelligence is reshaping approaches in diagnosing and treating people with mental disabilities by employing virtual therapists and chatbots. Chabot's and AI-driven tools can predict how patients will respond to different treatment approaches, whether it's through psychotherapy, the use of certain medications, or dietary changes.[23]

4. LEGAL AND REGULATORY FRAMEWORKS GOVERNING THE USE OF ARTIFICIAL INTELLIGENCE IN MENTAL HEALTHCARE SYSTEMS

Despite the numerous advantages, the application of AI tools in mental health presents several significant risks that could compromise the well-being and safety of patients. The integration of artificial intelligence tools in healthcare services, especially in the prevention and management of mental health conditions, introduces numerous legal and ethical dilemmas. Key concerns include the protection of privacy, confidentiality and security of sensitive patient data, all of which are vital in maintaining trust within the healthcare system. Additionally, AI's involvement in mental health risks exacerbating issues of discrimination, as algorithmic biases could affect treatment recommendations and outcomes.[24] The traditional physician-patient relationship, built on trust

21 Tianlin Zhang, Annika M. Schoene, Shaoxiong Ji & Sophia Ananiadou, "Natural language processing applied to mental illness detection: a narrative review". 4.

22 Ahmed Al Kuwaiti, Khalid Nazer, Abdullah Al-Reedy, *et al*., "A Review of the Role of Artificial Intelligence in Healthcare". *Journal of Personalized Medicine* 13 (6) (2023) 951, 5.

23 David B. Olawade, Ojima Z. Wada, Aderonke Odetayo *et al*., „Enhancing mental health with Artificial Intelligence: Current trends and future prospects". 5.

24 Ranko Sovilj, „Da li upotreba veštačke inteligencije u dijagnostikovanju i lečenju lica sa mentalnim poteškoćama otvara Pandorinu kutiju u savremenom svetu? – pravne i etičke dileme", In: *Aktuelnosti medicinskog prava – teorija, praksa i zakonodavstvo 6,* Ed. Hajrija Mujović (Beograd – Institut društvenih nauka & Novi Sad – Glasnik Advokatske komore Srbije, 2025). 40.

and personalized care, may also be undermined by the use of impersonal AI systems. This shift prompts crucial questions about liability specifically, who is responsible in the event of an error made by an AI tool. In light of these complexities, a central issue emerges regarding the regulatory status of AI tools in mental health. With many AI applications yet to be fully regulated, concerns persist about their potential negative effects on individuals and society. This uncertainty raises important questions about the safety and ethical implications of deploying AI tools in such a sensitive and personal area of healthcare.[25]

Through a critical analysis of existing legal norms and ethical standards related to the application of artificial intelligence in the prevention of mental health, an attempt is made to look at the existing barriers and shortcomings that exist in the mental health protection. The integration of artificial intelligence tools in mental health, particularly in the prevention and early intervention of mental health issues, has shown considerable promise. Traditionally, mental health treatment methodologies have adhered a one-size-fits-all approach, which may, in certain instances, result in outcomes that are not fully aligned with the individual needs of patients. AI-driven personalization enables psychotherapists to develop interventions that are meticulously tailored to an individual's unique challenges and strengths.[26] These advancements have primarily focused on improving accessibility to psychotherapy and counseling services, as well as maintaining patient anonymity, which could reduce the stigma often associated with seeking mental health.[27] However, the primary problem is the absence of a comprehensive and precisely defined normative framework that governs the use of artificial intelligence tools in the prevention of mental health, as well as the absence of generally accepted ethical standards.

No country to date has enacted legislation that explicitly regulates the utilization of artificial intelligence in the prevention of mental health disorders. Nevertheless, several jurisdiction, particularly in the United States, have commenced the implementation of laws that govern the application of AI in broader mental health contexts, including emotionally supportive chatbots, therapeutic tools, and AI Companions. Additionally, a variety of AI-related legislations have been proposed in the US Congress since the inauguration of President Trump in January 2017, including the SELF DRIVE Act, the FUTURE of Artificial Intelligence Act of 2017, and the AI JOBS Act of 2019.[28] The SELF DRIVE Act is the sole piece of legislation that has successfully passed one chamber, i.e., the US House of Representatives. However, none of the proposed acts directly address the legal and

25 Stephan Hoose & Kristina Kralikova, „Artificial Intelligence in Mental Health Care: Management Implications, Ethical Challenges, and Policy Considerations". *Administrative Sciences* 14 (2024), 3.

26 Patricia Gual-Montolio, *et al*. "Using Artificial Intelligence to Enhance Ongoing Psychological Interventions for Emotional Problems in Real- or Close to Real-Time: A Systematic Review". 3.

27 An additional problem in a number of European jurisdictions, including high-income countries with advanced healthcare systems and universal health insurance, is that the provision of publicly funded, cost-free psychological treatment for mental health disorders remains inadequate or largely unavailable. Structural barriers to accessing mental health services include, *inter alia*, waiting lists, co-payments, and insufficient allocation of resources, thereby compelling individuals with EDs who can afford this treatment within the private healthcare sector. Moreover, in certain EU Member States, public health insurance covers psychiatric but not psychological treatment, despite the existence of clinical guidelines confirming that specific psychological treatments, and in particular cognitive-behavioral therapy (CBT), have the highest level of evidence and can be considered as main treatments for people with mild to moderate anxiety or depression. Patricia Gual-Montolio, *et al*. "Using Artificial Intelligence to Enhance Ongoing Psychological Interventions for Emotional Problems in Real- or Close to Real-Time: A Systematic Review". 2.

28 Sara Gerke, Timo Minssen & Glenn Cohen, „Ethical and legal challenges of artificial intelligence-driven healthcare", In *Artificial Intelligence in Healthcare*, Eds. Adam Bohr & Kaveh Memarzadeh (Elsevier – Academic Press, 2020), 298.

ethical aspects of applying artificial intelligence in mental health prevention. For instance, the FUTURE of Artificial Intelligence Act of 2017 mandates the Secretary of Commerce to establish a Federal advisory committee tasked with providing counsel to the Secretary. This committee is further directed to examine and evaluate, *inter alia*, the integration of ethical standards into the development and implementation of artificial intelligence, as well as the potential impact of AI advancements on cost reductions in healthcare.[29]

On the other hand, the US Food and Drug Administration (FDA) has initiated the process of regulating certain medical devices based on artificial intelligence, including those utilized within the field of mental health. To date, the FDA has granted clearance or approval for approximately 40 AI-based medical devices. The FDA regulates the use of medical devices in the United States.[30] A medical device is defined in Section 201 (h) of the US Federal Food, Drug, and Cosmetic Act (FDCA) as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them; (B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or (C) intended to affect the structure or any function of the body of man or other animals; and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes." [31] The 21st Century Cures Act was enacted into law by former President Barack Obama on December 13, 2016. This legislation introduced an exemption under Section 520(o) of the Federal Food, Drug, and Cosmetic Act for medical software and certain decision support software that does not fulfill the definition of a medical device. Additionally, Section 201(h) of the FDCA was also amended to include a second sentence, explicitly clarifying that software functions falling under Section 520(o) of the FDCA are not classified as devices.[32]

In the meantime, several federal states of the US have commenced the regulation of artificial intelligence applications in healthcare, with a particular emphasis on governing the utilization of artificial intelligence in the prevention of mental health issues. State-level initiatives in the US regarding the regulation of artificial intelligence, particularly in the area of mental health and well-being, show a strong trend toward caution and responsibility. Each state appears to be taking unique approaches, but with a shared concern for ensuring transparency and patients safety. Governor JB Pritzker has officially enacted the Wellness and Oversight for Psychological Resources Act (WORP), positioning Illinois as a leader among states that are establishing legal parameters for artificial intelligence in the realm of behavioral healthcare. This Acts prohibits licensed therapists from using any AI-driven app to make therapeutic decisions or communicate directly with patients. Otherwise, violations could result in a $10.000 fine by the state's regulatory agency. Therapists can

29 Ibid.

30 Ibid., 306.

31 Federal Food, Drug, And Cosmetics Act, As Amended Through P.L. 118–83, Enacted September 26, 2024, Sec 201 (h). Available at: https://www.govinfo.gov/content/pkg/COMPS-973/pdf/COMPS-973.pdf (Accessed: 20.08.2025)

32 Sara Gerke, Timo Minssen & Glenn Cohen, „Ethical and legal challenges of artificial intelligence-driven healthcare", 307.

use AI for administrative support, such as note taking and planning.[33] New York has enacted the first legislation mandating safeguards for AI companions. Set to take effect on November 5, 2025, the law requires operators of AI companions to implement safety measures designed to detect and address expressions of suicidal ideation or self-harm by users. Additionally, the law mandates that operators provide regular disclosures to users, clearly informing them that they are engaging with an AI system, and not a human being.[34] The law applies to operators of AI companions with users within New York.[35] Operators of AI companions are hereby required to implement and maintain a protocol that includes reasonable measures to detect and address any expression of suicidal ideation or self-harm by a user. The law requires that, upon detection of such an expression, the operator shall promptly refer the user to a qualified crisis service provider, a crisis text line, or other appropriate crisis intervention service. Furthermore, the law mandates that operators of AI companions provide a clear and conspicuous notification, either verbally or in writing, informing the user that he is not engaging in communication with a human.[36]

Some US states have placed particular emphasis on regulating chatbots in the context of mental health protection. For instance, Utah passed HB 452 Act in March 2025. This Act established the Office of Artificial Intelligence Policy (OAIP) and issued guidelines for mental health chatbots, including mandatory disclosures that the user is not interacting with a human. This Act defines a "mental health chatbot" as an AI technology that must meet two conditions. First, the technology must employ generative AI to engage in interactive conversations with a user of the mental health chatbot, simulating the confidential communication that patient (user) would have with a licensed psychotherapist. Second, the "supplier" of the chatbot must either explicitly represent, or a reasonable person must believe, that the chatbot is capable of providing mental health therapy or assisting a user in managing or treating mental health conditions.[37] HB 452 Act prohibits suppliers of mental health chatbots from "selling" or "sharing" individually identifiable health information of a patient (user), or any content provided by the patient, except in the following circumstances: (1) when the information is disclosed to a healthcare provider with the consent of

33 Carrie Shepherd, "Illinois blocks AI from being your therapist". 2025. Available at: https://www.axios.com/local/chicago/2025/08/06/illinois-ai-therapy-ban-mental-health-regulation (Accessed: 21.08.2025)

34 Teylor Stenberg Erb & Maneesha Mithal, "New York Passes Novel Law Requiring Safeguards for AI Companions". Wilson Sonsini, 2025. Available at: https://www.wsgr.com/en/insights/new-york-passes-novel-law-requiring-safeguards-for-ai-companions.html (Accessed: 21.08.2025)

35 For the purposes of this law, "AI companions" are defined as systems employing artificial intelligence, generative AI, or "emotional recognition algorithms," which are specifically designed to simulate and sustain a human-like relationship with a user. Such systems shall be characterized by the following capabilities: (1) the retention of information regarding prior interactions and user preferences, thereby personalizing and facilitating ongoing engagement; (2) the ability to pose unsolicited or unprompted emotion-based inquiries that extend beyond mere responses to user prompts; and (3) the capacity to maintain an ongoing dialogue with the user concerning personal matters. For the purposes of this law, "emotional recognition algorithms" are defined as AI systems capable of detecting and interpreting human emotional signals in various forms, including but not limited to text (via natural language processing and sentiment analysis), audio (via voice emotion AI), video (via facial movement analysis, gait analysis, or physiological signals), or any combination thereof. Teylor Stenberg Erb & Maneesha Mithal, "New York Passes Novel Law Requiring Safeguards for AI Companions".

36 Teylor Stenberg Erb & Maneesha Mithal, "New York Passes Novel Law Requiring Safeguards for AI Companions".

37 Maneesha Mithal, Andrea Linna, Hale Melnick & Nawa Lodin, "Utah Enacts Mental Health Chatbot Law". Wilson Sonsini, 2025. Available at: https://www.wsgr.com/en/insights/utah-enacts-mental-health-chatbot-law.html (Accessed: 21.08.2025)

a patient residing in Utah, or (2) when the information is shared with a health plan at the request of a Utah patient. Additionally, a supplier may disclose individually identifiable health information to service providers, provided that such disclosure complies with the requirements of the HIPAA Privacy Rule, including by entering into a business associate agreement, as applicable.[38] On June 5, 2025, Nevada Governor Joe Lombardo signed AB 406, a law regulating the application of AI for mental and behavioral healthcare. AB 406 Act comes as other states, such as New York and Utah, have taken steps to regulate artificial intelligence chatbots that provide mental health services. This Act imposes restrictions on behavioral health providers, bans AI from acting as mental health professionals, and forbids school counselors from using AI in their duties.[39] As we can conclude, laws in several US states require clear disclosures when patients interact with AI, especially in sensitive areas like mental health. Accordingly, the provisions aim to protect vulnerable patients from potential harm, such as detecting self-harm or restricting AI from acting as a psychotherapist.

In the United Kingdom, the use of artificial intelligence in healthcare is governed by a framework of general legislation, including the Data Protection Act 2018, and the Medical Devices Act 2021, which collectively regulate certain applications of AI in healthcare sector. Furthermore, in June 2022, the Medicines and Healthcare products Regulatory Agency (MHRA) issued a guideline entitled Government Response to Consultation on the Future Regulation of Medical Devices in the United Kingdom, providing additional regulatory guidance on the use of AI in medical devices and related healthcare applications.[40] The guidance, in addition to secondary legislation, will structure the legal framework in the UK. As opposed to legislation, one of the advantages of guidance is that it allows for a flexible and reactive approach to change.[41]

In June 2023, the European Parliament has adopted an Artificial Intelligence Act. The classification of AI systems under the AI Act is predicated on a risk-based approach, whereby potential harms are assessed through an evaluation of both the probability of occurrence and the severity of the adverse events. The AI Act categorizes artificial intelligence systems based on levels of risk as: unacceptable risk, high-risk, limited risk, and minimal or no risk. Annex III of the AI Act sets forth a list of high-risk AI system use cases, encompassing, *inter alia*, remote biometric identification systems, as well as applications deployed in the healthcare sector for purposes such as the triage of emergency situations.[42] The level of unacceptable risk means that the artificial intelligence system must be deemed a clear threat to the safety, livelihoods and rights of people, and will be prohibited. High-risk applications are subject to additional legal requirements. In a healthcare system, these tools could include robot-assisted surgery, medical devices with artificial intelligence, or *in*

38 Maneesha Mithal, Andrea Linna, Hale Melnick & Nawa Lodin, "Utah Enacts Mental Health Chatbot Law"

39 Teylor Stenberg Erb, Maneesha Mithal, Andrea Linna & Hale Melnick, "Nevada Passes Law Limiting AI Use for Mental and Behavioral Healthcare". Wilson Sonsini, 2025. Available at: https://www.wsgr.com/en/insights/nevada-passes-law-limiting-ai-use-for-mental-and-behavioral-healthcare.html (Accessed: 21.08.2025)

40 Ranko Sovilj & Sanja Stojković Zlatanović, „Artificial Intelligence in Healthcare – Applications, Possible Legal Implications and Challenges of Regulation". In *Regional Law Review*, Ed. Mario Reljanović (Belgrade, Institute of Comparative Law, 2023), 230.

41 Nicholas Vollers & Alison Dennis, "AI Regulation in Healthcare: UK and EU Approaches". 2023. Available at: https://www.taylorwessing.com/en/insights-and-events/insights/2023/03/ai-regulation-in-healthcare-uk-and-eu-approaches (Accessed 14. 8. 2025).

42 Allison Gilbert *et al.*, "Artificial Intelligence in Healthcare and Regulation Challenges: A Mini Guide for (Mental) Health Professionals". 349.

vitro diagnostic medical devices.[43] Although the AI Act does not explicitly address the prevention of mental health issues, certain AI applications in this domain may fall under the AI Act's scope, contingent upon their intended use and the associated risks. For instance, if an AI tool is used for mental health prevention, including diagnosing conditions, predicting mental health crises, or analyzing relevant mental health data, it may be classified as a high-risk system, particularly if it affects patient' health or wellbeing. These tools will only be permitted to be placed on the EU if specified conditions are met, such as establishing a risk management system, complying with data governance requirements, and drawing up technical documentation.[44]

It is important to note that if an artificial intelligence system utilized in healthcare also qualifies as a medical device under the Medical Device Regulation, it must comply with the requirements established by the Medical Device Regulation.[45] The Medical Device Regulation applies to software as medical devices, including AI-based software, while the In Vitro Diagnostic Medical Devices Regulation applies to *in vitro* based diagnostics, including AI-based. The Medical Device Regulation also introduces new implementing and classification rules for software in Chapters II and III of Annex VIII. Particularly, the Medical Device Regulation contains a new classification rule that focuses explicitly on software.[46] According to this rule, "software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa (medium risk), except if such decisions have an impact that may cause: (1) death or an irreversible deterioration of a person's state of health, in which case it is in class III (highest risk), or (2) a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb (higher risk)".[47] In that case, depending on the potential impact of the decision, the AI-based Clinical Decision Support (CDS) software may be classified as a Class III, if it poses a risk of causing death or an irreversible deterioration of the patient's state of health, or as a Class IIb, in the event it may lead to a serious deterioration of the patient's health or a surgical intervention.[48]

Based on the aforementioned discussion, it can be concluded that the regulations include new approaches for more rigid pre-market control, increased clinical investigation requirements, enhanced surveillance across the devices lifecycle, and improved transparency by creating a European database of medical devices. However, many aspects specific to artificial intelligence are not taken into consideration, such as continuous learning of the AI models or the identification of algorithmic biases.[49]

43 Ranko Sovilj & Sanja Stojković Zlatanović, „Artificial Intelligence in Healthcare – Applications, Possible Legal Implications and Challenges of Regulation", 231.

44 Ibid.

45 Allison Gilbert *et al*., "Artificial Intelligence in Healthcare and Regulation Challenges: A Mini Guide for (Mental) Health Professionals". 349.

46 Sara Gerke, Timo Minssen & Glenn Cohen, „Ethical and legal challenges of artificial intelligence-driven healthcare", 311.

47 Regulation (EU) 2017/745 of thr European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, *Official Journal of the European Union*, L 117, Annex VIII, Chapter 3, 6.3 Rule 11.

48 Sara Gerke, Timo Minssen & Glenn Cohen, „Ethical and legal challenges of artificial intelligence-driven healthcare", 312.

49 Ranko Sovilj & Sanja Stojković Zlatanović, „Artificial Intelligence in Healthcare – Applications, Possible Legal Implications and Challenges of Regulation", 231-232.

5. LEGAL FRAMEWORK OF ARTIFICIAL INTELLIGENCE APPLICATION IN THE MENTAL HEALTHCARE SYSTEM OF THE REPUBLIC OF SERBIA

In the Republic of Serbia, the regulation of artificial intelligence in the healthcare system has not yet specifically regulated by a comprehensive legal framework that would exclusively refer to the application of artificial intelligence in healthcare. However, several regulations have an indirect or direct impact on the application of AI in healthcare system. The Law on Health Care, as a systematic legislative framework governing the provision of health services in the Republic of Serbia, does not include provisions related to the application of artificial intelligence in healthcare. However, the Law on Health Care provides a basis for regulating new health technologies, including information systems, decision support tools, and data analysis.[50]

The Republic of Serbia adopted a new Law on Personal Data Protection in November 2018, however its application has been postponed until 21 August 2019. The New Law is nearly identical to the EU's GDPR, it applies to automated decision-making and profiling, requires consent, grants data subject rights (access, erasure, portability), and mandates privacy-by-design and privacy-by-default.[51] Therefore, the main goal of the Law has been to ensure, in the era of internet and information technologies, an adequate and efficient protection of personal data, including health information, guaranteed as one of the major human rights and freedoms under the Constitution of the Republic of Serbia.

On the other hand, the Mental Health Protection Program in the Republic of Serbia for the Period 2019-2026 describes measures, conditions, and public policy instruments designed to prevent mental disorders, improve mental health, diagnose mental states, treat and rehabilitate persons with mental disorders, and respect human rights.[52] Despite this, neither the Program, nor the Law on the Protection of Persons with Mental Disabilities and its bylaws explicitly address the preservation mental health through the use of artificial intelligence tools in diagnostics and treatment.[53]

Recently, the Republic of Serbia has adopted a comprehensive strategy for artificial intelligence development, with a focus on education, research, innovation, and public sector integration. In January 2025, the Government of the Republic of Serbia has adopted the new Strategy for the Development of Artificial Intelligence in the Republic of Serbia for the period 2025-2030.[54] The incentives prioritize special support for the implementation of AI solutions in the fields of healthcare and biotechnology. The mechanisms and application of AI technology in improving health are at the top of the priority list. Thanks to the nature of AI, which overcomes language barriers and other traditional limitations, a wide range of advanced solutions, particularly in diagnostics, have been developed. These can be rapidly deployed in clinical settings to enhance patient care and effectively demonstrate the transformative potential of AI in healthcare.[55]

50 Law on Health Care, *Official Gazette of RS,* No. 25/2018 & 92/2023, Art. 48-52.

51 Law on Personal Data Protection, *Official Gazette of RS*, No. 87/2018.

52 Mental Health Protection Program in the Republic of Serbia for the Period 2019-2026, *Official Gazette of RS,* No. 84/2019.

53 Milena Škobo, Sanja Stojković Zlatanović & Marta Sjeničić, „Mental Health Challenges in the Educational Landscape of Serbia: Exploring Academic and Legal Perspectives". *Medicine, Law & Society* 17 (1) (2024), 124.

54 Strategy for the Development of Artificial Intelligence, *Official Gazette of RS,* No. 5/2025.

55 Strategy for the Development of Artificial Intelligence, 52-53.

Additionally, in February 2023, Serbia adopted non-binding document Ethical Guidelines for Development, Implementation and Use of Robust and Accountable Artificial Intelligence, aligned with the EU AI Act and UNESCO AI ethics. The basis for the adoption of the Guidelines is primarily the previous Strategy of Development of Artificial Intelligence for the Republic of Serbia for the period 2020–2025, which identified the ethical and safe use of AI as one of its five goals.[56]

The primary objective of adopting these Guidelines is to safeguard against the potential risks posed by artificial intelligence systems that could undermine or marginalize human and human agency, and to prevent the infringement of fundamental freedoms, including the right to act, think, and make decisions, to the extent that the legal protections and frameworks safeguarding these values are rendered ineffective, trivialized, or neglected. The focus is on fostering ecosystems that leverage artificial intelligence to enhance human productivity, optimize resource utilization in the workforce and societal functions, and ultimately improve the quality of human life. These guidelines flag healthcare AI systems (e.g., genetic or diagnostics tools) as high-risk, prompting voluntary compliance with risk management processes.[57] The Guidelines emphasizes principles like: explainability & verifiability; human dignity; non-harm; fairness, privacy, transparency, non-discrimination. According to Guidelines, the principle of fairness in healthcare means "the prohibition of discrimination in the provision of healthcare services on the basis of race, sex, gender, sexual orientation and gender identity, age, ethnicity, social origin, religion, political or other beliefs, property status, culture, language, health condition, type of illness, mental or physical disability or other personal characteristics that may give rise to discrimination".[58]

Serbia blends GDPR-style data protection, ethical AI guidelines, and new e-health infrastructure to protect patients. However, binding rules for AI application in healthcare, particularly in mental health, are still under development. In the interim, a working group has been established for the drafting of the Law on Artificial Intelligence, with the adoption of the said Law anticipated in the near future.[59]

6. CONCLUSION

While there is considerable legislative activity concerning AI in mental health, particularly with regard to chatbots and their therapeutic roles, there is currently no comprehensive legal framework that specifically regulates the use of AI in the prevention of mental health conditions, with the exception of a few US states that have recently adopted relevant regulation. Existing regulatory measures either regulate general AI in healthcare, mental health therapy applications, or mandate disclosing AI identity and handling crisis situations. These regulations are still evolving, and many

56 The previous Strategy for the Development of Artificial Intelligence was adopted in 2019, for the period 2020-2025. Strategy for the Development of Artificial Intelligence, *Official Gazette of RS,* No. 96/2019.

57 Ethical Guidelines for Development, Implementation and Use of Robust and Accountable Artificial Intelligence (Belgrade, 2023), 3.

58 Ibid., 13.

59 Održan prvi sastanak Radne grupe za izradu Nacrta zakona o veštačkoj inteligenciji Republike Srbije, 2024. Available at: https://nitra.gov.rs/en/ministarstvo/vesti/odrzan-prvi-sastanak-radne-grupe-za-izradu-nacrta-zakona-o-vestackoj-inteligenciji-republike-srbije, (Accessed 22. 8. 2025).

countries are in the early stages of developing mental health-specific rules and policies related to AI application. In light of the rapid advancements of technology, it is anticipated that future legal and regulatory measures will be required to delineate distinctly the roles and responsibilities associated with the application of AI technologies in the healthcare sector. The primary challenge lies in achieving a balance between fostering innovation in AI and upholding safety, privacy, and ethical standards, particularly in relation to the sensitive nature of mental health.

Given the absence of comprehensive legislation and a well-established legal tradition in this area, it is imperative that regulators approach the governance of artificial intelligence in mental healthcare with due diligence. Legal scholars and practitioners must exhibit ingenuity in interpreting existing legal frameworks, a process that complicates the development of a cohesive legal framework. In this context, decision makers and public policymakers should carefully consider potential barriers in formulating future regulations, thereby supporting the responsible and thoughtful integration of AI tools in mental health prevention, encouraging innovation and enhancing public awareness. The prompt and effective regulation of the numerous legal and ethical issues is essential to ensure that artificial intelligence serves as a useful instrument in the prevention and preservation of mental health, rather than a source of additional harm, abuse or discrimination.

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ПРИМЕНА ВЕШТАЧКЕ ИНТЕЛИГЕНЦИЈЕ У ОЧУВАЊУ МЕНТАЛНОГ ЗДРАВЉА – ПРАВНИ И РЕГУЛАТОРНИ ИЗАЗОВИ

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***Апстракт**: Болести менталног здравља све више преовлађују у савременом друштву и погађају милионе појединаца широм света у постиндустријској ери. Осим тога, последице COVID-19, социјална удаљеност и економска неизвесност узроковали су све већи број пацијената који се суочавају са анксиозношћу, депресијом и другим поремећајима изазваних стресом. Вештачка интелигенција (ВИ) нуди нове могућности у области менталног здравља, обухватајући алате који подржавају клиничке одлуке, иновативне стратегије лечења и алтернативне методе даљинског праћења пацијената. Такође, ВИ омогућава прецизне прогностичке процене и системе самосталног управљања подршком, што може значајно унапредити ефикасност у пружању услуга у очувању менталног здравља. Међутим, иако увођење вештачке интелигенције у области заштите менталног здравља нуди значајне предности, истовремено доноси и специфичне изазове. Као иновативна технологија, вештачка интелигенција је повезана са одређеним препрекама, ограничењима и изазовима који се морају превазићи ради адекватне интеграције у медицинској пракси. Да би се избегли потенцијални ризици и штете по безбедност пацијената и обезбедило њихово благостање, неопходно је успоставити свеобухватан правни и регулаторни оквир који ће усмеравати здравствене посленике у процесу интеграције вештачке интелигенције у клиничку праксу. Усвајањем Закона о вештачкој интелигенцији, Европска унија успоставила је правила за развој и примену система вештачке интелигенције. Међутим, нови регулаторни оквир може бити непрецизан здравственим посленицима у клиничкој пракси. Стога је циљ предметног истраживања анализа правног и регулаторног оквира у примени вештачке интелигенције у очувању менталног здравља, са посебним фокусом на недавно усвојене правне документе, првенствено прописе које су донеле поједине државе САД-а, Закон о вештакој интелигенцији ЕУ, друге релевантне међународне правне документе, као и разматрање потенцијалних ризика у примени вештачке интелигенције по безбедност пацијената.*

***Кључне речи**: Ментално здравље, Вештачка интелигенција; Федерално регулисање вештачке интелигенције у САД; Закон о вештачкој интелигенцији; Заштита пацијената; Правни и регулаторни оквир.*

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