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Entrepreneurial Law in the Field of Health Services in Electronic Medical Records

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Abstract

Entrepreneurship in the field of Electronic Medical Records (EMR)-based healthcare services presents both opportunities and challenges related to legal compliance, patient data protection, and professional ethics. This study aims to analyze the relevant legal aspects of EMR implementation and their implications for business model development and healthcare service innovation.

The method used is a systematic literature study with a qualitative-descriptive approach. Literature was obtained from academic databases and public repositories using the keywords "Electronic Medical Records", "health entrepreneurship", "health law", "privacy by design", and "telemedicine regulation" for the period 2020–2025. The analysis was conducted through thematic/content analysis with a focus on four main themes: the regulatory framework and legality of EMR, the implications of EMR for entrepreneurship and technology governance, legal risks and protection of healthcare workers, and implementation barriers related to infrastructure, human resources, and interoperability.

The study results indicate that the implementation of EMR plays a crucial role as a legal instrument, a means of digitizing services, and a basis for developing a regulatory-compliant entrepreneurial model. Implementation challenges include limited infrastructure, disparities in healthcare workforce competency, and varying levels of preparedness in healthcare facilities. Integrating legal principles, such as privacy by design and role-based access control, is key to minimizing legal risks while strengthening patient and stakeholder trust. In conclusion, strengthening the legal aspects of RME-based healthcare entrepreneurship is a prerequisite for ensuring a balance between innovation, legal protection, and business sustainability, while simultaneously improving the quality of healthcare services nationally.

Keywords: Electronic Medical Records, Health Entrepreneurship, Health Law

1. Introduction

The right to health is a fundamental right of every individual as regulated in Article 28H Paragraph (1) of the 1945 Constitution of the Republic of Indonesia. Efforts to improve the quality and availability of health service facilities are a strategic step to optimize public satisfaction with the quality of health services (Lukitawati, 2023). This inequality requires a cross-sectoral development approach in order to provide a comprehensive and sustainable impact (Lutfiana, 2025). Fulfillment of these rights requires collaboration between the

government and the private sector through the development of entrepreneurship in the provision of health services (Kementrian Kesehatan, 2023).

Understanding the legal aspects of entrepreneurship is a factor that needs to be considered, because the existence of legal entity status is an important foundation in carrying out business activities (Mulyanita, 2021). Realizing this right necessitates strategic collaboration between the government and the private sector, particularly through strengthening entrepreneurial practices in healthcare delivery (Lutfiana, 2025).

Entrepreneurship in the healthcare sector is considered a crucial strategy for expanding the reach of services and improving the quality of value provided, while strengthening a sustainable healthcare innovation ecosystem. Recent findings in Indonesia underscore the need for this strengthening *public health entrepreneurship* in response to future public health and service challenges (Pratomo et al., 2025). Furthermore, health entrepreneurship is an effective strategy for expanding access, improving service quality, and developing a sustainable innovation ecosystem (Larasati et al., 2024).

However, the healthcare sector is highly sensitive given its direct link to patient safety. Therefore, entrepreneurial practices in healthcare should be conducted within strict legal frameworks, including the implementation of a risk-based licensing system (*Online Single Submission Risk-Based Approach/ OSS-RBA*), regulations for the provision of telemedicine services, protection of patient data confidentiality, as well as compliance with professional ethical standards and legal protection provisions for consumers (F. Nasution & Ibrahim, 2024)

Digitalization of healthcare services—especially through the implementation of *Electronic Medical Records* (RME)—gives rise to specific legal obligations. Based on Minister of Health Regulation Number 24 of 2022, every healthcare provider is required to manage medical records, including in electronic form, while adhering to the principles of confidentiality, security, and system integration in healthcare facilities. The implementation of this regulation has direct implications for the design of business models and information system architectures for business actors, including through the application of the concept of *privacy by design*, role-based access control, and data breach incident management (*data breach*). The 2023–2024 literature review highlighted three key pillars of successful implementation: a reliable EMR system, effective operational governance, and the readiness of human resources and technological infrastructure in healthcare facilities (Siregar, 2024)

The implementation of EMR requires compliance with regulations, including patient data protection, cybersecurity, and adherence to professional ethical standards (Rubiyanti, 2023). In an entrepreneurial context, the implementation of EMR has implications for business model design, technology management, and healthcare service delivery strategies. *privacy by design*, role-based access control (*role-based access control*), and efforts to mitigate the risk of data breaches are essential components of the operations of businesses in this sector (El Harry & Santiago, 2024). Furthermore, EMR plays a crucial role in the legal realm as evidence in resolving medical disputes, which require a high level of data validity, integrity, and authentication (E. E. Nasution & Siregar, 2025).

However, the implementation of EMR in Indonesia still faces several obstacles, including limited information technology infrastructure, disparities in healthcare workforce competency, and differing levels of preparedness across service facilities. Therefore, examining the legal aspects of entrepreneurship in EMR-based healthcare services is strategically important for maintaining a balance between innovation, legal protection, and business sustainability, while ensuring compliance with applicable laws and regulations (Juliansyah, 2025).

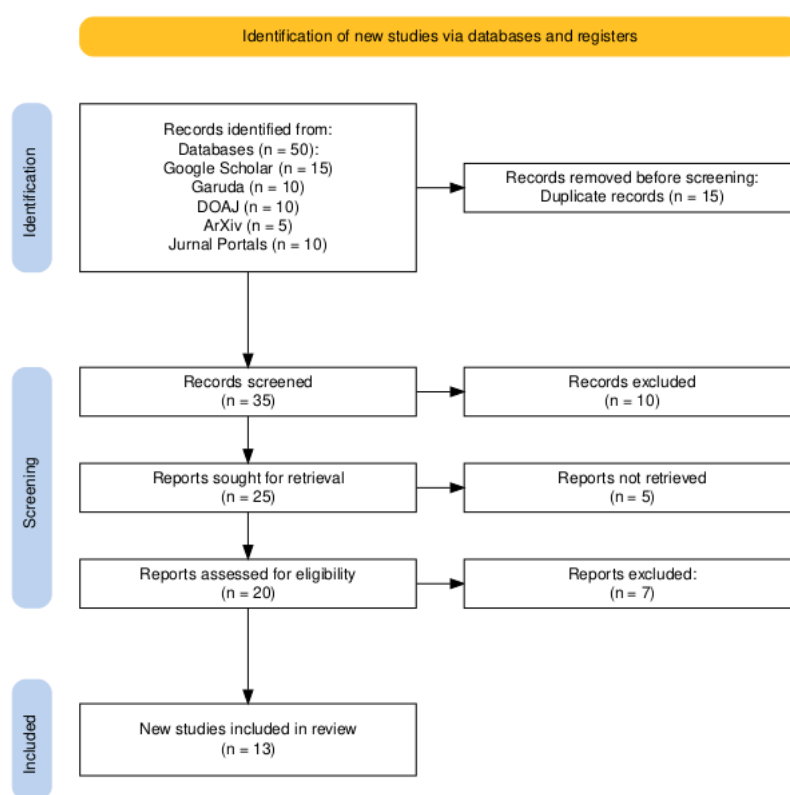
By deepening the study of RME from the perspective of entrepreneurial law in health services, this research is expected to contribute to the development of a more adaptive, innovative, and high-quality health service model (Kusuma Astuti et al., 2023).

2. Method

This research applies the method *systematic literature study*. A qualitative-descriptive approach was used to map the legal aspects relevant to Electronic Medical Record (EMR)-based healthcare entrepreneurship. A literature search was conducted on academic databases and repositories (Google Scholar, Garuda, DOAJ, arXiv, and institutional journal portals) using the keywords: “Electronic Medical Records”, “health entrepreneurship”, “health law”, “privacy by design”, and “telemedicine regulation” for the publication period **2020–2025**. Berikut diagram PRISMA penyaringan literatur dibawah ini:

Figure 1.

Prisma



Inclusion criteria included peer-reviewed articles, white papers, and legal studies addressing the legal implications of EMR on governance, business models, data protection, or clinical accountability; non-scientific documents and pre-2000 publications were excluded. The selection process was carried out in stages: initial identification → title and abstract screening → full-text assessment for relevance → thematic data extraction.

The analysis was carried out with *thematic/content analysis* to group the findings into main themes (E. E. Nasution & Siregar, 2025). The regulatory framework and legality of RME, (Juliansyah, 2025) the implications of RME on entrepreneurship models and technology governance, (Larasati et al., 2024) legal risks (e.g., the validity of RME as evidence) and protection of healthcare workers, and implementation barriers (infrastructure, human resources, interoperability). Synthesis of the results produced a legal issue map and

recommendations *legal-by-design* And *privacy-by-design* that can be adopted by health entrepreneurs and policy makers.

3. Result and Discussion

a. Electronic Medical Records (EMR) Implementation and Legal Compliance

Through a literature review, this study successfully revealed that the implementation of Electronic Medical Records (EMR) in healthcare facilities in Indonesia has become a key strategy in the digitalization of healthcare services. Based on the literature, EMR plays a role not only in efficiently storing patient data but also as valid evidence in resolving medical disputes (Basyarudin, 2022). This indicates that EMR implementation has significant legal implications, requiring all healthcare facilities to comply with applicable regulations (Sholkhan, 2024).

Minister of Health Regulation Number 24 of 2022 serves as the legal basis for managing medical records, including electronic ones. This regulation emphasizes the principles of confidentiality, security, and system integration, which serve as the foundation for EMR operations in healthcare facilities (Wahyuntara et al., 2024). Studies show that compliance with this regulation reduces the risk of litigation and increases clinical accountability, resulting in a feeling of protection for patients and a more legally secure healthcare facility.

Furthermore, research also faces various challenges, namely that EMR serves as an internal oversight instrument. This system enables audits of medical records, monitoring of service quality, and ensuring that standard operating procedures for clinical procedures are met (Hossain et al., 2025). Therefore, EMR implementation is not only related to technical and managerial aspects but also has important legal value in protecting patient rights (Neng Sari Rubiyanti, 2023).

b. Legal Aspects of Entrepreneurship in RME-Based Healthcare Services

Literature studies show that entrepreneurship in the field of EMR-based healthcare services requires a thorough understanding of legal aspects. This includes legal entity status, business permits, patient data protection, and adherence to professional ethics. Entrepreneurs developing EMR systems or digital medical services must ensure that their business models and technological architecture comply with applicable laws.

Draft privacy by design and role-based access control are important practices to protect patient data from leakage or misuse. Studies confirm that integrating legal aspects into healthcare entrepreneurship strategies allows business actors to reduce legal risks while increasing user trust.

Furthermore, the literature emphasizes the need for telemedicine regulations that support digital health entrepreneurship. Telemedicine systems integrated with EMR must comply with legal provisions, professional ethics, and consumer protection. This is key to ensuring the sustainability of digital health service innovation without creating legal issues (Wahyuntara et al., 2024).

c. RME Implementation Challenges

Despite its significant benefits, the implementation of EMR in Indonesia faces several challenges. First, limited information technology infrastructure is a major obstacle in some healthcare facilities, particularly in remote areas (Saputra, 2024). Inadequate infrastructure impacts data integration and system efficiency, thus affecting the overall quality of healthcare services.

Second, the competency of healthcare workers in using the EMR system remains variable. Studies show that inadequate human resource preparedness can lead to data input errors, the risk of information leaks, and inaccurate medical records (Amelia Septi

Ayuni et al., 2024). Therefore, training and certification for healthcare workers are essential aspects of EMR implementation.

Third, varying levels of preparedness among healthcare facilities result in varying levels of RME implementation. Some facilities are already capable of managing data digitally, while others still rely on manual or semi-digital systems, creating varying legal and managerial risks (Amelia Septi Ayuni et al., 2024)

d. The Role of RME in Data Protection and Professional Ethics

The literature confirms that EMR plays a crucial role in protecting patient data and meeting professional ethical standards (Wahyuntara et al., 2024). EMR systems designed according to privacy-by-design principles and role-based access control can minimize the risk of data breaches and maintain the confidentiality of patient information.

Furthermore, EMR serves as a means of professional oversight and accountability. Electronic documents can facilitate clinical audits, provide valid evidence, and support the legal resolution of medical disputes (Basyarudin, 2022). Thus, EMR serves not only as a digital health record but also as a legal and ethical instrument that strengthens the professionalism of healthcare workers

e. Implications of Entrepreneurship and Innovation in Healthcare

RME opens up entrepreneurial opportunities in the healthcare sector, particularly in the development of hospital management applications, telemedicine services, and digital health startups. Legal and regulatory literacy is crucial for sustainable innovation without creating legal risks.

Several studies have shown that business models that integrate legal, ethical, and data security principles can create sustainable innovation ecosystems. Businesses that are able to combine technology and legal compliance tend to be more trusted by patients and regulatory authorities, resulting in more stable and growing business opportunities.

4. Conclusion

Entrepreneurship in the EMR-based healthcare sector requires a deep understanding of legal aspects, telemedicine regulations, patient data protection, and professional ethics. Integrating legal principles into business models and technology architecture, such as privacy-by-design and role-based access control, is key to minimizing legal risks while enhancing patient and stakeholder trust.

The main challenges in implementing EMR include limited technological infrastructure, disparities in healthcare workforce competency, and differences in the readiness of healthcare facilities. However, implementing EMR in accordance with legal and ethical standards opens up opportunities for developing innovative digital healthcare services, expanding access to services, and creating a sustainable entrepreneurial ecosystem.

Overall, strengthening the legal aspects of RME-based healthcare entrepreneurship is a prerequisite for ensuring a balance between innovation, legal protection, and business sustainability, while also supporting improvements in the quality of healthcare services nationally.

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