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# Feasibility of Automated Prescription by Artificial Intelligence in Telemedicine Based on Health Law

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**ABSTRACT**

*Telemedicine, regulated under Law No. 17/2023 and Government Regulation No. 28/2024, lacks provisions on AI's role in prescription issuance, while Law No. 1/2024 on Electronic Information and Transactions facilitates medical digitization by recognizing electronic documents and digital signatures. The aim of this study was to evaluate the legal feasibility of automated prescribing by artificial intelligence systems in Telemedicine, in particular reviewing the void of norms governing the "signer" status of prescriptions by artificial intelligence. The research method used is normative legal research; includes the study of national legislative texts, the interpretation of key articles, as well as comparisons with international practices from the FDA (US) and EMA (European Union). The analysis shows that the current national legal regime only recognizes licensed doctors as the authorized parties to sign electronic prescriptions, so artificial intelligence can only function as a "Clinical Decision Support System" without the legal right to issue prescriptions independently. The results of the study also highlight the legal risks for artificial intelligence platform organizers and developers if automatic prescriptions are not verified by medical personnel, including potential malpractice lawsuits and violations of the Consumer Protection Law. In conclusion, to realize the issuance of prescriptions carried out by artificial intelligence, it is necessary to amend the Health Law and/or sectoral regulations that formalize algorithm certification standards, periodic audit mechanisms, and a scheme for the division of legal responsibilities between artificial*

*intelligence developers, platform providers, and supervising doctors.*

## INTRODUCTION

The transformation of digital healthcare services in Indonesia reached a significant milestone with the enactment of Law Number 17 of 2023 on Health (hereinafter the 2023 Health Law), which formally recognizes Telemedicine as a clinical service modality based on lawful digital communication technologies. The subsequent issuance of Government Regulation Number 28 of 2024 (hereinafter GR 28/2024) as its implementing regulation further mandates the integration of electronic medical records, standardization of interoperability, and consolidation of the national health information system.

Despite these advancements, neither instrument explicitly provides a normative framework for the use of artificial intelligence (AI) as a prescription-issuing entity, thereby raising fundamental concerns about the legitimacy of clinical outputs generated autonomously without physician authorization (Stallings, 2024). In contrast, Law Number 1 of 2024 concerning the Second Amendment to the Electronic Information and Transactions Law (ITE Law 2024) affirms the legal validity of electronic documents and signatures—provided they are processed through reliable electronic systems (DeRouen, 2024; Liu et al., 2024). This opens the door to digitized medical records and electronically signed prescriptions (Supriadi, Syahidin, & Yunengsih, 2024). However, the existing legal construct still hinges on human legal subjects, excluding AI algorithms from holding "signatory" status, thus creating a legal vacuum when AI autonomously generates prescriptions without physician oversight (Mienye et al., 2024).

International literature indicates that AI-based teleprescribing systems have been conceptually tested, but emphasize the need for robust clinical accountability equivalent to traditional care pathways (Mannas & Elvandari, 2022). Ethical and legal scholarship stresses the importance of identifying responsible parties in the event of therapeutic errors. In Indonesia, physicians remain the only authorized professionals to sign electronic prescriptions, limiting AI to a Clinical Decision Support System (CDSS) role.

Externally, the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have developed regulatory models for Software as a Medical Device (SaMD), which emphasize clinical validation, algorithmic transparency, and post-market surveillance. Indonesia may benefit from adopting similar approaches to safeguard patient rights while enabling technological innovation (Iancu et al., 2023).

From the perspective of Indonesian health law, Article 4 of the 2023 Health Law demands health services that are safe, high-quality, and accessible. If prescriptions are generated without physician involvement, legal liability may fall on platform operators or AI developers, under principles of product liability and consumer protection. The absence of clear accountability mechanisms not only risks malpractice claims but also

violates consumer rights to accurate information, as enshrined in Law Number 8 of 1999 on Consumer Protection.

This study is, therefore, essential in assessing the legal feasibility of AI-generated prescriptions in Indonesia. It seeks to evaluate whether AI algorithms can be recognized as signatories under the 2024 ITE Law and determine the legitimacy of their clinical application under the 2023 Health Law and GR 28/2024. The findings are intended to inform regulatory reforms that establish algorithm certification standards, define oversight responsibilities, and enforce a hybrid human-AI verification model to ensure the continued delivery of safe and accountable healthcare services (Mannas & Elvandari, 2022; Usman, 2020).

The integration of artificial intelligence (AI) into telemedicine has garnered significant attention in recent years, particularly in the context of automated prescription systems (Republik Indonesia, 2024). Previous research has explored the technical feasibility and clinical accuracy of AI-driven prescription tools, with studies highlighting their potential to reduce human error and enhance efficiency in healthcare delivery (Mannas & Elvandari, 2022). For instance, international frameworks such as the U.S. FDA's Software as a Medical Device (SaMD) and the European Medicines Agency's guidelines emphasize the importance of clinical validation and algorithmic transparency. However, these studies predominantly focus on technological and ethical aspects, leaving a critical gap in the examination of legal frameworks, especially in jurisdictions like Indonesia, where telemedicine is newly regulated but lacks specific provisions for AI autonomy in prescription issuance (Fields, 2020; United States Food and Drug Administration, 2021; European Medicines Agency, 2024).

A notable research gap lies in the absence of a normative framework addressing the legal status of AI as a prescriber within Indonesia's health law system. While the 2023 Health Law and Government Regulation No. 28 of 2024 recognize telemedicine, they remain silent on AI's role, creating ambiguity around the validity of AI-generated prescriptions and the allocation of liability in cases of therapeutic errors (Republik Indonesia, 2023; Repulik Indonesia, 2024). This gap is further exacerbated by the 2024 ITE Law, which validates electronic documents and signatures but does not account for non-human signatories. Consequently, the current legal regime fails to reconcile technological advancements with existing statutes, leaving stakeholders vulnerable to litigation and regulatory non-compliance (Iancu et al., 2023).

The urgency of this research stems from the rapid adoption of AI in healthcare and the pressing need to align innovation with patient safety and legal accountability. Without clear regulations, AI-driven prescriptions risk violating consumer protection laws and medical malpractice statutes, potentially undermining trust in telemedicine. For example, incorrect dosages or drug interactions generated by AI could lead to severe health consequences, with no established mechanism to hold developers or platform providers accountable. This research addresses these challenges by evaluating the legal feasibility of AI prescriptions and proposing actionable reforms to mitigate risks while fostering technological progress.

This study introduces novelty by examining the intersection of health law, digital authentication, and AI governance within the Indonesian context, a perspective largely unexplored in existing literature. Unlike prior works that focus on standalone technological or ethical issues, this research adopts a comprehensive normative legal approach, analyzing statutory gaps, comparative international models, and the implications of electronic signature laws for AI systems. By proposing a hybrid signature model and algorithm certification framework, the study offers innovative solutions to bridge the divide between AI autonomy and physician oversight, ensuring compliance with both the 2023 Health Law and the 2024 ITE Law.

The primary objective of this research is to assess the legal feasibility of AI-generated prescriptions in Indonesia and to formulate regulatory recommendations that balance innovation with patient protection. By identifying key legislative amendments—such as redefining legal subjectivity for AI and establishing post-market surveillance mechanisms—the study aims to provide a roadmap for policymakers. The benefits of this research extend to multiple stakeholders: healthcare providers gain clarity on liability, developers receive guidance on compliance, and patients enjoy safer, more transparent telemedicine services. Ultimately, this work contributes to the broader discourse on AI in healthcare by advocating for a legally sound and ethically robust framework tailored to Indonesia's evolving digital landscape.

## RESEARCH AND METHODS

This study adopts a qualitative normative legal research approach, focusing on doctrinal interpretation supported by comparative and statutory analysis. The research begins with an in-depth legal and regulatory analysis of primary Indonesian laws and regulations relevant to the issue, including the 2023 Health Law, Government Regulation Number 28 of 2024, the 2024 ITE Law, the Medical Practice Law of 2004, and the Consumer Protection Law of 1999. This stage identifies gaps, overlaps, and legal ambiguities concerning the legitimacy of artificial intelligence (AI) in issuing prescriptions within the Telemedicine framework.

The study is further strengthened by a comparative analysis of international regulatory models. These include the United States Food and Drug Administration’s Software as a Medical Device (SaMD) framework, the European Medicines Agency's principles on algorithmic safety and accountability, and the proposed European Union Artificial Intelligence Act. The study also examines the implementation of hybrid signature models in jurisdictions with mature Telemedicine regulations to extract applicable best practices for the Indonesian context. A literature review complements this analysis by examining scholarly publications, policy reports, and case studies addressing AI in healthcare, digital authentication, medical malpractice, and patient safety. This literature provides insight into the ethical and legal challenges posed by clinical automation and highlights the evolving global standards for medical AI systems.

The research employs a doctrinal approach to interpret fundamental legal concepts such as legal subjectivity, vicarious liability, non-repudiation, and electronic

evidence under Indonesian civil law traditions. It also explores how principles like due care and informed consent apply in an increasingly digitized healthcare environment. Finally, the methodology includes the formulation of a prescriptive legal framework. This involves proposing specific legislative reforms, including amendments to existing laws and the establishment of new technical and procedural standards. It also recommends the creation of institutional mechanisms for oversight, such as algorithm certification systems and post-market surveillance for high-risk AI. Through this comprehensive approach, the study aims to develop a coherent and actionable legal argument for the regulation of AI-generated prescriptions in Indonesia, balancing innovation with the imperative of patient protection and legal accountability.

## RESULT AND DISCUSSION

### Legal Status of Artificial Intelligence as a Prescription Issuing Entity in *Telemedicine* according to the Framework of Law No. 17 of 2023 concerning Health and Government Regulation No. 28 of 2024

The transformation of national health services after the passage of the 2023 Health Law opens up space for the use of information and communication technology in the implementation of health efforts, including Telehealth and *Telemedicine*. Article 25 paragraph (1) of the 2023 Health Law explicitly acknowledges the use of this technology, while paragraph (4) emphasizes that the provision of clinical services through Telehealth is realized in the form of *Telemedicine*. The operational framework is further outlined in GR 28/2024 which regulates infrastructure, types of services, human resources, and clinical standards for *Telemedicine* (Articles 558–564). However, both regulations maintain the traditional paradigm that medical personnel or licensed health workers , especially doctors, are the only subjects authorized to diagnose and sign electronic prescriptions.

Article 558 paragraph (6) of GR 28/2024 classifies the requirements of *Telemedicine* into four pillars: infrastructure, type of service, human resources, and clinical standards. In the third pillar, it is emphasized that human resources must include Medical Personnel and Health Workers who have a valid Registration Certificate (STR) and Practice License (SIP) (Article 562 paragraph (2)). This norm is in line with the Law of the Republic of Indonesia Number 29 of 2004 concerning Medical Practice which requires every medical practice, including prescription writing, to be carried out by a licensed doctor. Thus, the authority to issue prescriptions, both conventional and electronic, is *prima facie* limited to humans with certain professional qualifications.

The Minister of Health Regulation Number 20 of 2019 concerning the Implementation of *Telemedicine* Services between Health Service Facilities also emphasizes that doctors/specialists remain in charge of every clinical consultation and therapy *output*, including drug prescriptions (Articles 9–10). This regulation shows policy consistency: *Telemedicine* is recognized as an extension of conventional services, not as a substitute for the medical role of humans.

Artificial intelligence in the context of healthcare is generally categorized as *a Clinical Decision Support System* (CDSS) that provides recommendations for diagnosis,

prognosis, or therapy, but does not legally sign a prescription document. The WHO in its *Digital Interventions for Health System Strengthening* guidelines emphasizes that digital systems are *assistive*, not a substitute for the clinical authority of health professionals. Artificial intelligence in Indonesia has not yet been recognized as a functional legal subject that has the authority to make clinical decisions independently, due to the lack of a specific and adequate legal accountability framework.

The gap in norms is even more visible if Article 560 of PP 28/2024, which requires the registration of *Telemedicine applications* at the Ministry of Health, is read together with Article 551 which requires data security and interoperability standards. This regulation focuses verification on *electronic systems*, not on artificial intelligence entities that make decisions. As a result, if artificial intelligence automatically writes a prescription and affixes a certified electronic signature, there is no legal mechanism to identify the "signator" as required by the ITE 2024 Law, a law based on the concept of human legal subjects.

The ITE Law 2024 stipulates that an electronic signature is a signature that is linked to electronic data and is used as a means of verification and authentication of *the identity of the signer*. ITE Law 2024, Article 1 number 12) The condition for the reliability of certified electronic signatures lies in the guaranteed identity of the signatory party. In clinical practice, the identity must be traceable to a doctor who has a SIP, as required by the Medical Practice Act 2004. and Article 562 paragraph (2) of GR 28/2024. When artificial intelligence algorithms replace the signer function, the identity of individuals with professional authority is lost, so that electronic signatures, although technically valid, become *non-compliant* with the substantial requirements of the 2024 ITE Law.

Shift from *Humans in the Loop* to *machine in the loop* in health requires a redefinition of the concept *agency* and *Liability*. Without redefinition ut, all forms of medical transactions that contain prospective actions (e.g. drug delivery) have the potential to be null and void due to the non-fulfillment of the requirements of a legal subject.

Telemedicine clinical standards according to Article 563 of GR 28/2024 include operational procedures, communication, and patient confidentiality. Artificial intelligence that issues automatic prescriptions poses a *standard-setting gap problem* because the algorithm is not registered in any professional college, in contrast to doctors who are subject to the Indonesian doctor's code of ethics and malpractice mechanisms. Any therapeutic action should be auditable and traced to the person in charge of the medical. Where decisions are derived from artificial intelligence, the audit trail must reflect clinical logic and algorithm-based validation, but such an audit scheme is not yet required by GR 28/2024.

A comparative study shows that there is a tendency for regulators to hold off on granting permission for artificial intelligence for *autonomous prescription* until a transparent algorithm-based evaluation framework and a controlled *adaptive learning* mechanism are available. Indonesia, which still adheres to the "doctor as *gatekeeper*" model, needs to take a similar position so that the principle of prudence is maintained.

The unclear legal position of artificial intelligence as an automatic prescription issuer poses a double risk in the form of potential medical malpractice as well as a violation of consumer protection. A misdosed or misindicated prescription design can trigger a civil lawsuit under the Civil Code and criminal charges under Article 359 of the Criminal Code, where supervising doctors, platform providers, or artificial intelligence developers can be blamed. An example of *a case of Watson for Oncology* in the United States facing a legal claim for incorrect therapy recommendations. Without a clear responsibility-sharing scheme, the entire *Telemedicine ecosystem*, hospitals, online pharmacies, and algorithm providers, is exposed to the risk of litigation.

In the field of consumer protection, Article 4 letter c of Law Number 8 of 1999 requires business actors to provide correct and clear information. If artificial intelligence issues automated prescriptions without physician verification, the information patients receive does not meet *the informed choice* criteria, potentially violating consumers' rights to safety and security. Medical software certification in Indonesia must guarantee *safety-by-design* to close this loophole. (Psalm 18)

Based on the above analysis, there are at least three legislative agendas to formalize the legal status of artificial intelligence as a recipe publisher:

a. The addition of the definition of "Medical artificial intelligence systems" in the Health Law or PP 28/2024, including the affirmation that such systems can be subject to limited liability, subject to annual algorithm audits and software licenses.
b. Amendment to the ITE Law 2024 to allow "algorithmically authenticated electronic signatures" to be mapped to *the responsible physician* as the party who provides the final *override* of each prescription.
c. The preparation of the Regulation of the Minister of Health on Certification and Post-Market Surveillance of Artificial Intelligence-CDSS, requires multicenter clinical testing, *human-in-command* oversight, and automatic shutdown mechanisms when the system exceeds a certain threshold of error.

The above model parallels the FDA's (USA) and EMA's (EU) *Software as a Medical Device* framework , which requires clinical validation and continuous audit before the algorithm can produce independent therapeutic recommendations. The implementation of this framework not only maintains patient safety but also provides legal certainty for local innovators who want to develop prescription artificial intelligence.

The Health Law 2023 and Government Regulation 28/2024 have affirmed *Telemedicine* as an integral part of the national health transformation, but still maintain a doctor-centric model in prescribing issuance. Artificial intelligence, in its current legal configuration, only legitimately functions as a clinical decision-support tool, not a prescription issuing entity. The absence of explicit recognition of artificial intelligence as a "signatory" creates legal uncertainty in the context of the validity of electronic documents, malpractice liability, and consumer protection. Therefore, regulatory reforms, ranging from the redefinition of legal subjects to algorithm certification, are a sine *qua*

*non requirement* to legitimize the use of artificial intelligence in independent prescribing, while maintaining the principles of safety, accountability, and quality of health services.

The integration of the concept of *explainable artificial intelligence* is absolutely necessary so that doctors and patients are able to trace the basis of decision-making in the prescribing system, so that compliance with the principle *of informed consent* is maintained. A *regulatory technology* framework can also be adopted by the Ministry of Health to facilitate real-time algorithm compliance checks, especially on high-risk software in the field of pharmacotherapy. Machine learning validation for drug prescriptions should include multi-drug interaction simulations in order for polypharmacy to be prevented; This need has not been accommodated in Government Regulation Number 28 of 2024.

**Conformity of Automatic Prescription Issuance by Artificial Intelligence with the Provisions for the Validity of Electronic Documents and Digital Signatures in Law No. 1 of 2024**

The ITE Law 2024 lays down four pillars of the validity of electronic documents, namely the authentication of the identity of the signatory, the integrity of the content, the reliability of the electronic system, and the validity of digital evidence. This pillar is also a parameter for assessing whether or not prescriptions are automatically published by artificial intelligence in the *Telemedicine* ecosystem. This chapter discusses the extent to which automated prescribing practices meet all four requirements, map legal loopholes, and offer a realistic compliance model.

Article 1 number 4 of the 2024 ITE Law defines electronic documents as "any information created, sent, received, or stored in digital form" that can be seen, displayed, and heard. Doctor's prescriptions are categorized as electronic documents as long as they meet the required data structure: medical personnel identity, patient data, drug name, dosage, method of use, and electronic signature. Thus, the output of a new artificial intelligence algorithm is recognized as a "recipe" when the format contains the entire element and is stored in a reliable electronic system.

The 2023 Health Law has recognized electronic medical records, but still requires doctors to be the parties to enter and validate. When prescriptions are generated automatically, there is a disruption to the concept of "clinical drafts" because algorithms cut off the doctor's workflow at the verification critical point. Any automation of clinical action must still position the doctor as the *ultimate decision-maker* to guarantee the principle *of due care*. Without human verification, the validity of electronic documents is questionable because the legal subject of the signing is missing.

The ITE 2024 Law regulates electronic signatures in Article 11 and Article 12. The fundamental condition is the system's ability to uniquely identify signatories so that *non-repudiation* occurs, i.e. denial cannot be done later. This mechanism is indicated by the existence of electronic certificates issued by Electronic Certification Providers (PSrE) registered with the Ministry of Communication and Informatics. The identity is legally

attached to the doctor because the professional registration number and Practice License are listed on the certificate.

When a recipe is signed by the algorithm, two scenarios appear. First, the cryptographic key is issued on behalf of the business entity that owns the algorithm. Second, the key is issued in the name of the supervising physician but is used automatically by the system. The second scenario creates a risk *of signature delegation* where the key holder does not consciously perform the signing act. This risk has the potential to violate Article 1869 of the Civil Code regarding the validity of a letter under hand which requires the express consent of the signator. Therefore, the application of automatic prescriptions requires an *explicit consent mechanism* such as *a one-time approval token* before the doctor's key is used by the system.

Article 16A of the ITE Law 2024 requires a reliable, secure, and responsible electronic system so that electronic documents have legal force. *Reliability* is achieved when the software uses industry-standard cryptographic algorithms, has an immutable audit trail, and is regularly penetrated for penetration. ISO/IEC 27001 certification for information security management is the *best practice* adopted by regulators. For artificial intelligence, system reliability also demands transparency of training data, acceptable error limits, and *rollback procedures* in the event of recommendation failure.

In the context of a recipe, integrity means two things. First, the content of the prescription must not change along the transmission channel from the *Telemedicine provider* 's server to the pharmacy. Second, the clinical logic that determines the dose in the algorithm must be stable. The use of *blockchain* in the pharmaceutical supply chain can provide *tamper-evident ledgers* so that unofficial changes are detected immediately. However, *blockchain implementation* in Indonesia is constrained by infrastructure costs and the complexity of interoperability with SIMRS. Alternatively, there are *recommendations for hash-chaining* and *timestamping* that are lighter but still ensure integrity. (Sec. 26)

In the malpractice litigation process, the automatic prescription will be tested as electronic evidence in court. Article 5 paragraph 1 of the 2024 ITE Law recognizes that electronic evidence is equivalent to written evidence as long as it meets the requirements for authenticity, integrity, and accessibility. *Metadata* such as *time-stamps* and server IP addresses are crucial to confirm the authenticity of evidence. Artificial intelligence systems must store *structured log audits* that record API caller identities, clinical parameters, model versions, and inference results in order to be accepted as *best evidence*.

Without transparent logic, judges tend to doubt the testimony of experts defending algorithms because artificial intelligence models are "black boxes". Therefore, developers are required to provide *explainability modules* that at least outline the key clinical variables that affect output. This module also helps the supervising physician assess the suitability of the prescription to the patient's condition before the taxonomy of the decision is signed.

Conventional digital signing schemes place the responsibility on individual key holders. Automation does not necessarily shift the burden to the software, as the software

is not yet recognized as a legal subject in Indonesia. Artificial intelligence is simply a tool so that the owner of the tool or the party who uses it remains responsible. This is in line with the doctrine of *vicarious liability* in Article 1367 of the Civil Code: the employer is responsible for losses caused by his subordinates or work equipment.

In *Telemedicine practice*, the parties that may be sued are: the doctor in charge, the hospital or clinic provider of the platform, the artificial intelligence development company, and the pharmacy operator. The importance of *risk allocation* clauses in artificial intelligence device licensing agreements to limit indemnification. In Indonesia, the clause is bound by Article 18 paragraph 1 of the Consumer Protection Law, which prohibits the exoneration clause if it eliminates the consumer's right to health and safety. Therefore, the limitation of damages should not negate the patient's right to receive compensation.

To bridge the requirements of legal validity with clinical efficiency, some countries have adopted the *hybrid signature model*. There is a description of a two-layer pattern, where the algorithm prepares an electronic prescription, and then the system displays a *prompt* for the doctor to review and enter the signature PIN. This process generates a certified electronic signature that is cryptographically embedded in the recipe hash so that integrity is maintained. The system records that the doctor has read the artificial intelligence recommendations, given approval, and only afterwards is the prescription sent to the pharmacy.

This concept is in accordance with Article 11 paragraph 1 letter b of the 2024 ITE Law which requires exclusive control over signature making data. Exclusive control is achieved because only doctors know the PIN or hold a multi-factor authentication token. Tokens cannot be deposited on the server because the risk of compromise will give rise to *a negligence lawsuit*. The best implementation is a *separate hardware security module* that processes local signing on the physician's side.

The ITE Law 2024 does not yet establish the obligation to certify algorithms, but Article 16B authorizes the government to establish certain Electronic System Implementation Standards, which can be interpreted as the basis for derivative regulations regarding clinical artificial intelligence. The Ministry of Communication and Informatics will work with the Ministry of Health to issue a Joint Regulation requiring independent audits of high-risk category artificial intelligence devices such as prescription issuance. The audit included dataset bias testing, dose prediction accuracy, and validation of dangerous drug interactions.

The importance of *post-market surveillance schemes* through aggregated anonymous logs that are analyzed to detect error patterns. If the error ratio exceeds the threshold, the system reliability certificate may be revoked. This principle is in line with the "*predetermined change control* plan" approach adopted by the United States Food and Drug Administration for machine learning-based software.

Global trends suggest that the regulation of digital signatures is transforming towards the recognition of non-human entities as limited but still under human control. In the European Union, the *proposed Artificial Intelligence Act* contains mandatory

*human oversight* rules for artificial intelligence systems in the health sector. The surveillance model translates into a *fail-safe mechanism* requirement that allows doctors to cancel prescriptions if deemed inappropriate. Indonesia can adopt a similar mechanism through the revision of Permenkes 20 of 2019 to add the obligation of *manual override*.

There is a proposal to establish *a Medical Artificial Intelligence Oversight Board* that involves the medical profession and telematics experts to set algorithm-based signature technical standards. This institution can issue technical guidelines so that PSrE can validate cryptographic keys belonging to algorithms with a "*restricted authority*" attribute that only allows signing on the prescription domain. Thus, the principles of identity, integrity, and reliability are protected.

The ITE 2024 Law provides a firm legal framework regarding the validity of electronic documents and digital signatures, but its construction still rests on the subject of human law. Automated prescriptions issued by artificial intelligence are potentially legitimate as long as they meet four pillars: the identity of the signer, the integrity of the data, the reliability of the electronic system, and the acceptance as digital evidence. The challenge lies in meeting the requirements of identity and *non-repudiation* because algorithms are not legal subjects. The most realistic solution today is a *hybrid signature* model that puts doctors as the party that gives final approval through certified electronic signature means. Fulfillment of other pillars demands algorithmic audits, verified records, and information security certifications.

Regulatory reform needs to be directed at the issuance of technical standards for recipe algorithm certification, the enforcement of periodic audits, and post-market supervision mechanisms. Without all of that, automated recipe innovation will always be overshadowed by legal uncertainty and litigation risks. With the right compliance framework, the use of artificial intelligence can remain aligned with patient protection goals and the medical profession's precautionary principles.

Some EU jurisdictions have begun to require the implementation *of hash-chaining* on electronic medical records to ensure end-to-end integrity along the digital healthcare chain. The consideration of the use of post-quantum cryptographic algorithms is becoming increasingly relevant given the high sensitivity of treatment data. The product liability scheme for medical software is recommended to adopt the concept of *joint and multiple liability* so that the burden of proof is not fully borne by the patient. Additionally, the use of *blockchain* for drug dispensing tracking allows each automated prescription to be permanently documented and auditable by health authorities.

## CONCLUSION

While Indonesia's 2023 Health Law and PP 28/2024 acknowledge telemedicine services, they restrict prescription authority to licensed physicians, leaving artificial intelligence (AI) in a supporting role without addressing critical legal gaps regarding algorithmic accountability, clinical audits, and liability for therapeutic errors. Regulatory reforms must establish definitions for medical AI systems, implement high-risk software licensing, and mandate periodic algorithm audits, complemented by

the ITE Law's electronic signature framework which could validate e-prescriptions if it incorporates physician oversight through hybrid signatures, system reliability verification, and evidentiary standards - though this requires urgent development of technical specifications for information security audits, algorithm certification, and post-market surveillance to prevent violations of e-signature provisions and maintain clear accountability lines.

Future research should empirically evaluate pilot implementations of hybrid signature models in Indonesian telemedicine platforms to assess their effectiveness in balancing AI efficiency with physician oversight, while also analyzing comparative regulatory frameworks from countries with advanced AI healthcare governance to identify adaptable best practices. Additionally, multidisciplinary studies could develop standardized metrics for algorithmic transparency and clinical safety audits specific to Southeast Asian healthcare contexts, alongside sociolegal examinations of liability distribution models for AI-related medical errors to inform policymaking. These investigations should be conducted in partnership with the proposed cross-ministerial task force to directly feed into Indonesia's emerging regulatory sandbox for medical AI, ensuring research outcomes translate into practical guidelines for algorithm certification, incident reporting protocols, and phased public deployment strategies that prioritize patient safety.

## DAFTAR PUSTAKA

Republik Indonesia. (2023). Undang-Undang Nomor 17 Tahun 2023 tentang Kesehatan.

Republik Indonesia. (2024). Peraturan Pemerintah Nomor 28 Tahun 2024 tentang Peraturan Pelaksanaan Undang-Undang Nomor 17 Tahun 2023 tentang Kesehatan.

Republik Indonesia. (2024). Undang-Undang Nomor 1 Tahun 2024 tentang Perubahan Kedua atas Undang-Undang Nomor 11 Tahun 2008 tentang Informasi dan Transaksi Elektronik.

Mannas, Y. A., & Elvandari, S. (2023). Aspek Hukum Telemedicine di Indonesia. Jakarta: PT RajaGrafindo Persada – Rajawali Pers.

Latifi, R., Doarn, C. R., & Merrell, R. C. (Eds.). (2021). Telemedicine, Telehealth and Telepresence: Principles, Strategies, Applications, and New Directions. Cham: Springer Nature.

Fields, B. G. (2020). Regulatory, legal, and ethical considerations of telemedicine. Sleep Medicine Clinics, 15(3), 409–416.

United States Food and Drug Administration. (2021). Artificial Intelligence and Machine Learning Software as a Medical Device (SaMD) Action Plan. Silver Spring, MD: FDA.

European Medicines Agency. (2024). Reflection Paper on the Use of Artificial Intelligence (AI) in the Medicinal Product Lifecycle. Amsterdam: European Medicines Agency.

Usman, T. (2020). Keabsahan tanda tangan elektronik pada perjanjian jual beli barang dari perspektif hukum perdata. Indonesia Private Law Review, 1(2), 87–98.

Kristiyanti, C. T. S. (2022). Hukum Perlindungan Konsumen. Jakarta: Sinar Grafika.

Republik Indonesia. (2004). Undang-Undang Republik Indonesia Nomor 29 Tahun 2004 tentang Praktik Kedokteran.

Republik Indonesia. (2019). Peraturan Menteri Kesehatan Republik Indonesia Nomor 20 Tahun 2019 tentang Penyelenggaraan Pelayanan Telemedicine Antar Fasilitas Pelayanan Kesehatan.

World Health Organization. (2019). WHO Guideline: Recommendations on Digital Interventions for Health System Strengthening. Geneva: WHO.

Afrilies, M. H., et al. (2023). Legal aspects of telemedicine health services in the perspective of health law in Indonesia in the digital era. Journal of Advanced Health Informatics Research, 1(1), 41–46.

Nogaroli, R. (2025). Medical Liability and Artificial Intelligence: Brazilian and European Legal Approaches. São Paulo: Thomson Reuters Revista dos Tribunais.

Mannas, Y. A., & Elvandari, S. (2022). Hukum Kesehatan di Indonesia. Depok: Rajawali Pers.

Iancu, A., et al. (2023). Machine learning in medication prescription: A systematic review. International Journal of Medical Informatics, 180, 105241.

Cosgriff, P. S., & Memmott, M. J. (2024). Writing In-House Medical Device Software in Compliance with EU, UK, and US Regulations. Boca Raton: CRC Press.

Mienye, I. D., et al. (2024). A survey of explainable artificial intelligence in healthcare: Concepts, applications, and challenges. Informatics in Medicine Unlocked, 51, 101587.

DeRouen, E. (2024). Risk-Proofing Digital Health: A Guide to Ensuring Quality and Compliance. Seattle: Independently Published.

Liu, Q., et al. (2024). Large language model distilling medication recommendation model. arXiv preprint arXiv:2402.02803.

Barkatullah, A. H. (2022). Hukum Transaksi Elektronik di Indonesia: Sebagai Pedoman dalam Menghadapi Era Bisnis Digital E-Commerce di Indonesia (4th ed.). Bandung: Nusa Media.

Jessica, P. (2023). Cyber Notary dan Digitalisasi Tanda Tangan. Yogyakarta: Deepublish.

Supriadi, T. S. P., Syahidin, Y., & Yunengsih, Y. (2024). Implementation of digital signatures in the integrated patient progress notes system at XYZ Hospital Bandung. International Journal of Software Engineering and Computer Science, 4(2), 836–849.

Stallings, W. (2024). Cryptography and Network Security: Principles and Practice (8th ed.). Hoboken, NJ: Pearson.

Mason, S., & Seng, D. (Eds.). (2021). Electronic Evidence and Electronic Signatures (5th ed.). London: University of London Press.

Mayana, R. F., Santika, T., & Ramli, A. M. (2024). Legal issues of artificial intelligence–generated works: Challenges on Indonesian copyright law. Law Reform, 20(1), 54–75.

Vemula, A. (2024). European Digital Identity Regulation (Regulation (EU) 2024/1183): eIDAS 2.0. London: Independently Published.

Setiawan, A. B. (2022). Infrastruktur Kunci Publik dalam Penyelenggaraan Sertifikat Elektronik. Jakarta: CV Mitra Cendekia Media.

Bapatla, A. K., Mohanty, S. P., & Kougianos, E. (2022). PharmaChain: A blockchain to ensure counterfeit-free pharmaceutical supply chain. arXiv preprint arXiv:2202.02592.

Pasaribu, M. (2024). Penerapan kecerdasan buatan (artificial intelligence) dalam proses legislasi dan sistem peradilan di Indonesia. Jurnal Hukum dan Bisnis (Selisik), 10(2), 201–218.

Jonnagaddala, J., & Wong, Z. S. Y. (2025). Privacy preserving strategies for electronic health records in the era of large language models. NPJ Digital Medicine, 8, 34.

Aumasson, J. P. (2024). Serious Cryptography: A Practical Introduction to Modern Encryption (2nd ed.). San Francisco: No Starch Press.

van Staalduinen, J. H. (2024). European product liability for AI-based clinical decision support systems. In K. Prifti et al. (Eds.), Digital Governance (Information Technology and Law Series, Vol. 39, pp. 15–40). Cham: Springer.

Kushwaha, P., Srivastava, N., & Kushwaha, S. P. (2024). Enhancing clinical drug trial monitoring with blockchain technology. Contemporary Clinical Trials, 146, 107684.