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The Binding Power of Teraupetic Agreements Reviewed from Health Law

Farhan Fadhillah[1], Sudirman[2], Ismi Fadjriah Hamzah[3*]

[1,2,3,] Faculty of Law, Universitas Muhammadiyah Kendari, Kendari, Indonesia.
: ismi.fadjriah@umkendari.ac.id
Corresponding Author*

Abstract

Introduction: *The enactment of Law Number 17 of 2023 concerning Health has brought a paradigm shift in the arrangement of therapeutic agreements between health workers and patients.*
Purposes of the Research: *This study aims to analyze the binding power of therapeutic agreements by focusing on the legal position of the exoneration clause in informed consent and examining the form of settlement for patient losses.*
Methods of the Research: *Using normative legal research methods with Statute approach and conceptual approach.*
Results Main Findings of the Research: *This study reveals that therapeutic agreements have binding power based on the principle of adequate informed consent. However, the exoneration clause in informed consent faces stricter legal restrictions based on Law Number 17 of 2023, especially related to the expanded responsibility of hospitals. The research concludes that the binding power of therapeutic agreements must be balanced with the protection of patients' rights, and effective dispute resolution mechanisms are needed to ensure fairness for all parties.*

Keywords: Teraupetic Agreement; Tolerance Clause; Informed Consent.

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INTRODUCTION

The enactment of Law Number 17 of 2023 concerning Health has brought a paradigm shift in the legal relationship between health workers and patients. This law marks a new era of therapeutic agreement regulation that is the fundamental basis for health services in Indonesia. A therapeutic agreement is a special agreement (*sui generis*) that is established between health workers and patients based on *informed consent*. *Informed Consent* In practice, many hospitals include an exoneration clause in the *informed consent* form that aims to limit or eliminate the legal responsibility of health care facilities.[1] This phenomenon raises complex legal problems related to the balance between the protection of health workers and the protection of patients' rights. Law Number 17 of 2023 Article 441 expressly regulates the responsibilities of health service facilities that are broader and more centralized. This has direct implications for the validity of the exoneration clause that has been commonly used in informed consent of hospitals. This paradigm shift raises questions about the legal status of the exoneration clause and how to settle the losses suffered by patients. The practice of using exoneration clauses in *hospital informed consent* has become a global phenomenon that

[1] Hermien Hadiati Koeswadji, *Hukum Kedokteran (Studi tentang Hubungan Hukum dalam Mana Dokter sebagai Salah Satu Pihak)*, (Bandung: Citra Aditya Bakti, 1998), p. 78.

has generated academic and practical debate in various jurisdictions.[2] In Indonesia, before the enactment of Law Number 17 of 2023, regulations regarding the responsibility of health service facilities were still scattered in various regulations that often caused legal uncertainty.[3] The exoneration clause in question is generally in the form of a statement that the hospital is not responsible for losses incurred during the health service process, except in the case of legally proven negligence.[4] From the perspective of treaty law, the exoneration clause has the potential to conflict with the principles of balance of achievement (*equivalent exchange*) and good faith (*good faith*) as stipulated in the Civil Code. What's more, the relationship between hospitals and patients is often asymmetrical, where patients are in a position of weakness and lack equal bargaining power.[5] This condition is exacerbated by medical emergency situations that do not provide patients with the opportunity to negotiate or seek alternative health services.[6]

Law Number 17 of 2023 introduces a more comprehensive concept of responsibility through the provisions in Article 441 which states that health service facilities are legally responsible for all losses resulting from the negligence of health workers in the health service facilities. This provision marks a shift from an approach to individual health worker responsibility to broader institutional responsibility (*vicarious liability*).[7] This paradigm shift has significant implications for the validity of exoneration clauses that have been considered as a legal protection mechanism for hospitals.[8] The complexity of the problem is even more evident when there is a medical dispute where the patient suffers a loss, while the hospital argues that it has obtained consent through *informed consent* which contains an exemption clause.[9] This condition requires an in-depth study to ensure legal certainty for all parties involved in the therapeutic agreement. The use of exoneration clauses in health services in the international context has been significantly restricted through various court decisions and regulations.[10] The United States, through various state court rulings, has established that exoneration clauses in health care contracts cannot eliminate liability for gross negligence or intentional misconduct.[11] Similarly in the UK, *the Unfair Contract Terms Act 1977* has placed strict restrictions on the use of consumer-detrimental exaggeration clauses, including in the context of healthcare.

METHODS OF THE RESEARCH

This research uses a normative legal research type with a statutory and conceptual approach. Normative legal research is a method or method used in legal research that is carried out by researching existing literature materials.[12] As well as normative legal research that is determined by a process to find a rule of law, legal principles, and legal doctrines to answer the legal issues faced, in this research the legal issue is the legal responsibility of hospitals in health services reviewed from the civil law aspect.[13]

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[2] Tom L. Beauchamp and LeRoy Walters, *Contemporary Issues in Bioethics*, 8th Edition, (Boston: Wadsworth Cengage Learning, 2013), p. 156-157.
[3] Bahder Johan Nasution, *Hukum Kesehatan Pertanggungjawaban Dokter*, (Jakarta: Rineka Cipta, 2005), p. 45.
[4] Veronica Komalawati, *Peranan Informed Consent dalam Transaksi Terapeutik*, (Bandung: Citra Aditya Bakti, 1999), p. 234.
[5] Marc A. Rodwin, *Medicine, Money, and Morals: Physicians' Conflicts of Interest*, (New York: Oxford University Press, 1993), p. 89-91.
[6] Jay Katz, *The Silent World of Doctor and Patient*, (Baltimore: Johns Hopkins University Press, 2002), p. 124-126.
[7] David M. Studdert et al., "Medical Malpractice", *New England Journal of Medicine* 350, no. 3 (2004): 283-292.
[8] Anny Isfandyarie, *Tanggung Jawab Hukum dan Sanksi bagi Dokter*, (Jakarta: Prestasi Pustaka, 2006), p. 156.
[9] Fred Cohen, "Informed Consent and Medical Malpractice", *Journal of Legal Medicine* 15, no. 2 (1994): 181-209.
[10] Charles Vincent, *Patient Safety*, 2nd Edition, (Oxford: Wiley-Blackwell, 2010), p. 45-48.
[11] Tunkl v. Regents of University of California, 60 Cal. 2d 92, 383 P.2d 441 (1963).
[12] Peter Mahmud Marzuki, *Penelitian Hukum*, (Jakarta: Kencana Prenada Media Group, 2015), p. 87.
[13] *Ibid,* p. 45.

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RESULTS AND DISCUSSION

A. Concepts of Therapeutic Agreement, Informed Consent, and Exoneration Clauses

Therapeutic agreements are special agreements (*sui generis*) that have unique characteristics compared to agreements in general.[14] According to Leenen, a therapeutic agreement is an agreement between a doctor and a patient in the form of a legal relationship that gives birth to rights and obligations for both parties.[15] This agreement has specificity because its object is health services that concern the safety of human life, so it cannot be equated with ordinary commercial agreements.[16]

The main characteristics of therapeutic agreements include: first, the nature *of inspanningsverbintenis* (an agreement of effort) rather than *resultaatsverbintenis* (agreement of results).[17] This means that health workers are only obliged to make maximum efforts according to professional standards, not to guarantee the patient's recovery results.[18] Second, there is an element *of fiduciary duty* that creates a special relationship of trust between health workers and patients.[19] Third, the importance of *informed consent* as the basis for the validity of the agreement.[20]

Law Number 17 of 2023, therapeutic agreements have expanded the meaning and scope of responsibility. Not only individual health workers are responsible, but also health care facilities as institutions have broader responsibilities. This change reflects the evolution from the paradigm of individual responsibility to institutional responsibility in health services.[21]

Informed consent is a fundamental concept in bioethics and health law that recognizes the patient's right to autonomy in medical decision-making.[22] According to Beauchamp and Childress, *informed consent* consists of two main elements: information and consent.[23] The information element includes diagnosis, prognosis, treatment alternatives, risks and benefits, and consequences if treatment is not taken.[24] Elements of consent include patient competence, understanding of information, and voluntariness in providing consent.[25] The development of the concept *of informed consent* does not only function as legal protection for health workers, but also as a protection for patients' rights.[26] Law Number 17 of 2023 strengthens the position of *informed consent* as an instrument for the protection of patients' rights through more detailed regulations regarding the obligation to provide information and the patient's right to refuse medical procedures.

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[14] Sofwan Dahlan, *Hukum Kesehatan: Rambu-rambu bagi Profesi Dokter*, (Semarang: Badan Penerbit Universitas Diponegoro, 2000), p. 89-91.

[15] H.J.J. Leenen, *Handboek Gezondheidsrecht*, (Houten: Bohn Stafleu van Loghum, 2000), p. 156.

[16] Guwandi, *Dokter, Pasien dan Hukum*, (Jakarta: Balai Penerbit Fakultas Kedokteran Universitas Indonesia, 2004), p. 23-25.

[17] J. Guwandi, "Medical Error dan Hukum Medis", (Jakarta: Balai Penerbit FKUI, 2004), p. 45-47.

[18] Fred H. Miller, "Denying Access to Health Care: The Conflicting Duties of Health Care Providers", *American Journal of Law & Medicine* 16, no. 1-2 (1990): 147-173.

[19] Edmund D. Pellegrino and David C. Thomasma, *The Internal Morality of Clinical Medicine*, (New York: Oxford University Press, 1993), p. 78-81.

[20] Veronica Komalawati, "Informed Consent dan Perlindungan Pasien dalam Transaksi Terapeutik", *Jurnal Hukum Kesehatan* 2, no. 3 (1999), p. 234-237.

[21] Institute of Medicine, *To Err is Human: Building a Safer Health System*, (Washington, D.C.: National Academy Press, 2000), p. 26-28.

[22] Tom L. Beauchamp and James F. Childress, *Principles of Biomedical Ethics*, 7th Edition, (New York: Oxford University Press, 2013), p. 99-148.

[23] *Ibid*., p. 120-124.

[24] *Ibid*., p. 101-119.

[25] *Ibid*., p. 125-148.

[26] Ruth R. Faden and Tom L. Beauchamp, *A History and Theory of Informed Consent*, (New York: Oxford University Press, 1986), p. 235-273.

However, the use of *informed consent* as an instrument to include an exoneration clause poses its own problems. This is because *informed consent* is essentially intended to provide information about inherent medical risks, not to exonerate liability for avoidable medical negligence or error.[27] An *exoneration clause* is a clause in an agreement that aims to release or limit the liability of either party for losses that may arise from the performance of the agreement.[28] The exoneration clause in Indonesian treaty law is regulated indirectly through the principle of freedom of contract in Article 1338 of the Civil Code.

However, the use of exoneration clauses cannot be done indefinitely. There are several juridical restrictions on the exoneration clause, including: first, it cannot eliminate liability for unlawful acts committed intentionally (*opzet*) or gross negligence (*grove schuld*).[29] Second, it cannot contradict public order and decency. Third, it must meet the principles of propriety and balance in the agreement.[30] Health services for the use of exoneration clauses face stricter restrictions because they concern the public interest and human rights.[31] Law Number 17 of 2023 provides stricter restrictions on the use of exoneration clauses in health service agreements through regulations regarding mandatory service standards.

B. Legal Status of the Exoneration Clause in Hospital Informed Consent According to Law Number 17 of 2023

The legal position of the exoneration clause in informed consent of hospitals has undergone a fundamental paradigm change with the enactment of Law Number 17 of 2023 on Health. Prior to the enactment of this law, the practice of exoneration clauses in the medical world provided a relatively wide scope for healthcare facilities to limit their legal liability through contractual mechanisms[32]. The old paradigm places the principle of freedom of contract as the main foundation in the legal relationship between patients and hospitals, where exoneration clauses are treated as part of an agreement that binds both parties[33]. However, reality shows that this approach often results in inequality in bargaining positions between patients and hospitals, especially in medical emergencies that do not allow patients to have balanced negotiations.

The enactment of Law Number 17 of 2023 marks a significant transformation in viewing the responsibilities of health care facilities. This law introduces the concept of liability that is imperative and cannot be waived through agreements, including through the exoneration clause in informed consent. This change is based on the understanding that health services have special characteristics as public services that concern fundamental human interests, namely the right to health and safety[34]. Healthcare services cannot be treated in the same way as ordinary commercial transactions because they involve a high fiduciary relationship and significant information asymmetry between healthcare workers and patients[35].

Article 14 paragraph (1) of Law Number 17 of 2023 explicitly states that "Health Service Facilities are obliged to ensure the quality of health services provided in accordance with health service standards, professional standards, operational procedure standards, patient

[27] Alan Meisel and Mark Kuczewski, "Legal and Ethical Myths About Informed Consent", *Archives of Internal Medicine* 156, no. 22 (1996), p. 2521-2526.
[28] Mariam Darus Badrulzaman, *Kompilasi Hukum Perikatan*, (Bandung: Citra Aditya Bakti, 2001), p. 145-148.
[29] J. Satrio, *Hukum Perikatan, Perikatan yang Lahir dari Perjanjian*, Buku I, (Bandung: Citra Aditya Bakti, 1995), p. 234-237.
[30] Riduan Syahrani, *Seluk-Beluk dan Asas-Asas Hukum Perdata*, (Bandung: Alumni, 2000), p. 208-211.
[31] Norman Daniels, *Just Health: Meeting Health Needs Fairly*, (New York: Cambridge University Press, 2008), p. 156-159.
[32] Chrisdiono M. Achadiat, *Dinamika Etika dan Hukum Kedokteran dalam Tantangan Zaman*, (Jakarta: EGC, 2007), p. 89-92.
[33] Hermien Hadiati Koeswadji, *Hukum Kedokteran*, *Op. Cit.*, p. 156-158.
[34] World Health Organization, "*The Right to Health*", Fact Sheet No. 323, (Geneva: WHO Press, 2017), p. 2-4.
[35] Onno W. Purbo dan Aang Arif Wahyudi, *Mengenal E-Commerce*, (Jakarta: Elex Media Komputindo, 2001), p. 145.

safety standards, and the provisions of laws and regulations". This provision is strengthened by Article 53 paragraph (2) which states that "Health Services as referred to in paragraph (1) must meet health service standards". This provision has profound legal implications for the position of the exoneration clause, as it indicates that there are certain obligations that are non-derogable or cannot be waived through contractual agreements. The imperative nature of this obligation means that hospitals cannot use the exoneration clause to absolve itself of liability for failure to meet the standards that have been set.[36]

The concept of health service quality assurance in the context of this law includes multifaceted dimensions, including structural, process, and outcome aspects of health services.[37] The structural aspect is related to the availability of adequate resources, including competent health workers, facilities and infrastructure that are in accordance with standards, and an effective management system. The process aspect includes the implementation of medical procedures in accordance with established standard operating protocols and procedures, while the outcome aspect is related to the expected service results in accordance with the patient's condition and prognosis. The exoneration clause cannot be used to exclude the hospital's liability for failure in any or all of those aspects.[38]

The legal status of the exoneration clause in informed consent is significantly restricted in terms of its validity and scope. Law Number 17 of 2023 adopts an approach that expressly distinguishes between inherent medical risks and avoidable negligence or error. This is in line with Article 1338 of the Civil Code which states that "All agreements made lawfully shall be binding on those who make them", but with the limitation that such agreements must not be contrary to law, decency, and public order. In addition, Article 1320 of the Civil Code requires that for the validity of an agreement to meet four conditions: agreement, capability, certain things, and halal causes.[39] Inherent medical risk is a risk inherent in the condition of a particular disease or complexity of a medical procedure, which cannot be completely eliminated even if it has been carried out with optimal service standards, for this category of risk, the exoneration clause can still have legal validity as long as it has been adequately explained to the patient in a comprehensive and understandable informed consent process.

On the other hand, medical negligence or malpractice resulting from deviations from service standards cannot be excluded through an exoneration clause of any kind.[40] This restriction is based on Article 1365 of the Civil Code which states that "Every unlawful act, which brings harm to another person, obliges the person who, by mistake, publishes the loss, to compensate for the loss". In addition, Article 1366 of the Civil Code emphasizes that "Everyone is responsible not only for losses caused by his actions, but also for losses caused by negligence or lack of care". An exoneration clause that seeks to absolve the hospital of liability for negligence or error that could have been avoided would be contrary to the patient's fundamental rights and could be declared null and void. This is in line with the general legal principle that no one can free himself from the legal consequences of his own unlawful actions.

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[36] Avedis Donabedian, "The Quality of Care: How Can It Be Assessed?", *JAMA* 260, no. 12 (1988), p. 1743-1748.

[37] Institute for Healthcare Improvement, "The Triple Aim: Care, Health, and Cost" *Health Affairs* 27, no. 3 (2008): 759-769.

[38] Peter A. Singer and Edmund D. Pellegrino, "Clinical Ethics: An Introduction", in the John H. Evans (ed.), *The Concise Dictionary of Healthcare Ethics*, (Georgetown: Georgetown University Press, 2001), p. 45-48.

[39] *Ibid*., Article 1320.

[40] Anny Isfandyarie, *Tanggung Jawab Hukum dan Sanksi bagi Dokter*, *Op. Cit*., p. 178-181.

Law Number 17 of 2023 also adopts the principles of good faith and propriety as a basis for evaluating the validity of exoneration clauses in therapeutic agreements[41]. This principle is in line with Article 1338 paragraph (3) of the Civil Code which states that "The Agreement must be implemented in good faith". Consumer Protection, Law Number 8 of 1999 concerning Consumer Protection in Article 18 paragraph (1) letter a prohibits business actors from including standard clauses that state the transfer of responsibility of business actors. The principle of good faith requires both parties to the agreement to act with honesty, transparency, and not unfairly harm the interests of the other party. Healthcare services, hospitals that draft exoneration clauses must ensure that they are drafted in good faith, provide accurate and complete information to patients, and do not take unfair advantage of their superior position in terms of medical knowledge.

The principle of propriety relates to the balance between the rights and obligations of the parties to the therapeutic agreement. A proper exoneration clause is one that does not give undue advantage to one party while unfairly harming the other. Evaluation of the appropriateness of the exoneration clause should consider the context and circumstances in which the agreement was made, including the urgency of the patient's medical condition, the availability of alternative health services, and the level of bargaining power possessed by the patient.

The legal status of the exoneration clause in the era of Law Number 17 of 2023 is conditional and proportional, in the sense that its validity depends on the fulfillment of certain conditions set by law. The exoneration clause can only apply to risks that have been explicitly and comprehensively explained to the patient in the informed consent process, not to risks that are hidden or poorly communicated. Hospitals cannot use blanket or blanket exoneration clauses to absolve themselves of any form of liability, but must be specific about certain risks that may arise.[42]

C. Form of Settlement for Patients Who Suffer Losses due to Exoneration Agreements

The settlement of patients who have suffered losses due to the existence of an exoneration agreement in the era of Law Number 17 of 2023 has undergone a fundamental and more comprehensive evolution in providing protection of patients' rights. Despite the exception clause in informed consent, patients who suffer losses due to medical negligence or violations of service standards still have an inviolable right to compensation and fair settlement. This is in line with Article 4 letter h of Law Number 8 of 1999 which states that consumers are entitled to compensation, compensation and/or reimbursement, if the goods and/or services received are not in accordance with the agreement or not as they should be. Article 347 of Law Number 17 of 2023 emphasizes that "Everyone is entitled to compensation due to the fault or negligence of Health Workers and/or Health Service Providers".[43] This law recognizes that the exoneration clause cannot deprive patients of their basic right to legal protection when they suffer losses that could have been avoided through the application of appropriate service standards.

The new paradigm in patient loss settlement emphasizes a holistic and multidimensional approach, not only limited to financial compensation but also includes medical rehabilitation, psychological recovery, reputation restoration, and prevention of the

[41] Arthur L. Corbin, *Corbin on Contracts*, Vol. 1, (St. Paul: West Publishing, 1993), p. 234-237.
[42] Michael D. Green, "The Inability of Offensive Collateral Estoppel to Fulfill its Promise", *Iowa Law Review* 70, no. 1 (1984): 141-192
[43] Charles Vincent, *Patient Safety*, *Op. Cit*., p. 289-292.

recurrence of similar losses in the future.[44] Law Number 17 of 2023 adopts the principle of restorative justice that prioritizes the restoration of damaged relationships between patients and hospitals, as well as focusing on efforts to improve the system to improve the overall quality of health services. This approach is different from the traditional adversarial model which tends to be punitive and focuses on assigning faults and imposing punishments.

The non-litigation settlement mechanism is a top priority in handling patient losses based on Law Number 17 of 2023. Article 348 of Law Number 17 of 2023 states that "Dispute resolution in Health Services can be carried out through mediation, arbitration, or court". This law requires health service facilities to have an effective complaint handling and internal dispute resolution system that is easily accessible to patients, as stipulated in Article 29 letter r of Law Number 17 of 2023 which states that health service facilities are obliged to maintain medical records and handle complaints. Internal mediation involving hospital management, medical committees, and patient representatives is the first step that must be taken in resolving patient losses. This internal mediation process is designed to create a constructive dialogue between patients and hospitals, with the aim of reaching an agreement that benefits both parties without having to go through a lengthy, complex, and costly legal process.

If internal mediation is unsuccessful in reaching an agreement, the patient can apply for external mediation through an independent mediation institution that has special expertise in the field of health. This external mediation institution is expected to provide an objective and neutral perspective in resolving disputes between patients and hospitals. In addition to external mediation, patients can also choose the arbitration route that provides a binding award for both parties. The advantage of arbitration lies in its faster process than litigation in court, as well as arbitrators who can be selected based on specialized expertise in the medical and health law fields.[45] Although non-litigation mechanisms are prioritized, litigation pathways remain open and available to patients who do not obtain a satisfactory settlement through such alternative mechanisms. Patients can file a civil lawsuit based on the522efaultt of the therapeutic agreement in accordance with Article 1243 of the Civil Code which states that "Reimbursement of costs, losses and interest due to non-fulfillment of an agreement, will only begin to be obligatory, if the debtor, after being declared negligent in fulfilling his agreement, continues to neglect it, or if something that must be given or made, can only be given or made within the grace period that has been exceeded by him". In addition, lawsuits can also be filed based on unlawful acts in accordance with Article 1365 of the Civil Code due to medical negligence. Law Number 17 of 2023 provides a stronger position for patients in the evidentiary process in court, where hospitals must be able to prove that they have met all set service standards. In this context, the existence of an exoneration clause does not automatically exempt the hospital from lawsuits, but must be tested on the basis of facts relating to the implementation of service standards and the presence or absence of medical negligence.

The role of consumer protection institutions has been significantly strengthened in settling patient losses based on Law Number 17 of 2023. Article 49 of Law Number 8 of 1999 gives the authority to the Consumer Dispute Resolution Agency to handle and resolve consumer disputes through mediation or arbitration or adjudication. Furthermore, Article 52 of Law Number 8 of 1999 states that the Consumer Dispute Resolution Agency is

[44] Howard Zehr, *The Little Book of Restorative Justice*, (Intercourse: Good Books, 2002), p. 14-18.
[45] Gary B. Born, *International Commercial Arbitration*, 2nd Edition, (Kluwer Law International, 2014), p. 456-459.

authorized to impose administrative sanctions in the form of determining damages of up to IDR 200,000,000 (two hundred million rupiah). These institutions can mediate, provide settlement recommendations, and even impose administrative sanctions on hospitals that are proven to be detrimental to patients. The advantage of settlement through the Consumer Grievance Settlement Agency is that the process is relatively simple, low-cost, and easily accessible to the community, so it can be an effective alternative for patients who have limited resources to access other settlement routes.

An important innovation in Law Number 17 of 2023 is the strengthening of the implementation of a more comprehensive compensation and insurance system to protect patients. Article 349 of Law Number 17 of 2023 states that "Every Health Worker and Health Service Facility is required to have insurance or guarantees that provide legal protection in carrying out the practice or implementation of Health Services". This insurance system is designed to provide financial protection to patients who suffer losses, while also protecting healthcare workers and hospitals from excessive financial risks due to compensation claims. This insurance system is designed to provide financial protection to patients who suffer losses, while also protecting healthcare workers and hospitals from excessive financial risks due to compensation claims. In addition, the law also encourages the establishment of a special compensation fund that is independently managed to provide prompt compensation to patients who suffer certain losses.

The development of a no-fault compensation scheme is one of the important breakthroughs in the patient loss settlement system. This scheme allows patients to obtain compensation without having to prove any wrongdoing or negligence on the part of the hospital, with a main focus on recovering the condition of patients who have suffered losses due to health services.[46] This no-fault compensation approach can reduce the burden of proof for patients, speed up the compensation process, and reduce tension in the relationship between patients and hospitals. This system has been proven effective in various countries to provide better protection to patients while still encouraging improvement in the quality of health services.[47] Law Number 17 of 2023 also strengthens the monitoring and evaluation mechanism for the settlement of patient losses through the active role of various supervisory agencies. The Ministry of Health, the Indonesian Doctors Association, and other health professional organizations have an obligation to monitor and evaluate the effectiveness of the patient loss settlement system, as well as to provide recommendations for necessary improvements. This supervision includes evaluation of the implementation of the exoneration clause by hospitals, the quality of the informed consent process, and the effectiveness of the available dispute resolution mechanisms. The results of these monitoring and evaluations are used to continuously improve and develop better patient protection systems in the future.[48]

CONCLUSION

The enactment of Law Number 17 of 2023 concerning Health has brought a fundamental paradigm transformation in the arrangement of therapeutic agreements between health

[46] Troyen A. Brennan, "The Institute of Medicine Report on Medical Errors", *New England Journal of Medicine* 342, no. 15 (2000), p. 1123-1125.

[47] Marie M. Bismark et al., "Accountability Sought by Patients Following Adverse Events from Medical Care" *CMAJ* 175, no. 8 (2006), p. 889-894.

[48] Institute of Medicine, *Crossing the Quality Chasm: A New Health System for the 21st Century*, (Washington, D.C.: National Academy Press, 2001), p. 67-70.

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workers and patients. This transformation reflects a shift from the paradigm of individual responsibility to institutional responsibility, where the legal position of the exoneration clause in the hospital's informed consent is significantly restricted and only has legal validity for inherent risks that have been comprehensively explained. The patient loss settlement system has undergone a comprehensive evolution by prioritizing a holistic approach through non-litigation mechanisms, strengthening the compulsory insurance system, and implementing no-fault compensation schemes that provide better financial protection to patients while reducing excessive financial risk for healthcare providers. Overall, this transformation of health law has succeeded in creating a new balance between the protection of health workers and the protection of patients' rights within the framework of a more equitable therapeutic agreement, where the binding power of therapeutic agreements is no longer absolute but must be balanced with the interests of protecting the fundamental rights of patients, to ensure effective implementation, health care facilities need to immediately carry out a thorough reformulation Therapeutic agreement and informed consent system by eliminating blanket exconescension clauses, strengthening a comprehensive risk management system, and establishing an internal complaint handling system that is professional and accessible to patients. Meanwhile, policymakers should develop more detailed implementing regulations regarding the implementation of compulsory insurance systems and compensation schemes, strengthen the capacity of dispute resolution agencies including the Consumer Dispute Resolution Agency and mediation agencies, and carry out intensive and sustainable public socialization and education to all stakeholders. This paradigm shift requires adaptation from all parties in the health care system to create a health service ecosystem that is more transparent, accountable, and responsive to the needs and rights of patients, so that quality health services can be realized with balanced legal protection for all parties.

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