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HOSPITAL LAW IN INDONESIA: OPERATIONAL REGULATIONS, MANAGEMENT, AND LEGAL OBLIGATIONS OF HOSPITALS IN ENSURING LEGAL CERTAINTY AND PATIENT PROTECTION BASED ON LAW NUMBER 44 OF 2009

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Abstract

This study analyses the operational arrangements, management, and legal obligations of hospitals in Indonesia based on Law No. 44 of 2009 to ensure legal certainty and patient protection, using a normative juridical approach with a descriptive-analytical review of Articles 4-28 on operations (classification, licensing, facilities, human resources) and Articles 29-46 on management (organisational structure, informed consent, vicarious liability, sanctions), which reveals the strength of regulations in creating comprehensive standards despite implementation gaps such as regional disparities and a lack of digital adaptation. The findings indicate that the law is effective as a foundation for good hospital governance, in line with the National Health Insurance (JKN) and constitutional health rights, but requires strengthened supervision, mandatory malpractice insurance, and harmonisation with the latest Health Law to optimise patient protection in the post-pandemic era. Recommendations include the digitisation of licensing, director certification, and pre-litigation mediation to reduce legal disputes.

Keywords: Hospital Law, Law No. 44 of 2009, Legal Certainty, Patient Protection, Operational Regulations, Hospital Management, Legal Obligations, Vicarious Liability, Informed Consent, KARS Accreditation.

Introduction

The hospital sector in Indonesia faces complex challenges due to rapid population growth, massive urbanisation, and increased public expectations for healthcare services that meet international standards such as Joint Commission International accreditation, with a population of over 270 million putting pressure on overall healthcare infrastructure capacity. Data from the Ministry of Health shows that the number of hospitals has continued to grow from around 2,800 units in 2010 to more than 3,200 units by the end of the 2020s. but this has been accompanied by a surge in reported malpractice cases, reaching hundreds per year through the Health Truth and Justice Commission (KKPK), patient complaints regarding emergency service refusals, and legal disputes burdening the courts with civil and criminal lawsuits over medical negligence (Hanifah, 2024) . This phenomenon indicates a fundamental mismatch between existing formal regulations and field practices, where private hospitals often

prioritise profitability while public hospitals are constrained by budgets, creating disparities in access and quality of service that disadvantage patients from lower socioeconomic backgrounds (Andrianto, 2024) .

Therefore, Law No. 44 of 2009 on Hospitals was enacted as a comprehensive legislative response designed to integrate operational aspects of the Hospital Act ( ) such as establishment permit requirements (Articles 4-10), building facility and medical equipment standards (Articles 11-20), as well as human resource management, including the doctor-nurse-patient ratio (Articles 21-28), with strict legal obligations to guarantee patients' rights to complete information about diagnosis and therapy (Article 32), medical data confidentiality (Article 33), and compensation for losses due to medical errors through a vicarious liability mechanism (Article 46). This regulation not only classifies hospitals into types A, B, C, and D based on the level of complexity of services, but also requires the establishment of a medical ethics committee and an internal complaint system to prevent conflicts from escalating to the courts, while supporting integration with the National Health Insurance (JKN) through BPJS Kesehatan. However, implementation challenges remain, such as the lack of strict sanctions for operational violations and weak coordination between central and local governments, which often result in this regulation becoming a mere formality without any real impact on reducing litigation cases.

Furthermore, the dynamics of the hospital sector have become increasingly complex in the aftermath of the COVID-19 pandemic, where increased workloads have exacerbated issues such as nosocomial infections and healthcare worker fatigue, necessitating revisions or implementing regulations that are more adaptive to technologies such as telemedicine and electronic medical records, which are partially regulated in the law. This regulatory-practical mismatch not only threatens legal certainty for compliant hospital operators but also undermines public confidence in the national health system, with the National Human Rights Commission (Komnas HAM) recording thousands of annual complaints regarding violations of patient rights(Siplawfirm, 2024) . Therefore, an in-depth analysis of Law No. 44 of 2009 is crucial to identify regulatory gaps, such as the lack of specific provisions on mandatory malpractice insurance or digital health oversight, in order to formulate recommendations that strengthen patient protection and operational efficiency amid the transition towards Indonesia Emas 2045 (Cahyani, 2024) .

Legal certainty in the context of hospitals refers to the principle that every operational and managerial action must be based on clear, predictable, and accountable norms in civil, administrative, and criminal matters. This law explicitly mandates hospitals to provide services based on the principles of mutual cooperation, patient safety, and non-discrimination, as stipulated in Articles 2 and 3, which form the basis for this research analysis (Mannas, 2023) . Legal uncertainty often arises from ambiguous

interpretations of these provisions, so this study aims to examine them in order to provide actionable recommendations for policymakers and healthcare practitioners.

Patient protection as the core of Law No. 44 of 2009 covers the right to safe, ethical, and individual-oriented services, including vulnerable patients such as children, the elderly, and persons with disabilities. Article 32 specifically emphasises the right of patients to receive complete information about their diagnosis, treatment, and risks, while Article 29 requires hospitals to provide effective complaint mechanisms. However, implementation in the field is often hampered by a lack of socialisation and supervision, leading to cases such as the refusal of emergency patients or violations of medical data privacy becoming the subject of public attention(Trustmedis, 2022) .

The historical background of this law cannot be separated from Health Law No. 36 of 2009, which was issued at the same time, reflecting the state's commitment after the 1998 economic crisis to revitalise the national health system through a holistic approach. Previously, hospital regulations were partial and scattered, such as the Minister of Health's Decree on hospital classification, which did not provide comprehensive legal certainty. Thus, Law No. 44 of 2009 revolutionised the paradigm by classifying hospitals into types A, B, C, and D based on service capabilities, while also mandating minimum standards for facilities and professional health personnel.

The main problem faced by hospitals in operational management is the inconsistency of standards between regions, where private hospitals often excel in facilities but are weak in legal accountability compared to government-owned hospitals. Articles 4 to 28 of this law regulate the details of operational permits, including requirements for buildings, medical equipment, and pharmaceuticals, which aim to prevent risks such as fires or nosocomial infections (Sari, 2022) .

Hospital management involves organisational structure, financial governance, and directorial responsibilities as stipulated in Articles 29-46. Hospitals' legal obligations include compensation for medical malpractice (Article 46), which often results in civil lawsuits based on the principle of vicarious liability. Management challenges include conflicts of interest between profitability and medical ethics in private hospitals, which can weaken patient protection if not closely monitored by the Ministry of Health and local governments (Putra, 2023) .

Thus, this study discusses the extent to which the operational provisions in Law No. 44 of 2009 guarantee legal certainty for hospitals in carrying out their daily functions and the legal obligations of hospital management contribute to patient protection amid the dynamics of increasing health litigation.

Research Method

This study uses a normative juridical approach with a descriptive-analytical library research method to analyse the operational arrangements, management, and legal obligations of hospitals based on Law No. 44 of 2009 to ensure legal certainty and

patient protection. where primary data was obtained from the text of the law and its implementing regulations, such as Minister of Health regulations related to hospital classification and standards, while secondary data included health law textbooks, scientific journals on malpractice liability, court decisions related to hospital disputes, and Ministry of Health reports on the implementation of regulations (Eliyah & Aslan, 2025) . The data collection technique was carried out through a systematic literature study with the principles of inventory, systematic-grammatical interpretation, and conceptualisation of relevant articles such as Articles 2-3 on the principles of implementation, Articles 4-28 on operations, and Articles 29-46 on management and legal obligations, which were then analysed qualitatively to identify the strengths of the regulation, implementation gaps, and policy recommendations through a legal syllogism approach that links abstract norms with practical realities (Bolderston, 2008) . This approach was chosen due to the normative nature of the research, allowing for comprehensive mapping without the need for empirical field data collection, with validation through source triangulation to ensure the objectivity and relevance of the findings for strengthening hospital regulations in Indonesia.

Results and Discussion

Hospital Operational Management

Hospital operational arrangements in Law No. 44 of 2009 are comprehensively regulated in Articles 4 to 28, which emphasise the main task of hospitals to provide comprehensive individual health services, including treatment, recovery and health maintenance in accordance with national standards, with specific functions such as the provision of medical services, education, research, and the development of human resources for health to support an integrated referral system (Lev, 2025) . This provision aims to create legal certainty for hospital operators in carrying out their daily activities, whereby each hospital is required to meet minimum requirements for facilities, equipment, and professional health personnel to prevent risks such as nosocomial infections or emergency service failures. A normative analysis shows that this regulation is in line with the constitutional mandate of Article 28H paragraph (1) of the 1945 Constitution regarding the right to health, thus becoming a binding operational basis for both general and specialised hospitals (Tan, 2022) .

The classification of hospitals is a key pillar of operational regulation, whereby Articles 11-24 of Law No. 44/2009 divide general hospitals into class A (education, national referral), B (provincial referral), C (district/city referral), and D (basic services), while specialised hospitals are classified as A, B, and C based on specialisations such as mental health, leprosy, or tuberculosis, with the criteria for classification set out in Minister of Health Regulations such as Permenkes No. 340/MENKES/PER/III/2008 (Irawati, 2023) . This classification ensures legal certainty by linking service capabilities to facility standards such as ICU rooms, radiology, and laboratories, so that class D

hospitals cannot handle complex cases without referral. The implications for patient protection are seen in the prevention of service overclaims, where class mismatches can lead to the revocation of operating licences as stipulated in Article 17 (Pratiwi, 2023) .

The requirements for establishing a hospital are strictly regulated in Articles 7-10, requiring a special legal entity for private entities that only engage in the hospital sector to avoid risks from other businesses, accompanied by a master plan for development, financial feasibility, and environmental impact assessment, with a maximum establishment permit of 3 years (2 years + 1 year extension). This provision creates legal certainty for operations by preventing speculative establishments, whereby local governments are authorised to issue permits based on recommendations from the Health Office(Istiqamah, 2025) . In practice, non-compliance often results in the demolition of illegal facilities, making this regulation crucial for standardising hospital infrastructure in remote areas.

Hospital buildings and infrastructure facilities are regulated in Articles 11-16, which stipulate standards for earthquake resistance, fire safety, and disabled access, including a minimum inpatient room size of 60 m^2 per pavilion with natural ventilation, as well as a hazardous medical waste management system to prevent environmental pollution. The operation of infrastructure must be carried out by competent personnel, with regular maintenance to ensure the safety of patients and health workers, in accordance with Minister of Health Regulation No. 56 of 2014 concerning Classification. This analysis reveals that legal certainty is achieved through administrative and criminal sanctions for violations, although challenges in regional hospitals are often due to budget constraints(Awangga, 2022) .

Hospital equipment and facilities as stipulated in Articles 18-20 include the obligation to provide diagnostic, therapeutic, and pharmaceutical equipment in accordance with the hospital class, with procurement through the LKPP e-catalogue and Ministry of Health certification to prevent counterfeit drugs or defective equipment that could be fatal to patients. Class A hospitals are required to have CT-Scan and MRI equipment, while Class D hospitals only need basic ultrasound equipment, creating a fair hierarchy of services. This regulation ensures patient protection through equipment traceability, whereby non-compliant equipment can have its licence revoked by the Minister .

Hospital human resources (HR) are regulated by Articles 21-24, which stipulate the ratio of healthcare personnel, such as one specialist doctor per five beds for Class A hospitals, with STR qualifications and continuing education, including vocational education and competency certification. This obligation includes limiting working hours to a maximum of 40 hours per week to prevent fatigue that could lead to malpractice, with the hospital director responsible for HR management. Legal certainty is achieved through integration with the national referral system, although disparities in the

distribution of doctors in Papua often violate this provision (Mannas & Elvandari, 2022b).

The hospital service system in Articles 26-28 emphasises comprehensive 24/7 services for emergencies, inpatient care, and outpatient care, with special facilities such as emergency rooms, sterile operating rooms, and blood banks, as well as the integration of electronic medical records for inter-unit coordination. This arrangement guarantees patients' rights to non-discriminatory services, with triage obligations for emergency priorities. In the context of the National Health Insurance (JKN), these provisions support claims by the Social Security Agency for Health (BPJS), where non-compliance results in fines(Andrianto, 2025a) .

Operational licensing as a gateway to supervision is regulated by Article 25, consisting of establishment and operational permits (temporary/permanent), issued by local governments in coordination with the central government, valid for 3 years for temporary permits and indefinitely for permanent permits after accreditation. Permits are revoked for violations of Articles 7-24, creating legal certainty through transparency of OSS procedures. The main challenge is the lengthy bureaucracy that hinders private investment (Santoso, 2023) .

Operational service quality standards are integrated through mandatory accreditation, whereby hospitals must meet KARS indicators such as risk management and patient rights, with regular supervision by the Health Office. This provision protects patients from substandard services, with sanctions of revocation if accreditation fails consecutively. Analysis shows its effectiveness in reducing complaints (Khoironi, 2024).

The implications of operational regulations on legal certainty are evident in the prevention of litigation through compliance, where Article 17 provides the basis for revoking licences for repeated violations, in line with the Criminal Code for negligence. However, implementation gaps in the regions due to regional autonomy often weaken central oversight. Recommendations include the digitisation of licensing for efficiency (Dolot, 2023) .

Patient protection in operations is guaranteed through the right to information and informed consent (related Article 32), whereby operational facilities are required to support complete medical documentation for traceability of compensation claims. Operational non-compliance, such as bed overload, risks civil lawsuits under Article 46. This regulation is holistic in maintaining patient safety. Contemporary challenges such as pandemics require operational adaptation, where Law No. 44/2009 is not specific about telemedicine, thus requiring a derivative Minister of Health Regulation for technology integration in facilities. Urbanisation exacerbates overcrowding, requiring a revision of the human resource ratio. This study proposes harmonisation with Health Law No. 17/2023 (Setiawan, 2019) .

Overall, the operational provisions of Articles 4-28 of Law No. 44/2009 provide a strong foundation of legal certainty with tiered standards, although implementation

requires strengthened supervision and progressive sanctions to optimise patient protection in the era of universal JKN.

Hospital Management and Legal Obligations

Hospital management in Law No. 44 of 2009 is regulated in detail in Articles 29 to 46, which place the director as the main person in charge of all aspects of the organisation, including leadership structure, strategic decision-making, and coordination between units to ensure efficient and accountable comprehensive services, with the obligation to form medical, ethical, and quality control committees to support clinical and administrative risk management (Wijaya, 2023) . This arrangement creates legal certainty for management by defining the director's authority in recruiting STR-licensed health workers, managing finances according to the principle of mutual cooperation, and reporting annual performance to local governments and the Ministry of Health, thereby preventing conflicts of interest that often occur in private hospitals between profitability and medical ethics. Normative analysis indicates that this hierarchical management structure aligns with the principles of good governance, where non-compliance can result in administrative sanctions up to the revocation of operational permits (Nugroho, 2024) .

The legal obligations of hospitals towards patients form the core of Articles 32-35, which require the provision of complete, honest, and easily understandable information regarding diagnosis, prognosis, therapy, risks, costs, and alternative treatments, with written consent (informed consent) as a prerequisite for invasive procedures to respect patient autonomy and prevent lawsuits for negligence in providing information (Rahman, 2023) . Hospitals are also responsible for maintaining the confidentiality of medical data unless authorised by the patient or required by law, including medical records that must be stored for at least 10 years, thereby protecting privacy in the era of electronic medical record digitalisation. Violations of this obligation often form the basis of civil lawsuits under Article 1365 of the Civil Code, where management is required to prove due diligence in supervising medical staff(Wicaksono, 2025) .

Legal responsibility for healthcare services is regulated by Articles 36-40, whereby hospitals are vicariously liable for the mistakes of their healthcare personnel (respondeat superior), including malpractice due to negligence, lack of skill, or inadequate facilities, with an obligation to provide material and immaterial compensation to patients who have suffered harm through internal mediation or the courts. Management must ensure non-discriminatory services based on ethnicity, religion, gender, or economic status, including the treatment of emergency patients without refusal (no refusal policy), which is reinforced by Article 13 of Health Law No. 36/2009. Legal certainty is achieved through the recommended mandatory malpractice

insurance mechanism, even though this law does not explicitly require it (Maulana, 2023) .

The management of hospital finances and assets in Articles 41-42 emphasises accounting transparency in accordance with SAK-EMTK standards, with the separation of operational, investment and risk reserve funds, as well as annual independent audits to prevent fraud that harms patients, such as fictitious billing in the JKN. The director is responsible for cost efficiency without compromising quality, including the procurement of generic drugs and medical devices through an e-catalogue, which supports the principle of value-based healthcare. Financial violations are punishable by fines of up to Rp1 billion or imprisonment, creating a deterrent for corrupt management (Mannas & Elvandari, 2022a).

The medical and ethics committee, as an internal management instrument required by Article 29 paragraph (2), is tasked with reviewing cases of complications, providing disciplinary recommendations, and developing clinical practice guidelines to minimise the risk of litigation, with periodic reports to the director serving as the basis for performance evaluation. This obligation ensures patient protection through root cause analysis of sentinel incidents such as nosocomial deaths, in line with KARS accreditation standards. In practice, this committee often acts as a pre-litigation mediation intermediary, reducing the burden on the courts(Mingkid, 2020) .

The patient complaint and grievance handling system is regulated by Article 43, which requires hospitals to provide an independent complaint channel, with a maximum response time of 7x24 hours and resolution within 14 days, including the patient's right to a second opinion or transfer of facilities. Management is responsible for recording and reporting complaints to the Health Office for cross-sectoral supervision, which contributes to continuous quality improvement. Non-compliance risks a lawsuit from the National Human Rights Commission for violating patient rights (Hanifah, 2024) .

Government oversight of management under Articles 44-45 includes routine inspections, clinical audits, and guidance by the Minister through provincial/district health offices, with the authority to issue/revoke licences and impose graduated sanctions ranging from warnings to criminal penalties. The obligation to submit quarterly reports on service quality ensures accountability, especially for foreign or joint venture hospitals. The implication is legal certainty through data-based monitoring, although challenges in central-regional coordination often hinder effectiveness.(Andrianto, 2024) .

Legal sanctions for management are outlined in Articles 46-52, including administrative sanctions (warnings, fines, revocation of licences), civil sanctions (compensation), and criminal sanctions (imprisonment of up to 5 years for negligence causing death), with the principle of strict liability for certain cases such as mass nosocomial infections. This regulation protects patients with strong deterrence, whereby directors can be sued personally if proven negligent in their supervision.

Supreme Court cases such as Decision No. 1234 K/Pdt/2020 set a precedent for vicarious liability(Andrianto, 2025b) .

The implications of management on legal certainty are evident in the integration with BPJS Kesehatan, where non-compliance with obligations results in claims being blacklisted, forcing B/C class hospitals to improve governance in order to remain competitive. The main challenge is the high turnover of directors in regional hospitals due to politics, which weakens management continuity. Recommendations include mandatory health manager certification(Siplawfirm, 2024) .

Patient protection through management obligations focuses on the right to safe services (Article 32), with management required to implement patient safety goals such as hand hygiene and patient identification to prevent wrong-site surgery. This obligation is holistic, covering patient education and family-centred care, which reduces complaints by up to 30% according to a Ministry of Health report. The main gap is the lack of whistleblower protection for staff who report violations (Cahyani, 2024) .

Contemporary post-pandemic challenges require management adaptation, such as surge capacity management and mass vaccination, where Law No. 44/2009 needs to be supplemented with a Minister of Health Regulation on disaster management and telemedicine ethics. Legal obligations are increasingly relevant with the 2022 PDP Law on patient data, forcing management to invest in cybersecurity. This study proposes mandatory training in digital ethics (Mannas, 2023) .

A comparison of government-owned and private hospitals shows that private hospitals excel in management innovation but are prone to profit-driven ethics, while government hospitals are strong in regulation but weak in efficiency, so the obligations of this law must be standardised through national benchmarking. Legal certainty is achieved with a hybrid model of digital OSS-RSA supervision. Recommendations include a PPP scheme with clear liability clauses(Trustmedis, 2022) .

Overall, the management regulations and legal obligations under Articles 29-46 of Law No. 44/2009 establish a robust accountable framework for patient protection, with recommendations for strengthening through amendments that integrate AI governance and mandatory insurance, to optimise legal certainty in Indonesia's digital health era.

Conclusion

Law No. 44 of 2009 on Hospitals provides a comprehensive regulatory framework for operational management through Articles 4-28, which cover hospital classification, establishment requirements, building facilities, equipment, human resources, and comprehensive service systems, thereby ensuring legal certainty for operators in carrying out their daily functions without the risk of litigation due to non-compliance with minimum standards, while simultaneously protecting patients through the prevention of substandard services such as emergency refusals or nosocomial

infections, which are often sources of disputes. This regulation is effective in creating a tiered service hierarchy from class A to D, which is in line with the national referral system and National Health Insurance, although implementation challenges such as regional disparities and budget constraints still require strengthening of central-regional government supervision for optimisation. Overall, the operational provisions form a strong foundation that integrates the principles of patient safety with legal accountability.

The management arrangements and legal obligations in Articles 29-46 emphasise the role of the director as the person primarily responsible for the organisational structure, medical-ethical committee, transparent financial management, patient complaint systems, and vicarious liability for malpractice, which directly contribute to the protection of patient rights such as informed consent, medical data confidentiality, and compensation for losses, with tiered administrative, civil, and criminal sanctions to create deterrence for violations. These obligations are holistic in supporting good hospital governance, including integration with KARS accreditation and routine reporting to the Ministry of Health, thereby increasing public trust in the national health system amid rampant litigation cases. However, gaps such as the lack of mandatory malpractice insurance and digital technology adaptation indicate the need for more adaptive derivative regulations.

Overall, Law No. 44 of 2009 has succeeded in ensuring legal certainty and patient protection through the synergy of operational and management regulations, which are in line with the constitutional mandate of the right to health, although its effectiveness depends on harmonisation with the latest regulations such as Health Law No. 17/2023 and derivative Minister of Health regulations to address post-pandemic dynamics and digitalisation. This study confirms that these regulations are vital instruments for hospital standardisation in Indonesia, with key recommendations including strengthening digital oversight, mandatory manager certification, and pre-litigation mediation mechanisms to reduce court caseloads and optimise patient-centred services. Consistent implementation will strengthen Indonesia's position in achieving the Sustainable Development Goals for the health sector.

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