



# Hospital Governance and Legal Compliance in Indonesia: A Review of Accreditation Standards, Licensing Requirements, and Risk Management Obligations



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## ABSTRACT

**Introduction:** Hospitals, as healthcare institutions, hold a strategic position and face high levels of legal risk. The complexity of regulations in Indonesia demands the implementation of effective and legally compliant hospital governance, particularly in the areas of accreditation, operational licensing, and risk management. Non-compliance with these provisions has the potential to lead to administrative sanctions, legal disputes, and a decline in the quality and safety of healthcare services.

**Methods:** This study employed a narrative literature review, examining laws and regulations, government policies, accreditation guidelines, and national and international journal articles relevant to hospital governance and legal compliance. The literature search was conducted through scientific databases and official government sources, with inclusion criteria emphasizing relevance to the Indonesian context and the academic quality of the sources.

**Results:** The review indicates that the legal framework for hospital governance in Indonesia is built on three main pillars: accreditation as an instrument for improving patient quality and safety, licensing as operational legitimacy and state control, and risk management as a mechanism for preventing legal violations. The application of corporate governance and clinical governance principles is key to integrating legal compliance into managerial and clinical practices. However, implementation challenges remain, including inconsistent compliance, limited resources, and weak risk management integration.

**Conclusion:** Legally compliant hospital governance requires a comprehensive and sustainable approach that integrates accreditation, licensing, and risk management.

**Keywords:** hospital governance; legal compliance; hospital accreditation; licensing; risk management.

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## INTRODUCTION

Hospitals are a key component of the national healthcare system and serve as secondary and tertiary healthcare providers, providing complex clinical services to the public. According to data from the Indonesian Ministry of Health, by 2024-2025, the number of registered hospitals in Indonesia will reach approximately 3,155 facilities, consisting of general and specialized hospitals with various service classifications and population coverage. Of these, approximately 2,700 hospitals partner with the National Health Insurance (BPJS Kesehatan), which is legally required to meet a series of operational and legal standards, including the implementation of the Integrated System Regulatory

Framework (KRIS) and other accreditation requirements for its operational licensing.<sup>1</sup>

Legal compliance in hospital governance is closely related to operational legitimacy, service quality, and patient safety. Legislation positions hospitals not merely as medical service providers but also as legal entities obligated to comply with various administrative and technical requirements. This includes the requirement to hold a valid operational permit, meet infrastructure and human resource standards, and meet government-set accreditation requirements. Failure to fulfill these obligations not only impacts service quality but can also trigger administrative and legal sanctions, including license revocation, warnings, and potential litigation.<sup>2,3</sup>

One important indicator in

assessing a hospital's commitment to good governance is its accreditation status. The latest data shows that of the approximately 3,124 hospitals registered in the 2022 monitoring, approximately 2,559 hospitals (approximately 82%) have received national hospital accreditation at various levels, ranging from initial to full accreditation. A small number have received recognition from international institutions such as the Joint Commission International (approximately 2 hospitals, approximately 0.07%). This indicates that the majority of hospitals have undergone evaluations of their service and governance standards in accordance with legal requirements, although a gap remains with approximately 18% of facilities remaining unaccredited during the same period.<sup>1,4</sup>

The role of strong governance in hospitals is not only related to meeting minimum standards but also impacts service effectiveness. Strengthening corporate governance aims to ensure transparency, accountability, and responsibility in organizational management, while clinical governance emphasizes measurable clinical quality and safety. An empirical study in East Java Province, for example, found that 62.7% of the 346 hospitals studied had achieved accreditation, indicating that progress in meeting quality and governance standards is proportional to organizational characteristics such as size and ownership.<sup>4</sup>

These figures reflect that despite positive trends in hospital accreditation, variations and challenges remain in implementing these standards. Furthermore, government data also demonstrates disparities in hospital readiness to comply with operational compliance reforms such as the KRIS (Indonesian Healthcare and Social Security Agency) program. According to health officials, of approximately 2,700 BPJS partner hospitals, only approximately 1,436 facilities have met all KRIS criteria, while approximately 300 facilities still face significant challenges in meeting the requirements. These issues underscore the urgency of strengthening legal governance in the hospital sector, particularly regarding licensing, accreditation, and risk management. Disparities in compliance with operational standards and the low readiness of some facilities pose legal risks, given that licensing requirements encompass mandatory administrative and technical aspects. Poor legal compliance has the potential to lead to adverse consequences, ranging from administrative sanctions to medical litigation, which in turn impact the continuity of services and the credibility of healthcare institutions in the public eye.<sup>3,5</sup>

The aims of this paper is to analyze and synthesize the legal framework and practices of hospital governance in Indonesia, with an emphasis on accreditation, licensing, and risk management as the main pillars of legal compliance. This paper is expected to provide a comprehensive understanding for hospital managers and policymakers in strengthening effective and sustainable governance.

## METHOD

This study uses a narrative literature review approach to analyze hospital governance and legal compliance in Indonesia, focusing on accreditation, licensing, and risk management. This approach was chosen because it allows for a comprehensive exploration of the regulatory framework, theoretical concepts, and relevant empirical findings, while also providing space for critical analysis of the interrelationships between hospital governance policies and practices.

### Search Strategy

The literature search strategy was conducted systematically through various academic sources and official regulations. The scientific databases used included Google Scholar, Garuda (Garba Rujukan Digital), and national and international journal portals containing publications in the fields of health law, hospital management, and public policy. Additionally, legal documents and government policies were also searched through the official websites of relevant state institutions, such as ministries and accreditation bodies.

The keywords used in the search process were arranged thematically and combined using logical operators, including: “hospital governance,” “hospital governance,” “hospital legal compliance,” “Indonesian hospital accreditation,” “hospital licensing,” “clinical governance,” and “hospital risk management.” The search was conducted in both Indonesian and English to broaden the scope of the literature and obtain a comparative perspective relevant to the national context.

### Inclusion and Exclusion Criteria

Inclusion criteria were established to ensure the relevance and quality of the sources analyzed. The literature included in this review included: (1) scientific journal articles discussing hospital governance, legal compliance, or healthcare regulations; (2) laws and official policies governing hospital operations in Indonesia; and (3) publications highlighting managerial aspects, accreditation, and risk management in the hospital context.

Literature selected primarily included literature published within the last ten years, with the exception of fundamental regulations that are still in effect.

Conversely, literature was excluded if: (1) it was not directly relevant to the hospital context; (2) are merely opinions without a clear academic or regulatory basis; (3) discuss other countries' health systems without conceptual relevance to the Indonesian legal system; or (4) are not fully accessible, thus complicating critical analysis.

### Data Extraction

The data extraction process was conducted manually and in a structured manner by identifying key information from each selected source. The extracted data included: the legal basis and policies governing hospitals, the concepts and principles of hospital governance, the role of accreditation and licensing in legal compliance, and the risk management approach applied in hospital operations. All data was then categorized thematically to facilitate analysis and synthesis. The analysis was conducted by comparing and integrating findings from various sources to identify patterns, gaps, and policy implications. This approach enabled the development of a comprehensive understanding of how the legal framework and hospital governance in Indonesia interact to support legal compliance and the quality of healthcare services.

## RESULTS AND DISCUSSION

### Legal Framework for Hospital Governance in Indonesia

The legal framework for hospital governance in Indonesia is built on a set of regulations that position hospitals as healthcare institutions and legal entities with public obligations. These regulations not only govern the technical aspects of medical services but also encompass managerial responsibilities, organizational accountability, and the protection of patients and healthcare workers. Therefore, hospital governance must be understood as a system that integrates legal compliance, organizational management, and safe clinical practices.<sup>5</sup>

### Primary Legal Basis for Hospital Management

Laws governing hospitals and healthcare in general serve as the primary foundation for hospital governance in Indonesia. These regulations establish the principle that hospitals are required to provide quality, safe, and patient-centered healthcare services. Furthermore, hospitals are required to meet service standards, licensing requirements, and accreditation requirements as a form of state oversight and guidance.<sup>3,6</sup>

Derivative regulations, such as government regulations and ministerial regulations, serve to clarify the operational and technical provisions for hospital management. These regulations govern hospital organizational aspects, administrative obligations, and quality control and patient safety mechanisms. The existence of these layered regulations reflects the state's efforts to control healthcare risks that have the potential to significantly impact public safety. However, the complexity of regulations also demands adequate managerial capacity from hospitals. Without a comprehensive understanding of the applicable legal framework, hospitals risk non-compliance, which can lead to legal sanctions and a decline in public trust.<sup>3,6</sup>

### Management Roles and Responsibilities in Hospital Governance

From a governance perspective, hospitals are not only managed as service entities but also as organizations that must implement corporate governance principles. These principles emphasize the importance of a clear organizational structure, transparent division of authority, and accountable decision-making mechanisms. Hospital management is responsible for ensuring that all operational activities comply with legal provisions and established standards. In addition to corporate governance, regulations also require the implementation of clinical governance as a framework for controlling the quality of clinical services. Clinical governance positions patient safety and service quality as the collective responsibility of the organization, not solely the responsibility of individual healthcare workers. Within

this framework, hospital management is required to provide supporting systems, such as standard operating procedures, clinical audits, and reporting of patient safety incidents.<sup>6,7</sup>

The relationship between corporate governance and clinical governance demonstrates the multidimensional nature of hospital governance. Legal compliance cannot be achieved solely through administrative compliance; it requires integration between managerial policies and daily clinical practice. When these two aspects are aligned, hospitals are better able to manage risks, improve service quality, and fulfill their legal obligations.<sup>7</sup>

### Hospital Licensing Requirements and Operational Compliance

Hospital licensing is a legal instrument that serves as formal legitimacy for the provision of healthcare services and serves as a state control mechanism for the quality and safety of services. In the context of hospital governance in Indonesia, compliance with licensing requirements is inseparable from daily operational obligations, as licensing reflects the hospital's readiness to meet standards for infrastructure, human resources, and supporting facilities and infrastructure for healthcare services.<sup>5</sup>

### Operational Licensing and Hospital Classification

Hospital operational licensing is granted after a number of administrative and technical requirements stipulated by regulations have been met. The licensing process not only aims to ensure the legality of a hospital's establishment but also assesses the institution's ability to provide safe and quality healthcare services. One key aspect of licensing is hospital classification, which differentiates hospitals based on their type of service and capacity. This classification has direct implications for hospitals' obligations to meet operational standards and service responsibilities.<sup>8,9</sup>

In terms of infrastructure, hospitals are required to have buildings and physical facilities that meet safety and accessibility standards, as well as spatial planning that supports medical and non-medical

services. Compliance with established standards in the infrastructure is a crucial indicator in the licensing process, as it directly relates to the safety of patients and healthcare workers. Furthermore, the availability and suitability of medical devices are also crucial. Hospitals must ensure that all medical devices used meet quality and safety standards, and possess appropriate distribution and maintenance permits.<sup>8</sup>

Human resources are a central component of hospital operational licensing. Hospitals are required to have healthcare and support staff with the appropriate number and qualifications for the classification and type of services provided. Compliance with healthcare worker licensing requirements encompasses not only practice permits and registration, but also workload management, competency, and ongoing professional development. Non-compliance with human resources has the potential to reduce service quality and increase legal risks for hospitals.<sup>9</sup>

### Implications of Non-Compliance with Licensing Requirements

Non-compliance with licensing requirements has significant legal and administrative consequences. Violations can take various forms, ranging from operating a hospital without a valid license, discrepancies between the license held and the services provided, to failure to renew the license as required. This situation reflects weak internal controls and a lack of attention to legal compliance aspects of hospital governance. Administrative consequences for licensing violations can include warnings, operational restrictions, and even operational permit revocation. These administrative actions are intended to protect the public from substandard healthcare services. However, the impact on hospitals can be far-reaching, including disruption to service continuity, financial losses, and a decline in public trust.<sup>10</sup>

In addition to administrative sanctions, non-compliance with licensing also has the potential to result in more serious legal consequences. In certain situations, violations can be the basis for lawsuits if they result in harm to patients or other parties. Hospitals can face civil lawsuits and

other legal consequences for negligence in fulfilling licensing obligations. This demonstrates that licensing is not merely an administrative formality but an integral part of legal risk mitigation efforts.<sup>9</sup>

### **Accreditation as a Compliance Mechanism: The Role of Accreditation Bodies in Promoting Quality and Patient Safety**

Hospital accreditation constitutes a formalized compliance mechanism that integrates regulatory requirements with organizational governance and clinical practice. In the Indonesian context, accreditation administered by the Hospital Accreditation Commission (Komisi Akreditasi Rumah Sakit/KARS) is a mandatory prerequisite for hospital operational legitimacy and participation in the national health insurance scheme. This regulatory positioning elevates accreditation beyond a voluntary quality initiative, framing it as an enforceable instrument of legal and institutional accountability.<sup>11</sup>

Through structured standards, periodic surveys, and continuous evaluation, accreditation obliges hospitals to embed patient safety principles, standardized care processes, and documented management systems within routine operations. Evidence from health system research consistently demonstrates that accredited hospitals exhibit stronger safety cultures, higher compliance with clinical protocols, and more mature quality improvement infrastructures. Accordingly, accreditation operates as both a quality enhancement tool and a preventive legal mechanism by reducing the likelihood of adverse events and governance failures.<sup>12</sup>

Conversely, failure to achieve or maintain accreditation status may indicate deficiencies in internal control systems and organizational oversight, increasing exposure to administrative sanctions, reputational damage, and medico-legal risk. In this regard, accreditation functions as an external compliance driver that reinforces continuous quality improvement and patient safety as core obligations of lawful hospital practice.<sup>3</sup>

### **Critical Compliance Standards: Governance (TKRS) and Quality Improvement and Patient Safety (PMKP)**

The Governance Standard (Tata Kelola Rumah Sakit/TKRS) represents a central pillar of accreditation, emphasizing leadership responsibility, organizational accountability, and transparency in decision-making. TKRS requires hospital leadership to establish clearly defined governance structures, effective oversight mechanisms, and policies that ensure alignment between institutional objectives and regulatory obligations. Robust governance under TKRS is essential to translating statutory requirements into coherent managerial practices and sustaining organizational commitment to quality and patient safety.<sup>3,13</sup>

Complementing this framework, the Quality Improvement and Patient Safety Standard (Peningkatan Mutu dan Keselamatan Pasien/PMKP) operationalizes compliance at the clinical level. PMKP mandates systematic measurement of quality indicators, comprehensive incident reporting, root cause analysis, and the implementation of corrective and preventive actions. This standard ensures that clinical services adhere to professional norms and patient safety regulations through a continuous learning and improvement cycle.<sup>3,13</sup>

Together, TKRS and PMKP form an integrated compliance architecture within hospital accreditation. TKRS provides strategic governance and institutional control, while PMKP ensures consistent application of quality and safety principles in clinical practice. Deficiencies in the implementation of either standard may undermine patient safety and expose hospitals to legal and organizational risk, underscoring their critical role in sustaining compliant, high-quality, and safe healthcare delivery.<sup>3,13</sup>

### **Risk Management Regulation: Hospital Obligations in Identifying, Managing, and Reporting Clinical and Non-Clinical Risks**

Risk management in hospitals is a regulatory obligation designed to prevent adverse events, ensure patient safety, and mitigate legal exposure. Hospitals are

required to systematically identify, assess, manage, and monitor both clinical and non-clinical risks, including risks related to patient care, infrastructure, human resources, information systems, and organizational processes. This obligation reflects the recognition that failures in non-clinical domains may pose equivalent threats to patient safety and institutional integrity as clinical errors.<sup>14,15</sup>

Regulatory frameworks mandate the establishment of structured risk management systems, including risk registers, incident reporting mechanisms, and periodic risk evaluations. Effective implementation enables early detection of potential hazards and facilitates timely corrective actions. Conversely, inadequate risk identification and documentation reflect weak internal controls and undermine institutional accountability. Such deficiencies may result in repeated adverse events, increased patient harm, and heightened vulnerability to administrative sanctions and legal claims. Accordingly, risk management functions not only as a patient safety strategy but also as a core instrument of legal compliance and organizational resilience.<sup>14,15</sup>

### **Legal Compliance in Incident Management: Medical Records, Data Confidentiality, and Medical Malpractice Procedures**

Legal compliance in incident management is closely linked to the proper handling of medical records, protection of patient data, and adherence to established procedures in cases of alleged medical malpractice. Medical records constitute both clinical documentation and legal evidence, requiring accuracy, completeness, timeliness, and secure storage. Failure to maintain reliable medical records compromises continuity of care and weakens the hospital's legal position in the event of disputes or litigation.<sup>16,17</sup>

Data confidentiality represents a fundamental legal and ethical obligation. Hospitals must ensure that patient information is accessed, used, and disclosed only in accordance with legal provisions and professional standards. Breaches of confidentiality may result in administrative penalties, civil liability, and erosion of patient trust, particularly in

the context of increasing digitalization of health information systems.<sup>17</sup>

In cases of suspected medical malpractice, hospitals are obligated to follow standardized procedures that emphasize documentation, internal review, and dispute resolution mechanisms. Transparent handling of incidents, supported by comprehensive medical records and compliance with reporting obligations, is essential to ensure due process for both patients and healthcare professionals. Failure to comply with these procedures may escalate disputes, intensify legal risk, and damage institutional credibility. Therefore, effective incident management represents a critical intersection between patient safety, professional accountability, and legal compliance within hospital governance.<sup>16</sup>

### **Synergy of the Three Pillars: Accreditation, Licensing, and Risk Management in Achieving Legal Compliance**

Legal compliance in hospital governance is most effectively achieved through the synergistic integration of accreditation, licensing, and risk management as interdependent regulatory pillars. Accreditation provides a structured framework for quality and patient safety standards, licensing establishes formal legal legitimacy and state oversight, while risk management functions as an internal control mechanism to prevent regulatory breaches and adverse events. When implemented in isolation, each pillar offers limited protection; however, their integration creates a comprehensive compliance architecture that aligns regulatory requirements with operational practice.<sup>12,18</sup>

Accreditation standards translate licensing requirements into measurable organizational and clinical processes, ensuring that hospitals not only meet minimum legal thresholds but also sustain continuous quality improvement. Licensing, in turn, reinforces accreditation by linking compliance outcomes to operational legitimacy and service authorization. Risk management acts as a connecting mechanism, enabling early

identification of gaps in accreditation standards or licensing obligations and facilitating timely corrective actions. This synergy enhances institutional accountability, reduces legal exposure, and strengthens patient safety culture, positioning compliance as an ongoing organizational process rather than a periodic administrative obligation.<sup>3,12,18</sup>

### **Implementation Challenges: Barriers to Comprehensive Legal Compliance in Indonesian Hospitals**

Despite a robust regulatory framework, achieving comprehensive legal compliance in Indonesian hospitals remains challenged by multiple systemic and organizational barriers. One major obstacle is the variability in managerial capacity and leadership commitment, particularly in smaller or resource-limited hospitals, which impairs consistent implementation of accreditation standards, licensing requirements, and risk management systems. Limited understanding of regulatory obligations often results in compliance being treated as a documentation exercise rather than an integrated governance function.<sup>19,20</sup>

Resource constraints, including shortages of trained personnel, information systems, and financial capacity, further hinder effective compliance. These limitations affect the quality of risk identification, incident reporting, and follow-up actions, increasing the likelihood of repeated adverse events and regulatory violations. Additionally, the complexity and fragmentation of regulations contribute to implementation challenges, as hospitals must navigate overlapping legal provisions from multiple authorities.<sup>21</sup>

Cultural factors also play a significant role, particularly the persistence of blame-oriented approaches to errors, which discourage transparent reporting and learning from incidents. Without a supportive safety culture, risk management systems remain underutilized, weakening the overall compliance framework. Addressing these challenges requires strengthening institutional capacity, simplifying regulatory alignment, and fostering a culture of accountability and continuous improvement to ensure

sustainable legal compliance in Indonesian hospitals.<sup>19</sup>

## **CONCLUSION**

This review demonstrates that legal compliance in hospital governance is not a fragmented administrative obligation but a comprehensive and integrated process grounded in the synergy of accreditation, licensing, and risk management. Accreditation functions as a structured compliance mechanism that translates regulatory requirements into measurable standards of quality and patient safety. Licensing provides formal legal legitimacy and state oversight, while risk management operates as an internal control system that enables early identification and mitigation of clinical and non-clinical risks.

The integration of governance standards (TKRS) and quality improvement and patient safety standards (PMKP) further reinforces compliance by aligning leadership accountability with safe clinical practice. Effective management of medical records, data confidentiality, and incident handling including medical malpractice procedures—emerges as a critical interface between patient safety and legal accountability. Collectively, these elements underscore that sustainable compliance is achieved when regulatory adherence is embedded within organizational culture, leadership commitment, and continuous quality improvement processes.

## **AUTHORS CONTRIBUTION**

I.B.N.T.P. conceptualized the study, designed the methodology, and wrote the original draft. G.K.U conducted data extraction and contributed to the review and editing of the manuscript.

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None.

## **CONFLICT OF INTEREST**

The authors declare no conflict of interest related to this study.

## **ETHICAL CONSIDERATION**

Not applicable.

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