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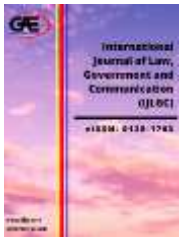

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THE MATRYOSHKA OF HEALTHCARE FACILITIES: A LEGAL ANALYSIS ON ESTABLISHING LAYERED PRIVATE HEALTHCARE FACILITIES IN MALAYSIA

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Abstract:

This manuscript evaluates whether Malaysia should permit layered private healthcare facilities—licensed hosts that co-locate third-party providers—and specifies the legal and governance pre-conditions for safe adoption. Drawing on Act 586 and the 2006 Regulations, recent Malaysian jurisprudence on non-delegable duties, and comparative oversight models from the United States (CMS[1]), Singapore (HCSA[2]), and England (CQC[3]), the analysis reaches a consistent conclusion: shared premises do not dilute accountability. The paper reframes the problem through a single research question—under what auditable safeguards, if any, should Malaysia license layered facilities—and advances four guardrail domains: (i) independent compliance proven by each co-located entity; (ii) transparent patient attribution and ethical advertising; (iii) conflict-of-interest management; and (iv) disciplined information governance. The manuscript adds a compliance checklist that links each guardrail to statutory or comparative authority, a standard co-location term sheet, a patient-facing attribution map, a role-based data-access matrix, and a short compliance vignette. The conclusion is practical: approve layering only where legal, physical, and operational separations are demonstrable ex ante; otherwise, refuse licensing to avoid risk transfer to patients and regulatory opacity.

Keywords:

Layered Health Facility; Private Healthcare; Licensing; Act 586

[1] Centers for Medicare & Medicaid Services (CMS)
[2] Healthcare Services Act (HCSA) by the Ministry of Health Singapore
[3] Care Quality Commission (CQC)

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Introduction

This paper reviews and reorganizes the available material on layered private healthcare facilities in Malaysia, with a focus on the legal obligations, regulatory expectations, and risk controls that apply when multiple service entities operate within a single licensed premises (Chin et al., 2019). The analysis is anchored in the Private Healthcare Facilities and Services Act 1998 [Act 586] and the Private Healthcare Facilities and Services (Private Hospitals and Other Private Healthcare Facilities) Regulations 2006 [*P. U. (A) 138/2006*], and it is informed by emerging jurisprudence that increasingly imposes non-delegable duties on private hospitals, narrowing the practical distance between independent contractors and the host institutions within which they operate (Hussain et al., 2019). We also consider the realities of dual practice and the corporatisation of health services, both of which complicate regulatory oversight in private settings (Fadzil et al., 2022). These pressures underscore the need for a robust and flexible legal framework that delineates the operational responsibilities of facility owners and third-party service providers, consistent with Malaysia's evolving private health market (Rosnah & Abdullah, 2002; WP & T, 2015). Taken together, the regulatory gap and rising demand for private care justify a recalibration of enforcement strategies to ensure patient safety and sustain standards of care (Chin et al., 2019; Hussain et al., 2019).

Research Question and Objectives

Research question:

Under what auditable safeguards, if any, should Malaysia license layered private healthcare facilities?

Research Objectives

(i) Analyse the Private Healthcare Facilities and Services Act 1998 [Act 586] and its 2006 Regulations and synthesize recent jurisprudence on non-delegable duty;
(ii) Map comparative oversight (CMS[4], HCSA[5], CQC[6]) to Malaysian licensing logic;
(iii) Design pre-approval guardrails and a pass/fail decision test for regulators;
(iv) Provide practical tools (checklists, matrices, and term sheets) to support inspection and enforcement.

Methodology

This study employs a doctrinal legal research methodology, supported by comparative regulatory analysis and a regulatory design approach, to examine the legal feasibility and governance implications of licensing layered private healthcare facilities in Malaysia. The core method involves a detailed analysis of Malaysian legislation, particularly the Private Healthcare Facilities and Services Act 1998 (Act 586) and its accompanying 2006 Regulations [P.U.(A) 138/2006]. These laws are interpreted to determine the statutory requirements for separate licensing, physical demarcation, and compliance obligations applicable when multiple providers operate within a single licensed premises. The study also examines judicial developments, with particular focus on the evolving Malaysian jurisprudence regarding non-delegable duties, ostensible agency, and hospital liability for the acts of independent contractors, drawing from recent decisions such as Siow Ching Yee v. Columbia Asia Sdn Bhd (2024).

[4] Centers for Medicare & Medicaid Services
[5] Healthcare Services Act
[6] Care Quality Commission

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To assess Malaysia's readiness and identify best practices, the study incorporates a comparative legal analysis of regulatory frameworks from three jurisdictions with established co-location governance models: the United States (CMS Conditions of Participation), Singapore (Healthcare Services Act), and England (Care Quality Commission registration rules). These comparative models provide benchmarks for minimum standards in licensing, patient attribution, data governance, and independent compliance, offering critical insight into how similar systems maintain single-point accountability despite shared premises. Beyond doctrinal and comparative analysis, the study uses a regulatory design framework to translate normative principles into operational tools. These include an audit-ready compliance checklist, a patient-facing attribution map to avoid confusion regarding the identity of service providers, a role-based data access matrix to safeguard patient information, and a standard co-location agreement template. These tools were developed to guide licensing decisions and facilitate consistent, transparent enforcement by regulatory authorities.

The research is guided by a single, outcome-driven question: Under what auditable safeguards, if any, should Malaysia license layered private healthcare facilities? All analyses in the paper aim to operationalise this question by defining practical licensing thresholds and compliance mechanisms. Although empirical fieldwork, such as interviews or inspection data, was not conducted, the doctrinal synthesis is comprehensive and fit-for-purpose within a policy and regulatory context. Future studies may build on this foundation by integrating empirical evidence from enforcement experiences or judicial reviews to further validate the proposed licensing framework.

Background and Definition

A layered health facility is a licensed establishment within which one or more third-party providers deliver services under contract while the host retains its own licence and brand. This model can expand capacity, accelerate access to subspecialty services, and spread capital costs, but it also multiplies legal and operational interfaces that may diffuse accountability for safety, quality, information governance, and complaints management (Amin et al., 2020; Lipsitz, 2012; McHugh et al., 2015; Pradhan et al., 2024; Siaw & Neng, 2025; Tritz, 2019).

Malaysian Legal and Regulatory Posture

Private Healthcare Facilities and Services Act 1998 [Act 586] encodes separation triggers: services that are not physically, administratively, or organisationally linked to the host require separate approval to establish (s. 13[1], Act 586) and a separate licence to operate (s. 21,586). The Private Healthcare Facilities and Services (Private Hospitals and Other Private Healthcare Facilities) Regulations 2006 [P. U. (A) 138/2006] operationalise and outline requirements involving physical demarcation (e.g., dedicated entrances, patient flows, wayfinding), and section 108, Act 586 prohibits misleading advertising to prevent confusion about provider identity (s.108, Act 586). Recent jurisprudence confirms that certain hospital functions—especially emergency care—are non-delegable duties and that ostensible-agency doctrines may attach liability to the host even when clinicians are contractors; Malaysian judiciary similarly rejects liability outsourcing via independent-contractor labels (In re Estate of Essex v. Grant County Public Hospital District No. 1, 2024; Ikuta, 2021; Olsman, 2022; Siow Ching Yee v. Columbia Asia Sdn Bhd, 2024).

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Comparative Oversight Models

Comparative practice is aligned on a core principle: co-location does not dilute accountability. In the United States, the Centers for Medicare & Medicaid Services (CMS) permits shared space, staff, or services only if each entity independently complies with the Conditions of Participation and can demonstrate separate governance, staffing, emergency coverage, documentation, and survey readiness. Singapore's Healthcare Services Act (HCSA) mandates service-based licensing with prior approval and written delineation of responsibilities for co-located services. England's Care Quality Commission (CQC) links each provider to specified regulated activities at defined locations, ensuring an auditable 'place of service' visible to regulators and the public.

Decision Framework for Approval or Refusal

Approval is justified only when the applicant proves legal, physical, and operational separation ex ante, and when each co-located entity can show independent compliance; otherwise, refusal is appropriate to prevent risk transfer and regulatory opacity.

The following translates the paper's legal and governance analysis into audit-ready tools for regulators and facility leaders. The aim is straightforward: convert high-level principles—single-point accountability, distinct entity/distinct compliance, and truthful patient attribution—into concrete evidence checks that can be verified during licensing and inspections. Each table targets one critical risk surface in layered premises, specifies the minimum documentary and operational artefacts expected, and frames a pass/fail threshold that prevents "borrowed compliance" and ambiguity about who is responsible for what, where, and for whom.

Table 1, Compliance Checklist (Pre-Approval), operationalises the approval test. It clusters requirements into core guardrails—legal separation, independent compliance, clinical governance and quality assurance, emergency cover and supervision, conflicts-of-interest controls, and information governance—and pairs each guardrail with the exact inspection questions and artefacts an applicant must produce (e.g., separate approval/licence where required; entity-specific staffing rosters and on-call arrangements; signed co-location agreement terms on credentialing, privileging, incident reporting, and audit rights). Reviewers should apply the checklist line-by-line and record explicit evidence for each item; absence of evidence at any decision node signals a remediation requirement or grounds for refusal. This keeps approvals disciplined, comparable across cases, and defensible on review.

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Table 1: Compliance Checklist (Pre-Approval)

Guardrail	Operational Requirement	Authority
Distinct entity, distinct compliance	Each entity shows separate governance, staffing, emergency cover, documentation, and survey readiness.	CMS[7]; HCSA[8]; CQC[9]
Standard co-location agreement	Terms on credentialing/privileging, supervision, on-call/emergency response, clinical governance/QAPI[10], records custody, indemnities, audit rights, termination.	Act 586[11]; CMS/HCSA/CQC practice
Patient-facing attribution	Provider-of-record identified in consent, signage, bills, websites, and advertisements; no misleading claims.	s. 108 Act 586; Act 290[12] HCSA Ads[13]
Conflict-of-interest controls	Declarations, public registers, mitigation plans; routine monitoring to prevent referral steering/financial entanglements.	NHS[14]-Wide Conflicts Of Interest Guidance (2017)
Information governance	Role-based access, audit trails, breach notification, bounded processing via contract; BAAs[15]/GDPR[16]-grade	HIPAA OCR[17]; ICO[18]

[7] Centers for Medicare & Medicaid Services
[8] Healthcare Services Act
[9] Care Quality Commission
[10] Quality Assurance and Performance Improvement
[11] Private Healthcare Facilities and Services Act 1998
[12] c
[13] Healthcare Services (Advertisement) Regulations 2021
[14] National Health Service (UK)
[15] Business Associate Agreement (U.S. HIPAA context)
[16] General Data Protection Regulation (EU law; mirrored in the UK as UK GDPR)
[17] Health Insurance Portability and Accountability Act Office for Civil Rights
[18] Information Commissioner's Office (United Kingdom)

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Guardrail	Operational Requirement	Authority
	clauses for special-category data.	

Source:

1. Centers For Medicare & Medicaid Services (CMS). Guidance For Hospital Co-Location With Other Hospitals or Healthcare Facilities (2019). https://www.cms.gov/files/document/qso-19-13-hospital-revised.pdf;
2. Healthcare Services Act 2020;
3. Care Quality Commission (2024, May 28). Provider Guidance Registration. https://www.cqc.org.uk/guidance-providers/registration/what-location#:~:text=A%20location%20is%20each%20premises,referred%20to%20as%20'branches';
4. Private Healthcare Facilities And Services Act 1998;
5. Medicines (Advertisement And Sale) Act 1956
6. Healthcare Services (Advertisement) Regulations 2021;
7. National Health Service (NHS). Managing Conflicts Of Interest In The NHS (2024). https://www.england.nhs.uk/long-read/managing-conflicts-of-interest-in-the-nhs/; 14,16. Health Insurance Portability And Accountability Act Of 1996;
8. Regulation (EU) 2016/679 (General Data Protection Regulation);
9. Information Commissioner's Office (n.d.). For The Public. https://ico.org.uk/for-the-public/)

Table 2, Patient-Facing Attribution Map, addresses the most frequent source of legal exposure in layered settings: patient confusion about provider identity. It sets out, by communication surface (consent forms, on-site signage and wayfinding, billing/invoices, websites and advertisements, patient information leaflets), what must be disclosed and how. The objective is to ensure that a reasonable patient can identify the provider-of-record at every touchpoint and that branding, consent, and charging are aligned. Inspectors should read this table in tandem with the advertising and consumer-protection controls, checking live artefacts (actual signs, sample bills, screenshots) rather than relying on policy statements. Any inconsistency—such as a host brand on a bill for a contractor's service—should be treated as an immediate corrective-action item.

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Table 2: Patient-Facing Attribution Map

Surface	What must appear	Legal basis
Consent form	Provider-of-record; contractor status if applicable; emergency cover information.	s. 108, Act 586[19]; HCSA Ads [20]
On-site signage/wayfinding	Clear branding per entity; distinct entrances/flows where required.	Part X, P. U. (A) 138/2006[21]
Billing/invoices	Legal name of the charging entity; contact for queries/refunds.	Act 599[22], s.108. Act 586
Websites/ads	Accurate service descriptions; no misleading claims of affiliation.	s. 108,Act 586; Act 290; HCSA Ads
Patient information leaflets	Who provides which service, where, and how to escalate complaints.	Act 586; CQC guidance[23]

Source:
1. Private Healthcare Facilities And Services Act 1998;
2. Healthcare Services (Advertisement) Regulations 2021;
3. The Private Healthcare Facilities And Services (Private Hospitals And Other Private Healthcare Facilities) Regulations 2006; 21. Consumer Protection Act 1999;
4. Medicines (Advertisement And Sale) Act 1956
5. Care Quality Commission (2024, May 28). Provider Guidance Registration. https://www.cqc.org.uk/guidance-providers/registration/whatlocation#:~:text=A%20location%20is%20each%20premises,referred%20to%20as%20'branches'.

Table 3, Role-Based Data Access Matrix, mitigates data-handling risks that arise when multiple entities operate under one roof. It specifies, by role (e.g., host clinician, third-party clinician, IT administrator, quality officer, billing staff), the permitted data, prohibited data/actions, and the access controls expected in practice (role-based access control, audit logs, breach notification pathways, and contract-bounded processing). Surveyors should test this matrix against real workflows—referrals, after-hours events, and cross-entity handovers—to confirm that access is both "minimum necessary" and auditable. Evidence should include user-access registers, sample audit-log extracts, and the relevant contractual clauses (e.g., business-associate-style provisions) governing third-party processing

[19] Private Healthcare Facilities and Services Act 1998
[20] Healthcare Services (Advertisement) Regulations 2021
[21] The Private Healthcare Facilities and Services (Private Hospitals and Other Private Healthcare Facilities) Regulations 2006
[22] Consumer Protection Act 1999
[23] Care Quality Commission Guidance and Regulation

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Table 3: Role-Based Data Access Matrix

Role	Permitted data	Prohibited data/actions	Controls
Host hospital clinician	Records of the host's patients for episodes under host care.	Access to third-party provider records absent referral or consent.	RBAC[24], audit logs, time-bound access.
Third-party provider clinician	Records of their patients; minimum necessary host data for shared cases.	Bulk exports; unrelated host records.	BAA[25]/GDPR[26] clauses, data minimisation.
IT admin (vendor)	Metadata is strictly necessary for maintenance.	Viewing PHI[27]/identifiable data.	Contractual NDA[28], least privilege, audit trails.
Quality/governance officer	De-identified or limited data sets for QAPI[29].	Identifiable data without a lawful basis.	Data processing register, DPIA[30], where required.
Billing staff	Billing data for their entity's patients.	Clinical notes beyond necessity.	Purpose limitation: access logs.

Source:

1. Centers For Medicare & Medicaid Services (CMS). Guidance For Hospital Co-Location With Other Hospitals or Healthcare Facilities (2019). https://www.cms.gov/files/document/qso-19-13-hospital-revised.pdf;
2. Healthcare Services Act 2020;
3. Care Quality Commission (2024, May 28). Provider Guidance Registration. https://www.cqc.org.uk/guidance-providers/registration/what-location#:~:text=A%20location%20is%20each%20premises,referred%20to%20as%20'branches';
4. Private Healthcare Facilities And Services Act 1998;
5. Health Insurance Portability And Accountability Act Of 1996;
6. Regulation (EU) 2016/679 (General Data Protection Regulation);
7. Information Commissioner's Office (n.d.). For The Public. https://ico.org.uk/for-the-public/)

Together, these three tables convert policy into practice. Table 1 sets the gate for approval, Table 2 protects patients at every visible interface, and Table 3 locks down the invisible but critical data layer. Used as a package, they provide a tight, repeatable mechanism to license

[24] Role-Based Access Control
[25] Business Associate Agreement (U.S. HIPAA context)
[26] General Data Protection Regulation (EU law; mirrored in the UK as UK GDPR)
[27] Protected Health Information
[28] Non-Disclosure Agreement
[29] Quality Assurance and Performance Improvement
[30] Data Protection Impact Assessment.

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only those layered configurations that can prove accountability at the bedside and demonstrate durable compliance under inspection pressure.

Compliance Vignette
A private hospital leases operating-theatre time to an independent endoscopy company. The host maintains its own surgical lists and emergency roster; the third-party runs daytime sessions. During a post-procedure bleed, the patient returns after hours. Under the co-location agreement, the host is responsible for emergency cover; the third-party must ensure on-call coordination and supply a handover summary accessible to the host. Regulator tests whether: (i) the host's emergency cover is independently adequate; (ii) the third-party's credentialing and supervision records are current; (iii) signage and bills identify the provider-of-record; and (iv) records access follows role-based rules. The case passes because each entity evidences independent compliance, and the patient journey shows single-point accountability.

Suitability and Readiness of Malaysia to Embrace the Concept of Layered Private Healthcare Facilities
Readiness is more than statutory permission; it is the capacity of the legal architecture, inspectorate, and market actors to deliver single-point accountability in practice. On balance, Malaysia shows partial readiness: the legal foundations are present, but enabling instruments, inspection tooling, and operational capabilities require targeted upgrades before large-scale adoption. The analysis below synthesises strengths, gaps, and actionable steps aligned to comparative standards.

Strength
On a legal framework basis, Act 586 already encodes separation triggers, while the Private Healthcare Facilities and Services (Private Hospitals and Other Private Healthcare Facilities) Regulations 2006 [*P. U. (A) 138/2006*] specify physical demarcation and wayfinding; section 108 addresses misleading advertising. Recent jurisprudence—domestic and comparative—supports the central premise that emergency and other core functions are non-delegable and that ostensible-agency risks rise in single-brand environments. These pillars are aligned with CMS[31]/HCSA[32]/CQC[33] logic.

Gaps
Malaysia lacks a codified, national 'co-location standard' that operationalises 'distinct entity, distinct compliance' instrumental policy. A directive or regulation should mandate a standard co-location agreement with minimum clauses on credentialing/privileging, supervision, on-call and emergency response, clinical governance/QAPI[34], records custody, audit rights, indemnities, and termination triggers; this converts abstract duties into enforceable terms visible at inspection.

Surveyors require checklists, scenario-based probes (e.g., after-hours complications, cross-roster emergencies), and authority to test independent readiness without reliance on 'borrowed compliance.' A competency framework and training curriculum should be rolled out with calibration exercises and joint audits in early pilots.

[31] Centers for Medicare & Medicaid Services
[32] Healthcare Services Act
[33] Care Quality Commission
[34] Quality Assurance and Performance Improvement

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Information governance needs to be strengthened. Co-location intensifies data-sharing and secondary-use risks. Role-based access, audit trails, breach duties, and contract-bounded processing should be standard; where comparators (HIPAA[35]/GDPR[36]) are used for benchmarking, the local instruments should expressly incorporate equivalent protections for special-category data and require third-party contracts.

Mixed

Layered Health Facility Models much align with private-sector investment and medical-tourism aspirations by de-risking capital-intensive services. Yet incentives can skew behaviour—e.g., referral steering or premiumisation—unless conflict-of-interest regimes (declarations, public registers, mitigation plans) are standardised and enforced. Equity safeguards, such as transparency on waiting times and escalation pathways for complications, should be specified to avoid two-tier distortions.

Essential

Even when corridors or rosters are shared, patients should experience clear provider attribution and seamless, accountable handovers. Design controls—dedicated entrances and flows, signage, 'who is responsible now' prompts in clinical areas—are not cosmetic; they are the safety rails that make accountability auditable.

Table 4: Malaysia Readiness Scorecard

Domain	Status	Priority Actions / Authority
Legal foundations	Strong	Maintain; issue explanatory circular linking to 'distinct entity, distinct compliance.'
Co-location standard & contracts	Weak	Publish mandatory co-location template (credentialing, supervision, emergency, QAPI[37], records, audit, indemnity, termination).
Inspectorate tooling & training	Moderate	Develop checklists, probes, calibration audits; resource inspectorate for pilots.
Conflict-of-interest governance	Moderate	Adopt NHS[38]-style declarations/registers and mitigation plans; audit referral flows.
Information governance	Weak	Mandate role-based access, audit logs, breach duties;

[35] Health Insurance Portability and Accountability Act
[36] General Data Protection Regulation (EU law; mirrored in the UK as UK GDPR)
[37] Quality Assurance and Performance Improvement
[38] National Health Service (UK)

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Domain	Status	Priority Actions / Authority
		BAA[39]/GDPR[40]-equivalent clauses for third parties.
Patient-facing attribution & advertising	Strong	Enforce s.108, Act 586[41]; align signage/consent/billing/websites; adopt HCSA Ad[42] rules as comparator.
Emergency cover & supervision	Moderate	Require independent readiness; prohibit pooled cover unless standards are met; test after-hours scenarios.

The revised framework turns descriptive regulatory content into an operational approval test. It links non-delegable duties and ostensible agency to concrete controls (e.g., independent emergency cover; unambiguous attribution), and it equips regulators with inspection-ready artefacts. While empirical data were not used, the doctrinal and comparative synthesis is rigorous and fit-for-purpose in a licensing and enforcement context. Future work could include case studies from inspections and judicial outcomes to further triangulate validity.

Conclusion

Layered private healthcare facilities are viable only as high-governance configurations that preserve single-point accountability at the bedside. Approval should be contingent on auditable legal, physical, and operational separation and on the guardrails specified herein. Where applicants cannot satisfy these conditions ex ante, licensing should be refused to avoid risk transfer to patients and erosion of regulatory visibility.

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[39] Business Associate Agreement (U.S. HIPAA context)
[40] General Data Protection Regulation (EU law; mirrored in the UK as UK GDPR)
[41] Private Healthcare Facilities and Services Act 1998
[42] Healthcare Services (Advertisement) Regulations 2021

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