

THEME

Applying Best Practices in Healthcare Delivery

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**LINKING ACCREDITATION
WITH THE LAW**

**Private Healthcare Facilities and
Services Act 1998 [Act 586]**

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Introduction



**THE PRIVATE HEALTHCARE
FACILITIES & SERVICES ACT
1998 [ACT 586]**

Act 586

- Preamble –
 - An Act to provide for the **regulation and control of private healthcare facilities and services** and other **health-related facilities and services** and **for matters related** hereto.
- Date of gazettelement: **27 August 1998.**
- Date of enforcement: **1 May 2006.**
- The provisions apply to all private healthcare facilities & services in Malaysia as delineated in Section 3 of the Act.

Act 586

- **Arrangement**

- XIX Parts
- 122 Sections

- **Regulations**

- Private Healthcare Facilities and Services (*Private Hospitals and Other Healthcare Facilities*) Regulations 2006.
- Private Healthcare Facilities and Services (*Private Medical Clinics or Private Dental Clinics*) Regulations 2006.

- **Orders**

- Private Healthcare Facilities and Services (*Official Identification Card*) Order 2006.

Goals of Act 586

1. Impose and ensure minimum standards in the private healthcare facilities and services (PHFS).
2. Ensure integrity among healthcare professionals.
3. Ensure professionalism among all healthcare professions.
4. Ensure quality of healthcare facilities and services e.g. Quality Assurance, Mortality Review etc.
5. Address social and national interest.

Relevant Parts under Act 586

Part III	Approval to establish or maintain of PHFS other than private clinics
Part IV	Licence to operate or provide of PHFS other than private clinics
Part V	Registration of Private Clinics
Part VI	Responsibilities of Licensee, Certificate Holder and Person in Charge
Part XII	Mortality Assessment
Part XIII	Quality of PHFS
Part XIV	Board of Management & Advisory Committee

Conditions for Approval to Establish or Maintain

- Status of Applicant (*Sect. 6*)
 - Sole Proprietor (RMP).
 - Partnership (+ ≥ 1 RMP).
 - Body Corporate (+ ≥ 1 RMP as member BOD).
- Criteria for 'zoning' (*Sect. 9*).
- Type of PHFS to establish or maintain (*Sect. 3*).
- Infrastructures (detail floor plans).
- Capability to provide the financial, material and human resources (plus management and administrative planning) (*Sect. 11*).

Conditions for Licence to Operate or Provide

- Status of Applicant (*Sect. 6*)
- Documentation (as prescribed)
 - Based on the types of facilities & services.
 - Require details of personnel.
- Inspection of (*Sect. 16*)
 - Infrastructures.
 - Facilities, Equipments, Services.
 - Policies, Standards, Records.
- Renewal every 2 years (*Sect. 22*).

Quality Assurance Establishment – Part XIV

Establishment of –

- Board of Management (*Sect. 77*).
- Medical or Dental Advisory Committee (*Sect. 78*).
- Midwifery Care Advisory Committee (*Sect. 79*).
- Nursing Advisory Committee (*Sect. 80*).

Quality Assurance Establishment – Part XIII

- Every PHFS shall have quality programmes and activities (*Sect. 74*)
 - Ensure quality and appropriateness of facilities and services.
- Power of Director General to give directions on Quality aspects (*Sect. 75*)
 - Issue directives, orders, guidelines relating to quality assurance.

Quality Improvement

- Patient Grievance Mechanism (*Sect. 36*).
- Incident Reporting (*Sect. 37*).
- Mortality Assessment (*Part XII – Sect. 64-73*)
 - Establishment of a committee.
 - Publication made shall not contain name or any information that could lead to the identification of the patient and practitioner.

Similarities



ACT 586 & ACCREDITATION

Similarities

- Similar intention to ensure patient safety and the provision of quality care.
- Major areas in accreditation include:
 1. Organisation and Management
 2. Human Resource and Management
 3. Policies and Procedures
 4. Facilities and Equipment; and
 5. Quality Improvement Activities and Safety
- Provisions available under Act 586 that address the above areas.

Organisation and Management

- Board of Director (est. ↓ Companies Act).
- Licensee.
- Board of Management (est. ↓ Act 586).
- Person in Charge (RMP/SRN but allows other person to be in charge of non-clinical matters e.g. CEO).
- Medical and Dental Advisory Committee etc.
- Head of Department/Discipline.
- Personnel.

Human Resource and Management

- Refers to the type of facilities and services.
- Professional (qualified, trained and experienced in the relevant disciplines).
- Specialists.
- Head of Department.
- Person to perform e.g. in dialysis treatment.
- Norms for the Nursing Staff/MA.
- Technical persons.
- Assistants/Nursing Aides.

Policies and Procedures

- Depend on the type of facilities and services.
- On Inspection especially renewal e.g.
 - Written policies on privileging and engagement of practitioners.
 - Procedures on administration of patients, incident reporting, infection control etc.
 - Department policies – standard, procedures, guidelines related to services provided.
 - Policy statement – staff identification, billing procedures, consent, patient's right etc.

Facilities and Equipments

- Depends on the type of facilities and services.
- Cross reference with other relevant laws implemented in Malaysia
 - Certificate of Fitness (CF) to occupy the building by the Local Authority.
 - Fire Certificate by Fire Department.
 - CF for autoclaves and lifts by DOSH.
 - Radio-ionising equipments by Atomic Energy Licensing Board etc.

Quality Improvement Activities and Safety

- Requirements to establish programmes and activities on quality.
- Incident Reporting.
- Assessable Death (Mortality Review).
- Functions of Advisory Committees.
- Infection control.
- Departmental policies.

Differences



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Definition (Wikipedia)

Law: Licensing or Registration – by the Regulator

Licence

- The verb **license** or **grant license** – give permission. The noun license or **licence** – permission as well as to the document memorializing that permission. License granted by a party ("licensor") to another party ("licensee") as an element of an agreement between those parties.
- A shorthand definition – "an authorization (by the licensor) to use the licensed material (by the licensee)."

Registration

- Licensure required in occupations where maintenance of standards is required to protect public safety.

Accreditation - ? by Peers

Accreditation

- A process in which certification of competency, authority, or credibility is presented.
- Organizations that issue credentials or certify third parties against official standards are themselves formally accredited by accreditation bodies (such as ISQua); - known as "accredited certification bodies".
- The accreditation process ensures that their certification practices are acceptable, typically meaning –competent to test and certify third parties, behave ethically, and employ suitable

Purpose

Act 586

- Allows PHFS to establish, maintain, operate or provide.
- Legal requirements under Act 586 and its Regulations.
- DG of Health's directives.

Accreditation

- Self assessment and external peer-review process.
- Assess level of performance.
- Monitor and improve performance on an ongoing basis.
- External review and validation to assure the quality of organisations of healthcare.
- Comply to the set standards.

Process

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2 stages for hospitals (*Sect. 3*):

1. Approval to establish or maintain (certificate of approval valid for 3 years) (*Sect. 14*).
2. Licence to provide or operate (renewal every 2 years) (*Sect. 22*).

Malaysian Hospital Accreditation Standards

5 major areas

1. Organisation and Management .
2. Human Resource and Management .
3. Policies and Procedures.
4. Facilities and Equipment.
5. Quality Improvement Activities and Safety.

Requirements/Standards

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- Various forms of requirements/standards addressing different aspects of services/facilities.
- Inspection checklist
- Minimal standards.
- Legally binding.
- Enabling clauses for exemption, fees control, social obligations, penalty etc.
- Ministry of Health.

Accreditation

- Established standards.
- Regarded as optimal and achievable.
- May be voluntary or mandatory.
- Ongoing improvement activities with continuous evaluation.
- External review and validation.

Impact

Act 586

- Further improvement based on required standards/new provisions, directives.
- Licensed or not (2 categories).
- If not licensed, shall not operate or provide.

Accreditation

- To improve quality.
- May be fully, partially or not accredited.
- If not accredited may operate or provide according to status of accreditation.

Matters for Consideration



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Matters to be Taken into Consideration

Current Practices on Accreditation

- In Malaysia accreditation is a voluntary programme.
- Similar practice in other countries such as USA, Canada, New Zealand and France (as in MSQH website).
- Mandatory for all healthcare facilities and services in some countries (requirements for incentives / Government's funding).

Matters to be Taken into Consideration

The consensus agreement between MOH and APHM in November 1995

- MSQH as an independent and non-profit making organisation to administer the accreditation programmes.
- The programmes shall be voluntary and independent of Government agencies, organised and administered by healthcare professionals under the auspices of a Society.

Matters to be Taken into Consideration

- Licensing
 - Legally binding and mandatory.
- Accreditation
 - Voluntary programme
 - Licence may be issued with or without accreditation
- If accreditation is to be included in the law, it will become mandatory with the following possibility:
 - No licence issued for unaccredited private hospitals or other healthcare facilities.

Matters to be Taken into Consideration

- Requirements under the Act which are supposed to be the minimal standard may be static until further amendment.
- Regulations, directives, orders, guidelines can be improved to address current situation and development; quality and standards.
- Similarly, the set standards under the accreditation programme would be dynamic and correspond with the new development of medical technology and provision.

Potential Linkages



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Potential Linkages

In tandem with the ongoing quality improvement

- Accreditation status **may** be used to facilitate licensing process of private hospitals in future.
- Accreditation continues as a voluntary activity.

Conclusion



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Conclusion

Accreditation process can be a **tool** –

- To facilitate the process for renewal of licence.
- To **continually** improve the performance of licensed PHFS especially in the provision of safe and quality healthcare.

*Thank
you*

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