REQUIREMENTS OF PRIVATE HEALTHCARE FACILITIES & SERVICES
ACT 1998 [ACT 586] & ITS REGULATIONS

GOVERNANCE FRAMEWORK

MALAYSIAN HOSPITAL ACCREDITATION PROGRAMME,
- 10TH MSQH SURVEYOR TRAINING WORKSHOP

8 May 2014
Auditorium Hospital Sungai Buloh, Selangor
1. Introduction
   ◦ Goals of Act 586
   ◦ Mode of Control
   ◦ Act 586 and its subsidiary legislation

2. Governance framework under Act 586
   ◦ Governance [Corporate/Clinical (Integrated)]
Part A:

INTRODUCTION
GOALS OF ACT 586

1. Impose and ensure **minimum standards** in the private healthcare facilities and services (PHFS).

2. Ensure **integrity** & **professionalism** among healthcare professionals.

3. Ensure **quality** of PHFS e.g. Quality Assurance, Mortality Review etc.

4. Address **social and national interest**.
MODE OF CONTROL (S.3, 4 & 85, Act 586)

1. APPROVAL TO ESTABLISH/MAINTAIN
   1. Private Hospital
   2. Private Psychiatric Hospital
   3. Private Ambulatory Care Centre
   4. Private Nursing Home
   5. Private Psychiatric Nursing Home
   6. Private Maternity Home
   7. Private Blood Bank
   8. Private Haemodialysis Centre (PHC)
   9. Private Hospice
   10. Private Community Health Centre
   11. Any other type of healthcare facility/service to be gazetted from time to time

2. LICENCE TO OPERATE/PROVIDE

3. REGISTRATION
   1. Private Medical Clinic
   2. Private Dental Clinic

4. SUBMIT INFORMATION

Facilities, Services & Qualified, trained experienced & skilled Personnel

Managed Care Organisations
ACT 586 & ITS SUBSIDIARY LEGISLATION

• Act 586
  ◦ 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 gazettement: 27 August 1998.
  • Date of enforcement: 1 May 2006.

• Arrangement of Act 586
  ◦ XIX Parts with 122 Sections

• The provisions apply to all private healthcare facilities & services in Malaysia as delineated in Section 3 & 4 of the Act.
**Act 586**
An Act to provide for the **regulations** and **control** of PHFS & other health-related facilities and services & for matters related hereto

[1 May 2006, P.U. (B) 93/2006]

19 Parts
122 Sections

**Gazette date:** 27 Aug 1998

**Enforcement date:** 1 May 2006
SUBSIDIARY LEGISLATIONS

1. Private Healthcare Facilities & Services (Private Medical Clinics or Private Dental Clinics) Regulations, 2006 [P.U. (A) 137/2006]
   ◦ 14 Parts with 109 Regulations & 7 Schedules (1 May 2006)

   ◦ 29 Parts with 434 Regulations & 13 Schedules (1 May 2006)


Private Healthcare Facilities & Services (Private Medical Clinics or Private Dental Clinics) Regulations 2006

14 Parts
109 Regulations & 7 Schedules

Gazette date: 1 April 2006
Enforcement date: 1 May 2006

<table>
<thead>
<tr>
<th>FIRST SCH</th>
<th>SECOND SCH</th>
<th>THIRD SCH</th>
<th>FOURTH SCH</th>
<th>FIFTH SCH</th>
<th>SIXTH SCH</th>
<th>SEVENTH SCH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form A-G</td>
<td>Application Fees</td>
<td>PIC</td>
<td>Patient Medical Record</td>
<td>Emergency Services</td>
<td>Social Contribution</td>
<td>Professional Fees</td>
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</table>
PRIVATE HEALTHCARE FACILITIES AND SERVICES (PRIVATE HOSPITALS AND OTHER PRIVATE HEALTHCARE FACILITIES) REGULATIONS 2006

29 Parts
434 Regulations & 13 Schedule

Gazette date: 1 April 2006
Enforcement date: 1 May 2006
# Private Healthcare Facilities and Services

## Regulations and Schedules

- **Gazette date:** 1 April 2006
- **Enforcement date:** 1 May 2006

29 Parts
434 Regulations & 13 Schedules

<table>
<thead>
<tr>
<th>FIRST SCH</th>
<th>SECOND SCH</th>
<th>THIRD SCH</th>
<th>FOURTH SCH</th>
<th>FIFTH SCH</th>
<th>SIXTH SCH</th>
<th>SEVENTH SCH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form 1-10</td>
<td>Type of Service</td>
<td>Application Fees</td>
<td>PIC</td>
<td>IR</td>
<td>Patient’s Medical Record</td>
<td>Personal Care</td>
</tr>
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<table>
<thead>
<tr>
<th>EIGHTH SCH</th>
<th>NINTH SCH</th>
<th>TENTH SCH</th>
<th>ELEVENTH SCH</th>
<th>TWELFTH SCH</th>
<th>THIRTEENTH SCH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic Emergency Services</td>
<td>Ambulances</td>
<td>Collecting Blood</td>
<td>Code of Ethics for Blood Donation &amp; Transfusion</td>
<td>Social or Welfare Contribution</td>
<td>Fee Schedule</td>
</tr>
</tbody>
</table>
Part B:

GOVERNANCE FRAMEWORK UNDER ACT 586
For healthcare it is integrated – Perspectives Act 586

**CORPORATE GOVERNANCE**
- The system of structures, rights, duties, and obligations by which corporations are directed and controlled

**CLINICAL GOVERNANCE**
- A systematic approach to maintaining and improving the quality of patient care within a health system
GOVERNING PROCESS

- **Entity of Applicant**: Licensee/Certificate Holder & Person in Charge

- **Type of Facilities**: infrastructures & equipments
  (Location, Flow, Minimum dimension, Clear Areas etc)

- **Type of Services**: General, specialty, subspecialties
  Support services – Clinical & non clinical

- **Personnel**:  
  - Healthcare professional (S.2), Technical staff (S.2), Personal care aides (S.34)  
  - All healthcare professional, technical and para-professional shall be qualified, trained and experienced to provide the healthcare facilities and services (including part-time, volunteer, locum tenens or honorarium)

- **Performance/Outcome**: continuous monitoring & renewal of licence (written policies, complaint, incident reporting, assessable death notification, patient medical records)

- **Enforcement**: Show cause notice, compound & court

- **Closure**: Direction, transfer or stop operation
### REGULATORY FRAMEWORK UNDER ACT 586

<table>
<thead>
<tr>
<th>Time</th>
<th>Before Operation</th>
<th>Certificate</th>
<th>On Operation</th>
<th>After Closure</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Approval Procedure</strong></td>
<td><strong>Registration</strong></td>
<td><strong>Form A</strong></td>
<td><strong>Form B/C; Form F/G</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Licensing</strong></td>
<td><strong>Zoning (No Objection letter)</strong></td>
<td><strong>Form 1 (Form 2)</strong></td>
<td><strong>Form 3</strong></td>
<td><strong>Form 4/7</strong></td>
</tr>
<tr>
<td><strong>Surveillance/ Monitoring</strong></td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

### Regulate/ Control

<table>
<thead>
<tr>
<th>Approval Procedure</th>
<th>Approval Procedure</th>
<th>Register</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Approval Procedure</strong></td>
<td><strong>Show Cause Notice</strong></td>
<td><strong>Written Notice</strong></td>
</tr>
<tr>
<td><strong>Undercover, Raid (with/without warrant); Investigation; Prosecution</strong></td>
<td><strong>Compound</strong></td>
<td><strong>Warning/Direction/Temporary Closure; Suspend or Revoke the Approval, Licence or Registration</strong></td>
</tr>
</tbody>
</table>

### Liable person

| Certificate Holder / Licensee; or Person in Charge | Certificate Holder / Licensee/Any person | Any person |
## REQUIREMENTS FOR THE REGISTRATION VS LICENSING PROCESS

<table>
<thead>
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<th>REGISTRATION &amp; LICENSING</th>
<th>ADDITIONAL FOR LICENSING</th>
</tr>
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<tbody>
<tr>
<td>• Organisation &amp; Management</td>
<td>• Consent</td>
</tr>
<tr>
<td>• Policy</td>
<td>• O &amp; G</td>
</tr>
<tr>
<td>• Registers, Rosters &amp; Returns</td>
<td>• Nursery</td>
</tr>
<tr>
<td>• Patient Grievance Mechanism</td>
<td>• Paediatric</td>
</tr>
<tr>
<td>• Patient’s Medical Record</td>
<td>• Anaesthesia</td>
</tr>
<tr>
<td>• Infection Control</td>
<td>• Surgical</td>
</tr>
<tr>
<td>• Standards of PHFS</td>
<td>• ICU</td>
</tr>
<tr>
<td>• Emergency</td>
<td>• CSSD</td>
</tr>
<tr>
<td>• Pharmaceutical</td>
<td>• Dietary</td>
</tr>
<tr>
<td>• Standards for Outpatient</td>
<td>• Blood bank</td>
</tr>
<tr>
<td>• Radiology or Imaging</td>
<td>• Haemodialysis</td>
</tr>
<tr>
<td>• Miscellaneous</td>
<td>• Rehabilitation</td>
</tr>
</tbody>
</table>

### Miscellaneous Areas
- Consent
- O & G
- Nursery
- Paediatric
- Anaesthesia
- Surgical
- ICU
- CSSD
- Dietary
- Blood bank
- Haemodialysis
- Rehabilitation
- ACC
- PNH
- Hospice
<table>
<thead>
<tr>
<th><strong>CLINICS [P.U. (A) 137/2006]</strong></th>
<th><strong>OTHER PHFS [P.U. (A) 138/2006]</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Plan of Organisation (r. 7 Vs r.11)</td>
<td>All as required for clinics +</td>
</tr>
<tr>
<td>• Person in Charge (r. 8 Vs r.12)</td>
<td>• Patient care &amp; treatment (r.14)</td>
</tr>
<tr>
<td>• Healthcare Professional Staff (r. 9 Vs r.13)</td>
<td>• Department (r.16)</td>
</tr>
<tr>
<td>• Treatment of Patient (r. 10 Vs r.14)</td>
<td>• Patient identification (r.18)</td>
</tr>
<tr>
<td>• Orders for diagnostic, procedure, medication or treatment (r.11 vs 15)</td>
<td>• Resuscitation facilities (r.20)</td>
</tr>
<tr>
<td>• Volunteers programme (r.12 vs 17)</td>
<td></td>
</tr>
<tr>
<td>• Incident reporting (r.13 vs 19)</td>
<td></td>
</tr>
</tbody>
</table>
### Governance Framework

<table>
<thead>
<tr>
<th>PRIVATE CLINICS (PMC &amp; PDC)</th>
<th>OTHER PHFS (HOSPITAL ETC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Certificate Holder</td>
<td>• Certificate Holder/Licensee</td>
</tr>
<tr>
<td>• Person responsible for the body corporate (Dental)</td>
<td>• Person responsible for the body corporate</td>
</tr>
<tr>
<td>• Person in Charge</td>
<td>• Board of Management</td>
</tr>
<tr>
<td></td>
<td>• Advisory Committee</td>
</tr>
<tr>
<td></td>
<td>• Person in Charge</td>
</tr>
<tr>
<td></td>
<td>• Head of Department</td>
</tr>
</tbody>
</table>
Certificate Holder/Licensee (Sec 2. Act 586)

- Approval to establish/maintain means approval to establish/maintain a PHFS than a PMC/PDC granted under paragraph 19(a), Act 586

- Licensee means a person to whom a licence to operate/provide a PHFS other than a PMC/PDC granted under paragraph 12(a), Act 586

- Certificate of Registration means a certificate issued under Section 27, Act 586

*Note: Person includes a body of persons, corporate or unincorporated (Section 3, Interpretation Acts 1948 & 1967)
## Certificate Holder/Licensee vs Facility (S. 6 & 7)

<table>
<thead>
<tr>
<th>Certificate Holder/Licensee</th>
<th>Medical Clinic</th>
<th>Dental Clinic</th>
<th>Nursing Home</th>
<th>Maternity Home</th>
<th>Hospice &amp; Haemodialysis</th>
<th>Others (Hospital, etc)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registered Medical Practitioner (RMP)</td>
<td>☑️</td>
<td></td>
<td>☑️</td>
<td>☑️</td>
<td>☑️</td>
<td>☑️</td>
</tr>
<tr>
<td>Registered Dental Practitioner (RDP)</td>
<td></td>
<td>☑️</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Registered Nurse (RN)</td>
<td></td>
<td></td>
<td>☑️</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Registered Midwife (RM)</td>
<td></td>
<td></td>
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<td>☑️</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Partnership (+ ≥ 1RMP)</td>
<td></td>
<td></td>
<td></td>
<td>☑️</td>
<td>☑️</td>
<td>☑️</td>
</tr>
<tr>
<td>Body Corporate (Companies Act 1965) (+ BOD ≥ 1RMP)</td>
<td></td>
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<td></td>
<td>☑️</td>
<td>☑️</td>
<td>☑️</td>
</tr>
<tr>
<td>Body Corporate (Companies Act 1965) (+ all BOD RDP)</td>
<td></td>
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<td>☑️</td>
</tr>
<tr>
<td>Society (Societies Act 1966)</td>
<td></td>
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<td></td>
<td></td>
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<td>☑️</td>
</tr>
</tbody>
</table>
S.2, Act 586

- “Person in charge” means a person possessing such qualification, training and experience as may be prescribed and who shall be **responsible for the management and control** of the private healthcare facility or service to which a licence or registration relates.

S. 31. Responsibilities

- (1)(a). A licensee or a holder of certificate of registration in respect of a licensed or registered private healthcare facility or service shall ensure that the licensed or registered private healthcare facility or service is **maintained or operated** by a person in charge.
S.32, Act 586

(1) A person in charge of a licensed or registered private healthcare facility or service shall hold such qualification, have undergone such training and possess such experience as may be prescribed.

(2) A person in charge shall carry out such duties and responsibilities as may be prescribed.

(prescribed ~ by the Minister by order or regulations made under this Act)
### Person in Charge vs Facility: r. 8 3rd Schedule (clinics) & r. 12, 4th Schedule (other PHFS)

<table>
<thead>
<tr>
<th><em>Person in Charge</em></th>
<th>RMP</th>
<th>RDP</th>
<th>RN</th>
<th>RM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Clinic</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dental Clinic</td>
<td></td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nursing Home</td>
<td>Yes (policy)</td>
<td></td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Maternity Home</td>
<td>Yes</td>
<td></td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Ambulatory Care</td>
<td>Yes</td>
<td></td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Others (Hospital, etc)</td>
<td>Yes</td>
<td></td>
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</tbody>
</table>

* Qualified, trained and experiences, in accordance to the healthcare facilities and services/specialties provided.
S.31(2), Act 586 – not withstanding paragraph (1)(a), different persons may be appointed to manage and assume the duties and responsibilities relating to **non-clinical matters** including financial, administration and management of non-clinical resources.
Board of Management (BOM)

- S.2, BOM means a board of trustee or directors or any other governing body in whom the *ultimate authority* and *responsibility for the conduct* of the PHFS specified in Part XIV are vested.

- S. 77 – The licensee shall establish a BOM of whom 2 members shall be from the Advisory Committees established under S 78 (b) or 79 (b), Act 586
Advisory Committee

- The licensee shall ensure, the establishment of the Advisory Committee whose members shall be RMP/RDP representing all RMP/RDP practising in the PHFS to advise the BOM, the licensee & PIC on all aspects relating to the medical/dental practices respectively (patient care).

- Medical Advisory Committee
- Medical and Dental Advisory Committee
- Midwifery Care Advisory Committee
- Nursing Advisory Committee
Person responsible for the body corporate

- Means any person who is a director or officer of the body corporate or who purports to act in such capacity or who is in any manner or to any extent responsible for the management of the affairs of the body corporate, or was assisting in such management.
Head of Department

• The licensee or PIC shall appoint a HOD who will be responsible for the management and control of the department (where ≥ 2 RMP/RDP in any one specialty in the PHFS)

• Shall have relevant qualification and experience on the specialty.
Governance Framework (Other PHFS)

Medical/Dental Advisory Committee (Patient care)

Board of Management (ultimate authority & responsibility)

LICENSEE

Certificate Holder

Person responsible for body corporate

PERSON IN CHARGE

Non Clinical Matters

Head of Department

Nursing Department

Medical Assistant

Mortality Assessment Committee (PHFS level) S. 72, Act 586

Quality Assurance Programme, S.74, Act 586

Infection Control Committee, reg. 49 (4/12)

Committee of Consulting Physician (+ ≥ 1 O&G), subreg. 145 (4)

Committee of Consulting Surgeon & Anesthetist, reg. 186

Pharmacy & Therapeutic Committee, reg. 248

Transfusion Committee, reg.300

Medical Record Review Committee, reg.413 (6/12)

Written policy, reg. 21

Written policy & procedure reg. 122

Written policy, reg. 161

Written policy, reg. 215

written policy, reg. 249

written policy on the quantum of fees to be charged subreg. 433(2)
Governance Framework (Clinics)

Certificate Holder of Registration

Person responsible for body corporate (Dental Clinic)

Person in Charge

non-clinical matter

Head of Pharmaceutical Services, reg. 78

Head of Radiological or diagnostic imaging Services, reg. 94

Mortality Assessment Committee (PHFS level) S. 72, Act 586

Quality Assurance Programme, S.74, Act 586

Written policy, reg. 14

Written policy on the quantum of fees to be charged subreg. 108 (2)
THANK YOU

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