OVERVIEW OF CONTROL OF INFECTIOUS DISEASE IN PRIVATE HEALTHCARE FACILITIES
The regulation for private hospitals was first established in 1971 with the enactment of the Private Hospitals Act 1971 (Act 43).

The regulatory control was through licensing and inspection of the healthcare facilities: private hospitals, nursing homes and maternity homes.

An issued or renewed license was valid for a year.
However, this Act did not provide adequate provisions to regulate all private healthcare facilities and services, such as medical and dental clinics, day surgeries, haemodialysis centres and hospice.

These limitations and omissions are addressed in the new Act, the Private Healthcare Facilities and Services Act 1988 (Act 586)
PRIVATE HEALTHCARE FACILITIES AND SERVICES ACT 1998 (ACT 586)

- Date of gazette: **27 August 1998**.
- Date of enforcement: **1 May 2006**.
- Replacing the Private Hospital Act 1971
PRIVATE HEALTHCARE FACILITIES AND SERVICES ACT 1998

Act
Private Healthcare Facilities And Services Act 1998
[Act 586] – XIX Part with 122 sections

It’s Regulations
1. Private Healthcare Facilities And Services (Private Medical Clinics or Private Dental Clinics) Regulations, 2006
   - 14 Parts with 109 regulations and 7 schedules
2. Private Healthcare Facilities And Services (Private Hospital and Other Private Healthcare Facilities) Regulations, 2006
   - 29 Parts with 434 regulations and 13 schedules

It’s Orders
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.
• **Registration activities for private clinics**
  1. Act 586
  2. Private Healthcare Facilities And Services (Private Medical Clinics or Private Dental Clinics) Regulations, 2006

• **Licensing activities for private healthcare facilities and services other than private clinics**
  1. Act 586
  2. Private Healthcare Facilities And Services (Private Hospital and Other Private Healthcare Facilities) Regulations, 2006

• **Handling Complaints & Enforcement activities & MCO**
  1. Act 586
  2. Private Healthcare Facilities And Services (Private Medical Clinics or Private Dental Clinics) Regulations, 2006
  3. Private Healthcare Facilities And Services (Private Hospital and Other Private Healthcare Facilities) Regulations, 2006
### PRIVATE HEALTHCARE FACILITIES IN JOHOR - UNTIL AUGUST 2015

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<thead>
<tr>
<th>NO</th>
<th>PRIVATE HEALTHCARE FACILITIES</th>
<th>NUMBER</th>
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<tbody>
<tr>
<td>1.</td>
<td>PRIVATE HOSPITAL</td>
<td>16</td>
</tr>
<tr>
<td>2.</td>
<td>PRIVATE AMBULATORY CARE CENTRE</td>
<td>10</td>
</tr>
<tr>
<td>3.</td>
<td>PRIVATE NURSING HOME</td>
<td>7</td>
</tr>
<tr>
<td>4.</td>
<td>PRIVATE MATERNITY HOME</td>
<td>15</td>
</tr>
<tr>
<td>5.</td>
<td>PRIVATE HAEMODIALYSIS CENTRE</td>
<td>76</td>
</tr>
<tr>
<td>6.</td>
<td>PRIVATE MEDICAL CLINIC</td>
<td>841</td>
</tr>
<tr>
<td>7.</td>
<td>PRIVATE DENTAL CLINIC</td>
<td>191</td>
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<td><strong>TOTAL</strong></td>
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</table>
INFECTION CONTROL IN PRIVATE HEALTHCARE FACILITIES AND SERVICES ACT 1998 AND IT’S REGULATIONS.
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
Part IX – Infection Control r.49

R 49 (1); Holder of certificate of registration (COR) or person in charge (PIC) of private facility or services (PFS) shall establish an Infection Control Committee (ICC) which shall be responsible for development of an active premise-wide infection control programme and infection control system with measures developed to prevent, identify and control infection acquired in or brought into the PFS.

(2) ICC shall meet at least once in every 4 month and shall hold special meeting when necessary to meet their responsibilities in dealing with infection control problems.

(3) Infection control programme shall include

(a) System for reporting, evaluating and maintaining data
(b) System to detect outbreak of infectious disease and inform appropriate authorities; and
(c) A system to prevent and control any outbreak of infectious disease which shall include but not limited to;
   i. Ensuring that any healthcare professional who contracts any infectious or communicable disease or who is a carrier to be taken off any duty; until he permitted to do so;
   ii. Ensuring any healthcare professional who attends any patient suffering from, or suspected of suffering from any infectious or CD to be withheld from attending any other pt, or from undertaking any duty; until he permitted to do so;
   iii. Ensuring that any healthcare professional who attends any patient in isolated rooms, suffering from, or suspected of suffering from any infectious or CD complies with barrier nursing procedures;
Ensuring that no room which has been occupied by patient suffering from, or suspected of suffering from any infectious or CD be occupied by any other patient until the room & its content has been disinfected in manner specified or approved by the ICC; and

(v) equipment, which may have become contaminated during treatment; to be withheld from use in connection with the treatment of any other patient until it has been appropriately disinfected

(4) Infection control staff shall be –

(a) appointed, trained and authorized to carry out monitoring & control activities and orientated regarding the programme and the system; and

(b) activities shall be documented, for follow-up action and use in education programme.

(5) licensee or PIC of PHFS shall institute adequate measures to safeguard all the healthcare professional staff and environment against biological hazards.

(6) licensee or PIC of PHFS shall comply with any directive or guideline issued by DG from time to time.

(7) Any person who contravenes this regulation commits an offence and shall liable on conviction to a fine not exceeding ten thousand ringgit or to imprisonment for a term not exceeding three months or to both.
# OTHER PROVISION

<table>
<thead>
<tr>
<th>PART</th>
<th>REGULATION</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>X (General provision for standard of PHFS)</td>
<td>51</td>
<td>Vector Control</td>
</tr>
<tr>
<td></td>
<td>58</td>
<td>Ceilings</td>
</tr>
<tr>
<td></td>
<td>68</td>
<td>Hand Washing Facilities</td>
</tr>
<tr>
<td></td>
<td>79</td>
<td>Clinical Examination And Examination Room</td>
</tr>
<tr>
<td></td>
<td>89</td>
<td>Ventilation</td>
</tr>
<tr>
<td></td>
<td>92</td>
<td>Hazardous Waste</td>
</tr>
<tr>
<td></td>
<td>94</td>
<td>Written Procedures (Housekeeping)</td>
</tr>
<tr>
<td>XII (Standard For Newborn Nursery Facilities)</td>
<td>156</td>
<td>Clothing</td>
</tr>
<tr>
<td></td>
<td>157</td>
<td>Hand Washing And Gowning Area</td>
</tr>
<tr>
<td>XVI (Special Requirements For CCU/ICU)</td>
<td>221</td>
<td>Facilities and Design Features</td>
</tr>
<tr>
<td>XXII (Special Requirements For HD)</td>
<td>304</td>
<td>Staffing</td>
</tr>
<tr>
<td></td>
<td>317</td>
<td>Control Measures to prevent cross-infection</td>
</tr>
<tr>
<td></td>
<td>319</td>
<td>Disposal of Infectious Waste</td>
</tr>
</tbody>
</table>
Private Medical/ Dental Clinic
Part VIII – Infection Control r.33

R 33 (1); Holder of certificate of registration (COR) or person in charge (PIC) of private medical clinic (PMC) or private dental clinic (PDC) shall be responsible for development of an active premise-wide infection control programme and infection control system with measures developed to prevent, identify and control infection acquired in or brought into the PMC or PDC.

(2) Infection control programme shall include

   (a) System for reporting, evaluating and maintaining data

   (b) System to detect outbreak of infectious disease and inform appropriate authorities; and

   (c) A system to prevent and control any outbreak of infectious disease which shall include but not limited to;

      i. Ensuring that any staff who contracts any infectious or communicable disease or who is a carrier to be taken off any duty; until he permitted to do so; and

      ii. Any equipment, which may have become contaminated during treatment; to be withheld from use in connection with the treatment of any other patient until it has been appropriately disinfected.
(3) Holder of COR or PIC shall institute adequate measures to safeguard all personnel and the environment against biological hazard.

(4) Holder of COR or PIC shall comply with any directive or guideline issued by Director General on managing infection control especially during outbreak of infectious disease.

(5) Contravenes this regulation commits an offence and shall liable on conviction to fine not exceeding 10,000 / imprisonment not exceeding 3 months or both
## OTHER PROVISION

<table>
<thead>
<tr>
<th>PART</th>
<th>REGULATION</th>
<th>DESCRIPTION</th>
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</thead>
<tbody>
<tr>
<td>IX (General provision for standard of PMC/PDC)</td>
<td>35</td>
<td>Vector Control</td>
</tr>
<tr>
<td></td>
<td>40</td>
<td>Ceilings</td>
</tr>
<tr>
<td></td>
<td>45</td>
<td>Plumbing</td>
</tr>
<tr>
<td></td>
<td>54</td>
<td>Hazardous Waste</td>
</tr>
<tr>
<td>XII (Standard For Outpatient Facilities And Services)</td>
<td>91</td>
<td>Medical outpatient services</td>
</tr>
<tr>
<td></td>
<td>92</td>
<td>Dental Outpatient Services.</td>
</tr>
</tbody>
</table>
INFECTION CONTROL ISSUES

Cases in Johor
In Mac 2005, a nephrologist from the Sultanah Aminah Hospital, Johor Bahru (HSAJB), advised a private HD centre in Kluang to screen their patients after suspecting something is amiss following his patient who has sero-convert to Hepatitis C after receiving haemodialysis from the said centre.

Result showed that 30 out of 62 patients had sero-converted to Hepatitis C.

The Johor State Health Department had instructed the centre to take immediate control measures, that includes separation of the infected patients from the non infected patients by using different haemodialysis machines. However, this was found to be inadequate.
Haemodialysis Quality And Standards

Medical Development Division
Ministry of Health Malaysia
An infectious control committee comprising of the Johore State Director of Health Services, a Consultant Nephrologists, a Pathologist and the Director of the Medical Practice Division, Ministry of Health met on 20 April 2005.

The committee conducted a visit to the centre and following were the findings:
Finding

Physical

- Total number of HD machine, 20; 7 HD machines were used for the infected patients whereby 6 for patients with Hepatitis C and one for patients with Hepatitis B and Hepatitis C. All are located in one open area, no separation.
- There were 5 reprocessing machines; 2 assigned for patients tested positive with Hepatitis C, one for patients with Hepatitis B and Hepatitis C and 2 for patients tested negative with Hepatitis C, same location, no separation.

Nephrologist

- No visiting nephrologists as the centre’s consultant

Staff

- The staff was cooperative and eager to help out to control the infection but do not know how as they were nursing aides led by a retired medical assistant without much nephrology trained.

Clinical Waste

- Clinical waste containers have been provided but used unnecessarily reflecting their ignorance (each container for each group of patients).
Recommendation

An infectious control committee ordered further control measures;

- **To confirm the patients current status** of Hepatitis B, C and HIV.
  - Blood samples from all 62 patients and eight staff will be taken for the investigation of Hepatitis B, Hepatitis C and HIV.
  - The blood samples will be sent to HSAJB immediately in batches

- **To have formal communication** with the Management of the Haemodialysis Centre to inform –
  - Immediate actions
  - Short term
  - Long term
The immediate actions need to be taken by the Management:

- **Not to take in any new patient until otherwise informed**
- To assign each haemodialysis machine for specific patients e.g. machine A only for patients 1, 2, 3 and 4
- To report any relevant news or any abnormal incident in the haemodialysis centre to the Kluang District Health Office
- To practice the infection control measures as directed by the Medical Officer of Health, Kluang district
- To provide a report for the Ministry of Health regarding actions taken.
• **To implement the Infection Control Measures**
  ◦ To practice proper cleaning and disinfection of the haemodialysis machine with disinfectant for about 30 minutes after each session, assist by the nephro-trained staffs.
  ◦ To use of disposable dialyser until the patients status are confirmed
  ◦ To practice proper aseptic techniques usage of disposable glove for each patient and proper hand washing techniques
  ◦ To request the Management to provide dedicated staff to cater for the infectious cases

• **To segregate the patients according to the blood Investigations results**
  • To segregate the infected cases to different rooms or partitions accordingly based on the four groups of patients; Hepatitis C, Hepatitis B, Hepatitis B and C and non-infected group
(2) The Short Term Plan

- To train and educate the staff regarding the infection control measures including proper handling of blood contaminated facilities and equipments such as syringes, needles, dialyser etc, hand washing technique, using proper barrier in carrying out the nursing care such as wearing disposable gloves etc

- To supervise and ensure the implementation of infection control measures and aseptic techniques in the haemodialysis centre by –

- scheduled visits by two staff nurses (everyday) from the Kluang District Hospital for a reasonable period
The long term actions to be taken by the Management;

- to provide and assigned different hand washing facilities with elbow tap for different groups of patients and the staff
- to employ a private nephrologists as the centre’s consultant
- to provide a proper isolation bay for infected patients
- to provide continuous renal nursing care and infection control training for the staff
- to have three - monthly blood investigation for all patients and to pay for the cost of investigation to ensure no new or recurrent infection
- to educate and counselling the patients and their family members under the supervision of Public Health team
- to do the contact tracing and pay for the cost of blood screening for the infected patients’ family
Since the directive, the above infection control measures have been fully complied.

Infectious control committee is satisfied that the above is the best that could be done to control such state of infection so far.

However, the committee does not preclude the possibility to recommend for an order of closure of the haemodialysis centre as provided under section 18(1)(a) of the Prevention and Control of Infectious Disease Act 1988 if the problems continues.
2ND CASE; SUDDEN DROP OF Hb COUNT IN LARGE GROUP OF PATIENT

Basis for Investigation

• On 28 Feb 2006 - received a complaint from Nephrologist (HSAJB) –
  • 19 patients develop heart failure – needed hospitalization & blood transfusion.
  • 1 patient have bacterial endocarditis with vegetative growth on Tricuspid valve.
• Initial visit to the centre was done by UKAPS on 1st March 2006
  • RO Water – small leak detected on 12/2 2006
  • 16/2/2006 – technician attended and replaced coupling
  • Routine maintenance including disinfection of loop – rinsing took 4 hour
  • 27/2/2006 – routine maintenance of reprocessor – found to be in good working order.
Investigation

1. FBPs & bilirubin level.
2. Full analysis for chemical in ROW.
3. EPO exchanged for fresh stock – while the batch that was being used was sent for test to exclude break in the cold chain.
4. Total bacteria count & Endotoxin levels checked in the ROW, HD machine & reprocessor.
5. pre & post HD haematocrit levels.
7. Patient, especially those who had transfusion were interviewed in detail.
8. Premise to prepare water piping layout and to check piping system.
Result came back

1. Significant drop in Hb from Jan – Feb; 2-6gms
2. No correlation drop of Hb between single-user & re-use dialyser.
3. No correlation between drop of Hb & ESR
4. No correlation drops of Hb & Aluminium levels
5. EPO supplier reported no evidence of break in cold chain protocol
6. Total bacterial count post disinfection came back on 27/2/2006; 202 (100)
7. The only possibility was the presence of biofilm in the piping.
Recommendation

- Re-piping
  - piping redone and complete on 28/3/2006
  - During re-piping - discover blind loop in first floor while dismantling
- Educate staff; ROW to be run daily
- Monthly endotoxin
<table>
<thead>
<tr>
<th>Kemudahan &amp; Peralatan</th>
<th>Profesional/Para Profesional</th>
<th>Perkhidmatan/Amalan</th>
</tr>
</thead>
</table>

1. Hospital swasta
2. Hospital psikiatri swasta*
3. Pusat jagaan ambulatori swasta
4. Rumah jagaan kejururawatan swasta
5. Rumah jagaan kejururawatan psikiatri swasta*
6. Rumah bersalin swasta
7. Bank darah swasta
8. Pusat hemodialisis swasta
9. Hospis swasta
10. Pusat kesihatan mental masyarakat swasta*
11. Klinik perubatan swasta
12. Klinik pergigian swasta
13. Kemudahan gabungan (dari No.1-10) *

* + Akta 615

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YET TO BE ENFORCED

<table>
<thead>
<tr>
<th>Pathology Laboratory</th>
<th>Pathology Laboratory Act 2007 [Act 674]</th>
<th>Allied Health professionals</th>
<th>Allied Health Professional Bill</th>
<th>Practise telemedicine Telemedicine Act 1997 [Act 564]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical devices</td>
<td>Medical Device Act 2012 [Act 737]</td>
<td>TCM practitioners</td>
<td>Traditional and Complementary Medicine Act 2013</td>
<td></td>
</tr>
</tbody>
</table>
THANKS YOU