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PRIVATE HEALTHCARE FACILITIES AND SERVICES ACT 1998

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LAWS OF MALAYSIA**Act 586****PRIVATE HEALTHCARE FACILITIES AND
SERVICES ACT 1998**

ARRANGEMENT OF SECTIONS

PART I**PRELIMINARY**

Section

1. Short title
2. Interpretation

PART II**CONTROL OF PRIVATE HEALTHCARE FACILITIES AND SERVICES**

3. Approval and licence
4. Registration
5. Unlicensed and unregistered private healthcare facility or service
6. Approval and licence may be issued to a sole proprietor, partnership or body corporate
7. Certificate of registration to operate private medical and private dental clinic

PART III**APPROVAL TO ESTABLISH OR MAINTAIN PRIVATE HEALTHCARE
FACILITIES OR SERVICES OTHER THAN A PRIVATE MEDICAL CLINIC
OR A PRIVATE DENTAL CLINIC**

8. Application for approval to establish or maintain
9. Matters to be considered before approval to establish or maintain is granted

Section

10. Refusal to process application for approval to establish or maintain
11. Reasons for refusal to grant approval to establish or maintain
12. Grant of or refusal to grant approval to establish or maintain
13. Separate approval to establish or maintain private healthcare facilities or services which are not physically, administratively or organizationally linked

PART IV

LICENCE TO OPERATE OR PROVIDE PRIVATE HEALTHCARE
FACILITY OR SERVICE OTHER THAN PRIVATE MEDICAL CLINIC
OR PRIVATE DENTAL CLINIC

14. Application for a licence to operate or provide to be made within three years
15. Application for licence to operate or provide
16. Inspection of premises
17. Refusal to process application for licence
18. Reasons for refusal to issue or renew a licence to operate or provide
19. Grant of or refusal to grant licence
20. Licence to specify type of private healthcare facility or service
21. Separate licence for private healthcare facilities or services which are not physically, administratively or organizationally linked
22. Duration and renewal of licence to operate or provide
23. Licence to be exhibited
24. Power to vary terms or conditions, or purpose of approval or licence

PART V

REGISTRATION OF A PRIVATE MEDICAL CLINIC AND A PRIVATE
DENTAL CLINIC

25. Application for registration
26. Refusal to process application for registration
27. Grant of certificate of registration
28. Certificate of registration to be exhibited
29. Power to vary terms or conditions of registration
30. Separate registration

PART VI

RESPONSIBILITIES OF A LICENSEE, HOLDER OF CERTIFICATE OF
REGISTRATION AND PERSON IN CHARGE

Section

- 31. Responsibilities
- 32. Person in charge
- 33. Change of person in charge
- 34. Personal care aide
- 35. Policy statement
- 36. Patient grievance mechanism
- 37. Incident reporting
- 38. Emergency treatment and services

PART VII

GENERAL PROVISIONS RELATING TO APPROVAL, LICENCE AND
REGISTRATION

- 39. Restriction on use of premises
- 40. Prohibition on extension and alteration
- 41. Transfer, *etc.*, of approval, licence and certificate
- 42. Registers

PART VIII

SUSPENSION AND REVOCATION OF APPROVAL AND LICENCE,
REFUSAL TO RENEW THE LICENCE, AND SUSPENSION, AND
REVOCATION OF REGISTRATION

- 43. Show cause
- 44. Grounds for suspension, *etc.*, relating to administration of private healthcare facility or service
- 45. Grounds for suspension, revocation, refusal to renew licence, *etc.*, relating to qualification of sole proprietor
- 46. Grounds for suspension, revocation, or refusal to renew approval, licence or certificate of registration

Section

- 47. Additional grounds
- 48. Representations
- 49. Power of Director General to suspend, revoke, or refuse renewal
- 50. Surrender of licence or certificate
- 51. Cessation of operation

PART IX

CLOSURE OF PRIVATE HEALTHCARE FACILITIES OR SERVICES

- 52. Order for temporary closure of private healthcare facilities of services
- 53. Conditions for closure, selling or otherwise disposing of private healthcare facility or service

PART X

BLOOD BANK

- 54. Interpretation
- 55. Prohibition on supply of natural human blood and blood product
- 56. Import and export of natural human blood and blood product
- 57. Issue of certificate to import and export natural human blood and blood product
- 58. Consent to test blood from donors

PART XI

BLOOD TRANSFUSION SERVICES

- 59. Storage facilities
- 60. Minimum blood supply
- 61. Maintain records of receipt and disposition of blood
- 62. Transfusion reactions
- 63. Recommendations to the Medical Advisory Committee

PART XII

MORTALITY ASSESSMENT

Section

- 64. Interpretation
- 65. Establishment of National Mortality Assessment Committee
- 66. Functions of National Mortality Assessment Committee
- 67. Reporting of assessable deaths
- 68. Medical and dental practitioners to provide information
- 69. Publication of information
- 70. Secrecy of information obtained by Committee
- 71. Protection of persons carrying out functions as members of Committee
- 72. Mortality assessment committee at private healthcare facility or service level
- 73. Independent investigation

PART XIII

QUALITY OF HEALTHCARE FACILITIES AND SERVICES

- 74. Quality of health care and services
- 75. Power of Director General to give directions
- 76. Power of Director General to issue directives, orders or guidelines relating to quality assurance

PART XIV

BOARD OF MANAGEMENT AND ADVISORY COMMITTEE

- 77. Board of Management
- 78. Medical or Dental Advisory Committee
- 79. Midwifery Care Advisory Committee
- 80. Nursing Advisory Committee
- 81. Penalty for non-compliance with any of the provision of this Part

PART XV

MANAGED CARE ORGANIZATION

Section

- 82. Interpretation of managed care organization
- 83. Contracts between private healthcare facility or service and managed care organization
- 84. Licensee and holder of certificate of registration to furnish information on managed care organization to Director General
- 85. Information by managed care organization
- 86. Register of managed care organizations

PART XVI

ENFORCEMENT

- 87. Appointment of Inspectors
- 88. Power of Inspector to enter and inspect
- 89. Power to search and seize
- 90. Search and seizure without warrant
- 91. Power to seal
- 92. Power to require information and examine persons
- 93. Duty to assist Inspector
- 94. Offences in relation to inspection
- 95. List of things seized
- 96. Forfeiture of things seized
- 97. No person entitled to costs, *etc.*, on seizure
- 98. Production of official identification card or badge
- 99. Compounding of offences
- 100. Institutions and conduct of prosecution

PART XVII

POWER OF MINISTER

- 101. Appeal

Section

- 102. Power of Minister to issue general directions
- 103. Power of Minister to exempt
- 104. Board of Visitors
- 105. Social or welfare contribution
- 106. Fee schedule
- 107. Power to make regulations

PART XVIII

MISCELLANEOUS

- 108. Advertisement
- 109. National Register
- 110. Service of notice
- 111. Delegation by Director General
- 112. Furnishing of information
- 113. Officers deemed to be public servants
- 114. Protection against suit and legal proceedings
- 115. Confidentiality of information
- 116. Private psychiatric hospital, psychiatric nursing home and community mental health centre
- 117. General offence and penalty
- 118. Contravention of subsidiary legislation

PART XIX

SAVING AND TRANSITIONAL PROVISIONS

- 119. Repeal
- 120. Saving and transitional provisions relating to existing licensed private hospital, maternity homes and nursing homes
- 121. Power of Minister to make additional transitional provisions
- 122. Saving and transitional provisions relating to existing private medical clinics and private dental clinics

LAWS OF MALAYSIA**Act 586****PRIVATE HEALTHCARE FACILITIES AND
SERVICES ACT 1998**

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.

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

BE IT ENACTED by the Seri Paduka Baginda Yang di-Pertuan Agong with the advice and consent of the Dewan Negara and Dewan Rakyat in Parliament assembled, and by the authority of the same, as follows:

PART I**PRELIMINARY****Short title**

1. This Act may be cited as the Private Healthcare Facilities and Services Act 1998.

Interpretation

2. In this Act, unless the context otherwise requires—

“approval to establish or maintain” means approval to establish or maintain a private healthcare facility or service other than a private medical clinic or a private dental clinic granted under paragraph 12(a);

“Board of Management” means a board of trustees or directors, or any other governing body in whom the ultimate authority and responsibility for the conduct of the private healthcare facilities or services specified in Part XIV are vested;

“Board of Visitors” means the Board of Visitors established under section 104;

“body corporate” means a body incorporated under the Companies Act 1965 [*Act 125*];

“certificate” means a certificate issued under section 57 authorizing the importation or exportation of blood products or natural human blood for transfusion purposes;

“certificate of registration” means a certificate issued under section 27;

“Director General” means the Director General of Health, Malaysia;

“Government healthcare facility” means any facility used or intended to be used for the provision of healthcare services established, maintained, operated or provided by the Government but excludes privatized or corporatized Government healthcare facilities;

“Government healthcare services” means any healthcare services provided, operated or maintained by the Government but excludes privatized or corporatized Government healthcare services;

“healthcare facility” means any premises in which one or more members of the public receive healthcare services;

“healthcare professional” includes a medical practitioner, dental practitioner, pharmacist, clinical psychologist, nurse, midwife, medical assistant, physiotherapist, occupational therapist and other allied healthcare professional and any other person involved in the giving of medical, health, dental, pharmaceutical or any other healthcare services under the jurisdiction of the Ministry of Health;

“healthcare services” includes—

- (a) medical, dental, nursing, midwifery, allied health, pharmacy, and ambulance services and any other service provided by a healthcare professional;
- (b) accommodation for the purpose of any service provided under this Act;
- (c) any service for the screening, diagnosis, or treatment of persons suffering from, or believed to be suffering from, any disease, injury or disability of mind or body;
- (d) any service for preventive or promotive health purposes;
- (e) any service provided by any healthcare para-professional;
- (f) any service for curing or alleviating any abnormal condition of the human body by the application of any apparatus, equipment, instrument or device or any other medical technology; or
- (g) any health-related services;

“licence to operate or provide” means a licence to operate or provide a private healthcare facility or service other than a private medical clinic or private dental clinic granted under paragraph 19(a);

“licensee” means a person to whom a licence to operate or provide a private healthcare facility or service other than a private medical clinic or private dental clinic granted under paragraph 19(a);

“hospice care or palliative care” means care of a terminally ill person that addresses the physical, psychological, emotional and social needs of the person or his family;

“midwifery care” means the assessment or monitoring or care of women during normal pregnancy or labour or during the post-partum period and of their normal newborns, and the conducting of spontaneous normal vaginal delivery;

“Minister” means the Minister charged with the responsibility for health;

“nursing care” means any care for patient that is provided by a registered nurse in accordance with the directions of a registered medical practitioner or registered dental practitioner and accepted nursing practice;

“personal care” means any function that an individual normally would perform personally, but for which the individual needs help from another because of advanced age, infirmity, or physical or mental limitation and may include such service as may be prescribed;

“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;

“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 any 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;

“premises” means any place, building or vehicle, whether permanent or temporary;

“prescribed” means prescribed by the Minister by order or regulations made under this Act;

“private ambulatory care centre” means any premises, other than a Government ambulatory care centre, private medical clinic or private dental clinic, primarily used or intended to be used for the purpose of performing any procedure related to the practice of medicine in any of its disciplines or any dental procedure and with continuous relevant private healthcare services including nursing services whenever a patient is in the premises, and in which healthcare, beds or other accommodation for the stay of any one patient for a period of not more than 23 hours is provided and from which patients are either discharged in an ambulatory condition without requiring constant or

continuous care or supervision and without danger to the continued well-being of the patient or transferred to a hospital;

“private blood bank” means any premises, other than a Government blood bank, used or intended to be used for collecting, screening, processing, storing or distributing natural human blood or blood product;

“private dental clinic” means any premises, other than a Government healthcare facility, used or intended to be used for the practice of dentistry and includes premises used by any person—

- (a) to treat or attempt to treat or profess to treat, cure, relieve or prevent any disease, deficiency or lesion or pain of the human teeth or jaws;
- (b) to perform or attempt to perform any operation on human teeth or jaws;
- (c) to perform any radiographic work in connection with human teeth or jaws or the oral cavity; or
- (d) to give any treatment, advice or attendance on or to any person in connection with the fitting or insertion for the purpose of fitting or fixing of artificial teeth or of a crown or bridge or an appliance for the restoration or regulation of the human teeth or jaws;

“private haemodialysis centre” means an ambulatory care centre, other than a Government haemodialysis centre, providing or intending to provide haemodialysis treatment, any other procedures or forms of treatment for the purification of human blood;

“private healthcare facility” means any premises, other than a Government healthcare facility, used or intended to be used for the provision of healthcare services or health-related services, such as a private hospital, hospice, ambulatory care centre, nursing home, maternity home, psychiatric hospital, psychiatric nursing home, community mental health centre, haemodialysis centre, medical clinic, dental clinic and such other healthcare or health-related

premises as the Minister may from time to time, by notification in the *Gazette*, specify;

“private healthcare services” means any services provided by a private healthcare facility;

“private hospice” means any premises used or intended to be used exclusively for providing hospice care or palliative care;

“private hospital” means any premises, other than a Government hospital or institution, used or intended to be used for the reception, lodging, treatment and care of persons who require medical treatment or suffer from any disease or who require dental treatment that requires hospitalization;

“private maternity home” means any premises, other than a Government maternity home, used or intended to be used for the reception of, and the provision of nursing care and midwifery care for, women in labour or of women immediately after childbirth;

“private medical clinic” means any premises, other than a Government healthcare facility, used or intended to be used for the practice of medicine on an outpatient basis including—

- (a) the screening, diagnosis or treatment of any person suffering from, or believed to be suffering from, any disease, injury or disability of mind or body;
- (b) preventive or promotive healthcare services; and
- (c) the curing or alleviating of any abnormal condition of the human body by the application of any apparatus, equipment, instrument or device;

“private nursing home” means any premises, other than a Government nursing home, used or intended to be used for the reception of, and the provision of nursing care for, persons suffering or convalescing from any sickness, injury or infirmity;

“register” means the register required to be maintained under section 42;

“registered dental practitioner” means any person who is registered as such under the Dental Act 1971 [*Act 51*] and who holds a valid practising certificate;

“registered medical practitioner” means any person who is registered as such under the Medical Act 1971 [*Act 50*] and who holds a valid practising certificate;

“registered midwife” means any person who is registered as such under the Midwives Act 1966 [*Act 436*] and who holds a valid practising certificate;

“registered nurse” means any person who is registered as such under the Nurses Act 1950 [*Act 14*] and who holds a valid practicing certificate;

“technical staff” means a medical laboratory technologist or scientific officer or any other person with the qualifications, training and experience recognized by the Director General.

PART II

CONTROL OF PRIVATE HEALTHCARE FACILITIES AND SERVICES

Approval and licence

3. No person shall establish or maintain any of the following private healthcare facilities or services without approval being granted under paragraph 12(a) or operate or provide any of such facilities or services without a licence granted under paragraph 19(a):

- (a) a private hospital;
- (b) a private psychiatric hospital;

- (c) a private ambulatory care centre;
- (d) a private nursing home;
- (e) a private psychiatric nursing home;
- (f) a private maternity home;
- (g) a private blood bank;
- (h) a private haemodialysis centre;
- (i) a private hospice;
- (j) a private community mental health centre;
- (k) any other private healthcare facility or service or health-related service as the Minister may specify, from time to time, by notification in the *Gazette*; and
- (l) a private healthcare premises incorporating any two or more of the facilities or services in paragraphs (a) to (k).

Registration

4. (1) No person shall establish, maintain, operate or provide a private medical clinic or private dental clinic unless it is registered under section 27.

(2) Notwithstanding subsection (1), a private medical clinic or private dental clinic which forms part of the premises of a licensed private healthcare facility and to which the clinic is organizationally, administratively and physically linked shall not be required to be registered separately but shall comply with such standards and requirements as may be prescribed.

Unlicensed and unregistered private healthcare facility or service

5. (1) A person who contravenes section 3 or 4 commits an offence and shall be liable, on conviction—

(a) in the case of an individual person—

- (i) to a fine not exceeding three hundred thousand ringgit or to imprisonment for a term not exceeding six years or to both; and
- (ii) for a continuing offence, to a fine not exceeding one thousand ringgit for every day or part of a day during which the offence continues after conviction; and

(b) in the case of a body corporate, partnership or society—

- (i) to a fine not exceeding five hundred thousand ringgit; and
- (ii) for a continuing offence, to a fine not exceeding five thousand ringgit for every day or part of a day during which the offence continues after conviction.

(2) Where an offence under section 3 or 4 is committed by a body corporate, a partnership or a society—

- (a) in the case of a body corporate, the person responsible for the body corporate;
- (b) in the case of a partnership, every partner in the partnership;
- (c) in the case of a society, its office bearers,

shall also be guilty of the offence and shall be liable, on conviction—

- (aa) to a fine not exceeding three hundred thousand ringgit or to imprisonment for a term not exceeding six years or to both; and

- (bb) for a continuing offence, to a fine not exceeding one thousand ringgit for every day or part of a day during which the offence continues after conviction.

Approval and licence may be issued to a sole proprietor, partnership or body corporate

6. (1) Approval to establish or maintain, or a licence to operate or provide may only be issued to—

- (a) a sole proprietor who is a registered medical practitioner;
- (b) a partnership which consists of at least one partner who is a registered medical practitioner; or
- (c) a body corporate whose board of directors consists of at least one person who is a registered medical practitioner.

(2) Notwithstanding subsection (1), approval to establish or maintain or a licence to operate or provide a private nursing home may be issued to a registered nurse if contractual arrangements have been made for a registered medical practitioner to visit the patients in such home at such frequency as may be prescribed.

(3) Notwithstanding subsection (1), approval to establish or maintain or a licence to operate or provide a private maternity home may be issued to a registered midwife if contractual arrangements have been made for a registered medical practitioner to visit the patients in such home at such frequency as may be prescribed.

(4) Notwithstanding subsection (1), approval to establish or maintain or a licence to operate or provide a private hospice or a private haemodialysis centre, on a voluntary or charitable basis, may be issued to a society registered under the Societies Act 1966 [Act 335].

Certificate of registration to operate private medical and private dental clinic

7. (1) A certificate of registration to establish, maintain, operate or provide a private medical clinic may only be issued to a registered medical practitioner.

(2) A certificate of registration to establish, maintain, operate or provide a private dental clinic may only be issued to a registered dental practitioner or a body corporate described in section 28 of the Dental Act 1971.

PART III

APPROVAL TO ESTABLISH OR MAINTAIN PRIVATE
HEALTHCARE FACILITIES OR SERVICES
OTHER THAN A PRIVATE MEDICAL CLINIC OR A
PRIVATE DENTAL CLINIC

Application for approval to establish or maintain

8. (1) An application for approval to establish or maintain a private healthcare facility or service other than a private medical clinic or a private dental clinic shall be made to the Director General—

- (a) in the prescribed form and manner;
- (b) accompanied by the prescribed fee; and
- (c) by submitting together with the application—
 - (i) a comprehensive plan for the establishment or maintenance of the proposed private healthcare facility or service including the site plan, building layout plan, design, construction, specification, the type of facility or service to be provided and the proposed arrangements for manpower recruitment including arrangements for manpower training;

- (ii) if the applicant is not a natural person but a company, partnership or society, a copy of its constituent document, duly verified by a statutory declaration made by an authorized officer of the applicant; and
- (iii) such other information, particulars or documents as may be deemed necessary for the purpose of determining the application and the suitability of the applicant.

(2) At any time after receiving the application the Director General may by written notice require the applicant to provide additional information, particulars or documents.

(3) The requirements under subsections (1) and (2) may differ as between different applicants and classes, categories, or descriptions of applications.

(4) Where additional information, particulars or documents required under subparagraph (1)(c)(iii) and subsection (2) is or are not provided by the applicant within the specified time or extended time, the application—

(a) shall be deemed to have been withdrawn; and

(b) shall not be further proceeded with,

without prejudice to a fresh application being made by the applicant.

(5) An application may be withdrawn at any time before it is granted or refused.

Matters to be considered before approval to establish or maintain is granted

9. In deciding whether or not to grant approval to establish or maintain a private healthcare facility or service other than a private

medical clinic or a private dental clinic, the Director General shall consider the following matters:

- (a) the nature of the healthcare facility or service to be provided;
- (b) the extent to which the healthcare facilities or services are already available in an area;
- (c) the need for the healthcare facility or service in an area;
- (d) the future need for the healthcare facility or service in an area; or
- (e) any other matter which in his opinion is relevant.

Refusal to process application for approval to establish or maintain

10. The Director General may refuse to proceed with an application for approval to establish or maintain a private healthcare facility or service other than a private medical clinic or a private dental clinic, or may require that the application be appropriately amended or completed and resubmitted or that a fresh application be submitted in its place if—

- (a) the application form as prescribed is not duly completed by reason of any omission or misdescription;
- (b) the application form contains an error or alteration;
- (c) the application does not comply with any other prescribed requirement; or
- (d) the applicant has not shown proof that he is a suitable person to be granted approval to establish or maintain a private healthcare facility or service.

Reasons for refusal to grant approval to establish or maintain

11. An application for approval to establish or maintain a private healthcare facility or service other than a private medical clinic or a private dental clinic shall not be granted by the Director General unless he is satisfied that—

- (a) the applicant is capable of providing adequate healthcare facilities or services;
- (b) the applicant is capable of providing adequate and efficient management and administration for the proper conduct of the private healthcare facility or service;
- (c) where the applicant is a sole proprietor, he has not been convicted of an offence involving fraud or dishonesty or is not an undischarged bankrupt;
- (d) no one who has been convicted of an offence involving fraud or dishonesty or who is an undischarged bankrupt—
 - (i) is a member of the board of directors, or is a person responsible for the body corporate, if the application is made by a body corporate; or
 - (ii) is a partner, if the application is made by a partnership; or
 - (iii) is an office bearer of a society, if the application is made by a society.

Grant of or refusal to grant approval to establish or maintain

12. Upon receiving and having considered the application for approval to establish or maintain a private healthcare facility or service other than a private medical clinic or a private dental clinic the Director General—

- (a) may grant such approval with or without any terms or conditions; or
- (b) may refuse the application with or without assigning any reason for such refusal.

Separate approval to establish or maintain private healthcare facilities or services which are not physically, administratively or organizationally linked

13. (1) Separate approval to establish or maintain shall be applied for private healthcare facilities or services other than a private medical clinic or a private dental clinic which are not physically, administratively or organizationally linked.

(2) Approval to establish or maintain a private healthcare facility or service other than a private medical clinic or a private dental clinic shall specify the type of private healthcare facility or service for which it is granted and the purpose for which the approval may be maintained.

PART IV

LICENCE TO OPERATE OR PROVIDE PRIVATE
HEALTHCARE FACILITY OR SERVICE
OTHER THAN PRIVATE MEDICAL CLINIC OR
PRIVATE DENTAL CLINIC

Application for a licence to operate or provide to be made within three years

14. (1) An application for a licence to operate or provide a private healthcare facility or service other than a private medical clinic or private dental clinic shall be made within three years from the date of the issuance of the approval to establish or maintain in respect of such facility or service.

(2) If a licence to operate or provide a private healthcare facility or service is not applied for within the time specified in subsection (1), the approval to establish or maintain granted under paragraph 12(a) shall be deemed to have been revoked unless an extension of that time is granted by the Director General.

Application for licence to operate or provide

15. (1) An application for a licence to operate or provide a private healthcare facility or service other than a private medical clinic or a private dental clinic shall be made to the Director General—

- (a) in the prescribed form and manner;
- (b) accompanied by the prescribed fee; and
- (c) by submitting together with the application such information, particulars and documents as may be specified by the Director General.

(2) At any time after receiving the application and before it is determined, the Director General may by written notice require the applicant to provide additional information, particulars or documents.

(3) The requirement under paragraph (1)(c) and subsection (2) may differ as between different descriptions of private healthcare facilities or services.

(4) Where additional information, particulars or documents required under paragraph (1)(c) and subsection (2) is or are not provided by the applicant within the specified time or extended time, the application—

- (a) shall be deemed to have been withdrawn; and
- (b) shall not be further proceeded with,

without prejudice to a fresh application being made by the applicant.

(5) An application may be withdrawn at any time before it is granted or refused.

Inspection of premises

16. (1) Upon receiving an application for a licence to operate or provide a private healthcare facility or service other than a private medical clinic or a private dental clinic, the Director General shall appoint in writing two or more persons, one of whom shall be a registered medical practitioner—

- (a) to inspect the premises of the private healthcare facility or service to ascertain that it complies with the building layout plan, design, construction and specification to which the approval to establish or maintain relates;
- (b) to inspect any equipment, apparatus, instrument, material, article, sample or substance or any other thing found in the premises, or any matter connected therewith; and
- (c) to inspect the premises of the private healthcare facility or service to ascertain that it complies with standards or requirements, including inspection of books, records, policies, standard operating procedures, clinical practice guidelines or the management or matters connected therewith.

(2) The persons appointed under subsection (1) shall submit a report of the inspection to the Director General as soon as practicable.

Refusal to process application for licence

17. The Director General may refuse to proceed with an application for a licence to operate or provide, or may require that the application be appropriately amended or completed and resubmitted or that a fresh application be submitted in its place if—

- (a) the application form as prescribed is not duly completed by reason of any omission or misdescription;
- (b) the application form contains an error or alteration; or
- (c) the application does not comply with any other prescribed requirement.

Reasons for refusal to issue or renew a licence to operate or provide

18. The Director General may refuse to issue or renew a licence if—

- (a) where the applicant is a natural person, the Director General is not satisfied as to the character and fitness of the applicant;
- (b) where the applicant is a body corporate, the Director General is not satisfied as to the character and fitness of the members of the board of directors or committee or board of trustees or other governing board of the body corporate;
- (c) where the applicant is a partnership, the Director General is not satisfied as to the character and fitness of the partners;
- (d) where the applicant is a society, the Director General is not satisfied as to the character and fitness of the office bearers;
- (e) in the opinion of the Director General the premises in respect of which the application is made are unsafe, unclean or unsanitary, or inadequately equipped; and
- (f) in the opinion of the Director General, the staff is inadequate or incompetent for the purpose of the private healthcare facility or service.

Grant of or refusal to grant licence

19. Upon receiving and having considered the report under section 16 and after giving it due consideration the Director General shall have the discretion—

- (a) to grant a licence to operate or provide a private healthcare facility or service other than a private medical clinic or a private dental clinic, with or without any terms or conditions, and upon payment of the prescribed fee; or
- (b) to refuse the application with or without assigning any reason for such refusal.

Licence to specify type of private healthcare facility or service

20. A licence to operate or provide a private healthcare facility or service other than a private medical clinic or a private dental clinic shall specify the type of private healthcare facility or service for which it is issued and the purpose for which the licence may be maintained.

Separate licence for private healthcare facilities or services which are not physically, administratively or organizationally linked

21. Separate licences shall be applied for private healthcare facilities or services other than private medical clinic or private dental clinic which are not physically, administratively or organizationally linked.

Duration and renewal of licence to operate or provide

22. (1) A licence to operate or provide a private healthcare facility or service other than a private medical clinic or a private dental clinic shall, unless sooner suspended or revoked, remain in force for a period of two years from the date on which it is issued, and may by application in the prescribed form and on payment of the prescribed fee be renewed for a similar period by the grant of a new licence.

(2) Sections 16 to 19 shall apply *mutatis mutandis* to an application for renewal of a licence to operate or provide.

(3) When renewing a licence the Director General may vary the terms or conditions attached to the licence and may impose additional terms and conditions.

Licence to be exhibited

23. A copy of the licence to operate or provide a private healthcare facility or service shall be exhibited in a conspicuous part of the premises of the private healthcare facility or service.

Power to vary terms or conditions, or purpose of approval or licence

24. The Director General may, on an application in writing to him, vary the terms or conditions of the approval to establish or maintain or licence to operate or provide a private healthcare facility or service by endorsement thereon or otherwise in writing by altering, in such manner as he thinks fit, the purpose or purposes to which the private healthcare facility or service is established, or maintained, or operated or provided, or the type of healthcare facility or service for which the licence is in force.

PART V

REGISTRATION OF A PRIVATE MEDICAL CLINIC AND A PRIVATE DENTAL CLINIC

Application for registration

25. (1) An application for the registration of a private medical clinic or private dental clinic shall be made to the Director General in the prescribed form and manner, and accompanied by the prescribed fee and such information, particulars and other documents as may be prescribed.

(2) At any time after receiving the application for registration and before it is determined, the Director General may by written notice require the applicant to provide additional information, particulars or documents.

(3) Where additional information, particulars or documents required under subsection (2) is or are not provided by the applicant within the specified time or extended time, the application—

(a) shall be deemed to have been withdrawn; and

(b) shall not be further proceeded with,

without prejudice to a fresh application being made by the applicant.

(4) An application may be withdrawn at any time before it is granted or refused.

Refusal to process application for registration

26. The Director General may refuse to proceed with an application for registration, and may require that the application be appropriately amended or completed and resubmitted or that a fresh application be submitted in its place if—

(a) the application form as prescribed is not duly completed by reason of any omission or misdescription;

(b) the application form contains an error or alteration; or

(c) the application does not comply with any other prescribed requirement.

Grant of certificate of registration

27. Upon receiving and having considered the application, the Director General may register the private medical clinic or private dental clinic with or without such terms or conditions as he may

deem necessary and issue a certificate of registration upon payment of the prescribed fee.

Certificate of registration to be exhibited

28. A copy of the certificate of registration shall be exhibited in a conspicuous part of the premises of the private medical clinic or private dental clinic.

Power to vary terms or conditions of registration

29. The Director General may, on an application in writing to him and upon payment of the prescribed fee, vary the terms or conditions of registration by endorsement on the certificate of registration or otherwise in writing.

Separate registration

30. Separate registration shall be required for—

- (a) a private medical clinic and a private dental clinic which are physically, administratively or organizationally linked to each other;
- (b) a private medical clinic which is not physically, administratively and organizationally linked to another licensed or registered private healthcare facility;
- (c) a private dental clinic which is not physically, administratively and organizationally linked to another licensed or registered private healthcare facility;
- (d) a private medical clinic which is not physically linked but is organizationally or administratively linked to a registered private medical clinic, or to a licensed healthcare facility or service;

- (e) a private dental clinic which is not physically linked but is organizationally or administratively linked to a registered dental clinic or to a licensed healthcare facility or service;
- (f) a private medical clinic or a private dental clinic which is under an individual medical or dental practitioner, as the case may be, sharing manpower, facilities or services, in the same premises but which are not administratively nor organizationally linked to each other; and
- (g) any other forms of organization or administration of private medical clinics or private dental clinics as the Director General may determine.

PART VI

RESPONSIBILITIES OF A LICENSEE, HOLDER OF CERTIFICATE OF REGISTRATION AND PERSON IN CHARGE

Responsibilities

31. (1) A licensee or a holder of a certificate of registration in respect of a licensed or registered private healthcare facility or service shall—

- (a) ensure that the licensed or registered private healthcare facility or service is maintained or operated by a person in charge;
- (b) inspect the licensed or registered private healthcare facility or service in such manner and at such frequency as may be prescribed;
- (c) ensure that persons employed or engaged by the licensed or registered private healthcare facility or service are registered under any law regulating their registration, or in the absence of any such law, hold such qualification and experience as are recognized by the Director General; and

- (d) comply with such other duties and responsibilities as may be prescribed.

(2) Notwithstanding 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.

(3) Where a licensee or a holder of a certificate of registration who is a sole proprietor contravenes subsection (1), he commits an offence and shall be liable on conviction to a fine not exceeding one hundred thousand ringgit or to imprisonment for a term not exceeding two years or to both.

(4) Where a licensee or a holder of a certificate of registration who is a body corporate, partnership or society contravenes subsection (1), it commits an offence and shall be liable, on conviction to a fine not exceeding three hundred thousand ringgit.

(5) Where an offence under subsection (1) is committed by a body corporate, a partnership or a society—

- (a) in the case of a body corporate, the person responsible for the body corporate;
- (b) in the case of a partnership, every partner in the partnership;
- (c) in the case of a society, its office bearers,

shall also be guilty of the offence and shall be liable, on conviction to a fine not exceeding one hundred thousand ringgit or to imprisonment for a term not exceeding two years or to both.

Person in charge

32. (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.

Change of person in charge

33. (1) It shall be the duty of a licensee or a holder of a certificate of registration to notify the Director General within fourteen days of its occurrence of any change in the person in charge of the private healthcare facility or service to which his or its licence or certificate of registration relates and the qualifications, training and experience of the new person in charge.

(2) The licensee or the holder of a certificate of registration who fails to comply with subsection (1) commits an offence.

Personal care aide

34. (1) It shall be the duty of the licensee of a private healthcare facility or service or the holder of a certificate of registration to ensure that persons providing personal care possess such qualification, have undergone such training and possess such experience as may be determined by the Director General.

(2) A personal care aide may perform duties, functions and services as may be prescribed.

(3) Notwithstanding subsection (1), a personal care aide cannot perform nursing care duties.

(4) Any person who contravenes this section commits an offence.

Policy statement

35. (1) A licensee of a private healthcare facility or service or the holder of a certificate of registration or the person in charge of a private healthcare facility or service shall make available, upon registration or admission, as the case may be, its policy statement with respect to the obligations of the licensee or holder of the certificate of registration to patients using the facilities or services.

(2) A policy statement shall cover such matters as may be prescribed.

Patient grievance mechanism

36. (1) The licensee of a private healthcare facility or service or holder of a certificate of registration shall establish a plan for grievance mechanism for patients using the premises of the private healthcare facility or service.

(2) A grievance mechanism plan and grievance procedure shall be as prescribed.

Incident reporting

37. (1) Notwithstanding any other report required by any other written law, a private healthcare facility or service shall report to the Director General, or any person authorized by him in that behalf, such unforeseeable and unanticipated incidents as may be prescribed.

(2) This section shall apply to any unforeseeable or unanticipated incident that occurs on or after the date of commencement of this Act.

Emergency treatment and services

38. (1) Every licensed and registered private healthcare facility or service shall at all times be capable of instituting, and making available, essential life saving measures and implementing

emergency procedures on any person requiring such treatment or services.

(2) The nature and scope of such emergency measures, procedures and services shall be as prescribed.

PART VII

GENERAL PROVISIONS RELATING TO APPROVAL, LICENCE AND REGISTRATION

Restriction on use of premises

39. (1) The premises to which a licence to operate or provide a private healthcare facility or service or a certificate of registration relates shall not be used for any purpose other than the purpose in respect of which the licence or certificate of registration is issued, and purposes reasonably incidental thereto.

(2) If the licensed or registered private healthcare facility or service is used in any manner contrary to subsection (1)—

- (a) where a licensee or the holder of the certificate of registration is a sole proprietor, he commits an offence and shall be liable on conviction—
 - (i) to a fine not exceeding one hundred thousand ringgit or to imprisonment for a term not exceeding two years or to both; and
 - (ii) in the case of a continuing offence, to a fine not exceeding one thousand ringgit for every day or part of a day during which the offence continues after conviction;
- (b) where the licensee or the holder of the certificate of registration is a body corporate, partnership or society, it commits an offence and shall be liable on conviction—

- (i) to a fine not exceeding three hundred thousand ringgit; and
 - (ii) in the case of a continuing offence to a fine not exceeding five thousand ringgit for every day or part of a day during which the offence continues after conviction; and
 - (c) where an offence under subsection (1) is committed by a body corporate, a partnership or a society—
 - (i) in the case of a body corporate, the person responsible for the body corporate;
 - (ii) in the case of a partnership, every partner in the partnership;
 - (iii) in the case of a society, its office bearers,
- shall also be guilty of the offence and shall be liable on conviction—
- (A) to a fine not exceeding one hundred thousand ringgit or to imprisonment for a term not exceeding two years or to both; and
 - (B) in the case of a continuing offence to a fine not exceeding one thousand ringgit for every day or part of a day during which the offence continues after conviction.

Prohibition on extension and alteration

40. (1) No person shall make any structural or functional extension or alteration to any licensed private healthcare facility or service or to any part thereof which affects—

- (a) the purpose for which the licensed private healthcare facility was established, maintained, operated or provided;

- (b) any of the terms or conditions of the approval to establish or maintain or licence to operate or provide; or
- (c) the standards of the facilities or services provided,

unless the prior written approval of the Director General is obtained.

(2) An application for the extension or alteration under subsection (1) shall be made to the Director General in the prescribed form and manner and shall be accompanied by the prescribed fee.

(3) If the Director General considers that an application under subsection (2) relates to proposals for extension or alterations—

- (a) that do not relate to or affect the care and safety of patients; or
- (b) that are minor in nature,

the Director General may waive the fee payable, or refund the fee paid, under subsection (2) in relation to an application for approval of extension or alteration.

(4) Any person who contravenes subsection (1) commits an offence.

Transfer, *etc.*, of approval, licence and certificate

41. (1) No approval to establish or maintain or licence to operate or provide a private healthcare facility or service or certificate of registration of a private medical or dental clinic shall be transferred, assigned, or otherwise disposed of unless the prior written approval of the Director General has been obtained.

(2) An application for the transfer, assignment, or disposal of an approval, a licence or a certificate of registration shall be made to the Director General in the prescribed form and manner and shall be accompanied by the prescribed fee.

(3) The Director General may on such application approve the transfer, assignment or disposal subject to such terms or conditions as he may impose by making an endorsement on the approval, licence or certificate of registration or may, if he thinks fit, refuse to approve the transfer, assignment or disposal.

Registers

42. (1) The Director General shall cause to be kept and maintained in such form and manner as may be prescribed—

- (a) a register of all private healthcare facilities or services licensed under this Act;
- (b) a register of all private medical clinics and private dental clinics registered under this Act; and
- (c) such other register or registers as he deems that the private healthcare facility or service should maintain.

(2) The registers in paragraphs 1(a) and (b) shall be deemed to be public document within the meaning of the Evidence Act 1950 [*Act 56*] and shall be open for public inspection and the public may make a search on and obtain extracts from the registers upon payment of a prescribed fee.

PART VIII

SUSPENSION AND REVOCATION OF APPROVAL AND LICENCE, REFUSAL TO RENEW THE LICENCE, AND SUSPENSION, AND REVOCATION OF REGISTRATION

Show cause

43. The Director General may serve on the holder of the approval to establish or maintain or a licensee under this Act a show cause notice of his intention to suspend or revoke the approval or licence or

refusal to renew the licence, as the case may be, and he may serve on a holder of a certificate of registration granted under this Act a show cause notice of his intention to suspend or revoke the registration.

Grounds for suspension, *etc.*, relating to administration of private healthcare facility or service

44. The Director General may issue the show cause notice in section 43 if he is satisfied that it is expedient so to do on the ground that the holder of the approval or the licensee or the holder of the certificate of registration, as the case may be—

- (a) has obtained the approval, licence or registration by any false or misleading statement;
- (b) has breached any term or condition imposed by the Director General on the approval, licence or registration;
- (c) has been convicted for an offence under this Act or any other written law;
- (d) has failed to comply with any direction, order or guideline given to him or it by the Minister or the Director General;
- (e) has used the premises to which the approval, licence or registration relates contrary to the purpose of the approval, licence or registration;
- (f) has operated or used the private healthcare facility or service in a manner which is detrimental to the interest of the public as the Director General may decide;
- (g) has established or maintained policies or issued directives that result in healthcare professionals contravening the code of professional conduct of the medical, dental or nursing or other healthcare profession issued by the Malaysian Medical Council, Malaysian Dental Council, Nursing Board or Midwifery Board or any other healthcare regulatory body, as the case may be; or

- (h) has ceased to operate the private healthcare facility or service.

Grounds for suspension, revocation, refusal to renew licence, etc., relating to qualification of sole proprietor

45. The Director General may issue the notice in section 43 if the holder of the approval or licensee or the holder of a certificate of registration is a sole proprietor—

- (a) who is a registered medical practitioner, and whose name has been struck off from the Malaysian Medical Register pursuant to paragraph 30(i) of the Medical Act 1971;
- (b) who is a registered dentist, and whose name has been struck off from the Malaysian Dental Register pursuant to paragraph 33(1)(a) of the Dental Act 1971;
- (c) who is a registered medical practitioner, and whose name has been suspended from the Malaysian Medical Register pursuant to paragraph 30(ii) of the Medical Act 1971;
- (d) who is a registered dentist, and whose name has been suspended from the Malaysian Dental Register pursuant to paragraph 30(1)(b) of the Dental Act 1971;
- (e) who is a registered nurse, and whose name has been struck off from the Register of Nurses pursuant to paragraph 32(a) of the Nurses Registration Regulations 1985 [*P.U. (A) 494/85*];
- (f) who is a registered midwife, and whose name has been struck off from the Register of Midwives pursuant to paragraph 13B(a) of the Midwives Act 1966;
- (g) who is a registered nurse, and whose name has been suspended from the Register of Nurses pursuant to paragraph 32(b) of the Nurses Registration Regulations 1985; or

- (h) who is a registered midwife, and whose name has been suspended from the Register of Midwives pursuant to paragraph 13B(b) of the Midwives Act 1966.

Grounds for suspension, revocation, or refusal to renew approval, licence or certificate of registration

46. The Director General may issue the notice in section 43 if the holder of the approval or licensee or the holder of a certificate of registration is a body corporate, partnership or society which does not remove member of its board of directors, partner or office bearers, as the case may be—

- (a) whose name has been struck off from the Malaysian Medical Register pursuant to paragraph 30(i) of the Medical Act 1971;
- (b) whose name has been struck off from the Malaysian Dental Register pursuant to paragraph 33(1)(a) of the Dental Act 1971;
- (c) whose name has been struck off from the Register of Nurses pursuant to paragraph 32(a) of the Nurses Registration Regulations 1985;
- (d) whose name has been struck off from the Register of Midwives pursuant to paragraph 13B(a) of the Midwives Act 1966;
- (e) whose name has been suspended from the Malaysian Medical Register pursuant to paragraph 30(ii) of the Medical Act 1971;
- (f) whose name has been suspended from the Malaysian Dental Register pursuant to paragraph 32(1)(b) of the Dental Act 1971;

- (g) whose name has been suspended from the Register of Nurses pursuant to paragraph 32(b) of the Nurses Registration Regulations 1985; or
- (h) whose name has been suspended from the Register of Midwives pursuant to paragraph 13B(b) of the Midwives Act 1966.

Additional grounds

47. The grounds set out in sections 44, 45 and 46 shall be in addition to such other ground as may be provided for under any other provision of this Act.

Representations

48. Upon receiving the notice under section 43 from the Director General, the holder of the approval, licensee or holder of the certificate of registration may submit representations to the Director General within twenty-one days.

Power of Director General to suspend, revoke, or refuse renewal

49. (1) After the expiry of the time determined in the notice for the making of representation and after considering any representation made under section 48, the Director General may—

- (a) suspend the approval, licence or registration for such period as he may determine and subject to such terms or conditions as he may impose;
- (b) revoke the approval, licence or registration, as the case may be;
- (c) refuse to renew the licence; or

- (d) issue a warning and give directions to the holder of the approval, licensee or the holder of the certificate of registration to rectify the situation to the satisfaction of the Director General.

(2) Any holder of the approval, licensee or holder of a certificate of registration aggrieved by the order of the Director General under subsection (1) may appeal to the Minister within thirty days from the service of the order on him or it, and the decision of the Minister to confirm, vary or revoke the order of the Director General shall be final and conclusive.

Surrender of licence or certificate

50. Where approval has been suspended or revoked or a licence has been suspended, revoked or refused renewal or a registration has been suspended or revoked under sections 44, 45 and 46, the holder of the approval, the licensee or holder of a certificate of registration shall surrender the approval or licence or certificate of registration, as the case may be, to the Director General.

Cessation of operation

51. During the period of the suspension of an approval, licence or registration or as from the date of the revocation of the approval, licence or registration, as the case may be, the holder of the approval, licensee or the holder of a certificate of registration shall not operate the private healthcare facility or service in respect of which the approval, licence or certificate of registration has been suspended, revoked or refused renewal, as the case may be.

PART IX

CLOSURE OF PRIVATE HEALTHCARE
FACILITIES OR SERVICES**Order for temporary closure of private healthcare facilities or services**

52. (1) The Director General may, if it appears to him that the continued operation of any private healthcare facility or service would pose a grave danger to the public, by notice in writing order the closure of the private healthcare facility or service for such period and upon such term, condition or direction as he thinks fit or until further notice, and may take such other measures as are necessary to protect the public from grave danger.

(2) Any order under subsection (1) shall be served on the licensee of such facility or service or the holder of a certificate of registration in respect of the facility or service or the person in charge of the facility or service and shall take effect from the date of service thereof.

(3) A sole proprietor who fails to comply with the order served on him under subsection (1) commits an offence and shall be liable on conviction—

(a) to a fine not exceeding fifty thousand ringgit or to imprisonment for a term not exceeding one year or to both; and

(b) in the case of a continuing offence, to a fine of one thousand ringgit for every day or part of the day during which the offence continues after conviction.

(4) A body corporate, partnership or society which fails to comply with the order served on it under subsection (1) commits an offence and shall be liable on conviction—

(a) to a fine not exceeding one hundred thousand ringgit; and

- (b) in the case of a continuing offence, to a fine of five thousand ringgit for every day or part of the day during which the offence continues after conviction.

(5) Where an offence under subsection (1) is committed by a body corporate, a partnership or a society—

- (a) in the case of a body corporate, the person responsible for the body corporate;
- (b) in the case of a partnership, every partner in the partnership;
- (c) in the case of a society, its office bearers,

shall also be guilty of the offence and shall be liable on conviction—

- (aa) to a fine not exceeding fifty thousand ringgit or to imprisonment for a term not exceeding one year or to both; and
- (bb) in the case of a continuing offence, to a fine of one thousand ringgit for every day or part of the day during which the offence continues after conviction.

Conditions for closure, selling or otherwise disposing of private healthcare facility or service

53. (1) Where the licensee of a private healthcare facility or service, or the holder of a certificate of registration, intends to close down, transfer, sell or otherwise dispose of the private healthcare facility or service, he or it shall give the Director General not less than thirty days notice in writing of his or its intention.

(2) The licensee or a holder of a certificate of registration whose licence or registration has been revoked or suspended, as the case may be, or who has been refused renewal of such licence shall notify the Director General in writing of his or its intention to close down,

transfer, sell or otherwise dispose of the private healthcare facility or service as soon as practicable.

(3) The licensee or the holder of a certificate of registration shall comply with such directions as the Director General may give with regard to the accommodation and care of the patients, and the care of medical records in the licensed or registered private healthcare facility or service, before closing down, transferring, selling or otherwise disposing of the licensed or registered private healthcare facility or service.

(4) Any person who contravenes this section commits an offence.

(5) The licensee or the holder of a certificate of registration shall surrender the licence or certificate of registration immediately upon the suspension, revocation, or refusal to renew the licence or suspension or revocation of the certificate or registration or discontinuance or closure of the operation of the premises.

PART X

BLOOD BANK

Interpretation

54. In this Part, unless the context otherwise requires—

“blood product” means any substance freshly derived from natural human blood and includes plasma, plasma component and blood cells but does not include any fractionated blood product;

“fractionated blood product” means plasma proteins obtained through a chemical manufacturing process;

“natural human blood” means unprocessed human blood;

“supply” means supply by way of sale, exchange or gift and includes receiving, keeping or storing for the purpose of supply.

Prohibition on supply of natural human blood and blood product

55. No person shall supply, agree to supply, offer to supply or hold himself out as being willing to supply natural human blood or blood product.

Import and export of natural human blood and blood product

56. Without prejudice to section 55, no person shall import or export natural human blood or blood product for transfusion purposes unless he holds a certificate issued under paragraph 57(1)(a) or (b).

Issue of certificate to import and export natural human blood and blood product

57. (1) The Director General may, on application made in the prescribed form and upon payment of a prescribed fee, issue a certificate authorizing any person, subject to such conditions and restrictions as may be imposed—

(a) to import or export blood products for transfusion purposes; or

(b) to import or export natural human blood for transfusion purposes.

(2) A certificate issued under subsection (1) may at any time be revoked by notice in writing.

(3) Upon receipt of the notice under subsection (2) from the Director General the person to whom the certificate under subsection (1) is issued, may submit representations to the Director General within such time as may be determined by the Director General in the notice.

(4) After the expiry of the time determined in the notice for the making of representation and after considering any representation made under subsection (3) the Director General may—

- (a) revoke the certificate;
- (b) issue a warning and give directions to the holder of the certificate to take any action to the satisfaction of the Director General; or
- (c) take no further action.

Consent to test blood from donors

58. The person in charge of a private healthcare facility or service intending to test blood from a donor shall obtain the donor's written consent to test his blood for such diseases as may be specified by the Director General from time to time and in accordance with such procedures as may be specified.

PART XI

BLOOD TRANSFUSION SERVICES

Storage facilities

59. (1) All private hospitals, private maternity homes and private ambulatory surgical care centres, and all other private healthcare facilities providing emergency care services regularly or surgical services, shall maintain proper blood storage facilities as may be prescribed.

(2) The storage facilities shall be under the adequate control and supervision of the person in charge of the private healthcare facility or service.

(3) Blood and blood products in the premises of such facility or service shall be stored in refrigerators.

(4) Refrigerators used or intended to be used for storing blood and blood products shall have an adequate alarm system and shall be

regularly inspected and otherwise shall be safe and adequate for the amount of blood and blood products to be stored.

Minimum blood supply

60. Every private hospital, private maternity home and private ambulatory surgical care centre, and any other private healthcare facility providing emergency services regularly or surgical services, shall maintain a minimum blood supply in its premises at all times for its daily use or be in a position to obtain blood quickly from other licensed blood banks or Government facilities for its daily needs.

Maintain records of receipt and disposition of blood

61. Every private hospital, private maternity home and private ambulatory surgical care centre and any other private healthcare facility providing emergency services regularly or surgical services shall maintain records indicating the receipt and disposition of all blood and blood products provided to patients in its premises.

Transfusion reactions

62. The person in charge or the licensee of every private hospital, private maternity home and private ambulatory surgical care centre and any other private healthcare facility providing emergency services regularly or surgical services shall investigate all transfusion reactions occurring in its premises.

Recommendations to the Medical Advisory Committee

63. The person in charge or licensee of every private hospital, private maternity home and private ambulatory surgical care centre, and any other private healthcare facility providing emergency care services regularly or surgical services, shall make recommendations to the Medical Advisory Committee regarding improvements in

transfusion procedure at the end of an investigation made under section 62.

PART XII

MORTALITY ASSESSMENT

Interpretation

64. In this Part, unless the context otherwise requires—

“assessable death” means a death that, in the opinion of any medical practitioner or dental practitioner, may be related to anesthesia or any anesthetic procedure, or medical technology or any medical procedure, or surgery or any surgical procedure;

“Committee” means a National Mortality Assessment Committee.

Establishment of National Mortality Assessment Committee

65. (1) The Director General shall have the power to establish a committee or committees each to be known as the National Mortality Assessment Committee.

(2) A Committee shall consist of a Chairman and such other members as may be appointed by the Director General.

(3) Notwithstanding subsection (2), the Director General may appoint a permanent member or members who shall sit in a Committee.

(4) Each member of a Committee shall hold office for such term and subject to such conditions as may be specified in his letter of appointment.

Functions of National Mortality Assessment Committee

66. (1) The Committee shall have the following functions:

- (a) to receive and consider information relating to assessable deaths;
- (b) to promote the safe and efficient use of anesthetic, medical or surgical procedures, or medical technology.

(2) Without prejudice to the generality of the following provisions, the Committee shall in carrying out its functions:

- (a) determine the extent, if any, to which—
 - (i) anesthesia or any anesthetic procedure;
 - (ii) medical technology or any medical procedure; or
 - (iii) surgery or any surgical procedure,contributed to the death;
- (b) determine whether the assessable death under subparagraph (2)(a)(i), (ii) or (iii) might have been averted had the effects or consequences of anesthesia or anesthetic procedure, medical technology or medical procedure, or surgery or surgical procedure, had been better or more fully understood or provided for.

(3) In performing its functions the Committee shall not allocate any blame to any medical or dental practitioner or to any other person.

Reporting of assessable deaths

67. (1) A person in charge of a private healthcare facility or service shall ensure that every medical practitioner or dental practitioner who administers any anesthesia or anesthetic or medical or surgical

procedure or uses any medical technology on a patient whose death is an assessable death shall, as soon as practicable, but in any case not more than 72 hours after he learns of the occurrence of that death, notify the Director General of the name of the patient, his opinion as to the cause of the death, and his own name and address.

(2) On receipt of any notification under subsection (1), the Director General shall forthwith in writing forward the information to the Chairman of a Committee.

Medical and dental practitioners to provide information

68. (1) For the purposes of the functions of a Committee, the Chairman may require any medical practitioner or dental practitioner or any other relevant person to supply all or any specified information in his possession relating to an assessable death, and to the anesthesia or anesthetic procedure or medical technology or medical procedure or surgery or surgical procedure relating to any assessable death, including clinical or medical records, and other material documents in his possession or under his control, notwithstanding subsection 112(4) or any rule of law or custom or practice to the contrary.

(2) Every medical practitioner and dental practitioner and any other person who has knowledge of an assessable death shall answer fully to the best of his knowledge and ability every relevant question asked of him by a Chairman of a Committee.

(3) The Chairman of a Committee shall give to the respective Committee all the information he receives under section 67 and this section in relation to an assessable death, other than—

- (a) the name of the deceased person;
- (b) the names of the medical practitioner or dental practitioner or any other person who carried out the anesthetic, medical or surgical procedure or who used any medical technology concerned; and

- (c) the name of the private healthcare facility or place where the death occurred.

Publication of information

69. (1) Subject to subsection (2), the Committee shall, in accordance with such directions as the Director General may, from time to time give, publish to persons concerned with anesthesia, anesthetic procedures, medical technology, medical procedures, surgery or surgical procedures, and to such other persons or classes of persons as the Director General may specify, any conclusion and recommendations it reaches in relation to the performance of its functions.

(2) No publication made under subsection (1) shall contain the name of, or any information that could lead to the identification of, any person whose death has been considered by a Committee or any medical practitioner or dental practitioner or any other person who has in any way been involved in the care or treatment of the deceased person.

(3) Notwithstanding subsections (1) and (2), the Chairman of a Committee shall furnish to the medical practitioner or dental practitioner whose patient's death was notified as an assessable death the conclusion and recommendations of the Committee.

Secrecy of information obtained by Committee

70. (1) All information obtained by a Committee or a mortality assessment committee established under section 72 by a private healthcare facility, or by any other person, in the course of the exercise of the functions of such committee or person, shall be treated as confidential except—

- (a) for purposes connected with those functions;
- (b) for the purpose of an investigation of any alleged crime;
or

(c) for the purpose of any criminal proceeding.

(2) Nothing in this section shall limit or affect the provisions of section 67, 68 or 71.

(3) Section 115 shall be read subject to the section.

(4) Any person who, whether directly or indirectly, divulges any information in contravention of subsection (1) commits an offence and shall be liable on conviction to a fine not exceeding one thousand ringgit.

(5) No person shall be compelled or permitted to divulge, in any civil proceeding, any information relating to an assessable death that he has acquired in the course of his duties under sections 67, 68 and 71 and no such information shall be admissible as evidence in any civil proceedings.

(6) Nothing in this section shall limit or affect the notification of deaths under any other written law relating to notification of deaths.

Protection of persons carrying out functions as members of Committee

71. (1) No person who does any act for any purpose connected with the functions of a Committee, including an act done pursuant to or in connection with the function of a mortality assessment committee established under section 72, shall be under any civil or criminal liability in respect of any such act, whether on the ground of want of jurisdiction, or mistake of law or fact, or on any other ground, unless he has acted in bad faith or without reasonable care.

(2) No proceedings, civil or criminal, shall be brought against any person in any Court in respect of any such act except by leave of a Judge of the High Court.

(3) Notice of any application for leave under subsection (2) shall be given to the person against whom it is sought to bring the

proceedings concerned; and that person shall be entitled to be heard against the application.

(4) Leave to bring such proceedings shall not be granted unless application for the leave is made within one year after the act complained of, or, in the case of a continuance of injury or damage, within one year after the cessation of the injury or damage.

(5) In granting the leave to bring any such proceedings, the Judge may limit the time within which the leave may be exercised.

Mortality assessment committee at private healthcare facility or service level

72. (1) Notwithstanding section 65, any private healthcare facility or service may establish at its level any mortality assessment committee to carry out similar functions as in section 66.

(2) The person in charge of a private healthcare facility or service shall appoint in respect of each mortality assessment committee a chairman who shall have the powers in section 68.

(3) Subject to subsection (4), a mortality assessment committee under this section shall, in accordance with such directions as the person in charge may, from time to time, give, publish to persons in the premises concerned with anesthesia, anesthetic procedures, medical technology, medical procedures, surgery or surgical procedures, and to such other persons and classes of person as the person in charge specifies, any conclusions and recommendations it reaches in the performance of its functions.

(4) No publication made under subsection (3) shall contain the name of, or any information that could lead to the identification of, any person whose death has been considered by the committee or any medical practitioner or dental practitioner or any other person who has in any way been involved with the care or treatment of that person.

(5) Notwithstanding subsections (3) and (4) the Chairman shall supply the medical practitioner or dental practitioner whose patient's death was notified as an assessable death with the conclusion and recommendations of the committee.

(6) Sections 70 and 71 shall apply *mutatis mutandis* to assessments of assessable deaths carried out by a mortality assessment committee at a private healthcare facility or service.

Independent investigation

73. (1) Nothing in this Part shall limit or affect any independent investigation conducted against any person under any disciplinary jurisdiction.

(2) For the purposes of this section, the Chairman or any other member of a Committee or the committee established under section 72 shall not be involved in the disciplinary proceeding exercise.

PART XIII

QUALITY OF HEALTHCARE FACILITIES AND SERVICES

Quality of healthcare facilities and services

74. (1) Every private healthcare facility or service shall have programmes and activities to ensure the quality and appropriateness of healthcare facilities and services provided.

(2) Information regarding such programmes and activities shall be furnished to the Director General as and when required by him.

Power of Director General to give directions

75. (1) Where the Director General is of the opinion that any prescribed requirement or any prescribed standard which applies to a private healthcare facility or service is not being observed by that

facility or service, the Director General may give to the holder of the approval, licensee or the holder of a certificate of registration in respect of such facility or service such directions in writing as he thinks necessary for the observance of the requirement or standard and shall state in the directions the period within which the holder of the approval, licensee or the holder of the certificate of registration is required to comply with the directions.

(2) Where in the opinion of the Director General the use of any apparatus, appliance, equipment, instrument, substance or any activity in a private healthcare facility or service or the manner in which any blood, blood product, human tissue or fluid or any product of the human body, substance or sample is used, collected, handled, stored or transported, or any other activity conducted is detrimental to the health and safety of any person therein or is otherwise unsuitable for the purpose for which it is used, the Director General may, by notice, direct the holder of the approval, licensee or the holder of a certificate of registration in respect of such facility or service to stop using the apparatus, appliance, equipment, instrument or substance or to stop the activity.

(3) The Director General may, by notice, further direct the holder of the approval, licensee or the holder of a certificate of registration to install or replace such apparatus, appliance, equipment, instrument, substance or any activity therein, and to adhere to such procedures as may be specified in the notice.

(4) The holder of the approval, licensee or the holder of a certificate of registration who fails to comply with the directions of the Director General under this section commits an offence and shall be liable on conviction—

(a) in the case of a sole proprietor—

- (i) to a fine not exceeding twenty thousand ringgit or to imprisonment for a term not exceeding four months or to both; and

- (ii) in the case of a continuing offence, to a fine of one thousand ringgit for every day or part of the day during which the offence continues after conviction;
- (b) in the case of a body corporate, partnership or society—
 - (i) to a fine not exceeding fifty thousand ringgit; and
 - (ii) in the case of a continuing offence, to a fine of five thousand ringgit for every day or part of the day during which the offence continues after conviction.
- (5) Where an offence under this section is committed by a body corporate, partnership or society—
 - (a) in the case of a body corporate, the person responsible for the body corporate;
 - (b) in the case of a partnership, every partner in the partnership;
 - (c) in the case of a society, its office bearers,shall also be guilty of the offence and shall be liable on conviction—
 - (aa) to a fine not exceeding twenty thousand ringgit or to imprisonment for a term not exceeding four months or to both; and
 - (bb) in the case of a continuing offence, to a fine of one thousand ringgit for every day or part of the day during which the offence continues after conviction.

Power of Director General to issue directives, orders or guidelines relating to quality assurance

76. The Director General may issue directives, orders or guidelines relating to the quality and standards of private healthcare facilities or services as he deems necessary.

PART XIV

BOARD OF MANAGEMENT AND ADVISORY COMMITTEE

Board of Management

77. (1) The licensee of a private hospital, private maternity home, private ambulatory care centre, private hospice, private psychiatric hospital or any other private healthcare facility or service as the Minister may specify, shall establish a Board of Management of whom two members shall be from the Medical Advisory Committee established under paragraph 78(b) or 79(b).

(2) Where a private hospital, private maternity home, private ambulatory care centre, private hospice, private psychiatric hospital or any other private healthcare facility or service as the Minister may specify, provides or intends to provide both medical and dental services, the licensee of such facility or service shall establish a Board of Management of whom two members shall be from the Medical and Dental Advisory Committee established under paragraph 78(c).

Medical or Dental Advisory Committee

78. The licensee of a private healthcare facility or service shall ensure that—

- (a) the medical and dental management of patients vests in a registered medical practitioner and a registered dental practitioner respectively;
- (b) where the facility or service is a private hospital, private ambulatory care centre, private hospice or private psychiatric hospital, there is established a Medical Advisory Committee whose members shall be registered medical practitioners representing all medical practitioners practising in the facility or service to advise the Board of Management, the licensee and person in charge on all aspects relating to medical practice;

- (c) where the facility or service is a private hospital, private ambulatory care centre, private hospice, private psychiatric hospital or any other private healthcare premises as the Minister may specify providing or intending to provide both medical and dental services, the licensee establishes a Medical and Dental Advisory Committee whose members shall be registered medical practitioners and registered dental practitioners representing all medical and dental practitioners practising in the private hospital, private ambulatory care centre, private hospice and private psychiatric hospital to advise the Board of Management, the licensee and person in charge on all aspects relating to medical and dental practices respectively.

Midwifery Care Advisory Committee

79. The licensee of a private maternity home shall ensure that—

- (a) the medical management of patients vests in a registered medical practitioner;
- (b) there is established a Medical Advisory Committee or a Midwifery Care Advisory Committee in accordance with paragraph (c) or (d);
- (c) where midwifery care is provided by registered midwives, there is established a Midwifery Care Advisory Committee whose members shall be registered midwives representing all midwives practising in the maternity home to advise on all aspects relating to midwifery care and the visiting medical practitioner shall be a member of the Midwifery Care Advisory Committee;
- (d) where midwifery care is provided by a registered medical practitioner, paragraph 78(b) shall apply.

Nursing Advisory Committee

- 80.** (1) The licensee of a private nursing home shall ensure that—
- (a) the medical management of patients vests in a registered medical practitioner or a visiting registered medical practitioner caring for the patients in the premises;
 - (b) there is established a Nursing Advisory Committee whose members shall be registered nurses representing all nurses practising in the nursing home to advise on all aspects relating to nursing care;
 - (c) the visiting registered medical practitioner is a member of the Nursing Advisory Committee.

Penalty for non-compliance with any of the provision of this Part

- 81.** Any person who contravenes any of the provisions of this Part commits an offence.

PART XV

MANAGED CARE ORGANIZATION

Interpretation of managed care organization

- 82.** (1) For the purpose of this Part, “managed care organization” means any organization or body, with whom a private healthcare facility or service makes a contract or has an arrangement or intends to make a contract or have an arrangement to provide specified types or quality or quantity of healthcare within a specified financing system through one or a combination of the following mechanisms:

- (a) delivering or giving healthcare to consumers through the organization or body’s own healthcare provider or a third party healthcare provider in accordance with the contract or arrangement between all parties concerned;

- (b) administering healthcare services to employees or enrollees on behalf of payors including individuals, employers or financiers in accordance with contractual agreements between all parties concerned.

(2) The Minister may from time to time by notification in the *Gazette* declare any type of healthcare delivery arrangement other than those specified in subsection (1) to be managed care organization.

Contracts between private healthcare facility or service and managed care organization

83. (1) The licensee of a private healthcare facility or service or the holder of a certificate of registration shall not enter into a contract or make any arrangement with any managed care organization that results in—

- (a) a change in the powers of the registered medical practitioner or dental practitioner over the medical or dental management of patients as vested in paragraph 78(a), and a change in the powers of the registered medical practitioner or visiting registered medical practitioner over the medical care management of patients as vested in paragraphs 79(a) and 80(a);
- (b) a change in the role and responsibility of the Medical Advisory Committee, or Medical and Dental Advisory Committee as provided under section 78, the Midwifery Care Advisory Committee as provided under section 79 or the Nursing Advisory Committee as provided under section 80;
- (c) the contravention of any provisions of this Act and the regulations made under this Act;
- (d) the contravention of the code of ethics of any professional regulatory body of the medical, dental, nursing or

midwifery profession or any other healthcare professional regulatory body; or

(e) the contravention of any other written law.

(2) The licensee or the holder of a certificate of registration or a managed care organization who enters into a contract or makes any arrangement in contravention of subsection (1) commits an offence and shall be liable on conviction—

- (a) in the case of a licensee or holder of a certificate of registration who is sole proprietor, to a fine not exceeding one hundred thousand ringgit or to imprisonment for a term not exceeding two years or to both;
- (b) in the case of a licensee or a holder of a certificate of registration who is body corporate, partnership or society, a fine not exceeding three hundred thousand ringgit; and
- (c) in the case of a managed care organization, a fine not exceeding five hundred thousand ringgit.

(3) Where an offence under subsection (2) is committed by a body corporate, a partnership or a society or a managed care organization—

- (a) in the case of a body corporate, the person responsible;
- (b) in the case of a partnership, every partner in the partnership;
- (c) in the case of a society, its office bearers,
- (d) in the case of a managed care organization, the person responsible,

shall also be guilty of the offence and shall be liable on conviction to a fine not exceeding one hundred thousand ringgit or to imprisonment for a term not exceeding two years or to both.

Licensee and holder of certificate of registration to furnish information on managed care organization to Director General

84. (1) A licensee or the holder of a certificate of registration having a contract or an arrangement with a managed care organization shall furnish such information relating to such contract or arrangement to the Director General as he may, from time to time, specify.

(2) A licensee or the holder of a certificate of registration who refuses or fails to furnish the information required under subsection (1) or furnishes false or misleading information commits an offence and shall be liable on conviction—

- (a) in the case of a sole proprietor, to a fine not exceeding ten thousand ringgit or imprisonment for a term not exceeding three months or to both; or
- (b) in the case of a body corporate, partnership or society, to a fine not exceeding fifty thousand ringgit.

(3) Where an offence under subsection (2) is committed by a body corporate, a partnership or a society—

- (a) in the case of a body corporate, the person responsible;
- (b) in the case of a partnership, every partner in the partnership;
- (c) in the case of a society, its office bearers,

shall also be guilty of the offence and shall be liable also on conviction to a fine not exceeding ten thousand ringgit or to imprisonment for a term not exceeding three months or to both.

Information by managed care organization

85. (1) A managed care organization or the owner of a managed care organization having a contract or an arrangement with a licensee

of a private healthcare facility or service or a holder of a certificate of registration shall furnish such information relating to the organization as may be required by the Director General.

(2) A managed care organization or the owner of a managed care organization who fails to furnish the information required under subsection (1) commits an offence and shall be liable on conviction—

- (a) in the case of a sole proprietor, to a fine not exceeding one hundred thousand ringgit; or
- (b) in the case of a body corporate, partnership or society to a fine not exceeding three hundred thousand ringgit.

(3) Where an offence under subsection (2) is committed by managed care organization or the owner of the managed care organization which is a body corporate, a partnership or a society—

- (a) in the case of a body corporate, the person responsible;
- (b) in the case of a partnership, every partner in the partnership;
- (c) in the case of a society, its office bearers,

shall also be guilty of the offence and shall be liable on conviction to a fine not exceeding one hundred thousand ringgit or to imprisonment for a term not exceeding two years or to both.

Register of managed care organizations

86. The Director General shall maintain a Register of managed care organizations having any contract or arrangement with any licensee of a private healthcare facility or service or any holder of a certificate of registration and such Register may contain such particulars as may be determined by the Director General.

PART XVI

ENFORCEMENT

Appointment of Inspectors

87. (1) The Director General may appoint such number of persons to be Inspectors as he deems necessary for the purposes of this Act.

(2) An Inspector may exercise all or any of the powers vested in him under this Part.

(3) The Director General shall have and may exercise all the powers vested in an Inspector under this Part.

Power of Inspector to enter and inspect

88. (1) An Inspector shall have the power to enter and inspect at any time any licensed or registered private healthcare facility or any premises which he suspects or has reason to believe to be used as a private healthcare facility or any other premises in or from which private healthcare services are provided without a licence or a certificate of registration.

(2) In the course of an inspection under this section the Inspector may—

- (a) inspect, test and examine any apparatus, appliance, equipment or instrument used or found in the facility or premises;
- (b) inspect, test, examine, take, remove and detain samples of blood, blood products, human tissue or fluid or any product of the human body, dialysate, chemicals or pharmaceuticals found in the facility or premises;
- (c) inspect, test, examine, take and remove all containers, articles and other things that the Inspector reasonably believes to contain or to have contained blood or blood

products, human tissue or fluid or any product of the human body, dialysate, chemicals or pharmaceuticals;

- (d) inspect any test or procedure or operation performed or carried out to ensure compliance with the provisions of this Act; and
- (e) inspect, make copies of and take extracts from any book, document, record or electronic material relating to the private healthcare facility or service or the premises.

Power to search and seize

89. (1) If it appears to a Magistrate upon written information on oath and after such enquiry as he considers necessary that there is reasonable cause to believe that—

- (a) any private healthcare facility or premises has been used or is about to be used for; or
- (b) there is in any private healthcare facility or premises evidence necessary to establish,

the commission of an offence under this Act, the Magistrate may issue a search warrant in respect of such facility or premises to an Inspector.

(2) An Inspector to whom a search warrant has been issued under subsection (1) may, at any time by day or by night and with or without assistance—

- (a) enter the private healthcare facility or premises, if need be by force; and
- (b) search the private healthcare facility or premises for and seize, and remove from the facility or premises, any book, record, document, apparatus, equipment, instrument, material, article, sample, blood, blood product, human tissue or fluid or any product of the human body,

dialysate, chemical, pharmaceutical, substance or any other thing—

- (i) in respect of which an offence has been committed;
- (ii) in respect of which an offence is suspected to have been committed; or
- (iii) that is reasonably believed to furnish evidence of the commission of the offence.

(3) An Inspector may—

- (a) break open any outer or inner door of any healthcare facility or premises, or any fence, enclosure, gate or other obstruction to the healthcare facility or premises, in order to effect entry thereinto;
- (b) remove by force any obstruction to entry, search, seizure or removal as he is empowered to effect under subsection (2);
- (c) detain every person found in the healthcare facility or premises until the facility or premises have been searched;
- (d) in the case of a mobile healthcare facility or premises, seize such healthcare facility or premises;
- (e) place any book, record, document, apparatus, equipment, instrument, material, article, sample, blood, blood product, human tissue or fluid or any product of the human body, dialysate, chemical, pharmaceutical, substance or other thing, in a container;
- (f) where any book, record, document, apparatus, equipment, instrument, material, article, sample, blood or blood product, human tissue or fluid or any product of the human body, dialysate, chemical, pharmaceutical, substance or other thing referred to in paragraph (e) has been seized on any private healthcare facility or premises

entered into in accordance with section 88 or 89, place the book, record, document, apparatus, equipment, instrument, material, article, sample, blood, blood product, human tissue or fluid or any product of the human body, dialysate, chemical, pharmaceutical, substance or other thing in a room, compartment or cabinet located on that private healthcare facility or premises;

- (g) mark, fasten and seal the container referred to in paragraph (e) or, as the case may be, the door or opening providing access to the room, compartment or cabinet referred to in paragraph (f).

Search and seizure without warrant

90. If an Inspector has reasonable cause to believe that by reason of delay in obtaining a search warrant under section 89—

- (a) the investigation would be adversely affected;
- (b) the object of the entry is likely to be frustrated;
- (c) the book, record, document, apparatus, equipment, instrument, material, article, sample, blood, blood product, human tissue or fluid or any product of the human body, dialysate, chemical, pharmaceutical, substance or other thing sought may be removed or interfered with; or
- (d) the evidence sought may be tampered with or destroyed,

he may exercise in, and in respect of, the private healthcare facility or premises all the powers referred to in section 89 in as full and ample a manner as if he were authorized to do so by warrant issued under that section.

Power to seal

91. (1) Where an Inspector has reasonable cause to believe that any premises or place is being used as a private healthcare facility or to provide any private healthcare services—

- (a) without being licensed or registered under this Act; or
- (b) in contravention of any of the conditions imposed by the Director General,

the Inspector may immediately take such steps as he deems necessary or by any means seal such premises or place.

(2) The person using the premises or place as a private healthcare facility or for providing private healthcare service shall, if the premises have been sealed—

- (a) within twenty-one days of such sealing produce to the Director General the licence or certificate of registration of the private healthcare facility or service; and
- (b) bear any cost incurred arising out of such action.

(3) The seal shall be removed if—

- (a) the person referred to in subsection (2) complies with the requirement of that subsection; or
- (b) an order of the court is obtained for such person to cease using the premises or place as a private healthcare facility or for providing private healthcare service,

whichever is the earlier.

(4) An Inspector acting under this section shall not be liable for any cost arising out of such action or any damage to the premises or place sealed under this section unless such damage was willfully done.

(5) Any action taken under this section in respect of any premises or place shall not prohibit the prosecution of any person using such premises or place as a private healthcare facility or for providing private healthcare service in contravention of this Act.

Power to require information and examine persons

92. (1) An Inspector making an investigation under sections 89 and 100 shall have the power to require information, whether orally or in writing, from any person acquainted with the facts and circumstances of the matter under investigation.

(2) Any person who, on being required by an Inspector to give information under this section, refuses to comply with such requirement or furnishes as true any information which he knows or has reason to believe to be false, untrue or incorrect, in whole or in part, commits an offence.

(3) When any information furnished under subsection (2) is proved to be false, untrue or incorrect, in whole or in part, it shall be no defence to allege that such information or any part thereof was misinterpreted or furnished inadvertently or without criminal or fraudulent intent.

(4) An Inspector making an investigation under this Act may exercise any or all of the powers conferred by section 111 of the Criminal Procedure Code [*Act 593*], and sections 112 to 116 of the Code shall apply to statements made by the persons examined in the course of such investigation.

Duty to assist Inspector

93. Whenever an Inspector exercises his powers under sections 88, 89, 90, 91 and 92 it shall be the duty of the licensee or a holder of a certificate of registration in respect of a licensed or registered private healthcare facility or service, a person in charge and an employee of such facility or service, or the owner or occupier of any premises

used as a private healthcare facility or from which private healthcare service is provided, and any person found therein—

- (a) to provide the Inspector with all such facilities and assistance as the Inspector may reasonably require;
- (b) to give the Inspector all reasonable information required by him in respect of the private healthcare facility or service or premises, as the case may be, relating to its management or any other matter connected therewith; and
- (c) to produce any book, record or document in his possession or custody or under his control or within his power to furnish relating to the affairs of the private healthcare facility or service or premises.

Offences in relation to inspection

94. A person who—

- (a) wilfully delays, impedes or obstructs an Inspector;
- (b) fails to provide the facilities or assistance, or refuses to furnish the information, required by an Inspector; or
- (c) without reasonable excuse fails or refuses to produce any book, record, document, apparatus, equipment, instrument, material, article, sample, blood, blood product, human tissue or fluid or any product of the human body, dialysate, chemicals, pharmaceuticals, substance or any other thing required by an Inspector,

in the exercise of any power conferred on the Inspector under sections 88, 89, 90, 91 and 92 shall be guilty of an offence and shall be liable on conviction to a fine not exceeding thirty thousand ringgit or to imprisonment for a term not exceeding six months or to both.

List of things seized

95. (1) Where any seizure is made under section 88, 89 or 90 on any private healthcare facility or premises the seizing Inspector shall prepare a list of the things seized from the premises.

(2) If the owner or the person in charge of the private healthcare facility or premises is present during the seizure, the list prepared under subsection (1) shall be given to him.

(3) For the purpose of this section, “owner” includes an agent or a representative of the owner.

Forfeiture of things seized

96. (1) Any thing liable to seizure or detention under this Act shall be liable to forfeiture.

(2) Where any book, record, document, apparatus, equipment or instrument, has been seized under this Act, the Director General may, at his discretion, temporarily release such book, record, document, apparatus, equipment or instrument to its owner on security being furnished to the Director General’s satisfaction that the book, record, document, apparatus, equipment or instrument will be surrendered to him on demand or produced before a court of competent jurisdiction on demand.

(3) An order for the forfeiture or for the release of all the things seized and liable to forfeiture under this Act shall be made by the court before which the prosecution with regard thereto has been held and an order for the forfeiture of the things seized shall be made if it is proved to the satisfaction of the court that an offence under this Act has been committed and that the things seized were the subject matter of or were used in the commission of the offence, notwithstanding that no person may have been convicted of such offence.

(4) If there is no prosecution with regard to any thing seized such thing shall be taken and deemed to be forfeited at the expiration of

one calendar month from the date of seizure unless before that date a claim thereto is made in the following manner:

- (a) a person asserting that he is the owner of the thing seized and that it is not liable to forfeiture may personally or by his agent authorized in writing give written notice to the Inspector in whose possession such thing is held that he claims the thing;
 - (b) in receipt of such notice the Inspector shall refer the claim to the Director General who may order that such thing be released or may direct such Inspector to refer the matter to a Magistrate or a Judge of a Sessions Court for a decision;
 - (c) the Magistrate or Judge to whom the matter is referred shall issue a summons requiring the person asserting that he is the owner of the thing seized and the person from whom it was seized to appear before him and on his appearance or default to appear, due service of the summons having been proved, the Magistrate or Judge shall proceed to the examination of the matter and, on proof that an offence under this Act has been committed and that the thing seized was the subject matter of or was used in the commission of such offence, shall order the thing to be forfeited and shall, in the absence of such proof, order its release.
- (5) If—
- (a) an Inspector who has seized any blood, blood product, human tissue or fluid or any product of the human body, dialysate, chemical, pharmaceutical or any other thing under section 89 or 90 is satisfied that the blood, blood product, human tissue or fluid or any product of the human body, dialysate, chemical, pharmaceutical or any other thing, contains a prescribed contaminant; and
 - (b) the blood, blood product, human tissue or fluid or any product of the human body, dialysate, chemical, pharmaceutical or any other thing is not required or is no

longer required to be retained for the purpose of any legal proceedings,

the Inspector shall cause the blood, blood product, human tissue or fluid or any product of the human body, dialysate, chemical, pharmaceutical or any other thing, to be destroyed.

No person entitled to costs, *etc.*, on seizure

97. No person shall, in any proceedings before any court involving any thing seized in the exercise or the purported exercise of any power conferred under this Part, be entitled to the costs of such proceedings or to any damages or other relief other than an order for the return of the thing seized unless such seizure was made without reasonable or probable cause.

Production of official identification card or badge

98. An Inspector exercising powers under this Part shall at all times carry an official identification card or badge in such form as may be prescribed, and no person shall be obliged to admit to his private healthcare facility or premises any person purporting to be an Inspector except upon production of the identification card or badge.

Compounding of offences

99. (1) The Director General may compound any offence committed by a private healthcare facility or service under this Act which is prescribed to be a compoundable offence by making a written offer to the holder of the approval or the licensee or holder of a certificate of registration or a person in charge of a private healthcare facility or service to compound the offence upon the payment to the Director General—

- (a) such sum of money as may be specified in the offer but which shall not be more than fifty per centum of the maximum fine to which the holder of the approval or the

licensee or holder of certificate of registration would have been liable if he or it had been convicted of the offence; and

(b) within such time as may be specified in the offer.

(2) No offer to compound shall be made without the written consent of the Public Prosecutor.

(3) An offer under subsection (1) may be made at any time after the offence has been committed but before any prosecution for it has been instituted.

(4) Where an offence has been compounded—

(a) no further proceedings shall be taken and no prosecution shall be instituted against the holder of the approval, licensee, holder of a certificate of registration or person to whom the offer to compound was made; and

(b) any book, record, document, apparatus, equipment, instrument, material, article, substance or any other thing seized in connection with the offence, may be released subject to such conditions as may be imposed.

(5) Any money received by the Director General under this section shall be paid into and form part of the Federal Consolidated Fund.

(6) Where the amount specified in the offer to compound is not paid within the time specified in the offer, or within such extended period as the Director General may grant, prosecution for the offence may be instituted at any time thereafter against the holder of the approval or the licensee or holder of the certificate of registration or the person to whom the offer was made.

Institution and conduct of prosecution

100. (1) A prosecution in respect of an offence under this Act shall not be instituted except by or with the consent in writing of the Public Prosecutor.

(2) Any officer authorized in writing by the Public Prosecutor under the Criminal Procedure Code may prosecute in any Court any case in respect of any offence under this Act.

(3) A person who is the investigating officer of an offence under this Act shall not prosecute the case in respect of that offence.

PART XVII

POWER OF MINISTER

Appeal

101. (1) Any person may appeal in writing to the Minister if he is aggrieved—

- (a) by the refusal of the Director General to grant him an approval under paragraph 12(b), to grant him a licence under paragraph 19(b), to renew his licence under subsection 22(1) or to grant him a certificate of registration under section 27;
- (b) with any of the terms or conditions imposed on an approval to establish or maintain under paragraph 12(a), a licence to operate or provide under paragraph 19(a), a licence to operate or provide upon its renewal under subsection 22(3) or a registration under section 27;
- (c) by a grant or refusal of an extension of time under subsection 14(2);
- (d) by the varying or refusal to vary a term or condition or purpose under section 24 or section 29;

- (e) by an approval or a refusal to approve any extension or alteration under subsection 40(1) or a transfer, assignment or disposal under subsection 41(3);
- (f) by an order of temporary closure under section 52; or
- (g) by a notice of revocation under subsection 57(2).

(2) The Minister may confirm, vary or rescind the decision appealed against and, in confirming, varying or rescinding the decision, may impose such terms or conditions as he deems just or necessary.

(3) The decision of the Minister under this section shall be final and conclusive.

Power of Minister to issue general directions

102. The Minister may, from time to time, give the Director General or any officer appointed under this Act general directions not inconsistent with the provisions of this Act as to the exercise of the powers and discretion conferred on and the duties required to be discharged by the Director General or officer under this Act.

Power of Minister to exempt

103. (1) The Minister may exempt any or any part of a private healthcare facility or service licensed or registered under this Act from the operation of any of the provisions of this Act—

- (a) subject to such restrictions or conditions as may be stipulated by the Minister, after consulting the Director General; and
- (b) if he is satisfied that such private healthcare facility will not pose any danger to public safety, or will not be operated in a manner that is detrimental to the interest of public health.

(2) Notwithstanding subsection (1), an exemption under this section may be withdrawn at any time and shall cease to have effect from the date of service of notice of such withdrawal.

(3) A decision of the Minister under this section shall be final and conclusive.

Board of Visitors

104. (1) The Minister may appoint a Board of Visitors for each private hospital.

(2) The Minister may determine the terms or conditions of the appointment of any member of the Board of Visitors including its chairman, their duties and functions and the procedure of the Board of Visitors.

(3) The private hospital shall pay to the members of the Board of Visitors such allowance as the Minister may from time to time specify by notification in the *Gazette* for attendance at meetings of the Board and travelling expenses for such attendance in the discharge of their duties as may be determined.

Social or welfare contribution

105. (1) The Minister may prescribe the type of social or welfare contribution or the quantum of social or welfare contribution that shall be provided, and the manner in which it shall be provided, by any private healthcare facility or service.

(2) The Minister may, from time to time, amend the type of social or welfare contribution and the quantum of social or welfare contribution imposed under subsection (1).

(3) A private healthcare facility or service shall provide the social or welfare contribution of the type and quantum prescribed under this section.

(4) Any private healthcare facility or service which fails to comply with subsection (3) commits an offence.

Fee schedule

106. (1) The Minister may make regulations prescribing a fee schedule for any or all private healthcare facilities or services or health related facilities or services.

(2) The Minister may, from time to time, after consulting the Director General, amend the fee schedule by order published in the *Gazette*.

(3) A private healthcare facility or service for which a fee schedule has been prescribed under this section shall comply with such fee schedule.

(4) A private healthcare facility or service which fails to comply with any fee schedule prescribed under this section commits an offence.

Power to make regulations

107. (1) The Minister may make such regulations as appears to him necessary or expedient for carrying out the provisions of this Act.

(2) Without prejudice to the generality of the powers conferred by subsection (1) regulations may be made for all or any of the following purposes:

- (a) to prescribe the manner of applying for an approval to establish or maintain, a licence to provide or operate, or a certificate of registration or a certificate to import and export natural human blood and blood product under this Act, the forms to be used, the fees or charges payable and the form of the approval, licence, certificate of registration and certificate to import and export natural human blood and blood product;

- (b) to prescribe the manner such national registry or registries as may be deemed necessary under this Act are to be kept and maintained;
- (c) to prescribe the terms, conditions and restrictions to be imposed on any approval, licence, certificate of registration or certificate and restrictions to be imposed on the applicant, licensee, holder of the certificate of registration, holder of the certificate or a person in charge;
- (d) to prescribe the circumstances under which a duplicate approval, licence or certificate may be issued and the fee payable;
- (e) to provide for the procedure of amendment of any particulars contained in any approval, licence, certificate of registration or certificate or its revocation and the issuance of a new licence, certificate of registration or certificate;
- (f) to prescribe the records to be kept of patients and persons treated in the private healthcare facilities or services including records of births and deaths of children, any miscarriages or stillbirths and of children so born who are removed from the private healthcare facilities or services otherwise than to the custody or care of any parent or person authorized by the parent;
- (g) to prescribe the manner of accessing a patient's medical records and the manner of obtaining a patient's medical report by the patient, the patient's representative or a healthcare provider;
- (h) to prescribe the records to be kept of the staff or any other person employed or engaged by a private healthcare facility or service;
- (i) to prescribe the minimum number of medical staff, dental staff, nursing staff, technical staff and other categories of staff to be employed or engaged in a private healthcare

facility or service and the minimum qualifications and experience required of such staff;

- (j) to prescribe the minimum standards of the apparatus, appliance, equipment, instruments, substance and other things to be provided and maintained by private healthcare facilities or services;
- (k) to prescribe the manner or type of training or continuing technical, medical, dental or nursing education or any other type of healthcare professional education to be provided by private healthcare facilities or services to their staff or any other person employed or engaged by the private healthcare facilities or services;
- (l) to prescribe the minimum standards and specifications in respect of siting, design and construction of private healthcare facilities or services;
- (m) to prescribe the minimum standards of accommodation, sanitation or other amenities in private healthcare facilities or services;
- (n) to prescribe the maximum bed or couch capacity or its equivalent in private healthcare facilities or services;
- (o) to prescribe the minimum standards of cleanliness and hygiene, including infection control, in private healthcare facilities and services;
- (p) to prescribe the minimum standards of safety, quality of care and welfare of patients in private healthcare facilities and services;
- (q) to prescribe the minimum standards and conditions required of services with respect to the collection, screening, processing, distribution, storage, dispensing, disposal and transfusion of human blood and blood products, and dialysate, chemical and pharmaceutical for

haemodialysis treatment and other forms of treatment or service;

- (r) to prescribe the management, control, and superintendence and care of private healthcare facilities and services;
- (s) to provide for acceptable quality assurance and quality control in respect of a private healthcare facilities and services;
- (t) to require the licensee, the holder of a certificate of registration or person in charge of a private healthcare facility or service to maintain such books, records or registers necessary for the proper enforcement and administration of this Act;
- (u) to require the furnishing of specified statistical information to the Director General and the manner of furnishing such information;
- (v) to require notification be given of any births or deaths occurring in a private healthcare facility or service;
- (w) to provide for the notification of the closure of a private healthcare facility or service and the directions to be given prior to closure;
- (x) to prescribe the duties and responsibilities of the healthcare professionals and personnel, Board of Management, Medical Advisory Committee, Medical and Dental Advisory Committee, Nursing Advisory Committee, Midwifery Advisory Committee, and visiting registered medical practitioner;
- (y) to prescribe the manner and form of applying for the transfer of approval, licence or certificate of registration in respect of, and the extension or alteration to, any private healthcare facility;

- (z) to prescribe the requirements and role of volunteers in private healthcare facilities and services, their training and supervision and to prescribe restrictions on their activities;
- (aa) to prescribe all matters relating to policy statements and all matters relating to grievance mechanism;
- (bb) to prescribe the organization of the private healthcare facility or services and the staff thereof;
- (cc) to prescribe the composition and duties and responsibilities of the committees which may be required to be set up by the private healthcare facilities or services;
- (dd) to prescribe the duties and functions of locum tenens and honorary consultants, their qualification, training and experience and supervision and to prescribe restrictions on their activities;
- (ee) to prescribe the types of unforeseeable or unanticipated incidents to be reported, the procedure for reporting, the manner of investigation to be conducted, the report and statistical data to be submitted;
- (ff) to prescribe matters relating to inspection and control;
- (gg) to prescribe the requirements to be satisfied for obtaining a valid consent for any anesthetic procedure, surgical operation or procedure, diagnostic procedure or medical procedure or treatment, the method of obtaining such consent, the conditions under which such consent may be dispensed with and for specifying the age at which and under what conditions a patient may give a valid consent for any anesthetic procedure, surgical operation or procedure, diagnostic procedure or medical procedure or treatment to be performed on a patient;
- (hh) to prescribe the fees that may be charged by private healthcare facilities and services or health-related services;

- (ii) to prescribe matters relating to patients' rights in relation to healthcare services provided by any healthcare facility or service, including patients' privacy, confidentiality of information and access to patients' medical reports and records;
- (jj) to prescribe the minimum standards and requirements for all healthcare facilities, healthcare services and health-related services in relation to any healthcare services provided by any healthcare professional including medical care services, nursing services, allied health services, technical services, services relating to all disciplines of medicine and surgery including obstetrics and gynaecology, anesthesia, surgery, psychiatric, paediatrics, pharmaceutical services, critical care or intensive care services, services relating to medical supply, dietary services, linen and laundry, surgical supply, blood transfusion services, blood bank services, haemodialysis treatment services, rehabilitation services, outpatient and inpatient services, ambulatory care services, radiological or diagnostic imaging services, radiotherapy and radioisotope services, telemedicine services, nursing home services, hospice and palliative care services, services relating to autopsies and mortuaries, ambulance services, other support and ancillary services and all other policies and programmes relating to healthcare services provided and maintained by a private healthcare facility or service;
- (kk) to prescribe any other matter relating to any healthcare or health-related facility or service or any matters which the Minister deems expedient or necessary for the purpose of this Act.

PART XVIII

MISCELLANEOUS

Advertisement

108. No private healthcare facility or service or health-related facility or service shall publish any advertisement—

- (a) in such a manner as to mislead the public on the type or nature of the healthcare facilities or services or health-related facilities or services provided; or
- (b) which is contrary to any direction on advertisement issued by the Director General.

National Register

109. The Director General may establish a National Register relating to blood donation and such register shall contain such particulars as may be prescribed.

Service of notice

110. (1) Every notice or document required or authorized to be served under this Act may be served—

- (a) by delivering a copy thereof to the person to be served;
- (b) by sending a copy thereof by prepaid registered post to the person to be served; or
- (c) by affixing a copy thereof to any conspicuous part of the premises to which it relates.

(2) Where a notice or document is served by prepaid registered post, it shall be deemed to have been served on the day succeeding

the day on which the notice or document would have been received in the ordinary course of post if the notice or document is addressed—

- (a) in the case of an individual, to the person's usual or last known abode or place of business; or
- (b) in the case of a body corporate, partnership or society to its registered place of business.

(3) Where the person or body corporate, partnership or society to whom there has been addressed a registered letter containing any notice which may be given under the provisions of this Act is informed of the fact that there is a registered letter awaiting him or it at the post office, and such person or body corporate, partnership or society refuses or neglects to take delivery of such registered letter, such notice shall be deemed to have been served upon him or it on the date on which he or it was informed.

Delegation by Director General

111. (1) The Director General may delegate to any officer under his control, direction and supervision, by name or office, the exercise or the performance of any power, duty or function conferred or imposed on the Director General under this Act except for the power to compound under section 99.

(2) Any delegation under this section shall not prevent the Director General from himself exercising or performing such delegated power, duty or function.

(3) A delegation made under subsection (1) may—

- (a) be made subject to such conditions, limitations or restrictions as may be specified in the instrument of delegation; and
- (b) be revoked or varied.

Furnishing of information

112. (1) The Director General may from time to time direct the holder of an approval, licensee, holder of a certificate of registration or holder of a certificate to furnish such information on the private healthcare facility or service or the clinic as he may require relating to—

- (a) its staff;
- (b) any apparatus, appliance, equipment or instrument used or to be used;
- (c) the condition, treatment or diagnosis of any of its patients or any person to whom the facilities or services thereof are or have been provided;
- (d) any analytical method or procedure used in carrying out any test; or
- (e) its operation.

(2) A holder of the approval, licensee, the holder of a certificate of registration or a holder of a certificate who refuses or fails to furnish information to the Director General in contravention of subsection (1), or gives any false or misleading information, commits an offence and shall be liable on conviction—

- (a) in the case of a sole proprietor, to a fine not exceeding thirty thousand ringgit or to imprisonment for a term not exceeding six months or to both; and
- (b) in the case of a body corporate, partnership or society to a fine not exceeding fifty thousand ringgit.

(3) Where an offence under subsection (1) is committed by a body corporate, a partnership or a society—

- (a) in the case of a body corporate, the person responsible for the body corporate;

(b) in the case of a partnership, every partner in the partnership;

(c) in the case of a society, its office bearers,

shall also be guilty of the offence and shall be liable on conviction to a fine not exceeding thirty thousand ringgit or to imprisonment for a term not exceeding six months or to both.

(4) Nothing in this section shall authorize—

(a) the Director General or any officer to inspect the medical record of any person treated in a private healthcare facility or service; or

(b) the Director General to obtain any information in respect of any person on any matter in paragraph 112(1)(c),

without the prior consent of that person or his representative.

(5) Notwithstanding subsection (4), the Director General or persons authorized by him in that behalf may inspect any book, document, records or electronic material for the purposes of sections 16, 88, 89, 90 and this section without the prior consent of the patient or person or his representative.

(6) The inspection under subsection (5) shall be for the purpose of determining the compliance by the licensee, holder of certificate of registration or person in charge of a private healthcare facility or service with the provisions of this Act and regulations made under this Act, and the confidentiality of any information of the patient or person obtained during such inspection shall be observed.

(7) For the purposes of subsections (4) and (5), “representative” of a person, means his executor or administrator or next of kin, if the person is deceased, or one of his parents or his guardian if the person is an infant or not capable of giving consent.

Officers deemed to be public servants

113. Every person appointed, or lawfully exercising the powers of a person appointed, under this Act shall be deemed to be a public servant within the meaning of the Penal Code [*Act 574*].

Protection against suit and legal proceedings

114. No action shall lie and no prosecution shall be brought, instituted or maintained against the Government, Minister, Director General, Inspector or any officer of the Government or any person acting under the direction of the Government, Minister, Director General, or Inspector, in any court for anything done or omitted to be done under this Act—

- (a) in good faith;
- (b) in the reasonable belief that it was necessary for the purpose intended to be served thereby; or
- (c) for carrying into effect the provisions of this Act.

Confidentiality of information

115. (1) Every person employed, retained or appointed for the purpose of the administration or enforcement of this Act shall preserve secrecy with respect to all information that comes to his knowledge in the course of his duties and shall not communicate any information to any other person except—

- (a) to the extent that the information is to be made available to the public under this Act;
- (b) in connection with the administration or enforcement of this Act or any proceedings under this Act;

- (c) in connection with any matter relating to professional disciplinary proceedings, to a body established under any law regulating a health profession;
- (d) to the person's counsel, upon the person's request where the information relates to any healthcare service provided to him; or
- (e) with the consent of the patient or legal guardian to whom the information relates.

(2) Any person who contravenes subsection (1) commits an offence and shall be liable on conviction to a fine not exceeding one thousand ringgit.

Private psychiatric hospital, psychiatric nursing home and community mental health centre

116. (1) The licensee or person in charge of a private psychiatric hospital, psychiatric nursing home or community mental health centre shall comply with any written law relating to mental disorders and mentally disordered persons.

(2) An application for the establishment of a private psychiatric hospital or a private psychiatric nursing home shall not be considered for approval until a written law allowing for the establishment of such facilities comes into operation.

General offence and penalty

117. (1) A person who contravenes any of the provisions of this Act for which no express provision making its contravention an offence has been provided commits an offence.

(2) Where no penalty is expressly provided for an offence under this Act, a person who commits such offence shall be liable on conviction—

(a) in the case of a natural person—

- (i) to a fine not exceeding ten thousand ringgit or to imprisonment for a term not exceeding three months or to both; and
- (ii) for a continuing offence to a fine not exceeding five hundred ringgit for every day or part of a day during which the offence continues after conviction;

(b) in the case of a body corporate, partnership or society—

- (i) to a fine not exceeding thirty thousand ringgit; and
- (ii) in the case of a continuing offence, to a fine not exceeding two thousand ringgit for every day or part of a day during which the offence continues after conviction.

(3) Where an offence under subsection (1) is committed by a body corporate, a partnership or a society—

- (a) in the case of a body corporate, the person responsible for the body corporate;
- (b) in the case of a partnership, every partner in the partnership;
- (c) in the case of a society its office bearers, shall also be guilty of the offence and shall be liable, on conviction—
 - (i) to a fine not exceeding ten thousand ringgit or to imprisonment for a term not exceeding three months or to both; and
 - (ii) in the case of a continuing offence, be liable to a fine of five hundred ringgit for every day or part of the day during which the offence continues after conviction.

Contravention of subsidiary legislation

118. Any subsidiary legislation made under this Act may provide that the contravention of any provision in the subsidiary legislation shall be an offence and that the person who commits the offence is punishable, on conviction, with a fine or a term of imprisonment or both but may not provide for the fine to exceed ten thousand ringgit or the term of imprisonment to exceed three months.

PART XIX

SAVING AND TRANSITIONAL PROVISIONS

Repeal

119. The Private Hospitals Act 1971 [*Act 43*] is repealed.

Saving and transitional provisions relating to existing licensed private hospitals, maternity homes and nursing homes

120. (1) All private hospitals, maternity homes and nursing homes licensed or deemed to have been licensed under the Private Hospitals Act 1971 shall, on the date of coming into operation of this Act, be deemed to have been licensed under this Act.

(2) The provisions of this Act shall apply to such private hospitals, maternity homes and nursing homes as if such private hospitals, maternity homes and nursing homes were licensed under this Act.

(3) The Director General may vary or revoke any condition imposed on any private hospital, maternity home and nursing home.

Power of Minister to make additional transitional provisions

121. (1) The Minister may prescribe additional provisions as he considers necessary or expedient for the purpose of removing any

difficulties occasioned by the application of this Act on private hospitals, maternity homes and nursing homes, which have been approved, established or licensed under the Private Hospitals Act 1971.

(2) The power of the Minister under subsection (1) shall include the power to make such modifications so as to give effect to the provisions of this Act.

Saving and transitional provisions relating to existing private medical clinics and private dental clinics

122. A person who immediately before the date of commencement of this Act was maintaining or operating a private medical clinic or private dental clinic may continue to maintain, provide or operate the private medical clinic or private dental clinic without registration under this Act if within the first six months of the date of commencement of this Act an application for registration is made under this Act.

LAWS OF MALAYSIA**Act 586****PRIVATE HEALTHCARE FACILITIES AND SERVICES
ACT 1998****LIST OF AMENDMENTS**

Amending law

Short title

In force from

—NIL—

LAWS OF MALAYSIA

Act 586

**PRIVATE HEALTHCARE FACILITIES AND SERVICES
ACT 1998**

LIST OF SECTIONS AMENDED

Section	Amending authority	In force from
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—NIL—
