



LAWS OF MALAYSIA

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Act 674

PATHOLOGY LABORATORY ACT 2007

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PATHOLOGY LABORATORY ACT 2007

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LAWS OF MALAYSIA**Act 674*****PATHOLOGY LABORATORY ACT 2007**

An Act to provide for the regulation and control of pathology laboratories and for matters connected therewith.

[]

ENACTED by the Parliament of Malaysia as follows:

PART I**PRELIMINARY****Short title and commencement**

1. (1) This Act may be cited as the Pathology Laboratory Act 2007.

(2) This Act comes into operation on a date to be appointed by the Minister by notification in the *Gazette* and the Minister may appoint different dates for the coming into operation of different provisions of this Act.

Interpretation

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

“pathologist” means a registered medical practitioner who possesses the qualifications, training and experience in the discipline of pathology as approved by the Director General;

*NOTE—This Act is not yet in force.

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

“Pathology Laboratory Advisory Committee” means a Pathology Laboratory Advisory Committee established under subsection 46(1);

“medical laboratory technologist” means any person who holds a qualification in medical laboratory technology as approved by the Director General;

“class and speciality” means the classification or categorization of the pathology laboratory into the different level of services according to the class or speciality of the pathology laboratory;

“approval” means an approval to establish or maintain a pathology laboratory granted under paragraph 8(a);

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

“private dental clinic” means a private dental clinic registered under the Private Healthcare Facilities and Services Act 1998 [Act 586];

“private medical clinic” means a private medical clinic registered under the Private Healthcare Facilities and Services Act 1998;

“licence” means a licence to operate or provide a pathology laboratory granted under paragraph 16(a);

“pathology laboratory” means any premises in which pathology services are provided;

“licensed pathology laboratory” means a pathology laboratory in respect of which a licence is in force;

“approved pathology laboratory” means a pathology laboratory in respect of which an approval is in force;

“person in charge” means a person appointed under section 25;

“scientific officer” means any person who holds a qualification in science and having the experience in pathology laboratory as approved by the Director General;

“authorized officer” means any pathologist, scientific officer, medical laboratory technologist or any other person authorized by the Director General under section 52;

“holder of an approval” means a person to whom an approval is granted under this Act;

“licensee” means a person to whom a licence is granted under this Act;

“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;

“pathology services” means any services in the analysis and examination of samples of human tissue or fluid or any other product of the human body or for assessing any change in the physiological state of human beings for the purposes of preventing, diagnosing or treating diseases in human beings;

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

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

“healthcare professional” has the meaning assigned to it in the Private Healthcare Facilities and Services Act 1998;

“record” includes slides, blocks, documents or data in respect of the operation of the pathology laboratory.

*NOTE—Companies Act 1965 [*Act 125*] was repealed by Companies Act 2016 [*Act 777*]*—w.e.f.* 31 January 2017.

PART II

CONTROL OF PATHOLOGY LABORATORY

Approval and licence to establish or maintain, *etc.*, pathology laboratory**3. (1) No person shall—**

- (a) establish or maintain a pathology laboratory in any premises without an approval granted under paragraph 8(a); or
- (b) operate or provide a pathology laboratory without a licence granted under paragraph 16(a).

(2) A person who contravenes subsection (1) commits an offence and shall, on conviction, be liable—

(a) in the case of a sole proprietor—

- (i) to a fine not exceeding two hundred thousand ringgit or to imprisonment for a term not exceeding ten years, or to both; and
- (ii) for 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; or

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

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

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

4. (1) An approval to establish or maintain or a licence to operate or provide a pathology laboratory may only be granted or 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.

PART III

APPROVAL TO ESTABLISH OR MAINTAIN A
PATHOLOGY LABORATORY

Application for approval

5. (1) An application for an approval to establish or maintain a pathology laboratory shall be made to the Director General—

- (a) in the prescribed form and manner;
- (b) accompanied by the prescribed fees; and
- (c) by submitting together with the application—
 - (i) a comprehensive plan for the establishment or maintenance of the proposed pathology laboratory including the site plan, building layout plan, design, construction material and any other prescribed requirement;
 - (ii) the proposed class and speciality to be provided;
 - (iii) the proposed arrangements for manpower recruitment including arrangements for manpower training;
 - (iv) the proposed laboratory equipment for the class and speciality to be provided;

- (v) if the applicant is a body corporate or partnership, a copy of its constituent document, duly verified by a statutory declaration made by an authorized officer of the applicant; and
- (vi) such other information, particulars or documents as may be specified by the Director General 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 a written notice require the applicant to provide any additional information, particulars or documents.

(3) Where any additional information, particulars or documents required under subsection (2) is not provided by the applicant within the period specified in the notice or any extension of time as may be granted by the Director General, the application shall be deemed to be withdrawn and shall not be further proceeded with, without prejudice to a fresh application being made by the applicant.

(4) An application for an approval may be withdrawn by a written notice to the Director General at any time before the application is granted or refused.

Matters to be considered before approval is granted

6. In deciding whether or not to grant an approval to establish or maintain a pathology laboratory, the Director General shall consider the following matters:

- (a) the class and speciality to be provided;
- (b) the extent to which the pathology laboratory is already available in an area;
- (c) the need for the pathology laboratory in an area;
- (d) the future need for the pathology laboratory in an area; or
- (e) any other matter which in his opinion is relevant.

Reasons for refusal to grant approval

7. An application for an approval to establish or maintain a pathology laboratory shall not be granted by the Director General unless he is satisfied that—

- (a) the applicant is capable of providing the pathology laboratory services;
- (b) the applicant is capable of providing adequate and efficient management and administration for the proper conduct of the pathology laboratory;
- (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) where the applicant is a partnership, no partner has been convicted of an offence involving fraud or dishonesty or is an undischarged bankrupt; or
- (e) where the applicant is a body corporate, no member of the board of directors or person responsible for the body corporate has been convicted of an offence involving fraud or dishonesty or is an undischarged bankrupt.

Grant of or refusal to grant approval

8. Upon receiving and having considered the application for an approval to establish or maintain a pathology laboratory, the Director General may—

- (a) grant the approval with or without any terms or conditions and upon payment of the prescribed fees; or
- (b) refuse the application with or without assigning any reason for such refusal.

Duration of approval

9. (1) An approval shall, unless sooner suspended or revoked, be valid for a period not exceeding three years from the date the approval is granted.

(2) Subject to subsection (1), where a holder of an approval faces any technical difficulties in establishing or maintaining a pathology laboratory, he may apply in writing to the Director General for an extension of time accompanied with any proof of the difficulties and the prescribed fees.

(3) The Director General may grant an extension of time applied under subsection (2) with or without any terms or conditions if he is satisfied with the proof submitted under subsection (1).

Separate approval for pathology laboratory

10. A separate approval shall be applied for each pathology laboratory irrespective of whether the pathology laboratory is physically, administratively or organizationally linked with another pathology laboratory.

Approval to specify class and speciality of pathology laboratory

11. An approval to establish or maintain a pathology laboratory shall specify the class and speciality of the pathology service for which it is granted and the purpose for which the pathology laboratory may be established or maintained.

PART IV

LICENCE TO OPERATE OR PROVIDE A PATHOLOGY LABORATORY

Application for licence

12. (1) An application for a licence to operate or provide a pathology laboratory shall be made to the Director General after an approval has been granted to establish or maintain a pathology laboratory—

(a) in the prescribed form and manner;

(b) accompanied by the prescribed fee; and

(c) by submitting together with the application—

(i) the approval letter; and

(ii) any information, particulars and documents as may be specified by the Director General.

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

(3) Where any additional information, particulars or documents required under subsection (2) is not provided by the applicant within the period specified in the notice or any extension of the time as may be granted by the Director General, the application shall be deemed to be withdrawn and shall not be further proceeded with, without prejudice to a fresh application being made by the applicant.

(4) An application for a licence may be withdrawn by a written notice to the Director General at any time before the application is granted or refused.

Application for licence to be made within three years

13. (1) An application for a licence under section 12 shall be made within three years from the date of the granting of the approval in respect of the pathology laboratory.

(2) If no application for a licence is made within the time specified in subsection (1), the approval shall be deemed to have been revoked unless an extension of time is granted by the Director General under subsection 9(3).

Inspection of premises

14. (1) Upon receipt of an application for a licence under section 12, at least two authorized officers shall inspect—

(a) the premises of the pathology laboratory to ascertain that it complies with the site plan, building layout plan, design, construction material and any other prescribed requirements;

- (b) any equipment, material or any other thing found in the pathology laboratory to ascertain that it complies with the requirement or standard as may be prescribed; and
- (c) any record, policy, standard operating procedure, clinical practice guideline, document pertaining to quality management system, manpower requirement, organizational structure or any other matters connected therewith.

(2) Where the authorized officers find that the pathology laboratory does not comply with any of the matter specified under subsection (1), they shall give a written notice to the applicant of the non-compliance and any rectification which shall be made within a specified time and re-inspect the pathology laboratory after the expiry of that period.

(3) The authorized officers shall submit a report of the inspection to the Director General as soon as practicable.

Reasons for refusal to grant licence

15. The Director General may refuse to grant a licence unless—

(a) he is satisfied that—

- (i) where the applicant is a natural person, as to the character and fitness of the applicant;
- (ii) where the applicant is a body corporate, as to the character and fitness of any member of the board of directors; or
- (iii) where the applicant is a partnership, as to the character and fitness of any partner,

and the premises complies with the requirement of subsection 14(1);
and

(b) in his opinion—

- (i) the premises in respect of which the application is made is safe, clean, sanitary and adequately equipped;

- (ii) the staff is adequate or competent for the purpose of the pathology laboratory; and
- (iii) the proposed arrangement for the management of the pathology laboratory is adequate or suitable.

Grant of or refusal to grant licence

16. After having considered an application under subsection 12(1) and the report submitted under subsection 14(3) and after giving it due consideration, the Director General may —

- (a) grant a licence to operate or provide a pathology laboratory with or without any terms or conditions and upon payment of the prescribed fee; or
- (b) refuse the application with or without assigning any reason for such refusal.

Licence to specify class and speciality of pathology laboratory

17. (1) A licence shall specify the class and speciality of pathology laboratory for which it is granted and the purpose for which the licence may be maintained.

(2) A licensee who operates or provides any class and speciality which is not specified in the licence commits an offence and shall, on conviction, be liable —

- (a) in the case of a sole proprietor —
 - (i) to a fine not exceeding fifty thousand ringgit or to imprisonment for a term not exceeding three years, 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; or

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

- (i) to a fine not exceeding one hundred thousand ringgit; 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.

Separate licence for pathology laboratory

18. A separate licence shall be applied for each pathology laboratory irrespective of whether the pathology laboratory is physically, administratively or organizationally linked with another pathology laboratory.

Duration of licence

19. A licence shall, unless sooner suspended or revoked, be valid for a period not exceeding three years.

Licence to be exhibited

20. (1) The licence shall be exhibited in a conspicuous part of the premises of the pathology laboratory.

(2) A licensee who contravenes subsection (1) commits an offence.

Renewal of licence

21. (1) A licensee may make an application for the renewal of a licence not later than one hundred and eighty days before the date of expiry of the licence—

- (a) in the prescribed form and manner;
- (b) accompanied by the prescribed fees; and

(c) by submitting together with the application any information, particulars or documents as may be specified by the Director General.

(2) Upon receipt of the application under subsection (1), the authorized officer may inspect the licensed pathology laboratory.

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

(4) The Director General may refuse to renew a licence if the licensee—

(a) has failed to comply with any of the provisions of this Act; or

(b) has failed to comply with any terms or conditions of the licence.

Additional class and speciality

22. (1) Where a licensee intends to provide additional class and speciality other than the class and speciality specified in the existing licence, he shall make an application for an approval to provide additional class and speciality, and if the approval is granted, he shall make an application for a licence.

(2) Where the Director General approved the application for a licence to provide the additional class and speciality, he shall notify the licensee of his decision and request the licensee to submit the existing licence.

(3) Upon receipt of the existing licence, the Director General shall grant a new licence to the licensee which shall specify the additional class and speciality approved in addition to the class and speciality specified in the existing licence.

(4) The licence granted under subsection (3) shall, unless sooner suspended or revoked, be valid for a period not exceeding the existing licence.

(5) A person who contravenes subsection (1) commits an offence and shall, on conviction, be liable—

(a) in the case of a sole proprietor—

- (i) to a fine not exceeding fifty thousand ringgit or to imprisonment for a term not exceeding one year, 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; or

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

- (i) to a fine not exceeding one hundred thousand ringgit; 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.

Cessation of providing class and speciality

23. (1) Where a licensee intends to cease providing any class and speciality, he shall—

(a) inform the Director General by a written notice of his intention and the date he decides to cease providing the class and speciality; and

(b) submit the existing licence to the Director General.

(2) The notice of cessation shall be accompanied by the prescribed fees.

(3) Upon receiving the notice of cessation and the licence under subsection (1), the Director General may—

(a) issue a direction with regard to the care of patients' samples and medical records including patients' laboratory results in the licensed pathology laboratory; and

- (b) vary the licence by deleting the class and speciality the provision of which is ceased, with or without any additional terms or conditions.

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

PART V

RESPONSIBILITIES OF A LICENSEE OR PERSON IN CHARGE

Responsibilities of licensee

24. (1) A licensee shall—

- (a) appoint a person in charge who shall be responsible in the management and control of the licensed pathology laboratory and the supervision of the staff employed or engaged in different class and speciality of the laboratory;
- (b) inspect the licensed pathology laboratory in such manner and at such frequency as may be prescribed;
- (c) ensure that any healthcare professional employed or engaged in the pathology laboratory is registered under any law regulating their registration;
- (d) ensure that any healthcare professional other than the healthcare professional under paragraph (c) shall possess the qualification and experience as approved by the Director General;
- (e) ensure that samples received and results issued shall be made through a registered medical practitioner or registered dental practitioner accordingly;
- (f) ensure that medical and dental management of the patients vests in a registered medical practitioner and a registered dental practitioner respectively;
- (g) maintain a policy to comply with any code of professional conduct issued by the relevant body governing the healthcare professional under paragraph (c);

- (h) establish and maintain the methods to be followed and the minimum standards to be observed in the use, maintenance, storage or disposal of equipment, dangerous substances or other hazardous materials in the licensed pathology laboratory;
- (i) establish and maintain the measures to be taken and the practices to be followed or avoided for the protection and safety of the public, persons employed or engaged in, and the working environment of the licensed pathology laboratory; and
- (j) comply with other duties and responsibilities as may be specified by the Director General.

(2) A person who contravenes subsection (1) commits an offence and shall, on conviction, be liable—

(a) in the case of a sole proprietor—

- (i) to a fine not exceeding one hundred thousand ringgit or to imprisonment for a term not exceeding five 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; or

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

- (i) to a fine not exceeding two hundred thousand ringgit; and
- (ii) for 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.

Person in charge

25. (1) A person in charge of a licensed pathology laboratory shall hold such qualification, have undergone such training and possess such experience as may be specified by the Director General.

(2) Notwithstanding subsection (1), a licensee who is a sole proprietor, may appoint himself as a person in charge.

(3) If a licensee holds more than one licence, he shall appoint a different person to be a person in charge of different class and speciality in each licensed pathology laboratory.

Change of person in charge

26. (1) A licensee shall notify the Director General within fourteen days of its occurrence of any change in the person in charge of any class and speciality of the licensed pathology laboratory to which the licence relates and of the qualifications, training and experience of the new person in charge.

(2) A person who contravenes subsection (1) commits an offence.

Grievance mechanism

27. (1) The licensee shall establish a plan for grievance mechanism for clients of the licensed pathology laboratory.

(2) A person who contravenes subsection (1) commits an offence and shall, on conviction, be liable—

(a) in the case of a sole proprietor—

- (i) to a fine not exceeding thirty thousand ringgit or to imprisonment for a term not exceeding two years, 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; or

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

- (i) to a fine not exceeding fifty thousand ringgit; 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.

Incident reporting

28. (1) Notwithstanding any other report required by any other written law, the licensee shall report to the Director General, any unforeseeable or unanticipated incidents as may be prescribed.

(2) A person who contravenes subsection (1) commits an offence and shall, on conviction, be liable—

(a) in the case of a sole proprietor—

- (i) to a fine not exceeding fifty thousand ringgit or to imprisonment for a term not exceeding three years, 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; or

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

- (i) to a fine not exceeding one hundred thousand ringgit; 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.

Records to be kept and produced

29. (1) The licensee shall keep or caused to be kept records relating to the operation of the licensed pathology laboratory for a period as may be specified by the Director General.

(2) The Director General may require the licensee to produce the records for inspection.

(3) A person who fails to keep or refuses to produce the records under subsection (1) or (2) commits an offence and shall, on conviction, be liable—

(a) in the case of a sole proprietor—

- (i) to a fine not exceeding thirty thousand ringgit or to imprisonment for a term not exceeding two years, 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; or

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

- (i) to a fine not exceeding fifty thousand ringgit; 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.

PART VI

SUSPENSION AND REVOCATION OF APPROVAL OR LICENCE

Suspension or revocation of approval or licence

30. (1) The Director General may suspend or revoke an approval or a licence if he is satisfied that—

(a) the holder of an approval or the licensee has—

- (i) obtained the approval or licence by any false or misleading statement;
- (ii) breached any term or condition imposed by the Director General on the approval or licence;

- (iii) failed to comply with any of the provisions of this Act;
 - (iv) been convicted for an offence under this Act or any other written law;
 - (v) failed to comply with any directive, order or guideline given to him or it by the Minister or the Director General;
 - (vi) used the premises to which the approval or licence relates contrary to the purpose of which the approval or licence is granted;
 - (vii) operated or provided the licensed pathology laboratory in a manner which is detrimental to the interest of the public as the Director General may decide;
 - (viii) established or maintained policies or issued directives that result in the healthcare professional employed or engaged by the pathology laboratory contravening the code of professional conduct issued by the relevant body governing such healthcare professional;
 - (ix) ceased to operate or provide the licensed pathology laboratory for more than thirty days without prior notice given and approval obtained from the Director General; or
 - (x) failed to maintain the standard and quality required for the operation of the licensed pathology laboratory; or
- (b) where the holder of an approval or the licensee—
- (i) is a sole proprietor, whose name has been struck off or suspended from the Malaysian Medical Register pursuant to subparagraph 30(i) or (ii) of the Medical Act 1971; or
 - (ii) is a body corporate or partnership, which does not remove a member of its board of directors or

partner, as the case may be, who is a registered medical practitioner, whose name has been struck off or suspended from the Malaysian Medical Register pursuant to subparagraph 30(i) or (ii) of the Medical Act 1971.

Show cause notice

31. The Director General may, before suspending or revoking an approval or a licence, give the holder of the approval or the licensee a show cause notice in writing of his intention to do so and require the holder of the approval or the licensee to make a representation within twenty one days from the date the notice is received by the holder of the approval or the licensee as to why the approval or the licence should not be suspended or revoked.

Power of Director General to suspend or revoke

32. (1) The Director General shall, after the expiry of the period of twenty-one days and after considering any representation made by the holder of an approval or the licensee under section 31, decide whether to suspend or revoke the approval or the licence or to take no further action.

(2) Where the Director General decides to suspend an approval or a licence, he shall issue to the holder of the approval or the licensee a suspension order with recommendations for rectification and on how to manage a patient's sample or medical records including a patient's laboratory result with or without any terms or conditions.

(3) The suspension order issued under subsection (2) shall take effect from the date on which the suspension order is served on the holder of an approval or the licensee.

(4) A suspension order shall be withdrawn if the holder of an approval or the licensee complies with the recommendations for rectification and any terms and conditions as may be specified in the suspension order to the satisfaction of the Director General.

(5) Where a holder of an approval or licensee fails to comply with any recommendation for rectification and any terms and conditions as may be specified in the suspension order to the satisfaction of the Director General, the Director General shall issue a revocation order to the holder of the approval or the licensee.

(6) Where the Director General decides to revoke an approval or a licence, he shall issue to the holder of the approval or the licensee a revocation order with recommendations on how to manage a patient's sample or medical records including a patient's laboratory result.

(7) The revocation order issued under subsections (5) and (6) shall take effect from the date on which the revocation order is served on the holder of the approval or the licensee.

Effect of suspension

33. (1) Where a suspension order is issued under subsection 32(2)—

(a) to the holder of an approval, he shall immediately cease to establish or maintain the pathology laboratory; or

(b) to a licensee, he shall—

(i) immediately cease to operate or provide partly or wholly the licensed pathology laboratory; and

(ii) comply with recommendations on how to manage a patient's sample or medical records including a patient's laboratory result as may be specified in the suspension order.

(2) A person who contravenes subsection (1) commits an offence and shall, on conviction, be liable—

(a) in the case of a sole proprietor—

(i) to a fine not exceeding two hundred thousand ringgit or to imprisonment for a term not exceeding ten years, or to both; and

- (ii) for 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; or

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

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

Effect of revocation

34. (1) Where a revocation order is issued under subsection 32(5) or (6)—

(a) to the holder of an approval, he shall immediately cease to establish or maintain the pathology laboratory; or

(b) to the licensee, he shall—

- (i) immediately cease to operate or provide partly or wholly the licensed pathology laboratory; and
- (ii) comply with recommendations on how to manage a patient's sample or medical records including a patient's laboratory result as may be specified in the revocation order.

(2) An approved pathology laboratory or licensed pathology laboratory under subsection (1) shall be closed—

(a) where there is no appeal against the revocation order, on the expiration of fourteen days from the date on which the revocation order is served on the holder of an approval or the licensee; or

(b) where there is an appeal against the revocation order, and—

- (i) the revocation order is confirmed by the Minister without any terms or conditions, from the date of the confirmation; or
- (ii) the appeal is confirmed by the Minister with terms and conditions, from the date the licensee fails to comply with the terms and conditions.

(3) Where an approval or a licence has been revoked, the holder of the approval or the licensee shall surrender the approval or the licence to the Director General within fourteen days after the closure of the approved pathology laboratory or the licensed pathology laboratory.

(4) A person who contravenes this section commits an offence and shall, on conviction, be liable—

(a) in the case of a sole proprietor—

- (i) to a fine not exceeding two hundred thousand ringgit or to imprisonment for a term not exceeding ten years, or to both; and
- (ii) for 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; or

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

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

PART VII

CLOSURE OF PATHOLOGY LABORATORY

Order for closure of pathology laboratory

35. (1) The Director General may, if it appears to him that the continued operation of any licensed pathology laboratory would pose a grave danger to the public, by a written notice order the closure of the licensed pathology laboratory for such period and upon such terms and conditions or direction as he thinks fit, and may take such other measures as are necessary to protect the public from the grave danger.

(2) Any order under subsection (1) shall be served on the licensee or any person in charge of the licensed pathology laboratory and shall take effect from the date the order is served.

(3) A person who fails to comply with the order issued under subsection (1) commits an offence and shall, on conviction, be liable—

(a) in the case of a sole proprietor—

- (i) to a fine not exceeding two hundred thousand ringgit or to imprisonment for a term not exceeding ten years, or to both; and
- (ii) for 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; or

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

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

Closure of a licensed pathology laboratory

36. (1) Where a licensee intends to close a licensed pathology laboratory, he shall give the Director General not less than thirty days notice in writing of his intention and the date the closure is to take effect.

(2) Upon receiving the notice under subsection (1), the Director General may issue an order with regard to the care of a patient's samples or medical records including a patient's laboratory results in the licensed pathology laboratory.

(3) The licensee shall comply with the order issued under subsection (2) before closing the licensed pathology laboratory.

(4) The closure of the licensed pathology laboratory shall take effect on the date specified in the notice under subsection (1) and within fourteen days of that date, the licensee shall surrender the licence.

(5) A notice to close the licensed pathology laboratory may be withdrawn by a written notice to the Director General at any time before the closure takes effect.

(6) A person who contravenes subsection (1) or (4) commits an offence.

(7) A person who contravenes subsection (3) commits an offence and shall, on conviction, be liable—

(a) in the case of a sole proprietor—

- (i) to a fine not exceeding fifty thousand ringgit or to imprisonment for a term not exceeding three years, 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; or

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

- (i) to a fine not exceeding one hundred thousand ringgit; 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.

No costs, damages, *etc.*, on order for closure

37. No person shall, in any proceedings before any court in respect of an order for closure of a licensed pathology laboratory under subsection 35(1), be entitled to the costs of the proceedings or to any damages or other relief for any financial loss suffered by reason of the closure, notwithstanding that the licensed pathology laboratory has complied with all the provisions of this Act.

PART VIII

**GENERAL PROVISIONS RELATING TO APPROVAL OR
LICENCE**

Power to vary terms or conditions of approval or licence

38. The Director General may, on an application in writing to him and upon payment of the prescribed fees, vary the terms and conditions of an approval or a licence by endorsement thereon or otherwise in writing by altering, in such manner as he thinks fit, the purpose to which the pathology laboratory is established or maintained or operated or provided, or the class and speciality of the pathology laboratory to which the licence is in force.

Assessment of operation

39. (1) A licensee shall, if required by the Director General to do so, submit any record or other information relating to the operation of the licensed pathology laboratory in respect of which a licence has been granted for the purposes of assessment or examination of the pathology services provided.

(2) In submitting any record or other information for assessment or examination under subsection (1), the licensee shall pay to the Director General the costs of the assessment or examination and any other costs as may reasonably be incurred in connection with the assessment or examination.

(3) The Director General may, after having considered the record or information submitted under subsection (1) and after being satisfied that the licensed pathology laboratory has failed to maintain the standard or quality required of its operation in respect of which the licence has been granted, suspend or revoke the licence.

(4) The costs payable under subsection (2) shall be determined by the Director General.

(5) A person who contravenes subsection (1) commits an offence.

Restriction on use of premise

40. (1) The premise to which an approval or licence relates shall not be used for any purpose other than the purpose in respect of which the approval or the licence is granted and purposes reasonably incidental thereto.

(2) A person who contravenes subsection (1) commits an offence and shall, on conviction, be liable—

(a) in the case of a sole proprietor—

- (i) to a fine not exceeding fifty thousand ringgit or to imprisonment for a term not exceeding three years, 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; or

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

- (i) to a fine not exceeding one hundred thousand ringgit; 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.

Prohibition on extension and alteration

41. (1) Unless with prior written approval of the Director General, no person shall make any structural extension or alteration to any licensed pathology laboratory, or to any part thereof which affects—

- (a) the purpose for which the licensed pathology laboratory was operated or provided;
- (b) any of the terms or conditions of the approval or licence; or
- (c) any prescribed requirements or standards of the licensed pathology laboratory.

(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) A person who contravenes subsection (1) commits an offence and shall, on conviction, be liable—

(a) in the case of a sole proprietor—

- (i) to a fine not exceeding thirty thousand ringgit or to imprisonment for a term not exceeding two years, 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; or

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

- (i) to a fine not exceeding fifty thousand ringgit; 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.

Transfer of approval or licence

42. (1) A holder of an approval or a licensee shall not transfer or assign the approval or the licence except with the prior written approval of the Director General.

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

(3) The Director General may approve the transfer or assignment of an approval or a licence subject to the terms and conditions as he may impose or refuse the application for the transfer or assignment, with or without assigning any reason.

(4) A person who contravenes subsection (1) commits an offence and shall, on conviction, be liable—

(a) in the case of a sole proprietor—

- (i) to a fine not exceeding one hundred thousand ringgit or to imprisonment for a term not exceeding five 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; or

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

- (i) to a fine not exceeding two hundred thousand ringgit; and
- (ii) for 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.

Register

43. (1) The Director General shall keep and maintain or cause to be kept and maintained a register of the approved pathology laboratory or the licensed pathology laboratory.

(2) The register under subsection (1) shall be deemed to be a 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 register upon payment of a prescribed fee.

PART IX

QUALITY OF PATHOLOGY LABORATORY

Quality of pathology laboratory

44. (1) A licensed pathology laboratory shall have programmes and activities as may be prescribed to ensure the quality of services provided by the licensed pathology laboratory.

(2) The licensee shall furnish any information in respect of the programmes and activities to the Director General as and when required by the Director General.

(3) A person who contravenes subsection (1) commits an offence and shall, on conviction, be liable—

(a) in the case of a sole proprietor—

- (i) to a fine not exceeding fifty thousand ringgit or to imprisonment for a term not exceeding three years, 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; or

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

- (i) to a fine not exceeding one hundred thousand ringgit; 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.

(4) A person who contravenes subsection (2) commits an offence and shall, on conviction, be liable—

(a) in the case of a sole proprietor—

- (i) to a fine not exceeding ten thousand ringgit or to imprisonment for a term not exceeding one year, 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; or

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

- (i) to a fine not exceeding thirty thousand ringgit; 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.

Power of Director General to give directives

45. (1) Notwithstanding subsection 44(1), the Director General may issue directives, orders or guidelines relating to the quality and standards of a licensed pathology laboratory as he thinks necessary.

(2) Where the Director General is of the opinion that any prescribed requirement or standard which applies to a licensed pathology laboratory is not being observed by a licensee, the Director General may give to the licensee such directives in writing as he thinks necessary for the observance of the requirement or standard and shall state in the directives the period within which the licensee is required to comply with the directives.

(3) Where the Director General is of the opinion that the use of any equipment in a licensed pathology laboratory or the manner in which any product of the human body 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 intended,

the Director General may, by a written notice, direct the licensee to stop using the equipment or product of the human body or to stop the activity.

(4) The Director General may, by a written notice, further direct the licensee to install or replace such equipment or replace the activity therein, and to adhere to such procedures as may be specified in the notice.

(5) The licensee who fails to comply with the directives of the Director General under this section commits an offence.

PART X

PATHOLOGY LABORATORY ADVISORY COMMITTEE

Pathology Laboratory Advisory Committee

46. (1) Each licensee shall establish a Pathology Laboratory Advisory Committee for the licensed pathology laboratory which membership, duties and responsibilities shall be as may be prescribed.

(2) A person who contravenes subsection (1) commits an offence.

PART XI

MANAGED CARE ORGANIZATION

Interpretation

47. (1) For the purpose of this Part, “managed care organization” means any organization or body with whom a licensed pathology laboratory enters into a contract or has an arrangement or intends to enter into a contract or have an arrangement to provide specified quality or quantity of pathology services within a specified financing system through one or a combination of the following mechanisms:

(a) providing pathology services 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; or

- (b) providing pathology services to employees or enrollees on behalf of the payers 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 organization or body that enters into a pathology laboratory services arrangement, other than those specified in subsection (1), to be a managed care organization.

Contract between licensed pathology laboratory and managed care organization

48. (1) No licensee shall enter into a contract or make any arrangement with any managed care organization that results in—

- (a) a change in the duties or responsibilities of the Pathology Laboratory Advisory Committee;
- (b) the contravention of the code of professional conduct issued by the relevant body governing the healthcare professional; or
- (c) the contravention of any provisions of this Act or any other written law.

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

- (a) in the case of a licensee who is a sole proprietor, to a fine not exceeding fifty thousand ringgit or to imprisonment for a term not exceeding three years, or to both;
- (b) in the case of a licensee who is a body corporate or partnership, a fine not exceeding one hundred thousand ringgit; or

- (c) in the case of a managed care organization, a fine not exceeding one hundred thousand ringgit.

(3) Where an offence under subsection (2) is committed by a managed care organization, the person responsible for the managed care organization shall also be guilty of the offence and shall, on conviction, be liable to a fine not exceeding fifty thousand ringgit or to imprisonment for a term not exceeding five years, or to both.

Obligation to furnish information on contract with managed care organization

49. (1) A licensee who enters into a contract or has an arrangement with a managed care organization shall furnish such information relating to the contract or arrangement to the Director General as may be required by the Director General.

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

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

Information by managed care organization

50. (1) A managed care organization which enters into a contract or has an arrangement with a licensee shall furnish such information relating to the managed care organization as may be required by the Director General.

(2) A managed care organization who refuses or fails to furnish the information required under subsection (1) or furnishes false or misleading information commits an offence and shall, on conviction, be liable to a fine not exceeding fifty thousand ringgit.

(3) Where an offence under subsection (2) is committed, the person responsible for the managed care organization shall also be guilty of the offence and shall, on conviction, be liable to a fine not exceeding thirty thousand ringgit or to imprisonment for a term not exceeding two years, or to both.

Register of managed care organization

51. (1) The Director General shall keep and maintain a register of managed care organizations which enter into any contract or have any arrangement with any licensee and such register may contain such particulars as may be determined by the Director General.

(2) The register under subsection (1) shall be deemed to be a public document within the meaning of the Evidence Act 1950 and shall be open for public inspection and the public may make a search on and obtain extracts from the register upon payment of a prescribed fee.

PART XII

ENFORCEMENT

Appointment of authorized officer

52. (1) The Director General may appoint in writing such number of persons to be authorized officer as he thinks necessary for the purposes of this Act.

(2) An authorized officer may exercise all of the powers vested in him under this Act.

(3) The appointment of an authorized officer shall be published in the *Gazette* as soon as practicable.

Power of authorized officer to enter and inspect

53. (1) An authorized officer shall have the power to enter and inspect at any time any licensed pathology laboratory or any premises which he suspects or has reason to believe is being used as a pathology laboratory without licence.

(2) In the course of an inspection under this section, the authorized officer may—

- (a) test, examine, take, remove or detain any equipment used or found in the pathology laboratory or premises;
- (b) test, examine, take, remove or detain samples of blood, blood product, human tissue or fluid or any product of the human body, dialysate, chemical, pharmaceutical, substance or any other similar things found in the pathology laboratory or premises;
- (c) test, examine, take, remove or detain any containers, articles and other things that the authorized officer reasonably believes to contain or to have contained blood, blood product, human tissue or fluid or any product of the human body, dialysate, chemical, pharmaceutical, substance or any other similar things found in the pathology laboratory or premises;
- (d) inspect any test or procedure or operation performed or carried out in the pathology laboratory to ensure compliance with the provisions of this Act; or
- (e) inspect, take, make copies of or make extracts from any record found in the pathology laboratory or premises.

Power to search and seize

54. (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 pathology laboratory or premises has been used or is about to be used for; or
- (b) there is in any pathology laboratory or premises evidence necessary to establish,

the commission of an offence under this Act, the Magistrate may issue a warrant authorising any authorized officer named therein to enter the pathology laboratory or premises at any reasonable time by day or by night with or without assistance and if need be by force and there to—

- (i) search the pathology laboratory and seize any book, record, 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 that is reasonably believed to furnish evidence of the commission of the offence;
- (ii) take samples of any sample, blood, blood product, human tissue or fluid or any product of the human body, dialysate, chemical, pharmaceutical, substance or any other thing found in the pathology laboratory or premises for the purpose of ascertaining, by testing or otherwise, whether an offence has been committed; and
- (iii) make copies of or take extracts from any book, record, material or any other article found in the pathology laboratory or premises.

(2) An authorized officer may in the exercise of his powers under this section if it is necessary to do so—

- (a) break open any outer or inner door of, or any fence, enclosure, gate or other obstruction to the pathology laboratory or premises, in order to effect entry;
- (b) remove by force any obstruction to entry, search, seizure or removal as he is empowered to effect; and
- (c) detain every person found in the pathology laboratory or premises until the pathology laboratory or premises has been searched.

(3) Where the pathology laboratory or premises is mobile in nature, the authorized officer may seize the pathology laboratory or premises.

Search and seizure without warrant

55. If an authorized officer has reasonable cause to believe that by reason of delay in obtaining a search warrant under section 54—

- (a) the investigation would be affected;
- (b) the object of the entry is likely to be frustrated; or
- (c) the book, record, 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 which are the evidence of contravention is likely to be tampered with, removed, damaged or destroyed,

he may enter the pathology laboratory or premises and exercise, in respect of the pathology laboratory or premises, all the powers referred to in section 54 as if he were authorized to do so by a warrant issued under that section.

Access to computerized data

56. (1) An authorized officer conducting a search under this Act shall be given access to computerized data whether stored in a computer or otherwise.

(2) For the purpose of subsection (1), the authorized officer shall be provided with the necessary password, encryption code, decryption code, software or hardware or any other means required for his access to enable comprehension of the computerized data.

List of things seized

57. (1) Except as provided in subsection (2), where any book, record, 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 is seized under this Act, the seizing officer shall prepare a list of things seized and a copy of the list shall be given to the licensee, person in charge, or occupier of the pathology laboratory or premises, as the case may be, which has been searched under section 53, 54 or 55.

(2) Where the licensed pathology laboratory or premises is unoccupied, the authorized officer shall whenever possible post a list of the things seized conspicuously on the pathology laboratory or premises.

Release of things seized

58. If any thing has been seized under this Act, the Director General may at any time after that, but before it is forfeited under this Act, release the things seized which are not otherwise required for the purpose of any proceedings under this Act, or for the purpose of any prosecution under any other law, to the person as he determines to be lawfully entitled to the thing, and in such event, neither the Director General nor the Government shall be liable to any proceedings by any person if the seizure and the release of the thing had been effected in good faith.

Power to seal

59. (1) Where, by reason of their nature, size or amount, it is not practicable to remove any book, record, 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 under section 53, 54 or 55, the authorized officer shall by any means—

- (a) place the book, record, 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 in that licensed pathology laboratory or premises; and
- (b) mark, fasten and seal the container, door or opening providing access to the room, compartment or cabinet.

(2) The authorized officer may by any means seal any pathology laboratory or premises where he has reasonable cause to believe that—

- (a) the pathology laboratory is contravening any of the terms and conditions imposed by the Director General or prescribed requirements or standards; or

(b) the premises is being used as a pathology laboratory without being licensed under this Act.

(3) Where any licensed pathology laboratory has been sealed, the licensee shall, within twenty-one days of such sealing produce to the Director General the proof that the licensee has complied with the terms and conditions or prescribed requirements or standards and bear any cost incurred arising out of such action.

(4) Where any premises has been sealed, the person occupying or using the premises as a pathology laboratory shall, within twenty-one days of such sealing produce to the Director General the licence and bear any cost incurred arising out of such action.

(5) The seal under subsection (2) shall be removed if the person referred to in subsection (3) complies with the requirement of that subsection or an order of the court is obtained for such person to cease using the licensed pathology laboratory.

(6) The seal under subsection (2) shall be removed if the person referred to in subsection (4) complies with the requirement of that subsection or an order of the court is obtained for such person to cease using the premises as a pathology laboratory.

(7) It shall be an offence for any person without lawful authority to break, tamper with or damage the seal referred to in subsection (1) or (2) or remove any book, record, apparatus, equipment, instrument, material, article, sample, blood, blood product, human tissue or fluid or any product of the human body, dialysate, pharmaceutical, substance or other things under seal or to attempt to do so.

Power to require attendance of person acquainted with case

60. (1) An authorized officer making an investigation under this Act may by order in writing require the attendance before him of any person who appears to the authorized officer to be acquainted with the facts and circumstances of the case, and such person shall attend as so required.

(2) If any such person refuses to attend as so required, the authorized officer may report such refusal to a Magistrate who shall issue a summons to secure the attendance of such person as may be required by the order made under subsection (1).

Examination of person acquainted with case

61. (1) An authorized officer making an investigation under this Act may examine orally or in writing any person supposed to be acquainted with the facts and circumstances of the case.

(2) The person shall be legally bound to answer all questions relating to such case put to him by the authorized officer, but such person may refuse to answer any questions the answer to which would have a tendency to expose him to criminal charge, penalty or forfeiture.

(3) A person making a statement under this section shall be legally bound to tell the truth, whether or not such statement is made wholly or partly in an answer to questions.

(4) An authorized officer examining a person under subsection (1) shall first inform that person of the provisions of subsections (2) and (3).

(5) A statement made by any person under this section, whether or not caution has been administered to him under subsection (2) shall, whenever possible, be reduced into writing and signed by the person making it or affixed with his thumb-print, as the case may be—

(a) after it has been read to him in the language in which he made it; and

(b) after he has been given an opportunity to make any correction he may wish.

Admissibility of statements in evidence

62. (1) Except as provided in this section, no statement made by any person to an authorized officer in the course of an investigation made under this Act shall be used in evidence.

(2) When any witness is called for the prosecution or for the defence, other than the accused, the court shall, on the request of the accused or the prosecutor, refer to any statement made by the witness to an authorized officer in the course of an investigation under this Act and may then, if the court thinks fit in the interest

of justice, direct the accused to be furnished with a copy of it and the statement may be used to impeach the credit of the witness in the manner provided by the Evidence Act 1950.

(3) Where the accused had made a statement during the course of an investigation, such statement may be admitted in evidence in support of his defence during the course of the trial.

(4) Nothing in this section shall be deemed to apply to any statement made in the course of an identification parade or falling within section 27 or paragraphs 32(1)(a), (i) and (j) of the Evidence Act 1950.

(5) When any person is charged with any offence in relation to—

- (a) the making; or
- (b) the contents,

of any statement made by him to an authorized officer in the course of an investigation made under this Act, the statement may be used as evidence in the prosecution's case.

Duty to assist authorized officer

63. Whenever an authorized officer exercises his powers under this Act it shall be the duty of the licensee or person in charge or an employee of the licensed pathology laboratory or the owner or occupier of any premises used as a pathology laboratory and any person found therein—

- (a) to provide the authorized officer all facilities and assistance as the authorized officer may reasonably require;
- (b) to give the authorized officer all reasonable information required by him in respect of the licensed pathology laboratory 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 licensed pathology laboratory or premises.

Forfeiture of goods, etc., seized

64. (1) Any book, record, 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 seized in exercise of any power conferred under this Act shall be liable to forfeiture.

(2) 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 have been convicted of such offence.

(3) Where there is no prosecution with regard to anything seized, such thing shall be taken and deemed to be forfeited at the expiration of one calendar month from the date of service of a notice to the last known address of the person from whom the thing was seized indicating that there is no prosecution in respect of such thing, unless before that date a claim thereto is made in the manner as set out in subsections (4), (5) and (6).

(4) Any person asserting that he is the owner of the thing seized under subsection (3) and that it is not liable to forfeiture may personally or by his agent authorized in writing give written notice to the authorized officer in whose custody such thing is held that he claims the thing.

(5) On receipt of the notice referred to in subsection (4), the authorized officer shall refer the matter to a Judge of a Sessions Court for a decision.

(6) The Judge to whom a matter is referred under subsection (5) 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 the Judge, and on his appearance or default to appear, due service of the summons having been proved, the 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.

(7) Subject to subsection (2), any things forfeited or deemed to be forfeited shall be delivered to the authorized officer and shall be disposed of in a manner to be determined by the Director General.

(8) If the authorized officer is satisfied that any blood, blood product, human tissue or fluid or any product of the human body, dialysate, chemical, pharmaceutical, substance or any other thing, contains a hazardous contaminant, the authorized officer shall cause the blood, blood product, human tissue or fluid or any product of the human body, dialysate, chemical, pharmaceutical, substance or any other thing, to be destroyed in a manner to be determined by the Director General.

Cost of holding goods, *etc.*, seized

65. Where anything seized under this Act is held in the custody of the Government pending completion of any proceedings in respect of an offence under this Act, the cost of holding such thing in custody shall, in the event of any person being found guilty of an offence, be a debt due to the Government by such person and shall be recoverable accordingly.

Production of official identification card or badge

66. Every authorized officer exercising powers under this Act shall at all times carry an official identification card or badge in such form as may be prescribed and no person shall admit into the pathology laboratory or premises any person purporting to be an authorized officer except upon production of the official identification card or badge.

Compounding of offences

67. (1) The Director General may, with the written consent of the Public Prosecutor, compound any offence which is prescribed to be a compoundable offence committed by any person under this Act by making a written offer to such person to compound the

offence upon payment to the Director General such amount not exceeding fifty per centum of the amount of maximum fine for that offence within such time as may be specified in the offer.

(2) 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 and where the amount specified in the offer 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 person to whom the offer was made.

(3) Where an offence has been compounded under subsection (1)—

- (a) no prosecution shall thereafter be instituted in respect of such offence against the person whom the offer to compound was made; and
- (b) any book, record, apparatus, equipment, instrument, material, article or any other thing seized in connection with the offence, may be forfeited, destroyed or returned to that person, as the Director General deems fit after taking into consideration the nature of the offence and subject to such terms and conditions as may be imposed.

Institution of prosecution

68. No prosecution for or in respect of an offence under this Act shall be instituted except by or with the consent in writing of the Public Prosecutor.

PART XIII

MISCELLANEOUS

Non-application of the Act

69. This Act shall not apply to—

- (a) any public pathology laboratory established, maintained, operated or provided by the Government;

- (b) any pathology laboratory established, maintained, operated or provided by a registered medical practitioner in a private medical clinic for the purpose of performing any tests specified in the First Schedule in the course of treating his patients;
- (c) any pathology laboratory established, maintained, operated or provided by a registered dental practitioner in a private dental clinic for the purpose of performing any of the tests specified in the Second Schedule in the course of treating his patients; or
- (d) any test specified in the Third Schedule conducted by a person in a premises other than a licensed pathology laboratory.

Offences in relation to inspection

70. A person who—

- (a) assaults, impedes, obstructs or interferes with, or refuses an authorized officer access to any pathology laboratory or premises;
- (b) fails to provide assistance, or refuses to furnish the information required by an authorized officer;
- (c) without reasonable excuse fails or refuses to produce any thing required by an authorized officer in the course of his inspection; or
- (d) alters the approval or licence,

shall be guilty of an offence and shall, on conviction, be liable to a fine not exceeding fifty thousand ringgit or to imprisonment for a term not exceeding three years, or to both.

Offences committed by body corporate or partnership

71. (1) Where a body corporate contravenes any provision of this Act or any regulations made thereunder, every person who at the time of the commission of the offence is a director,

manager, secretary or other like officers of the body corporate or was purporting to act in any such capacity or was in any extent responsible for the management of any of the affairs of the body corporate or was assisting in such management—

- (a) may be charged severally or jointly in the same proceedings with the body corporate; and
- (b) be deemed to be guilty of the offence unless, having regard to the nature of his functions in that capacity and to all circumstances, he proves that—
 - (i) the offence was committed without his knowledge, consent or connivance; and
 - (ii) he took all reasonable precautions and had exercised due diligence to prevent the commission of the offence.

(2) Where a partnership contravenes any provision of this Act or any regulations made thereunder, every partner of the partnership at the time of the commission of the offence shall be deemed to have contravened the provision and may be charged jointly in the same proceedings with the partnership, or severally, and every such partner shall be deemed to be guilty of the offence unless he proves that—

- (i) the offence was committed without his knowledge, consent or connivance; and
- (ii) he took all reasonable precautions and had exercised due diligence to prevent the commission of the offence.

(3) A person guilty of an offence under subsection (1) or (2) shall, on conviction, be liable to the same amount of fine and period of imprisonment as the fine and imprisonment imposed on the sole proprietor committing the offence.

Appeal

72. (1) Any person who is aggrieved by any decision of the Director General as specified in subsection (2) may appeal to the Minister in the prescribed form and manner within thirty days from the date the decision is communicated to such person.

(2) The decisions of the Director General which may be appealed are—

- (a) the refusal to grant an approval or licence under this Act;
- (b) the refusal to renew a licence under this Act;
- (c) the imposition of any terms and conditions on an approval or licence under this Act;
- (d) the imposition of any terms and conditions on the renewal of a licence upon its renewal under this Act;
- (e) the refusal of an extension of time under subsection 9(3);
- (f) the issuance of a revocation order under this Act;
- (g) the issuance of an order of closure under subsection 35(1);
- (h) the refusal to approve any extension or alteration under subsection 41(1);
- (i) the refusal to approve any transfer or assignment under subsection 42(3); or
- (j) any other decisions made by the Director General under this Act.

(3) The Minister may, after scrutinizing the appeal, confirm, revoke or vary any decision of the Director General as specified under subsection (2) and impose any terms or conditions to the decision, as he deems just or necessary.

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

Power to exempt

73. (1) The Minister may exempt any licensed pathology laboratory from the application of any of the provisions of this Act subject to such restrictions or conditions as he may imposed.

(2) An exemption under subsection (1) may be withdrawn at any time by the Minister and shall cease to have effect from the date of service of notice of such withdrawal.

Fee schedule

74. (1) The Minister may make regulations prescribing a fee schedule for any licensed pathology laboratory.

(2) The Minister may amend the fee schedule by order published in the *Gazette*.

(3) A licensed pathology laboratory for which a fee schedule has been prescribed under this section shall comply with such fee schedule.

(4) A person who fails to comply with subsection (3) commits an offence and shall, on conviction, be liable—

(a) in the case of a sole proprietor—

- (i) to a fine not exceeding fifty thousand ringgit or to imprisonment for a term not exceeding three years, 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; or

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

- (i) to a fine not exceeding one hundred thousand ringgit; 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.

Advertisement

75. (1) No licensed pathology laboratory shall publish any advertisement—

(a) in such a manner as to mislead the public on the class and speciality of the licensed pathology laboratory;

- (b) which contravenes any written law regulating advertisement for medical matters or purposes; or
- (c) which is contrary to any directive on advertisement issued by the Director General.

(2) A person who contravenes subsection (1) commits an offence and shall, on conviction, be liable—

(a) in the case of a sole proprietor—

- (i) to a fine not exceeding fifty thousand ringgit or to imprisonment for a term not exceeding three years, 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; or

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

- (i) to a fine not exceeding one hundred thousand ringgit; 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.

Delegation by Director General

76. (1) The Director General may delegate to any officer under his control, direction and supervision any of his power, duty or function under this Act, except the power under sections 52 and 67, and when so delegated such power shall be exercised by the officer under the control of and subject to such direction and restriction as may be specified by the Director General.

(2) A delegation under subsection (1) may be revoked at any time by the Director General and shall not prevent the Director General from exercising the delegated powers himself.

Furnishing of information

77. (1) The Director General may from time to time direct the holder of an approval or the licensee to furnish such information on the licensed pathology laboratory as he may require relating to—

- (a) its staff;
- (b) any equipment, materials or any other things used or to be used;
- (c) the diagnosis of any person whose sample has been tested;
- (d) any analytical method or procedure used in carrying out any test;
- (e) its operation;
- (f) all matters relating to policy statement; or
- (g) the duties, functions and experience of *locum tenens* and honorary consultants, their experience and supervision and restrictions on their activities.

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

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

(3) Nothing in this section shall authorize the Director General or any officer authorized by him to inspect the medical record of any person whose sample has been tested in a licensed pathology laboratory or to obtain any information in respect of any person on any matter specified under paragraph (1)(c) without the prior written consent of the person or his representative.

(4) Notwithstanding subsection (3), the Director General or any officer authorized by him may inspect any record or material for the purposes of section 53, 54, 55 or 56 without the prior written consent of the person or his representative.

(5) The inspection under subsection (4) shall be for the purpose of determining the compliance with the provisions of this Act and regulations made under this Act by the licensee, the holder of an approval or the person in charge of the licensed pathology laboratory, and the confidentiality of any information of any person obtained during such inspection shall be observed.

(6) For the purposes of subsections (3) and (4), “representative” of a person means—

- (a) if a person is a deceased, his executor, administrator or next of kin;
- (b) if the person is a minor, his mother, father or guardian; or
- (c) if the person is not capable of giving consent, his next of kin.

Service of notice

78. (1) A notice or order required or authorized to be served under this Act may be served personally or by registered post.

(2) Where a notice or order is served by registered post, it shall be deemed to have been served on the day on which the notice or order would have been received in the ordinary course of the post if the notice or order is addressed—

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

(3) Where the person, body corporate or partnership 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 at the

post office, and such person, body corporate or partnership refuses or neglects to take delivery of such registered letter, such notice shall be deemed to have been served upon him on the date on which he was informed.

Officers deemed to be public servants

79. An authorized officer appointed under this Act shall be deemed to be a public servant within the meaning of the Penal Code [*Act 574*].

Protection of officers

80. No action or prosecution shall be brought, instituted or maintained in any court against—

- (a) the Director General, an authorized officer or any officer duly appointed under this Act for or on account of or in respect of any act ordered or done for the purpose of carrying into effect this Act; and
- (b) any other person for or on account of or in respect of any act done or purported to be done by him under the order, directives or instruction of the Director General, an authorized officer or any officer duly appointed under this Act or if the act was done in good faith in a reasonable belief that it was necessary for the purpose intended to be served thereby.

Disclosure of confidential information

81. (1) Any person who makes use of or discloses to any other person any confidential information obtained by virtue of the provisions of this Act commits an offence.

(2) Nothing in subsection (1) shall operate to prevent the disclosure of information where the disclosure is made—

- (a) for or in connection with the due administration of this Act;

- (b) for the purpose of any legal proceedings;
- (c) for the purpose of any investigation conducted under this Act;
- (d) in connection with any matter relating to professional disciplinary proceedings;
- (e) to a body established under any law regulating a healthcare professional;
- (f) to any counsel who is approved in writing by the client of the licensed pathology laboratory, requesting for the information which relates to any pathology services provided to that person;
- (g) to any person or any officer who is approved in writing by the Minister as a proper person to receive the information; or
- (h) for or in connection with the preparation by the Government of relevant health statistics or health registries in respect of the operation of this Act.

(3) Any person who contravenes subsection (1) commits an offence and shall, on conviction, be liable to a fine not exceeding fifty thousand ringgit or to imprisonment for a term not exceeding three years, or to both.

Social or welfare contribution

82. (1) The Minister may prescribe the type of social or welfare contribution or the quantum of social or welfare contribution not inconsistent with the provision of this Act that shall be provided by any licensed pathology laboratory.

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

(3) Any licensed pathology laboratory which fails to comply with subsection (1) commits an offence.

General offence and penalty

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

(a) in the case of a sole proprietor—

- (i) to a fine not exceeding ten thousand ringgit or to imprisonment for a term not exceeding one year, 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; or

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

- (i) to a fine not exceeding thirty thousand ringgit; 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.

Contravention of subsidiary legislation

84. 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 shall, on conviction, be liable to a fine or a term of imprisonment, or both but may not provide for a fine which exceeds ten thousand ringgit or a term of imprisonment which exceeds one year.

Power to amend Schedule

85. The Minister may from time to time amend the Schedules by order published in the *Gazette*.

Power to make regulations

86. (1) The Minister may make such regulations as may be necessary or expedient for the purpose of carrying into effect the provisions of this Act.

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

- (a) to prescribe the circumstances under which a duplicate approval or licence may be issued and the fee payable;
- (b) to prescribe the procedure of amendment of any particulars contained in any approval or licence or its replacement with a new approval or licence and the fee payable;
- (c) to prescribe the records of persons whose sample has been tested in the licensed pathology laboratory and the manner in which such records are to be kept and issued;
- (d) to prescribe the manner of accessing a person's laboratory results and the manner of obtaining the laboratory results by the person, the person's representative or a healthcare provider;
- (e) to prescribe the records to be kept of the healthcare professional, staff or any other person employed or engaged by a licensed pathology laboratory;
- (f) to prescribe the minimum number, qualification or experience required of healthcare professionals including pathologists, scientific officers, medical laboratory technologists or other technical staff or other categories of staff to be employed or engaged in a licensed pathology laboratory;
- (g) to prescribe the minimum standards of the equipment, materials and other things to be used, provided and maintained by a licensed pathology laboratory;
- (h) to prescribe the type of training, continuing technical or medical education or any other type of healthcare professional education to be provided by a licensee to the healthcare professional, staff or any other person employed or engaged by the licensed pathology laboratory;

- (i) to prescribe the minimum standards and specifications in respect of design and construction of a licensed pathology laboratory;
- (j) to prescribe the minimum standards of sanitation or other amenities in a licensed pathology laboratory;
- (k) to prescribe the minimum standards of cleanliness and hygiene, including infection control in a licensed pathology laboratory;
- (l) to prescribe the minimum standards and conditions required of pathology services with respect to the collection, screening, analysis, processing, handling, transportation, distribution, storage, or disposal of samples;
- (m) to prescribe the management, control, and supervision of a licensed pathology laboratory;
- (n) to prescribe the acceptable quality assurance and quality control in respect of a licensed pathology laboratory;
- (o) to prescribe the programmes and activities of a licensed pathology laboratory to ensure the quality of services provided;
- (p) to prescribe the form and particulars to be contained in the records or register kept or maintained under this Act;
- (q) to prescribe the statistical information to be furnished by the licensee to the Director General and the manner of furnishing such information;
- (r) to prescribe the procedure for notification of the closure of a licensed pathology laboratory;
- (s) to prescribe the manner and form of applying for the transfer or assignment of the approval or licence in respect of, and the extension or alteration to the licensed pathology laboratory;
- (t) to prescribe the procedure for reporting incidents, the report and statistical data to be submitted by a licensee;

- (u) to prescribe the categorization of pathology laboratories into different classes and specialties which may or may not be performed in particular classes and specialties of licensed pathology laboratories;
- (v) to prescribe the membership, duties and responsibilities of a Pathology Laboratory Advisory Committee; or
- (w) to provide for any matter which under this Act is required or permitted to be prescribed or which are necessary or expedient to be prescribed to give effect to this Act.

Transitional

87. (1) Any person who is operating or providing a pathology laboratory before the commencement of this Act and intends to continue to operate or provide the pathology laboratory on or after such commencement shall, not later than six months from the date of commencement of this Act, apply to the Director General for a licence under this Act.

(2) Pending the decision by the Director General on the application for a licence made under subsection (1), the applicant shall be deemed to be licensed under this Act and no action shall be taken against the applicant for operating or providing a pathology laboratory without a licence.

(3) Where a licence is granted by the Director General under paragraph 16(a) pursuant to an application made under subsection (1), the applicant shall within six months from the date the licence is granted, take the necessary action to comply with the terms and conditions imposed in the licence, if any.

(4) Where a licence is not granted by the Director General under paragraph 16(b), the applicant referred to in subsection (2) shall cease to be deemed to be licensed under that subsection from the date the applicant is notified of the decision of the Director General or, if there is an appeal under section 72, the date of the decision of the Minister on that appeal.

FIRST SCHEDULE

[Paragraph 69(b)]

TESTS EXEMPTED WHEN PERFORMED BY REGISTERED
MEDICAL PRACTITIONER IN HIS OWN PREMISES

Blood glucose estimation

Haematocrit estimation

Haemoglobin estimation

Erythrocyte sedimentation rate

Total and differential white cell count

Platelet count

Clotting time

Bleeding time

Examination of blood film

Microscopic examination of urine

Microscopic examination of Gram and Ziehl-Nielson stained film

Microscopic examination for fungi in skin, hair and nails

Rapid Plasma Reagin card test

Pregnancy test by immune chemical method

Chemical test for occult blood

Sreening test for urine by using dipstick or its equivalent

SECOND SCHEDULE

[Paragraph 69(c)]

TESTS EXEMPTED WHEN PERFORMED BY REGISTERED
DENTAL PRACTITIONER IN HIS OWN PREMISES

Blood glucose estimation

Haematocrit estimation

Haemoglobin estimation

Total and differential white cell count

Platelet count

Clotting time

Bleeding time

Rapid Plasma Reagin card test

Screening test for urine by using dipstick or its equivalent

THIRD SCHEDULE

[Paragraph 69(d)]

TESTS EXEMPTED GENERALLY

Blood glucose estimation by using simple instrumentation specifically designed for home use

Urine test for glucose

Urine pregnancy test

LAWS OF MALAYSIA

Act 674

PATHOLOGY LABORATORY ACT 2007

LIST OF AMENDMENTS

Amending law	Short title	In force from
	– NIL –	

LAWS OF MALAYSIA**Act 674****PATHOLOGY LABORATORY ACT 2007****LIST OF SECTIONS AMENDED**

Section	Amending authority	In force from
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– NIL –
