

PRIVATE HOSPITALS AND MEDICAL CLINICS ACT
(CHAPTER 248, SECTION 22)

PRIVATE HOSPITALS AND MEDICAL CLINICS
REGULATIONS

ARRANGEMENT OF REGULATIONS

PART I

GENERAL

Regulation

1. Citation
2. Definitions
3. Application for licence
4. General duty of licensee
5. Licence fees
6. Renewal of licence
7. Display of licence
8. Advertisement of services
9. Notification of cessation, etc., of private hospital, medical clinic, clinical laboratory or healthcare establishment
10. Persons who may manage private hospital, etc.
11. Duty of manager of private hospital
12. Records

PART IA

QUALITY ASSURANCE COMMITTEES AND QUALITY ASSURANCE
ACTIVITIES

- 12A. Prescribed healthcare institutions and requirements for quality assurance committees
- 12B. Quality assurance activities

PART II

PRIVATE HOSPITALS

13. Licensee of private hospitals
14. Maternity home
15. Beds and bed utilisation
16. Operation theatres facilities

Regulation

17. Intensive care unit
18. Specialised procedures or services
19. Back-up utility supply
20. Anaesthesia services
21. Blood services
22. Dietetic services
23. Emergency services
24. Laboratory services
25. Medical services
26. Nursing services
27. Pharmaceutical services
28. Drugs, etc.
29. Radiology services
30. Provision of other unrelated services
31. *[Deleted]*
32. Equipment
33. Infection control
34. Fire precautions

PART III

MEDICAL CLINICS

35. Licensee of medical clinics
36. Patients under treatment
37. Special care services
38. Facilities for surgery
39. Facilities for anaesthesia
40. Resuscitation facilities
41. Drugs
42. Equipment
43. Clinic practices
44. Test or examination of samples taken at medical clinic
45. Premises of medical clinic to be properly separated from premises used for other services
46. *[Deleted]*

PART IV

CLINICAL LABORATORIES

47. Person to whom licence for clinical laboratory may be issued

Regulation

48. Responsibilities of licensee
49. Requisite qualifications of person managing clinical laboratory
50. Personnel
51. Facilities
52. Quality control
53. Records of specimens
54. Report on tests
55. Outsourcing of conduct of test and examination of samples
56. Kinds of clinical laboratories

PART IVA

EMERGENCY PREPAREDNESS PLANNING

- 56A. Emergency response plans and emergency response teams
- 56B. Participation in emergency preparedness exercises

PART V

MISCELLANEOUS

57. List of private hospitals, etc.
 58. Exemption
 59. Use of title or name
 60. Penalty
- The Schedules
-

[1st January 1993]

PART I

GENERAL

Citation

1. These Regulations may be cited as the Private Hospitals and Medical Clinics Regulations.

Definitions

2.—(1) In these Regulations, unless the context otherwise requires —

“community health centre” means a medical clinic in which only services in support of any treatment by a medical practitioner (such as services rendered by any health professional other than a medical practitioner) are provided for the management of any chronic illness or disability;

[S 450/2013 wef 01/08/2013]

“electronic licensing system” means the electronic licensing system provided by the Ministry of Health for the purposes of application or renewal of a licence under the Act;

[S 411/2003 wef 01/09/2003]

“licence” means the licence referred to in section 2 of the Act;

“licensee” means the holder of a licence;

“registered midwife” means a person registered as a midwife under the Nurses and Midwives Act (Cap. 209);

“registered nurse” means a person registered as a nurse under the Nurses and Midwives Act.

(2) For the purpose of these Regulations, the reference to the number of beds of a private hospital shall include beds which are located in the premises of another licensed private hospital but which, under an arrangement between the first and second mentioned private hospitals, are intended for the use of patients who are admitted to and who are under the management and care of the first mentioned private hospital.

Application for licence

3.—(1) Every application for the issue or renewal of a licence shall be made to the Director in the appropriate form set out in the electronic licensing system of the Ministry of Health at <http://elis.moh.gov.sg>.

[S 450/2013 wef 01/08/2013]

(2) The Director may make any modification or amendment necessary to the form for an application or renewal of a licence for the purpose of facilitating the submission of that form.

(3) The form for the application or renewal of a licence and any document accompanying the application shall be submitted to the Director —

- (a) using the electronic licensing system;
- (b) by post;
- (c) by telefax; or
- (d) in person.

[S 411/2003 wef 01/09/2003]

General duty of licensee

4.—(1) Every licensee of a private hospital, medical clinic, clinical laboratory or healthcare establishment shall comply with such directions or guidelines as may be given or issued by the Director from time to time in respect of any matter relating to the management, operation, maintenance or use of any private hospital, medical clinic, clinical laboratory or healthcare establishment.

(2) The licensee of a private hospital, medical clinic, clinical laboratory or healthcare establishment shall notify the Director of any changes in the appointment of any person as its manager or deputy manager, within 7 working days from the date of appointment of that person.

Licence fees

5.—(1) The fee payable for any licence or any renewal thereof shall be as specified in the Fourth Schedule, and shall be paid by inter-bank GIRO or such other method of payment as the Director may specify.

(2) *[Deleted by S 450/2013 wef 01/08/2013]*

(3) Where any licence is revoked, the Director may, if he considers appropriate, remit or refund any part of the fee paid under this regulation in respect of the licence.

[S 450/2013 wef 01/08/2013]

(4) Where an application for a licence is withdrawn before the application has been approved, the applicant shall pay an administrative fee of 20% of the licence fee payable for the licence

or \$100, whichever is the greater, and such administrative fee may be deducted from any licence fee already paid for the licence.

(5) An applicant for a licence may, at any time before the licence is issued, apply to the Director to —

(a) amend the name of the private hospital, medical clinic, clinical laboratory or healthcare establishment which appears on the application form he has submitted; or

(b) include another person as a proposed licensee.

(6) Where an application for any amendment under paragraph (5) is made after the application for a licence has been approved by the Director, the Director may, on payment of an administrative fee of \$100, approve the application for the amendment and issue a licence incorporating such amendment.

(7) Subject to paragraph (7A), an application for any amendment to a licence which has been issued shall be made by way of an application for a fresh licence and shall be accompanied by the appropriate fee specified in the Fourth Schedule.

[S 450/2013 wef 01/08/2013]

(7A) Where the application referred to in paragraph (7) is for an amendment to the name of the private hospital, medical clinic, clinical laboratory or healthcare establishment appearing on the licence, the Director may, on payment of a fee of \$100 by the licensee, issue a licence incorporating such amendment.

[S 450/2013 wef 01/08/2013]

(8) Where a licence is lost, damaged or destroyed, the Director may, on the application of the licensee and on payment of a fee of \$100, issue a duplicate licence.

Renewal of licence

6.—(1) Any application for the renewal of a licence shall be made to the Director not later than 2 months before the date of the expiry of the licence.

(2) Where an application for the renewal of a licence is made after the date mentioned in paragraph (1), the applicant shall pay a late

payment fee which shall be 20% of the fee payable for the renewal of the licence or \$100, whichever is the greater.

Display of licence

7. Every person to whom a licence is issued shall display the current licence issued in a conspicuous place at the private hospital, medical clinic, clinical laboratory or healthcare establishment, as the case may be.

Advertisement of services

8. All advertisements of the services of every private hospital, medical clinic or clinical laboratory shall be in accordance with the guidelines issued by the Director.

Notification of cessation, etc., of private hospital, medical clinic, clinical laboratory or healthcare establishment

9.—(1) Where a licensee intends to cease operating, or intends to let, sell or in any way dispose of a private hospital, medical clinic, clinical laboratory or healthcare establishment, he shall notify the Director of his intention in writing not less than 30 days before the cessation of operation, letting, sale or disposal of the hospital, clinic, laboratory or healthcare establishment, as the case may be.

(2) Any licence issued to the licensee shall upon the cessation of operation, letting, sale or disposal of the private hospital, medical clinic, clinical laboratory or healthcare establishment be deemed to be revoked.

(3) Every licensee of a private hospital, medical clinic or healthcare establishment who intends to cease operating or to let, sell or in any way dispose of the private hospital, medical clinic or healthcare establishment shall —

- (a) take all measures as are reasonable and necessary to ensure that, until the cessation of operation, letting, sale or disposal of the private hospital, medical clinic or healthcare establishment is completed, every person who remains a patient thereof continues to be provided with adequate and proper accommodation and care;

- (b) take all measures as are reasonable and necessary to ensure that the medical records of every patient in the hospital, medical clinic or healthcare establishment are properly transferred to the hospital, medical clinic or healthcare establishment to which such patient is to be transferred; and
- (c) comply with such directions as the Director may give with regard to the accommodation, medical records and care of the patients in the hospital, medical clinic or healthcare establishment pending the completion of the cessation of operation, letting, sale or disposal of the private hospital, medical clinic or healthcare establishment, as the case may be.

(4) Every licensee of a clinical laboratory shall comply with any directions as the Director may give with regard to the completion of testing of specimens already received, acceptance of new specimens and other ancillary matters before the cessation of operation, letting, sale or disposal of the clinical laboratory.

Persons who may manage private hospital, etc.

10.—(1) The person who shall manage a maternity home, nursing home, medical clinic, clinical laboratory or healthcare establishment shall be as follows:

- (a) in the case of a maternity home, a medical practitioner, a registered nurse or a registered midwife;
- (b) in the case of a nursing home, a medical practitioner or a registered nurse;
- (c) in the case of a medical clinic used by a medical practitioner, a medical practitioner;
- (d) in the case of a medical clinic used by a dentist, a dentist;
- (e) in the case of a clinical laboratory, a person who has any of the qualifications specified in regulation 49; and
- (f) in the case of a healthcare establishment, a suitably qualified person approved by the Director.

(2) The person who shall manage a private hospital, other than a maternity home or a nursing home, shall be the manager or a person responsible for the administration or management of the hospital.

(3) A person who is responsible for the management of a private hospital, maternity home, nursing home, medical clinic, clinical laboratory or healthcare establishment shall not be absent therefrom for any length of time, unless arrangements are made for the private hospital, maternity home, nursing home, medical clinic, clinical laboratory or healthcare establishment to be placed under the supervision of a person who is similarly qualified to manage that hospital, home, clinic, laboratory or healthcare establishment.

Duty of manager of private hospital

11. Every manager of a private hospital shall ensure that every patient be informed, on or before his admission to the private hospital, of the estimated total charges which are likely to be incurred in respect of his hospitalisation and treatment.

Records

12.—(1) Every licensee of a private hospital, medical clinic or healthcare establishment shall keep and maintain proper medical records and shall in addition cause to be recorded therein in respect of each patient such particulars as may be specified in any guidelines issued by the Director from time to time.

(1A) The licensee under paragraph (1) shall —

- (a) take all reasonable steps, including implementing such processes as are necessary, to ensure that the medical records in paragraph (1) are as accurate, complete and up-to-date as are necessary for the purposes for which they are to be used;
- (b) implement adequate safeguards (whether administrative, technical or physical) to protect the medical records against accidental or unlawful loss, modification or destruction, or unauthorised access, disclosure, copying, use or modification;

- (c) periodically monitor and evaluate the safeguards in sub-paragraph (b) to ensure that they are effective and being complied with by the persons involved in handling the medical records;
- (d) ensure that each person handling the medical records is aware of his role and responsibility in maintaining the confidentiality, integrity and availability of the medical records; and
- (e) take reasonable care in the disposal or destruction of the medical records so as to prevent unauthorised access to the records.

[S 189/2011 wef 15/04/2011]

(2) Every licensee of a clinical laboratory shall keep and maintain laboratory records of all specimens received and examinations conducted by him and the results thereof.

(3) The records referred to in paragraphs (1) and (2) shall be retained by the licensee of the private hospital, medical clinic, clinical laboratory or healthcare establishment for such periods as may be required by the Director.

PART IA

QUALITY ASSURANCE COMMITTEES AND QUALITY ASSURANCE ACTIVITIES

[S 831/2010 wef 02/01/2011]

Prescribed healthcare institutions and requirements for quality assurance committees

12A.—(1) For the purposes of section 11 of the Act, the licensee of every healthcare institution prescribed in the first column of the Sixth Schedule shall —

- (a) establish the quality assurance committee or committees specified in the second column of the Sixth Schedule corresponding to that healthcare institution or the class of healthcare institutions to which that healthcare institution belongs; and

(b) ensure that each quality assurance committee of the healthcare institution complies with the requirements set out in this regulation and in the directives specified in the third column of the Sixth Schedule corresponding to that quality assurance committee, as published on the Internet website of the Ministry of Health at <http://www.moh.gov.sg> and updated from time to time (referred to in this regulation as the directives applicable to that quality assurance committee).

(2) A quality assurance committee of a healthcare institution shall consist of such members of the medical and nursing staff and any other administrative and ancillary staff of the healthcare institution, and such other persons, as may be specified in the directives applicable to that quality assurance committee.

(3) A quality assurance committee of a healthcare institution shall —

(a) maintain an ongoing quality assurance programme in accordance with the directives applicable to that quality assurance committee for the purpose of —

(i) monitoring and evaluating the overall quality and appropriateness of the patient care that is provided, and the practices and procedures that are carried out, by the healthcare institution;

(ii) identifying and solving problems which may from time to time arise in connection with the functions of the healthcare institution; and

(iii) pursuing opportunities for the improvement of the patient care and other services that are provided by the healthcare institution;

(b) carry out the duties and comply with the requirements and processes set out in the directives applicable to that quality assurance committee;

(c) conduct such other quality assurance activity or programme as may be required from time to time by the Director; and

- (d) furnish the Director with such records relating to any quality assurance activity undertaken by the healthcare institution as may be required from time to time by him.
- (4) A copy of every directive specified in the Sixth Schedule may be obtained —
- (a) in print from the office of the Ministry of Health, College of Medicine Building, 16 College Road, Singapore 169854 during such hours as the office is open for business; and
- (b) in electronic form from the Internet website of the Ministry of Health at <http://www.moh.gov.sg>.

[S 831/2010 wef 02/01/2011]

Quality assurance activities

12B. The licensee of any healthcare institution which is not a healthcare institution prescribed under regulation 12A shall, whenever required by the Director —

- (a) participate in such quality assurance activities as may be specified by the Director; and
- (b) furnish to the Director such information as the Director may require in relation to the quality assurance activities of the healthcare institution.

[S 831/2010 wef 02/01/2011]

PART II

PRIVATE HOSPITALS

Licensee of private hospitals

13. A licence for a private hospital may only be issued to the owner, or the person having the management or control, of a private hospital.

[S 308/2008 wef 01/07/2008]

Maternity home

14. A licensee of a maternity home shall not permit any abnormal delivery to be conducted or any operation to be performed on any

person at its premises except in an emergency or life threatening situation.

Beds and bed utilisation

15.—(1) Where any private hospital (not being a nursing home or maternity home) intends to increase the number of its beds exceeding 10% of the maximum number of beds for which it is licensed, it shall obtain the prior written approval of the Director.

(2) The number of beds in a maternity home or a nursing home shall not be increased in excess of the maximum number of beds for which it is licensed unless the prior approval of the Director has been obtained.

(3) Every private hospital shall submit monthly to the Director in such form as he may direct, particulars of its bed utilisation.

Operation theatres facilities

16.—(1) Where it is intended to carry out surgical or invasive procedures in a private hospital, an operation theatre shall be provided and properly equipped.

(2) All surgical operations or endoscopic procedures, other than those which would normally be carried out by a medical practitioner or a dentist in his consultation room, shall be performed in an operating theatre.

Intensive care unit

17.—(1) A maternity, medical, surgical or children's hospital or a hospital with any combination of these specialities shall have an intensive care unit.

(2) Every private hospital, other than a maternity home which provides obstetric services, shall have a neonatal intensive care unit or make adequate arrangements for neonatal intensive care services to be provided.

Specialised procedures or services

18.—(1) Where a private hospital intends to perform any specialised procedure or service as specified in the

Second Schedule, the licensee of the hospital shall obtain the prior approval of the Director in writing by making an application to the Director.

(2) The application referred to in paragraph (1) shall be submitted to the Director not less than 30 days before the intended commencement of the specialised procedure or service.

Back-up utility supply

19.—(1) Every private hospital shall have, in addition to normal electrical supply, emergency power and lighting in all patient care areas.

(2) Life support equipment shall be connected to emergency power at all times.

(3) Every private hospital shall have emergency water supply in its operating theatres, birthrooms and intensive care units.

Anaesthesia services

20.—(1) Where surgical or obstetric services are provided in a private hospital, there shall be an anaesthesia service.

(2) All general anaesthesia, spinal anaesthesia and epidural anaesthesia shall be provided only by an anaesthetist or a trained medical practitioner under the supervision of an anaesthetist.

Blood services

21.—(1) Every private hospital, other than a psychiatric hospital, convalescent hospital or nursing home, shall have an adequate supply of blood, including facilities for the proper storage and administration of blood and blood products, and such facilities shall be under the supervision of qualified personnel.

(2) In the case of a maternity home, it may either comply with paragraph (1) or ensure that blood shall be made available at the home within half an hour when it is required by any patient at the home.

Dietetic services

22. The licensee of every private hospital, other than a maternity home, shall ensure that the private hospital employs, or makes arrangements with, a qualified dietician to supervise the dietary aspects of patient care and to ensure that proper dietary requirements are complied with.

[S 308/2008 wef 01/07/2008]

Emergency services

23. Every private hospital shall at all times be capable of instituting and making available essential life saving measures and implementing emergency procedures on any person.

Laboratory services

24.—(1) Every private hospital, other than a psychiatric hospital, convalescent hospital, maternity home or nursing home, shall have a laboratory service which shall be under the supervision of a qualified person and the laboratory shall comply with regulations 50 to 55.

(2) Any reference to a licensee of a clinical laboratory in regulations 50 to 55 shall include a licensee of a private hospital which has laboratory services.

(3) There shall be at least one medical technologist personally present and in attendance at all times in a private hospital.

Medical services

25.—(1) Every private hospital shall ensure that every medical practitioner who has been granted clinical privileges shall provide services only within the scope of the clinical privileges granted.

(2) The scope of individual clinical privileges granted by the hospital to any medical practitioner shall be within those areas of competence of the medical practitioner.

(3) Every private hospital shall ensure that every patient shall have an attending medical practitioner who shall have overall responsibility for the patient's general medical condition.

(4) Every private hospital, other than a nursing home, with 50 or more beds shall have at least one medical practitioner on duty at all times.

(5) Every private hospital, other than a nursing home, with less than 50 beds shall have one medical practitioner available at its premises within half an hour of call.

(6) Every nursing home shall have one medical practitioner available at its premises within half an hour of call or shall make alternative arrangements to ensure that patients receive prompt and appropriate medical care.

(7) The licensee of a nursing home shall ensure that every patient in the nursing home is reviewed by a medical practitioner within 48 hours of admission thereto.

(8) Where, under paragraph (5) or (6), a resident medical practitioner is not provided, the patient must be informed before admission.

Nursing services

26.—(1) Every private hospital shall have a nursing service which shall be under the supervision of a registered nurse and which shall comprise an adequate number of appropriately trained nurses or, in the case of a maternity hospital, an adequate number of appropriately trained nurses and midwives, to provide an acceptable standard of care to patients.

(2) All nurses and midwives employed in the nursing service of a private hospital shall be registered or enrolled under the Nurses and Midwives Act (Cap. 209).

Pharmaceutical services

27.—(1) Every private hospital, other than a maternity home or a nursing home, shall have a pharmaceutical service under the supervision of a registered pharmacist.

(2) All personnel employed in the pharmaceutical service shall work under the direct supervision of a registered pharmacist.

(3) The supervising pharmacist shall be responsible for all activities including the preparation and dispensing of medicinal products and the maintenance of appropriate records.

Drugs, etc.

28. Every private hospital shall ensure that all drugs, chemicals, biological and medicinal products shall comply with the requirements of any written law relating to such products.

Radiology services

29.—(1) Every private hospital (other than a psychiatric hospital, convalescent hospital, maternity home or nursing home) shall have a radiology service which shall —

- (a) be under the supervision of a radiologist;
- (b) comply with regulations 50 to 55; and
- (c) have among its equipment a static X-ray machine and a mobile X-ray machine.

(2) All radiological examinations shall be conducted by a qualified radiographer or a qualified medical practitioner.

(3) Where a private hospital is licensed as a psychiatric hospital or convalescent hospital, adequate arrangements shall be made for patients to have access to X-ray facilities.

Provision of other unrelated services

30. Where a private hospital also provides within its premises —

- (a) services that are available for use by persons who are not inpatients of the hospital; or
- (b) services that are unrelated to the reception, lodging, treatment and care of persons who require medical treatment or suffer from any disease,

the licensee of the private hospital shall ensure that the privacy and safety of the inpatients of the private hospital are not compromised by its provision of such services.

31. [*Deleted by S 831/2010 wef 02/01/2011*]

Equipment

32.—(1) Every private hospital shall provide medical and surgical equipment, instruments, appliances and materials necessary for patient care which shall be adequate, functional and effective.

(2) Every private hospital, other than a maternity home or nursing home, shall have a complete set of resuscitation and monitoring equipment including a defibrillator in each intensive care unit, operating theatre complex and Accident and Emergency unit.

(3) All wards and special units in a private hospital referred to in paragraph (2) shall either be provided with similar equipment or there should be ready access to such equipment.

Infection control

33.—(1) Every private hospital shall have an Infection Control Programme with an appointed Infection Control Committee, documented infection control activities and written policies and guidelines to deal with any infection acquired or brought into the hospital.

(2) Every private hospital shall have isolation wards or facilities for persons found or suspected to be suffering from any infectious disease.

(3) Any room or equipment which has been used by a patient suffering or suspected to be suffering from any infectious disease shall not be used by any other patient until it is adequately disinfected.

(4) In this regulation, “infectious disease” means any of the diseases specified in the First Schedule to the Infectious Diseases Act (Cap. 137).

[S 233/2003 wef 30/04/2003]

Fire precautions

34. Every private hospital shall take adequate precautions against the risk of fire in accordance with any law relating to fire safety.

PART III

MEDICAL CLINICS

Licensee of medical clinics

35. A licence for a medical clinic may be issued to a medical practitioner, a dentist or such other person as the Director thinks fit.

Patients under treatment

36.—(1) The licensee of a medical clinic shall ensure that every patient of the medical clinic is provided with adequate safety, privacy and comfort when such patient is undergoing consultation, examination or treatment.

(2) In the course of treatment of any patient, a medical clinic shall not provide lodging or accommodation for a period exceeding 12 hours.

Special care services

37. Where the licensee of a medical clinic intends to establish any special care service as specified in the Third Schedule, he shall obtain the prior approval of the Director in writing by making an application to the Director not less than 30 days before the intended commencement of the special care service.

Facilities for surgery

38. Where a medical clinic intends to perform ambulatory surgery, it shall provide adequate and proper facilities which shall include facilities for recovery from anaesthesia.

Facilities for anaesthesia

39.—(1) Every medical clinic which performs procedures requiring the use of anaesthesia shall ensure that all general anaesthesia, spinal anaesthesia and epidural anaesthesia be performed either by an anaesthetist or a medical practitioner or a dentist under the supervision of an anaesthetist.

(2) Where general anaesthesia, spinal anaesthesia or epidural anaesthesia is administered, the operating medical or dental practitioner and the anaesthetist shall be 2 different persons.

Resuscitation facilities

40. Every medical clinic shall have resuscitation facilities for emergencies.

Drugs

41.—(1) All personnel in a medical clinic, other than registered pharmacists, shall work under the direct supervision of the medical practitioner or the dentist, as the case may be.

(2) The medical practitioner or the dentist in a medical clinic shall be fully responsible for all activities involved in the preparation and dispensing of medicinal products, including the maintenance of appropriate records.

(3) Every medical clinic shall comply with regulation 28 when dealing with drugs.

Equipment

42.—(1) Every medical clinic shall have medical and surgical equipment, instruments, appliances and materials which shall be functional, effective and comply with established or recommended procedures for their maintenance and use.

(2) Every equipment used in any endoscopic, operative or invasive procedure on the patient shall be rendered sterile by the appropriate procedure of sterilisation.

(3) Where a medical clinic provides a laboratory service or a radiology service, the licensee of the medical clinic shall ensure that —

- (a) the medical clinic is provided with adequate and appropriate equipment for the service to be carried out accurately and safely, and that the service is carried out by a suitably trained person; and

- (b) the laboratory service or radiology service so provided complies with regulations 50 to 55.

Clinic practices

43.—(1) Every licensee of a medical clinic shall not delegate any duty to any staff which can only be performed by the medical practitioner or the dentist.

(2) All clinical procedures shall be carried out by a medical practitioner, dentist or other qualified person who has adequate training and experience in the use of any equipment used for carrying out such procedures.

Test or examination of samples taken at medical clinic

44. Where any sample of any matter derived from a human body is taken at a medical clinic for test or examination for the purpose of providing information for the diagnosis, prevention or treatment of any disease or for the assessment of the health of any person, the licensee of the medical clinic shall ensure that such sample is tested or examined —

- (a) by a licensed clinical laboratory;
- (b) where the medical clinic provides a laboratory service which is capable of performing the requisite test or examination, by a suitably qualified person employed to carry out the laboratory service at the medical clinic; or
- (c) where the sample is intended to be sent for testing or examination abroad, by a foreign clinical laboratory which has been accredited by an accreditation body approved by the Director.

Premises of medical clinic to be properly separated from premises used for other services

45.—(1) Any premises that are being used as a medical clinic shall be physically separated from premises that are being used for the provision of other services.

(2) The premises being used as a medical clinic shall have a separate entrance from those premises being used for the provision of those other services.

46. [*Deleted by S 831/2010 wef 02/01/2011*]

PART IV

CLINICAL LABORATORIES

Person to whom licence for clinical laboratory may be issued

47. A licence for any premises to be used as a clinical laboratory may be issued to —

- (a) a medical practitioner who has the relevant higher qualification and training in any of the disciplines specified in regulation 56(a) to (j); or
- (b) a person who has a degree in medicine or any other higher qualification in any of the disciplines specified in regulation 56(a) to (j) that is acceptable to the Director, and who has at least 5 years' relevant working experience in a clinical laboratory acceptable to the Director.

Responsibilities of licensee

48. Every licensee of a clinical laboratory shall be responsible for —

- (a) the proper administration of the laboratory and the compliance with any written law;
- (b) the close supervision over technical staff in their performance of examinations; and
- (c) notifying the Director immediately of staff changes or any other change that may affect the conditions governing the issue of the licence.

Requisite qualifications of person managing clinical laboratory

49. No person shall be appointed to manage a clinical laboratory unless he has —

- (a) a degree in medicine or a basic degree in a relevant science subject that is acceptable to the Director; and
- (b) at least 5 years' relevant working experience in a clinical laboratory acceptable to the Director.

Personnel

50. Every clinical laboratory shall be staffed by at least one trained person in each of the disciplines in which it is licensed to practise.

Facilities

51.—(1) All facilities in a clinical laboratory shall be adequate for the proper and efficient performance of any category of examinations for which it is licensed to undertake, and for its functions to be performed with accuracy, timeliness and safety.

(2) The equipment in such laboratories shall be regularly checked for accuracy and calibration.

Quality control

52.—(1) The licensee of a clinical laboratory shall ensure that there is an effective and documented quality control programme for the clinical laboratory.

[S 831/2010 wef 02/01/2011]

(2) The licensee of a clinical laboratory shall —

- (a) ensure that quality control measures (including external quality assessments) are taken for every type of test performed at the clinical laboratory;
- (b) keep proper records and details of the quality control measures taken at the clinical laboratory under sub-paragraph (a); and
- (c) submit to the Director as and when required by him any of the records kept under sub-paragraph (b).

(3) The Director may issue guidelines specifying the standards of test performance for procedures performed by clinical laboratories and institute evaluation programmes, including surprise checks, on the accuracy of examination results.

(4) Where the licensee of a clinical laboratory intends to use the clinical laboratory to perform any specialised test or service as specified in the Fifth Schedule, he shall, before the clinical laboratory commences performing any such specialised test or service, obtain the prior approval of the Director in writing.

(5) An application for the Director's approval under paragraph (4) —

- (a) shall be made in such form or manner as the Director may require; and
- (b) shall be submitted to the Director not less than 90 days before the date on which the clinical laboratory is to commence performing the specialised test or service.

Records of specimens

53. Every licensee of a clinical laboratory shall keep records of specimens which shall include —

- (a) the name of the person from whom the specimen was taken, his age, national registration identity card number and address;
- (b) the name of the person who referred the specimen; and
- (c) the date and type of examination performed, examination result of each specimen and the person who performed the examination.

Report on tests

54.—(1) Every report of any test or examination performed by a clinical laboratory shall be retained by the clinical laboratory.

(2) The report shall state the name and address of the clinical laboratory and shall be signed by the licensee of the clinical laboratory or his authorised representative, who shall be a person suitably qualified in the relevant discipline.

(3) Where the test or examination to which the report relates has been outsourced to another clinical laboratory under regulation 55, the report shall —

- (a) state clearly the name and address of the clinical laboratory in which the test or examination was performed; and
- (b) be accompanied by the original copy of the report of the clinical laboratory which performed the test or examination.

Outsourcing of conduct of test and examination of samples

55.—(1) Subject to paragraph (2), all tests and examinations to be performed by a clinical laboratory shall be performed at the licensed premises of such clinical laboratory.

(2) The licensee of a clinical laboratory shall not outsource the conduct of any test or examination or any part thereof except to —

- (a) another licensed clinical laboratory; or
- (b) any foreign clinical laboratory which has been accredited by an accreditation body approved by the Director.

Kinds of clinical laboratories

56. Every clinical laboratory shall, according to the tenor of the licence issued in respect thereof, be used only for one or more of the following disciplines:

- (a) anatomic pathology;
- (b) chemical pathology;
- (c) cytogenetics;
- (d) forensic pathology;
- (e) haematology;
- (f) histocompatibility;
- (g) immunology;
- (h) medical microbiology;
- (i) transfusion medicine;
- (j) any other discipline acceptable to the Director.

PART IVA

EMERGENCY PREPAREDNESS PLANNING

*[S 308/2008 wef 01/07/2008]***Emergency response plans and emergency response teams**

56A. The licensee of a private hospital shall ensure that the private hospital —

- (a) has established viable emergency response plans covering such aspects, and in relation to such general or specific national medical emergencies, as the Director may specify; and
- (b) has established and equipped an operationally-ready emergency response team that may be called upon by the Director in the event of a national medical emergency to provide emergency response services.

*[S 308/2008 wef 01/07/2008]***Participation in emergency preparedness exercises**

56B. The licensee of a private hospital, medical clinic, clinical laboratory or healthcare establishment shall ensure that the private hospital, medical clinic, clinical laboratory or healthcare establishment, as the case may be —

- (a) participates in such planning, design and conduct of national medical emergency preparedness exercises as may be required by the Director, for the purpose of evaluating the emergency preparedness and response capabilities of the national healthcare system; and
- (b) has drawn up and put in place emergency infection control measures, including isolation strategies, isolation facilities and infection control equipment to control and prevent the spread of infectious diseases.

[S 308/2008 wef 01/07/2008]

PART V

MISCELLANEOUS

List of private hospitals, etc.

57. The Director shall cause to be published in the *Gazette* once in every 2 years a list of private hospitals, medical clinics, clinical laboratories and healthcare establishments licensed by him under these Regulations.

Exemption

58. The Minister may, subject to such terms or conditions as he may impose, exempt any private hospital, medical clinic, clinical laboratory or healthcare establishment from all or any of the provisions of these Regulations.

Use of title or name

59. Any occupier of any premises which is not licensed under these Regulations shall not, except with the prior approval of the Director, use the name “hospital”, “medical clinic”, “dental clinic”, “medical centre”, “dental centre”, “medical surgery”, “dental surgery”, “clinical laboratory”, “medical laboratory”, “healthcare establishment” or any other term or name to imply similarity to the practices and premises of a private hospital, medical clinic, clinical laboratory or healthcare establishment.

[S 831/2010 wef 02/01/2011]

Penalty

60. Any person who contravenes any of the provisions of these Regulations or who fails to comply with any direction issued by the Director under these Regulations shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$2,000 or to imprisonment for a term not exceeding 12 months or to both.

FIRST SCHEDULE

[Deleted by S 411/2003, wef 01/09/2003]

SECOND SCHEDULE

Regulation 18(1)

SPECIALISED PROCEDURES OR SERVICES IN PRIVATE HOSPITALS

1. Blood and blood product collection, processing, storage, distribution and transfusion services (including autologous blood transfusion).
2. Assisted reproduction services.
3. Neonatal intensive care unit.
4. Nuclear medicine, imaging and assay services.
5. Renal dialysis.
6. Sperm banking.
7. Radiation oncology.
8. Tissue banking.

THIRD SCHEDULE

Regulation 37

SPECIAL CARE SERVICES IN MEDICAL CLINICS

1. Blood and blood product collection, processing, storage, distribution and transfusion services (including autologous blood transfusion).
2. Ambulatory surgery (including minimally invasive surgery and laparoscopy).
3. Endoscopy.
4. Assisted reproduction services.
5. Lithotripsy.
6. Renal dialysis.
7. Specialised cardiac investigation.
8. Specialised diagnostic radiology.

FOURTH SCHEDULE

Regulation 5(1) and (7)

FEES

*First column**Second column*

1. Subject to paragraph 2, the fees payable for the various licences issued under section 5 of the Act shall be as follows:

- | | |
|--|---|
| <p>(a) for a licence issued for a private hospital (other than a maternity home, a nursing home, or a private hospital which is a charity under the Charities Act (Cap. 37)), having —</p> | |
| (i) 1,000 beds and above | <p>(A) \$4,950, where the licence is for a period not exceeding one year</p> <p>(B) \$9,900, where the licence is for a period of 2 years</p> |
| (ii) 100 to 999 beds | <p>(A) \$3,850, where the licence is for a period not exceeding one year</p> <p>(B) \$7,700, where the licence is for a period of 2 years</p> |
| (iii) less than 100 beds | <p>(A) \$2,200, where the licence is for a period not exceeding one year</p> <p>(B) \$4,400, where the licence is for a period of 2 years</p> |
| (b) for a licence issued for a maternity home | <p>(i) \$550, where the licence is for a period not exceeding one year</p> <p>(ii) \$1,100, where the licence is for a period of 2 years</p> |

FOURTH SCHEDULE — *continued**First column*

(c) for a licence issued for a nursing home

(d) for a licence issued for —

(i) a medical clinic or a dental clinic (other than a medical clinic or a dental clinic which is a charity under the Charities Act); or

(ii) a clinic that is both a medical clinic and a dental clinic (other than a medical clinic and dental clinic which is a charity under the Charities Act),

that is used —

(A) by a doctor or a dentist

Second column

(i) \$550, where the licence is for a period not exceeding one year

(ii) \$1,100, where the licence is for a period of 2 years

(AA) \$660, in any case where the licence is for a period not exceeding one year, and the licensee has a previous history of non-compliance with the Act or any regulations made thereunder, the terms and conditions of a licence, or any directions or guidelines given or issued by the Director

FOURTH SCHEDULE — *continued*

First column

Second column

- | | |
|--|---|
| | (AB) \$385, in any other case where the licence is for a period not exceeding one year |
| | (AC) \$770, where the licence is for a period of 2 years |
| | (AD) \$900, where the licence is for a period of 5 years |
| (B) by 2 to 5 doctors, dentists, or doctors and dentists | (BA) \$890, in any case where the licence is for a period not exceeding one year, and the licensee has a previous history of non-compliance with the Act or any regulations made thereunder, the terms and conditions of a licence, or any directions or guidelines given or issued by the Director |
| | (BB) \$550, in any other case where the licence is for a period not exceeding one year |
| | (BC) \$1,100, where the licence is for a period of 2 years |
| | (BD) \$1,350, where the licence is for a period of 5 years |

FOURTH SCHEDULE — *continued*

<i>First column</i>	<i>Second column</i>
(C) by more than 5 doctors, dentists, or doctors and dentists	(CA) \$1,090, in any case where the licence is for a period not exceeding one year, and the licensee has a previous history of non-compliance with the Act or any regulations made thereunder, the terms and conditions of a licence, or any directions or guidelines given or issued by the Director (CB) \$825, in any other case where the licence is for a period not exceeding one year (CC) \$1,500, where the licence is for a period of 2 years (CD) \$1,600, where the licence is for a period of 5 years
(e) for a licence issued for a community health centre	(i) \$1,090, where the licence is for a period not exceeding one year (ii) \$1,150, where the licence is for a period of 2 years (iii) \$1,310, where the licence is for a period of 5 years
(f) for a licence issued for a clinical and X-ray laboratory	(i) \$1,100, where the licence is for a period not exceeding one year

FOURTH SCHEDULE — *continued*

<i>First column</i>	<i>Second column</i>
(g) for a licence issued for a clinical laboratory	(ii) \$2,200, where the licence is for a period of 2 years (i) \$880, where the licence is for a period not exceeding one year (ii) \$1,760, where the licence is for a period of 2 years
(h) for a licence issued for an X-ray laboratory	(i) \$880, where the licence is for a period not exceeding one year (ii) \$1,760, where the licence is for a period of 2 years
(i) for a licence issued for a private hospital which is a charity under the Charities Act	\$12, where the licence is for a period not exceeding 2 years
(j) for a licence issued for a medical clinic, a dental clinic or a clinic that is both a medical clinic and a dental clinic, which is a charity under the Charities Act	(i) \$12, where the licence is for a period not exceeding 2 years (ii) \$30, where the licence is for a period of 5 years

2. Where a clinic referred to in paragraph 1(d) provides any special care service as specified in the Third Schedule, there shall be payable for a licence issued for such clinic, in addition to the appropriate licence fee specified in paragraph 1(d), the following fee:

(a) in any case where the licence is for a period not exceeding one year	\$550
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FOURTH SCHEDULE — *continued**First column**Second column*

- | | |
|---|----------|
| (b) in any case where the licence
is for a period of 2 years | \$1,100. |
|---|----------|

[S 450/2013 wef 01/08/2013]

FIFTH SCHEDULE

Regulation 52(4)

SPECIALISED TESTS AND SERVICES

1. Blood Group ABO and Rhesus (*D*) Type tests.
2. Acid-Fast Bacilli (Smear) test.
3. Human Immunodeficiency Virus test.
4. Malaria Parasite test.
5. Legionella test.

SIXTH SCHEDULE

Regulation 12A(1) and (4)

QUALITY ASSURANCE COMMITTEES

<i>First column</i>	<i>Second column</i>	<i>Third column</i>
<i>Prescribed healthcare institution</i>	<i>Quality assurance committee(s) required</i>	<i>Applicable directives</i>
1. Every licensed private hospital (excluding nursing homes)	(a) At least one Mortality and Morbidity Quality Assurance Committee (b) At least one Serious Reportable Event Quality Assurance Committee	(a) Directives for Review of Mortality and Morbidity (b) Directives for Review of Serious Reportable Events
2. Every licensed nursing home	At least one quality assurance committee	Directives for Quality Assurance

SIXTH SCHEDULE — *continued*

<i>First column</i>	<i>Second column</i>	<i>Third column</i>
<i>Prescribed healthcare institution</i>	<i>Quality assurance committee(s) required</i>	<i>Applicable directives</i>
		Committees (Nursing Homes)
3. Every licensed medical clinic providing special care services listed under the Third Schedule	(a) At least one Mortality and Morbidity Quality Assurance Committee (b) At least one Serious Reportable Event Quality Assurance Committee	(a) Directives for Review of Mortality and Morbidity (b) Directives for Review of Serious Reportable Events
4. The following medical clinics: (a) National Healthcare Group Polyclinic (Ang Mo Kio) (b) National Healthcare Group Polyclinic (Bukit Batok) (c) National Healthcare Group Polyclinic (Choa Chu Kang) (d) National Healthcare Group Polyclinic (Clementi) (e) National Healthcare Group Polyclinic (Hougang) (f) National Healthcare Group Polyclinic (Jurong)	(a) At least one Mortality and Morbidity Quality Assurance Committee for each medical clinic (b) At least one Serious Reportable Event Quality Assurance Committee for each medical clinic	(a) Directives for Review of Mortality and Morbidity (b) Directives for Review of Serious Reportable Events

SIXTH SCHEDULE — *continued*

<i>First column</i>	<i>Second column</i>	<i>Third column</i>
<i>Prescribed healthcare institution</i>	<i>Quality assurance committee(s) required</i>	<i>Applicable directives</i>
(g) National Healthcare Group Polyclinic (Toa Payoh)		
(h) National Healthcare Group Polyclinic (Woodlands)		
(i) National Healthcare Group Polyclinic (Yishun)		
(j) National Skin Centre		
(k) Singhealth Polyclinic — Bedok		
(l) Singhealth Polyclinic — Bukit Merah		
(m) Singhealth Polyclinic — Geylang		
(n) Singhealth Polyclinic — Marine Parade		
(o) Singhealth Polyclinic — Pasir Ris		
(p) Singhealth Polyclinic — Queenstown		
(q) Singhealth Polyclinic — Sengkang		
(r) Singhealth Polyclinic — Tampines		

SIXTH SCHEDULE — *continued*

<i>First column</i>	<i>Second column</i>	<i>Third column</i>
<i>Prescribed healthcare institution</i>	<i>Quality assurance committee(s) required</i>	<i>Applicable directives</i>
(s) Student Health Centre		
5. The following licensed private hospitals: (a) Alexandra Hospital (b) Changi General Hospital (c) Fortis Surgical Hospital (d) Gleneagles Hospital (e) Institute of Mental Health/Woodbridge Hospital (f) Johns Hopkins Singapore International Medical Centre (g) Khoo Teck Puat Hospital (h) KK Women’s and Children’s Hospital (i) Mount Alvernia Hospital (j) Mount Elizabeth Hospital (k) Mount Elizabeth Novena Hospital (l) National Heart Centre of Singapore (m) National University Hospital	At least one Peer Review Learning Quality Assurance Committee	Directives for Peer Review Learning

SIXTH SCHEDULE — *continued*

<i>First column</i>	<i>Second column</i>	<i>Third column</i>
<i>Prescribed healthcare institution</i>	<i>Quality assurance committee(s) required</i>	<i>Applicable directives</i>
(n) Parkway East Hospital		
(o) Raffles Hospital		
(p) Singapore General Hospital		
(q) Tan Tock Seng Hospital		
(r) Thomson Medical Centre		

[S 831/2010 wef 02/01/2011]

[S 493/2014 wef 01/08/2014]

[G.N. Nos. S 572/91; S 200/96; S 331/97; S 119/98;
S 8/2000; S 145/2000; S 256/2000; S 90/2001;
S 424/2001]

LEGISLATIVE HISTORY
PRIVATE HOSPITALS AND MEDICAL CLINICS
REGULATIONS
(CHAPTER 248, RG 1)

This Legislative History is provided for the convenience of users of the Private Hospitals and Medical Clinics Regulations. It is not part of these Regulations.

1. G. N. No. S 572/1991 — Private Hospitals and Medical Clinics Regulations 1991

Date of commencement : 1 January 1993

2. 1993 Revised Edition — Private Hospitals and Medical Clinics Regulations

Date of operation : 1 April 1993

3. G. N. No. S 200/1996 — Private Hospitals and Medical Clinics (Amendment) Regulations 1996

Date of commencement : 3 May 1996

4. G. N. No. S 331/1997 — Private Hospitals and Medical Clinics (Amendment) Regulations 1997

Date of commencement : 1 August 1997

5. G. N. No. S 119/1998 — Private Hospitals and Medical Clinics (Amendment) Regulations 1998

Date of commencement : 1 April 1998

6. 1998 Revised Edition — Private Hospitals and Medical Clinics Regulations

Date of operation : 15 September 1998

7. G. N. No. S 8/2000 — Private Hospitals and Medical Clinics (Amendment) Regulations 2000

Date of commencement : 7 January 2000

8. G. N. No. S 145/2000 — Private Hospitals and Medical Clinics (Amendment No. 2) Regulations 2000

Date of commencement : 1 April 2000

9. G. N. No. S 256/2000 — Private Hospitals and Medical Clinics (Amendment No. 3) Regulations 2000

Date of commencement : 1 June 2000

- 10. G. N. No. S 90/2001 — Private Hospitals and Medical Clinics (Amendment) Regulations 2001**
Date of commencement : 1 April 2001
- 11. G. N. No. S 424/2001 — Private Hospitals and Medical Clinics (Amendment No. 2) Regulations 2001**
Date of commencement : 10 September 2001
- 12. 2002 Revised Edition — Private Hospitals and Medical Clinics Regulations**
Date of operation : 31 January 2002
- 13. G. N. No. S 223/2003 — Private Hospitals and Medical Clinics (Amendment) Regulations 2003**
Date of commencement : 30 April 2003
- 14. G. N. No. S 237/2003 — Private Hospitals and Medical Clinics (Amendment No. 2) Regulations 2003**
Date of commencement : 8 May 2003
- 15. G. N. No. S 411/2003 — Private Hospitals and Medical Clinics (Amendment No. 3) Regulations 2003**
Date of commencement : 1 September 2003
- 16. G. N. No. S 308/2008 — Private Hospitals and Medical Clinics (Amendment) Regulations 2008**
Date of commencement : 1 July 2008
- 17. G. N. No. S 831/2010 — Private Hospitals and Medical Clinics (Amendment) Regulations 2010**
Date of commencement : 2 January 2011
- 18. G. N. No. S 189/2011 — Private Hospitals and Medical Clinics (Amendment) Regulations 2011**
Date of commencement : 15 April 2011
- 19. G. N. No. S 450/2013 — Private Hospitals and Medical Clinics (Amendment) Regulations 2013**
Date of commencement : 1 August 2013
- 20. G. N. No. S 493/2014 — Private Hospitals and Medical Clinics (Amendment) Regulations 2014**
Date of commencement : 1 August 2014