LAWS OF GUYANA

HEALTH FACILITIES LICENSING ACT

CHAPTER 33:03

Act
26 of 2007

Current Authorised Pages

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of
Subsidiary Legislation

Note

Similar regulations were published as Regulations 5 /2008.

Note
on
Repeal

This Act repeals the Public Hospitals Ordinance, Cap 139 and the Private Hospitals Act, Act No. 2 of 1972.

CHAPTER 33:03

HEALTH FACILITIES LICENSING ACT

ARRANGEMENT OF SECTIONS

SECTION

CHAPTER 33:03

HEALTH FACILITIES LICENSING ACT

26 of 2007 **An Act to provide for the licensing of Health Facilities and for related matters.**

[1ST MAY, 2008]

Short title. **1**. This Act may be cited as the Health Facilities Licensing Act.

Interpretation. **2**. In this Act –

"assessor" means an assessor appointed under section 21;

"health facility" means a place in which one or more members of the public receive health services or treatment and includes, but is not limited to, a hospital, a health centre, a health post, a training institution for health professionals, a laboratory, a diagnostic or therapeutic clinic, a nursing home, a place where chronic or extended care services are offered, a hospice, a place where rehabilitation health services are provided, a medical or surgical clinic, an emergency care centre, or any other place that may be prescribed;

"inspector" means an inspector appointed under section 18;

"licence" means a licence issued by the Minister under this Act;

"Minister" means the Minister responsible for Health and includes any person designated by the Minister to act

on the Minister's behalf;

"Ministry" means the Ministry of Health;

"National Health Plan" means the National Health Plan 2003-2007, dated March, 2003, as it may be amended from time to time;

"patient" means a person who receives health services in a health facility;

"prescribed" means prescribed by the regulations;

"regulations" means the regulations made under this Act, unless the context otherwise requires.

Application of Act.

3. This Act applies to a health facility or class of health facilities that is prescribed.

Licence required.

4. (1) No health facility shall be operated except under the authority of a licence issued by the Minister.

(2) No person shall use, in the title of a place, the term "hospital", "health clinic", "health centre", "health post" or other term that is prescribed unless the person is licensed under this Act.

Transitional.

5. (1) A person who operates a health facility on the date that this Act comes into force may, within one year after the date on which this Act comes into force, submit a proposal for a licence to continue to operate the facility.

(2) Sections 6 (2), (3) and (4) and sections 7, 8 and 9 apply with necessary modifications to a proposal referred to in subsection (1).

(3) Notwithstanding subsection 2, a person who

operates a health facility on the date that this Act comes into force may continue to operate the facility without a licence –

(a) where the person does not submit a proposal under subsection (1), for one year after the date on which this Act comes into force; and

(b) where the person submits a proposal and is served with a notice that the Minister proposes to issue a licence to the person, until the person is issued the licence.

(4) Any regulation that applies to health facilities operated by persons under this Act or to licensees may be made applicable to health facilities under subsection (3) and to the persons who operate the facilities.

(5) Where the Minister has reasonable and probable grounds to believe that a health facility referred to in subsection (3) is being operated or will be operated in a manner that is prejudicial to the health, safety or welfare of any person, the Minister shall so inform the person who operates the health facility.

(6) The Minister shall give notice to the person who operates the facility of the grounds on which he believes under subsection (5) that the facility is being operated in a manner that is prejudicial to the health, safety or welfare of any person.

(7) The Minister shall afford the person who operates the health facility an opportunity of making representations on his behalf and of advancing reasons or producing evidence to show that the health facility is being operated in a manner conducive to the health, safety and

welfare of persons.

(8) The Minister shall, in consultation with the Central Board of Health (the views of which body he is not obliged to accept), consider the representation, reasons and evidence advanced under subsection (7) in deciding whether he shall permit the health facility to continue to operate under this section or by notice direct that subsection (3) does not apply to the health facility effective on the date specified in the notice and accordingly communicate his decision to the person who operated the health facility.

(9) A direction under subsection (5) is final.

(10) A person who is notified that subsection (3) does not apply to the health facility shall forthwith cease to operate the facility that is the subject of the notice.

Request for proposals.

6. (1) The Minister may request proposals for the establishment and operation of a health facility.

(2) Persons interested in establishing and operating a health facility may submit proposals to the Minister.

(3) A proposal shall set out –

(a) the business and professional experience of the person submitting the proposal;

(b) details, nature and cost of the service or services to be provided in the health facility;

(c) details of the physical requirements of the proposed health facility;

(d) the projected planning, capital and operating costs of the health facility;

(e) the revenue source or sources for the costs referred to in paragraph (d) and the financial viability of the proposed health facility;

(f) the role of the proposed health facility and service or services proposed to be offered in it, in the context of the National Health Plan and other action plans of the Ministry;

(g) details of the system that will be established to ensure the monitoring of the results of the service or services to be provided in the health facility;

(h) details of the nature, source and training of the professional staff proposed for the health facility;

(i) any other information relevant to the requirements and limitations specified in the request for proposals as determined by the Minister.

(4) The Minister shall consider the proposals and may request additional information in respect of any proposal.

Issuance of licence.

7. (1) The Minister may issue a licence to a person who has submitted a proposal for the establishment and operation of a health facility where the Minister is of the opinion that –

(a) the proposal meets the criteria specified in the request for proposals;

(b) the quality and the standards of the health facility or of the service or services to be provided in the facility will comply with regulations, or in the absence of regulations, will conform to the generally accepted quality and standards for the facility and the service or services to be provided in the facility;

(c) the person will operate the health facility competently and with honesty and integrity;

(d) the person will establish and maintain a system to ensure the monitoring of the results of the service or services provided in the health facility;

(e) the person will operate the health facility in compliance with the contents of the proposal, including staffing.

(2) The Minister may issue a licence subject to the limitations and conditions as he considers necessary in the circumstances, including the payment of fees prescribed.

(3)The licensee shall notify the Minister immediately where there is –

(a) a change in the service or services provided in the health facility;

(b) a proposed change in the location of the health facility; or

(c) a change to any other thing that relates to a term or conditions of the licence.

Notice of proposal to refuse licence.

8. (1) Where the Minister proposes to refuse to issue a licence to any person, the Minister shall serve notice of the proposed action on the person who submitted the proposal for a licence.

(2) A notice under subsection (1) shall inform the person on whom it is served that the person is entitled to written reasons for the refusal, if a request is received by the Minister from the person, within seven days of the receipt by the person of the notice of refusal.

(3) Upon receipt and examination of the written reasons for the refusal the person on whom it is served may ask the Minister to review his decision.

Minister may withdraw request.

9. At any time after the Minister requests a proposal for the establishment and operation of a health facility and before a licence is issued, the Minister may withdraw his request.

Transfer of a licence.

10.(1) A licence is not transferable without the consent of the Minister.

(2) In deciding whether to consent to the transfer of a licence, the Minister shall treat the proposed transferee of the licence as if the proposed transferee were an applicant for a licence and, for the purpose of the transfer, section 7 (1) applies with necessary modifications.

(3) In consenting to the transfer of a licence, the Minister may attach to the licence such limitations and

conditions as the Minister considers necessary in the circumstances.

Expiry of licence.

11. Every licence expires annually on the anniversary of its issuance or renewal, unless it is revoked by or is surrendered to the Minister before that date.

Licence not to be used as security.

12. A licence shall not be used as security for the payment or performance of an obligation, and there shall be no transaction purporting to use a licence as security for the payment or performance of an obligation.

Contracts.

13.(1) A licensee shall not enter into a contract that may result in –

(a) a change in the beneficial ownership of the licence without a corresponding transfer of the licence; or

(b) a person acquiring or increasing an interest affecting the control of a corporation while it is a licensee.

(2) Subsection (1) does not apply if the licence includes a condition as to the ownership or control of the licence and the contract would not result in a breach of a condition.

Order by Minister to take control.

14.(1) Where the Minister is of the opinion that a health facility should continue to operate after the expiry, surrender, suspension or revocation of the licence, after the death of the licensee or after the licensee ceases to operate the facility, the Minister may by order direct that control and operation of the facility be vested in the Minister for a period not exceeding one year.

(2) Where the Minister takes control of and

operates a health facility under subsection (1), the Minister has all the powers of the licensee and the Minister may appoint one or more persons to operate the facility and each person so appointed is a representative of the Minister.

(3) Where the Minister takes control of a health facility, the licensee, former licensee or estate of the licensee, as the case may be –

(a) is not entitled to payment for any service that is provided by the facility while the facility is under the control of the Minister;

(b) is entitled to reasonable compensation for the use of the property of the licensee, former licensee or estate of the licensee while the facility is under the control of the Minister.

Revocation and refusal to renew licence.

15.(1) The Minister may revoke, suspend or refuse to renew a licence where –

(a) the licensee or an employee of the licensee is in contravention of this Act, the regulations or any other Act or regulation that applies to the health facility or to the licensee or an employee of the licensee, or condition of the licence;

(b) there is a breach of a limitation or condition of the licence;

(c) any person has made a false statement in the proposal submitted to the Minister in respect of the health

facility;

(d) any person has made a false statement in the application for renewal of the licence;

(e) any person has made a false statement in any report, document or other information required to be furnished by this Act, the regulations or any other Act or regulations that apply to the health facility;

(f) there is reasonable ground for belief that the health facility is not being or will not be operated in accordance with the law and with honesty and integrity;

(g) there is reasonable ground for belief that the health facility is being operated or will be operated in a manner that is prejudicial to the health, safety or welfare of any person;

(h) the licensee has ceased operating the health facility for a period of at least six months and is not taking reasonable steps to prepare the facility to re-open; or

(i) the licensee has entered into a contract mentioned in section 13 contrary to that section.

(2) If the Minister is of the opinion upon reasonable grounds that the health facility is being operated

in a manner that poses an immediate threat to the health or safety of any person, the Minister, by a written order, may suspend the licence of the facility.

(3) An order under subsection (2) takes effect immediately upon its issuance or on the date set out in the order.

(4) An order under this section may direct a health facility to do any of the following on or before the date set out in the direction of the order where the Minister considers it in the public interest to do so –

(a) to provide specified services to a specified extent or of a specified volume;

(b) to cease to provide specified services;

(c) to increase or decrease the extent or volume of specified services.

(5) The Minister may give directions in an order to a health facility under this section that the Minister considers in the public interest.

(6) The Minister may amend or revoke the direction in an order made under this section where the Minister considers it in the public interest to do so.

(7) A person whose licence is suspended under this section shall carry out any directions set out in the order and shall cease to operate the facility upon the issuance of the order or on the date set out in the order.

(8) Before the Minister gives a direction in an order made under this section, he shall afford the licensee an opportunity to make representations.

Notice to revoke, suspend or refuse to renew licence.

16.(1) Where the Minister proposes to revoke, suspend or refuse to renew a licence under section 15 (1), the Minister shall serve notice of the proposed action, together with written reasons for the action, on the licensee.

(2) A notice under subsection (1) shall inform the licensee that he is entitled to a hearing by a judge if he delivers to the Minister and the Attorney General, within fifteen days after the notice under subsection (1) is served on him, notice in writing requiring a hearing.

(3) Where, before the expiry of a licence, a licensee has applied for renewal of the licence and paid the prescribed fee, the licence shall be deemed to continue –

(a) until the renewal is granted; or

(b) where the licensee is served with notice under subsection (1) that the Minister proposes to refuse to grant the renewal, until the time for giving notice requiring a hearing has expired and, where a hearing is required, until the matter has been decided by the court.

(4) The decision of the Court is final.

(5) Except where otherwise provided, any notice by this Act to be served may be served personally.

Appointment of supervisor.

17.(1) Where it is essential in the public interest, the Minister may appoint a person as a supervisor of a health facility.

(2) Unless the appointment provides otherwise, a supervisor has the exclusive right to exercise all of the powers –

(a) of the board of the corporation, where the health facility is owned or operated by a corporation; and

(b) of the individual, where the health facility is owned or operated by an individual.

(3) The Minister may specify the powers and duties of a supervisor appointed under this section and the terms and conditions governing those powers and duties and the supervisor shall carry out every direction of the Minister.

(4) If, after the appointment under subsection (1), the corporation or individual continues to have the right to act with regard to any matters, any such act of the corporation or individual is valid only if approved in writing by the supervisor.

(5) A supervisor has the same rights as the board, corporation or individual in respect of the documents, records and information of the health facility.

(6) A supervisor shall report to the Minister as required by the Minister.

(7) In making a decision in the public interest under this section, the Minister may consider any matter he regards as relevant including, without limiting the generality of the foregoing –

(a) the quality of the management and administration of the health facility;

(b) the proper management of the health care system in general;

(c) the availability of financial resources for the management of the health care system and for the delivery of health care services;

(d) the accessibility to health services in the community where the health facility is located; and

(e) the quality of the care and treatment of patients.

Appointment of inspectors by Minister.

18.(1) The Minister may appoint in writing one or more persons as inspectors.

(2) In an appointment under subsection (1), the Minister may limit the duties or authority, or both, of an inspector in the manner the Minister considers necessary or advisable.

(3) Where the Minister is of the opinion that it is necessary or advisable that an inspection be made of a health facility licensed under this Act to ensure that this Act, the regulations and the limitations and conditions of the licence are being complied with, the Minister may direct one or more inspectors to make the investigation and to report to the Minister.

(4) An inspector shall make the inspections the Minister requires under subsection (3) and shall submit reports and interim reports in respect of the inspections as are required by the Minister.

Inspection of health facilities.

19.(1) An inspector may, at any reasonable time, without warrant, enter any premises of a health facility to make an inspection –

(a) in respect of a health facility operated by a person not licensed under this Act by reason of section 5, to ensure that the quality and standards of service provided in the facility comply with the regulations or, in the absence of regulations, conform to generally accepted quality and standards for the health facility and the service or services provided in the facility; and

(b) in respect of a health facility operated by a person licensed under this Act, to ensure that the Act, the regulations and the limitations and conditions, if any, have been complied with.

(2) Upon an inspection under this section, the inspector –

(a) has the right to inspect the premises and the operations carried out on the premises;

(b) has the right to free access, at any reasonable time, to all books of account, documents, correspondence and records, including payroll, employment, patient and drug records and any other records that are relevant for the purposes of the inspection, regardless of the form or medium in which the records are kept, but if the books, documents, correspondence or records are kept in a form or medium that is not legible, the inspector is entitled to require the

person in charge of them to produce a legible copy for examination by the inspector.

(c) has the right to remove, upon giving a receipt for it and showing his certificate of appointment issued by the Minister, any material referred to in paragraph (b) that relates to the purpose of the inspection for the purpose of making a copy, provided that the material is promptly returned to the person in charge of the premises from which the material was removed;

(d) has the right, at any reasonable time, to make and take or require to be made or taken, any samples of any substance on the premises;

(e) has the right to remove, upon giving a receipt for it and showing his certificate of appointment issued by the Minister, any sample referred to in paragraph (d) that relates to the purpose of the inspection for the purpose of making an analysis; and

(f) may question a person on matters that are or may be relevant to an inspection under this Act.

(3) It is a condition of every licence that the licensee and employees of the licensee shall co-operate fully with an inspector carrying out inspection of a health facility operated by a licensee.

Obstruction of inspector.

20. No person shall obstruct an inspector or withhold or conceal from an inspector any book, document, correspondence, record or thing relevant to the subject matter of an inspection.

Appointment of assessors.

21. (1) The Minister may appoint persons in writing as assessors.

(2) Where the Minister considers it necessary or advisable that assessments be carried out of the quality and the standards of services provided in a health facility, the Minister may give notice in writing to the licensee or operator of the health facility.

(3) An assessor shall report to the Minister in the determined form and in detail, with supporting material and at the times the Minister requires.

Powers of assessors.

22.(1) An assessor, after giving written notice to the licensee operator of a health facility, for the purposes of assessing the care provided to one or more persons in the health facility, may –

(a) inspect and receive information from records or from notes, charts and other material relating to patient care and reproduce and retain copies; and

(b) interview the licensee or operator and the employees of the licensee of the health facility on matters that relate to the quality and standards of service provided in the health facility.

(2) A notice under subsection (1) shall, where practicable, state the subject matter of the interview and the

identity, if known, of the person or persons to be interviewed.

(3) A licensee or operator who receives written notice under subsection (1) shall forthwith give written notice to each person who may be interviewed of the subject matter of the interview.

Assessment.

23.(1) It is the function of an assessor to carry out assessments of the quality and standards of services provided in health facilities.

(2) It is a condition of every licence that the licensee and employees of the licensee shall co-operate fully with an assessor carrying out an assessment of a health facility operated by the licensee.

(3) The co-operation required of a licensee includes –

(a) permitting the assessor to enter and inspect the premises of the health facility;

(b) permitting the assessor to inspect records, including patient records;

(c) providing to the assessor information requested by the assessor in respect of records, including patient records on the care of patients in the health facility;

(d) providing the information mentioned in paragraph (c) in the form requested by the assessor;

(e) permitting the assessor to take and remove samples of any substance on

the premises of the health facility;

(f) providing samples mentioned in paragraph (e) as requested by the assessor; and

(g) conferring with the assessor when requested to do so by the assessor.

Admissibility of copies.

24. (1) Copies of material removed from premises under this Act and certified as being true copies of the originals by the person who made them are admissible in evidence to the same extent as and have the same evidentiary value as the material of which they are copies.

(2) A certificate or report of an analysis of a sample removed from premises under this Act that purports to be signed by the laboratory technician who carried out the analysis shall be received in evidence as proof, in the absence of evidence to the contrary of the facts stated in the certificate or report without proof of the signature or position of the person appearing to have signed the certificate or report.

Confidential information.

25.(1) In this Act "confidential information" means information obtained by a person employed in the administration of this Act or making an assessment or inspection under this Act in the course of the person's employment, assessment or inspection and that relates to a patient or former patient of a health facility.

(2) No person shall communicate confidential information to any person except in accordance with subsection (4).

(3) Subsection (2) applies to any person whether or not that person is or was employed in the administration of this Act or is or was an assessor or inspector under this Act.

(4) A person employed in the administration of this Act, an assessor or an inspector or any person who obtains confidential information pursuant to this subsection may communicate confidential information-

(a) in connection with the administration or enforcement of any Act or any proceedings under any Act;

(b) in connection with matters relating to professional disciplinary proceedings, to a statutory body governing a health profession;

(c) to the person's counsel; or

(d) with the consent of the patient or former patient to whom the information relates.

(5) No person employed in the administration of this Act or who made an inspection or assessment under this Act shall be required to give testimony in a civil action or proceeding with respect to any information obtained in the course of the person's employment, assessment or inspection except in a proceeding under an Act.

(6) A court may exclude the public from proceedings to enforce any Act if the court is of the opinion that confidential information may be disclosed of such a nature, having regard to the circumstance, that the desirability of avoiding disclosure of that information in the interests of any patient or former patient to whom it relates outweighs the desirability of adhering to the principle that hearings be open to the public.

Immunity.

26. No action or other proceeding for damages shall be commenced against an inspector, or an assessor for any act done in good faith in the performance or intended performance of any duty or in the exercise or intended exercise of any power under this Act or the regulations, or for any neglect or default in the performance or exercise in good faith of such power or duty.

Offences.

27. (1) Every person who contravenes sections 4, 10, 12, 13, 20 or 25 commits an offence.

(2) Every person who contravenes a regulation under this Act commits an offence.

(3) Every person who is guilty of an offence under this Act is liable on summary conviction to a fine of two hundred and fifty thousand dollars and to imprisonment for six months and in the case of a continuing offence, to an additional fine of fifty thousand dollars for every day during which the offence continues subsequent to the date to which the conviction relates.

(4) Where a corporation is convicted of an offence under this Act, the penalty shall be twice that prescribed under subsection (3).

(5)The Court that convicts a person of an offence under this Act may, in addition to any other penalty, order that the person pay compensation or make restitution to any person who suffered a loss as a result of the offence.

Annual Report.

28. The Minister after the end of each year shall prepare an annual report on the administration of this Act and submit it to the National Assembly if the Assembly is sitting, if not, within fifteen days of the commencement of the next sitting.

Regulations.

29.(1) The Minister may make regulations –

(a) governing the process for submitting proposals;

(b) governing applications for renewals of licences;

(c) prescribing forms and providing for their use;

(d) prescribing fees for licences, for transfers of licences and for renewals of licences;

(e) classifying health facilities;

(f) respecting and governing the care, treatment and services provided in health facilities;

(g) prescribing and governing the quality and the standards of services provided in health facilities and the method by which these standards will be made available;

(h) prescribing and governing the quality and the standards of health facilities;

(i) prescribing and governing all matters in relation to the employees of health facilities;

(j) prescribing and governing the construction, establishment, location, equipment, maintenance and repair

of, additions and alterations to, and operation of health facilities;

(k) prescribing the books, records and accounts that shall be kept by health facilities, including their form and content and the place or places where they shall be kept;

(1) requiring the accounts of health facilities to be audited and requiring health facilities to furnish information or accounts as may be required by the Minister;

(m) prescribing and governing the records that shall be kept by health facilities with respect to the care and treatment of patients of the health facility;

(n) governing the reports and returns that shall be made to the Minister by health facilities;

(o) requiring and governing the system or systems that shall be kept by health facilities to monitor the results of the services provided in health facilities;

(p) governing access to patient or drug records and specifying persons who may have access to such records;

(q) establishing rules, regulating the ownership and use of health care information including the disclosure, access security and privacy of

information;

(r) governing the qualification of assessors and inspectors for the purpose of assessments and inspections;

(s) providing for the establishment and use of trust accounts and other methods to safeguard the valuables and assets of patients;

(t) establishing rules relating to admission, registration and discharge of patients, residents and outpatients;

(u) regulating methods of recovering amounts owed to a health facility;

(v) requiring written agreement between a health facility or class of health facilities and any person for the purpose of providing instruction in the health facility or class of health facilities and prescribing provisions that shall be included in any agreement;

(w) prescribing other duties of assessors;

(x) prescribing other duties of inspectors;

(y) regulating the governance, control, management, conduct, operation and use of health facilities;

(z) prescribing anything authorized or

required to be prescribed by this Act.

(2) In a regulation under subsection (1), the Minister may delegate the determination of any matter to any person the Minister designates in writing.

(3) Any regulation made under subsection (1) may be made applicable to different classes of health facilities.

Resolution of conflicting provisions.

30. Where the provisions of any other law conflict with the provisions of this Act, the provisions of this Act shall prevail only to the extent of the inconsistency.

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SUBSIDIARY LEGISLATION

Reg. 7/2008

HEALTH FACILITIES LICENSING REGULATIONS

made under section 29

ARRANGEMENT OF REGULATIONS

REGULATION

REGULATION

REGULATION

REGULATION

Reg. 7/2008

HEALTH FACILITIES LICENSING REGULATIONS

made under section 29

Citation.

1. These Regulations may be cited as the Health Facilities Licensing Regulations.

Interpretation.

2. In these Regulations –

"anesthesiologist" means a medical practitioner with specialty training in anesthesiology qualified to practice as an anesthesiologist;

"blood bank" means a blood recruitment, transmission and storage facility;

"cardiologist" means a medical practitioner who is an internist with specialty training in the disease of the heart qualified to practice as a cardiologist;

"clinical laboratory" means a facility where clinical tests, other than tests performed by a medical laboratory, are performed on individuals;

"community health worker" means a person who is selected by a community to provide basic health care in the community, and who has completed a community health worker programme approved by the Minister;

"diagnostic imaging facility" means a facility where services are provided in interventional radiology, ultrasound, diagnostic X ray imaging services techniques including static radiography, dynamic radiography, computerized tomographs, magnetic resonance imaging, positron emission tomography or other

similar devices;

"diagnostic radiographer" means a person who is trained as a diagnostic radiographer to a standard acceptable to the Minister;

"dialysis centre" or "dialysis clinic" means a health facility centre where artificial renal replacement therapy is performed including haemo-dialysis or peritoneal dialysis;

"health centre" means a health facility that provides primary health care and ordinarily working at least from Monday to Friday with a part-time or full-time medex or community health worker, where in-patient services are limited to over-night stays to stabilize or observe a patient and if a nurse or midwife is present, to perform routine health care deliveries;

"hospital" means a facility that provides on a daily basis, medical consultations, laboratory and diagnostic radiology services, scheduled and non-scheduled out –patient and in-patient care for stay not exceeding fourteen days and medical nursing services;

"human tissue bank" means a supply of human tissue that is used in aid of or in lieu of surgical procedures;

"licensed" means licensed under the Act;

"maternity ward" means a ward or area earmarked in a hospital or health centre where human babies are delivered;

c. 32:04 "medex" means a person who is registered as a medex under the Medex Act;

"Medical Council" means the Medical Council of Guyana established by section 3 of the Medical Practitioners Act;

c. 32:02

"medical laboratory" means a health facility for the examination and testing of materials or fluids derived from the human body for the purposes of providing information on the diagnosis, prevention or treatment of diseases;

"medical physicist" means a person who is trained to provide oversight, maintenance and quality control of radiation equipment and to provide radiation protection programmes;

"medical laboratory technologist" means a person who is trained as a medical laboratory technologist to a standard acceptable to the Minister;

c. 32:02

"medical practitioner" means a person qualified to practice medicine or surgery and who is duly registered as a medical practitioner under the Medical Practitioners Act and whose name appears in the register of the Medical Council;

Cap. 137
1953 Rev.

"midwife" means a person who is registered as a midwife under the Nurses and Midwives Registration Ordinance;

"nephrologists" means a medical practitioner who is an internist with specialty training in nephrology and who is registered with the Medical council as a nephrologists;

Cap. 137
1953 Rev.

"nurse" means a person who is registered as a nurse under the Nurses and Midwives Registration Ordinance;

"nurse anesthetics" means a nurse with specialty training in anesthesiology;

"nurse assistant" means a person who has completed a nurse assistant training programme approved by the Minister;

"oncology clinic" means a clinic for the treatment of persons suffering from neoplastic diseases or tumors;

"out-patient clinic" means a healthy facility where diagnosis, treatment, ambulatory care, or health information, or any combination thereof is provided;

"pathologist" means a medical practitioner with specialty and qualified to practice as a pathologist;

"pathology laboratory" means a facility where cytology, surgical pathology and autopsies are preformed;

c. 32:07 "pharmacist" means a person who is registered as a pharmacist under the Pharmacy Practitioners Act;

"radiologist" means a medical practitioner with specialty training in radiology and qualified to practice as a radiologist;

c.32:06 "regional health authority" means a regional health authority established under the Regional Health Authorities Act;

Cap. 137 1953 Ed. "registered nurse" means a person who is registered as a nurse under the Nurses and Midwives Registration Ordinance;

"static radiography" means radiography where morphological information is obtained from the

patient;

"surgical centre" means a place where surgery is performed under general, local or regional anesthesia.

Health facilities prescribed.

3. These regulations apply to the following health facilities which are prescribed as health facilities under section 2 of the Act –

(a) Blood Banks;

(b) Diagnostic Imaging facilities;

(c) Dialysis Centres or Dialysis Clinics;

(d) Health Centres;

(e) Hospitals;

(f) Human Tissue Banks;

(g) Maternity Wards;

(h) Medical Laboratories;

(i) Nursing Homes;

(j) Oncology Clinic with Radiation Therapy;

(k) Pathology and Clinical Laboratory; and

(l) Surgical Centres.

Obligations of licensee of the health facilities.

4. (1) Except as otherwise provided, every licensee of a health facility that is licensed as a health facility referred to

in regulation 3 shall ensure that the requirements of Part II of these Regulations are met.

(2) Every person who operates a health facility prescribed in these Regulations on the commencement of the Act and required to obtain a licence within the time permitted under section 5 of the Act to continue to operate the health facility shall comply with these Regulations, notwithstanding that he is not a licensee under the Act.

Request for submission of proposals for licence to establish and operate health facility.

5. (1) Any operator of a health facility of a class prescribed in regulation 3 which exists on the date of commencement of the Act shall within thirty days from that date inform the Minister through the office of the Director of Standards and Technical Services of his intention to continue to operate for a period of one year from the date of commencement of the Act and further indicate whether the operator intends to submit a proposal for a license under section 5 of the Act within that period of one year.

(2) The proposal for a license to establish and operate a health facility in accordance with these Regulations, whether it is a proposal for obtaining a license under section 5 or to establish and operate a new health facility under section 6 of the Act shall be made in Form I to these Regulations and shall conform to the provisions of section 6(3) of the Act, these Regulations and the generally accepted quality and standards for the health facility and services provided or proposed to be provided in the health facility.

Form I

(3) The applicant shall submit twelve copies of the proposal in Form I accompanied by the prescribed fee and supporting documents to the Minister through the Office of the Director of Standards and Technical Services of the Ministry of Health.

Form I

(4) The application may be delivered by hand or

sent by post but when it is hand delivered, a receipt of the Ministry of Health stating the time, date and the official who received the application shall be furnished to the person delivering the application.

(5) In case the application is received by mail, the date of receipt of the documents in the Office of the Director of Standards and Technical Services of the Ministry of Health shall be reckoned as the date of the proposal and that office shall acknowledge the receipt of the package by post or e-mail immediately and in no case later than the next working day.

Scrutiny of the application by the Director of Standards and Technical Services.

6. (1) Within fourteen days from the date of receipt of a proposal in the prescribed form, the Director of Standards and Technical Services shall scrutinize the proposal and where the proposal is incomplete, inform the applicant of the particulars of the shortcomings for rectification within a specified time.

(2) If the Director of Standards and Technical Services finds that a proposal is in order, he shall place the proposal before the Minister for consideration for granting of a license.

Consideration of proposal by the Minister.

7. (1) Within fourteen days from the date of receipt of the proposal complete in all respects, the Minister shall publish a notice in the Official Gazette that a proposal has been received by him for issuance of a licence to continue to operate a health facility operating on the date of commencement of the Act or to establish a new health facility, as the case may be, along with the particulars of the applicant, the specified location and the nature of the health facility to he established.

(2) Where a proposal for a licence to continue the operation of a health facility has been deemed to be in conformity with the provisions of section 6(3) of the Act the

Minister shall cause the health facility to be inspected to ensure that the facility meets with all the minimum requirements for grant of a licence and shall take into consideration the recommendations of the inspector and the outcome of the consultation with the Chief Medical Officer and the Board of Health.

(3) Where a proposal to establish a new health facility has been *prima facie* found to be in conformity with the requirements of the Act, the Minister shall issue a provisional licence in Form II to establish the health facility on the condition that the health facility shall meet the minimum standards prescribed by the Act, prior to operating the health facility.

Form II

Form II

(4) Before issuance of a final licence in Form II appended to these Regulations the Minister shall cause the inspection of the facility and after taking into consideration the recommendations of the inspection team and taking into consideration the outcome of the consultation with the Chief Medical Officer and the Board of Health, he shall issue a licence or he may reject the application for the licence specifying the reasons for such rejection.

Appointment of inspectors.

8. (1) Every person appointed to be an inspector under the Act shall possess the qualifications specified by the Minister to conduct the inspection of the health facility.

(2) The letter of appointment of an inspector shall state the name of the inspector, his qualifications, the duration of his appointment, the inspection to be carried out and the name and address of the health facilities or the local limits of jurisdiction.

(3) The inspector shall carry out inspections from time to time so as to ensure that due compliance with the provisions of the Act are made by the licensee of the health

facility.

Appointment of assessors.

9. (1) Every person appointed to be an assessor under the Act shall possess the qualifications specified by the Minister to conduct assessment of quality and standards of services provided by the health facilities.

(2) The instrument of appointment of every assessor shall state the name of the assessor, his qualifications, duration of his appointment, the assessment to be carried out and the name and address of the health facility where the assessment is to be carried out and the duration of appointment.

Fees.

10. The fee payable for the various services under the Act shall be as follows –

(i) Fee for issuance of a licence to establish and operate a health facility under the Act …. One hundred thousand dollars.

(ii) Annual fee for renewal of a licence … twenty thousand dollars.

(iii) Permission to transfer a licence … twenty thousand dollars.

(iv) Any miscellaneous service including making a change in any entry in the licence … ten thousand dollars.

PART II
GENERAL REQUIREMENTS

Requirements to be fulfilled by the health facilities.

11. Except is otherwise provided, every health facility shall –

(a) have a policy making body on governance and administration;

(b) have a designated official responsible and accountable for medical care;

(c) have a documented administrative structure;

(d) have an individual responsible for the administration of the facility;

(e) have an updated Manual of Administrative Procedure (including operational routine, procedures and standards);

(f) have sufficient numbers of qualified staff in the employment of the health facility and present during the operating hours of the health facility commensurate with the type of services being offered at the facility;

(g) have a personnel office with files on all staff members that include certification of training;

(h) display for public information –

(i) the visiting hours, where relevant;

(ii) the names and qualifications of the medical practitioners or other professionals attending the health facility;

(j) hold staff meetings at least every quarter in a year including all

categories of staff.

Maintenance of medical records of patients.

12. (1) An up-to-date medical record of each patient shall be maintained in the health facility.

(2)The medical record shall bear the assigned date for each entry made in it and shall also include the following particulars with respect to the patient –

(i) name, address and phone number, where available;
(ii) age and sex;
(iii) relevant history of illness or injury and physical findings;
(iv) diagnosis;
(v) a list or a copy of a list, of all diagnostic tests and procedures carried out by the facility on the patient, together with the date of the tests or procedures, and the results, or a copy of the results, where available, including a copy of the original test procedure;
(vi) clinical observations, including results of treatment;
(vii) allergy history;
(viii) for pediatric patients, immunization records;
(ix) where there is a referral, a copy of the original referral;
(x) patient contact information;
(xi) patient consent to treatment form.

(3) The medical records and reports of patients shall be treated as confidential information and, except as

provided in paragraph (4), (5), (6) or (7), no person shall be allowed to examine a patient's medical record or be given any information, copy or item from a patient's medical record.

(4) A person who is treating a patient may examine the patient's health record or obtain any information or item or copy from the health record only for the purpose of providing health care or assisting in the provision of health care to the patient.

(5) Copies from a patient's health record shall be provided on request to a patient or a personal representative who is authorized by the patient to obtain copies from the record, or if the patient is dead, the patient's legal representative.

(6) Paragraph (3) does not apply to a person making a report that is required to be made under any law relating to public health or any other written law or any authority dealing with disciplinary proceedings against any health professional.

(7) Paragraph (3) does not apply to a person who is collecting data for a study that is approved by the Minister from a health facility owned or operated by the Ministry of Health or by a Regional Health Authority, provided that the person agrees not to release or publish any identifying information.

(8) A copy of the medical record of every patient either in paper or in electronic form shall be retained for at least ten years following the last visit of the patient to the health facility.

(9) Every maternal death and pre-natal death in the health facility shall be reported to the Chief Medical Officer within twenty-four hours of the occurrence and all

other deaths shall be reported on a weekly basis to the Chief Medical Officer.

(10) The medical record unit in the health facility shall be adequately staffed to ensure that the requirements of these Regulations are met.

Equal access to care.

13. All patients shall be treated equally regardless of age, place of birth, race, creed, nationality, gender or sexual orientation.

Patient care arrangements.

14. (1) Every health facility shall be so designed and equipped as to be able to carry out the operations that the facility is licensed for in a safe and effective manner.

(2) The waiting areas and patient registration areas of every health facility shall be readily accessible to patients, including physically challenged persons.

(3) All the areas of a health facility shall be so constructed and located as to ensure patient privacy and confidentiality without compromising patient care.

(4) Where a health facility provides emergency medical care, wheelchairs and other ambulating aids as are necessary for patients in the emergency circumstances shall be readily available at the facility.

(5) Where a health facility may require a patient to provide a specimen, the area for the procurement of specimens shall be in a room that is separate from the room in which patients are examined.

(6) Paragraph (5) does not apply with respect to a patient who is bed ridden.

(7) Every health facility shall have an examination

room that is properly equipped and commensurate with the type of services being offered at the facility.

(8) Every health facility shall have, wherever it is possible, at least one closed wash room and a sink with running water or a clean wash-basin with a supply of potable water for hand washing.

(9) The sink or wash basin referred to in paragraph (8) shall be available near to the location where a patient is required to give specimens for laboratory examination.

(10) Where a health facility contains a medical laboratory, the sink referred to in paragraph (8) shall be in the form of a fixture that is so constructed as to permit flushing of the eyes, the body and clothes with large quantities of water so as to neutralize any hazardous or corrosive substances in case of an accident.

(11) Every health facility shall have a sufficient number of flush toilets and washrooms or latrines to handle the number of patients and employees of the facility and such toilets and washrooms or latrines shall be conveniently located for the patients and employees.

Equipment and supplies.

15. (1) In every health facility there shall be sufficient storage space for patient records and pharmaceutical supplies.

(2) Every health facility shall establish a preventative maintenance programme to ensure that the equipment required by any manufacturer to be checked or calibrated is done with a frequency that is in accordance with the specifications of the manufacturer.

(3) Biological and other supplies requiring

refrigeration shall be stored in a refrigerated enclosure and the refrigeration system should have a continuous temperature monitoring system.

(4) Infectious materials shall be stored in clearly marked containers designed specifically for storage of infectious waste that meet the requirements specified by the Guyana Bureau of Standards.

(5) Flammable liquids in excess of ten gallons shall be contained in a storage cabinet with a capacity of at least sixty gallons that meets the requirements of the Guyana Fire Service.

(6) "No smoking" signs shall be posted at areas in which flammable gases or liquids are stored.

(7) Every health facility shall install in its premises approved fire extinguishers in good working order in the number required by the Guyana Fire Service.

Rights of patients.

16. (1) Every health facility shall provide the patients with considerate and respectful care at all times and under all circumstances with due regard to their personal dignity.

(2) No patient shall be denied privacy concerning any matter related to the medical history of the patient.

(3) Patients shall be provided with care that is appropriate in the circumstances.

(4) Patients shall be informed of the identity and professional status of persons providing them care.

(5) The person who is responsible for coordinating a patient's care shall provide information to the patient or his authorised relative attending to him with respect to the

patient's diagnosis, current prognosis, if known any treatment or procedures to be undertaken.

Consent. c. 32:05.

17. (1) Except where otherwise provided under the provisions of the Medical Termination of Pregnancy Act, no treatment or procedure shall be performed in a health facility on a patient without the voluntary, competent and informed consent of the patient or, where the patient is a minor, the consent of a relative, legal representative or guardian of the patient.

(2) For the purpose of paragraph (1), "informed consent" includes advising the patient in terms that can be understood by the patient of the risks, benefits and alternatives of all proposed treatments or procedures.

(3) Every consent under this regulation shall be in writing.

(4) Where a patient is unable to give informed consent because the patient is physically impaired, mentally impaired, debilitated or incompetent in any other way so as not to be able to give informed consent, written consent shall be obtained from a relative or legal representative of the patient prior to the administration of the treatment or procedure on the patient.

(5) Where a patient is illiterate but is otherwise able to give informed consent, the patient may give written consent by marking the consent form with the patient's mark and having it witnessed.

(6) When a patient is unable to give informed consent, and there is no relative, legal representative, guardian or other person designated by the patient for this purpose and delay in medical treatment would endanger the life or a limb of the patient, the consent of the patient may be

presumed, unless it is obvious from a previous declared expression of the patient that consent would be refused in the situation.

Policies and procedures.

18. Every health facility shall have written policies and procedures that specify the scope and conduct of the care and services that it provides and those shall include at least –

(a) the mechanism used to inform a client of the medical practitioner or other health care personnel responsible for the care of the client;

(b) the keeping of patient medical records, including a reference to the confidentiality of patient information, the safeguard of medical records, the release of information to authorized individuals and any consent required for treatment of a patient or the administration of any procedure on a patient;

(c) the scope of treatment and procedures to be performed in patient care areas, including general and specific treatments and procedures that may be performed;

(d) the mechanism for the provision of care to a minor not accompanied by a parent or guardian;

(e) the location and storage of medications, supplies and equipment;

(f) the dispensing of medication in

accordance with legal requirements and the responsibility for maintaining the integrity of an emergency drug supply;

(g) infection control measures;

(h) the methods used to ensure that the facility is sanitary and free from nuisance;

(i) the methods used by the facility to ensure that the safety and well being of patients and employees are assured; and

(j) the mechanism used to make reports to the Ministry of Health.

Sanitation and safety.
c. 99:06

19. (1) The occupational safety and health of persons at work in every health facility shall be the same as are required under the Occupational Safety and Health Act.

(2) Every health facility shall be smoke free and the licensee shall ensure that no person smokes or holds lighted tobacco in the facility or in the nine metres radius surrounding any entrance or exit to the facility.

(3) The premises of every health facility shall be kept in a clean and hygienic, sanitary condition and free from nuisance in accordance with the Environmental Protection Act and any other law.

c. 20:05

(4) Syringes, needles, lancets or other blood-letting devices capable of transmitting infection from one person to another shall be disposed of in accordance with the requirements of the Guyana Solid Waste Management

Division of the Ministry of Local Government.

(5) Every health facility shall ensure that linen, gauze, bandages or any other material that is contaminated with blood or other bodily fluid shall be treated as infectious waste in accordance with regulation 14.

(6) Any specimen collected from a patient that is transported locally in Guyana shall be transported in accordance with the requirements of the Guyana Solid Waste Management Division of the Ministry of Local Government.

(7) Any specimen collected from a patient that is transported abroad for assessment shall be shipped in accordance with shipping guidelines as set out in IATA Regulation 650**.**

Disposal of infectious and radioactive wastes.

20. (1) Infectious waste, other than the infectious waste referred to in regulation 19(4), shall be kept separately from other wastes and shall be –

(a) stored in double impervious plastic bags that are each at least 2mm. in thickness, that are securely fastened, that are conspicuously marked "infectious waste" and that when full do not exceed 25 pounds in weight;

(b) transported in receptacles that are conspicuously marked "infectious waste";

(c) processed to render the waste harmless or shall be held for pick-up in specially marked non-metal containers separate from regular waste;

(d) secure from unauthorized persons;

(e) secure from birds and animals;

(f) removed otherwise than by mechanical means or compacted;

(g) deposited other than in any sanitary landfill; and

(h) disposed of in accordance with the requirements of the Guyana Solid Waste Management Division of the Ministry of Local Government.

(2) Broken or leaking bags of infectious waste shall not be permitted to be transported from a health facility unless it is re-bagged in accordance with these Regulations.

(3) Where trash that may constitute a hazard to any person or thing is compacted and the integrity of the container is compromised, the container shall be handled as infectious waste under this regulation.

(4) All radioactive wastes shall be stored, transported and disposed of in accordance with the requirements of the Guyana Solid Waste Management Division of the Ministry of Local Government.

(5) This regulation does not apply to articles that are dirty or contaminated but are intended to be reused after they have been cleared and sterilized.

PART III
BLOOD BANKS

Blood Banks to comply with Part III.

21. (1) Every licensee of a health facility that is licensed as a Blood Bank shall ensure that the requirements of

this Part are met.

(2) Every licensee of a health facility that contains a Blood Bank and every person who operates a Blood Bank under section 5 of the Act shall also ensure that the requirements of this Part are met.

Staff.

22. Every Blood Bank shall be under the supervision and direction of a medical practitioner or a pathologist.

Procedure.

23. Every Blood Bank shall meet the requirements of the Caribbean Regional Standards for Blood Banks and Transfusion Services, 2001, as amended from time to time.

PART IV
DIAGNOSTIC IMAGING FACILITIES

Diagnostic imaging facilities to comply with Part IV.

24. (1) Every licensee of a health facility that is licensed as a diagnostic imaging facility shall ensure that the requirements of this Part are met.

(2) Every licensee of a health facility that provides diagnostic imaging services and every person who operates a diagnostic imaging service under section 5 of the Act shall also ensure that the requirements of this Part are met.

Staff.

25. Every facility having a diagnostic imaging facility shall be under the direct supervision of a medical practitioner.

Policies and procedures.

26. (1) Every diagnostic imaging facility shall have written policies and procedures for monitoring and evaluating the effective management, safety and operation of imaging equipment so as to minimize the risks of the patients, personnel and the public and maximize the quality of the diagnostic information.

(2) The premises of every health facility that has an x-ray department or unit shall conform to the following structural requirements for protection from radiation –

(i) radiation protection for the walls of the facility shall be a lead equivalent of 2mm;

(ii) where there is a room above the facility, radiation protection in the ceiling of the facility shall be a lead equivalent of 2 millimetres.

(iii) where there is a room below the facility, radiation protection in the floor of the facility shall be a lead equivalent to 2 millimetres.

(3) For the purposes of paragraph (2), a lead equivalent of 2 millimeters means –

(a) a single brick wall at least nine inches thick;

(b) a six inch thickness of solid concrete; or

(c) two millimetres of lead sheeting.

(4) An x-ray department or unit shall consist of an x-ray room that is at least 18 square metres, a darkroom that is at least 7.5 square metres and an office or storeroom that is at least 8 square metres in size.

(5) The waiting areas and change rooms shall be so situated that it prevents exposure to radiation.

(6) Radiation protection for patients shall consist of gonad shields or lead rubber aprons where it is necessary to support a patient during an examination.

(7) Radiation protection for operations shall consist of –

(a) radiation monitoring badges from a recognized company or organization;

(b) lead rubbers, aprons and gloves when the operator is in the x-ray room with the patient;

(c) a control desk that is behind a lead protective screen with a lead glass window for the operator to stand behind; and

(d) radiation equipment so installed that it does not point to the control panel.

(8) The performance of equipment shall be monitored and calibration of machines shall be checked by a medical physicist at least every six months in accordance with the specifications of the manufacturers and the records of such monitoring and calibration shall be kept in the health facility and shall be readily available upon the request of an inspector.

(9) Machines in the X-ray requiring calibration shall be calibrated as soon as practicable.

(10) Images shall be clearly labeled with the examination date, patient's identification and image orientation and a written report of the image results shall be included with the patient's medical record.

(11) X-rays shall be taken by a diagnostic radiographer and shall be interpreted by a radiologist or, where no radiologist is available, by a medical practitioner.

(12) The X-ray equipment shall be grounded.

PART V
DIALYSIS CLINICS

Dialysis clinics to comply with Part V.

27. (1) Every licensee of a health facility that is licensed as a dialysis centre or as a dialysis clinic shall ensure that the requirements of this Part are met.

(2) Every licensee of a health facility that includes a dialysis clinic and every person who operates a dialysis clinic shall ensure that the requirements of this Part are met.

Staff.

28. Every health facility licensed as a dialysis center or that includes a dialysis clinic shall be under the direct supervision of a nephrologist.

Policies and procedures.

29. (1) Every health facility providing dialysis services to patients shall have written policies and procedures for maintaining, monitoring and evaluating management, safety and operation of equipment in the facility and of services provided in the facility.

(2) The policies and procedures referred to in paragraph (1) shall be so designed as to minimize the risks of the patients, personnel and the public and to maximize the quality of dialysis care.

Nursing station.

30. Every dialysis clinic shall have a central nursing station.

Dialysis treatment area.

31. (1) In every dialysis clinic, there shall be an adequate number of sinks for implementing precautionary measures relating to infection control according to standards established by the American Professions of Infection Control until alternate standards to be followed in Guyana are laid down by the Minister.

(2) Walls and floors shall be smooth and washable so that decontamination procedures can be carried out easily.

(3) Every dialysis clinic shall ensure that in addition to the dialysis treatment area the following areas in the clinic are clearly defined –

(a) clean up area;

(b) clean supply room;

(c) equipment storage;

(d) water treatment area;

(e) lockers and bathrooms for patients and staff;

(f) general reception area;

(g) waiting room for patients and visitors.

Infection control.

32. Used blood-lines and dialysers shall be treated as infectious waste in accordance with regulation 20.

Water control.

33. The quality of water used in the dilution of dialysis concentrate shall be in accordance with AAM1 water treatment equipment and quality recommendations for dialysis until alternate standards to be followed in Guyana are laid down by the Minister.

PART VI
HOSPITALS

Hospitals to comply with Part VI.

34. Every licensee of a health facility that is licensed as a hospital and every person who operates a health facility as a hospital under section 5 of the Act shall ensure that the

requirements of this Part are met.

Staff.

35. Every hospital shall have a team of medical staff and the medical staff shall be under the direct supervision of a medical practitioner.

Accommodation.

36. Every hospital shall have ready access to –

(a) a licensed medical laboratory, either on or off the premises;

(b) a licensed Blood Bank, either on or off the premises.

Governance and administration.

37. (1) Every hospital shall be governed by a policy making body and its by-laws shall include a written administrative medical care in the hospital.

(2) Every hospital shall designate a person who is responsible for and accountable for continuing medical care in the hospital.

(3) The by-laws of every hospital shall –

(a) provide for a manual of administrative procedures to be employed by the hospital;

(b) require a personnel office that contains a list of all medical practitioners and paramedical professionals on the hospital staff with their qualifications and training;

(c) require staff meetings at least once a month and the meetings shall include all categories of staff;

(d) set out the visiting hours of the hospital and require them to be prominently displayed to the public;

(e) require a medical practitioner, or where a medical practitioner is not available, a medex, to be on duty twenty-four hours per day;

(f) require daily rounds of the wards of the hospital;

(g) provide that a specific person or persons shall be responsible during daily rounds for following up on each patient who is admitted to the hospital;

(h) require that the staff on duty in the hospital shall know how to contact all medical staff who are on duty at any particular time;

(i) provide for written procedures to deal with the preparation and sterilization of all materials of the hospital;

(j) provide for written procedures to ensure that cleaning takes place in standardized fashion including instruction for the use of disinfectants and the elimination of biological and other wastes;

(k) provide for a designated individual who shall be responsible for ensuring that the hospital is cleaned on a daily

basis; and

(l) require the establishment of a protocol to deal with highly contagious diseases.

Emergency services.

38. (1) Every hospital shall have an emergency department that is located at a specific easily accessible dedicated site at the hospital and that has a medical practitioner and a nurse available on duty twenty-four hours a day with the duty chart prominently displayed at a conspicuous place.

(2) The emergency service shall have adequate provision of life saving First Aid medicines and equipments.

(3) The emergency service at a hospital shall include an arrangement to refer the patient to the nearest facility that has the capability of providing the specialty service required by the patient.

Food services.

39. (1) Food services in a hospital shall be supervised by a dietician or food service supervisor who shall maintain or ensure the maintenance of a list of diets appropriate for the pathology of the types of patients served by the hospital.

(2) A diet manual shall be available at all times.

(3) Each food service worker shall be –

(a) the holder of a valid food handlers certificate issued by the municipality or public health department where the worker is employed, as the case requires; and

(b) so dressed as to make him easily

identifiable as a food service worker.

(4) The food preparation area in a hospital shall be –

(a) so constructed that all external openings to the area are fly-proof; and

(b) restricted to food service workers only.

(5) Patients on special diets shall not be permitted to receive food from sources external to the hospital except as provided in paragraphs (6) and (7).

(6) Where the food service in a hospital is contracted out, the hospital shall ensure that –

(a) all patient diets are monitored by a dietician or food service supervisor; and

(b) the contract with the external supplier provides for inspection under the Act.

(7) When any relative of a patient or other person desires to bring food for a patient he shall consult and obtain prior permission of the competent authority of the hospital.

(8) Food for patients shall be covered from the time it leaves the food preparation area until it reaches the patient.

Sterilization.

40. (1) Every hospital shall have access to a specific dedicated site for the preparation and sterilization of materials of the hospital.

(2) The sterilization equipment shall consist of an

autoclave, instrument sterilizer and a stove or oven and shall be tested regularly and at least twice a year to ensure that they are in proper working order to sterilize the materials being placed in them.

Dispensing of drugs.

41. (1) Every hospital shall have a specific site that is dedicated for the pharmacy and the site shall provide for the conservation and refrigeration of drugs.

(2) The pharmacy in a hospital shall be administered and controlled by a pharmacist who provides drugs to in-patients and to out-patient clinics of the hospital on a restricted schedule to be fixed by the hospital administration and to the emergency department on a twenty-four hour basis.

(3) The hospital pharmacist shall keep a medication profile for each patient receiving drugs from the pharmacy.

Registers and indexes.

42. (1) Every hospital shall keep the following registers –

(i) a register of admissions and discharges for both in-patients and out- patients;

(ii) an emergency department register;

(iii) an operating room register;

(iv) a maternity ward register;

(v) a register of births;

(vi) a register of deaths.

(2) Every Hospital shall keep the following indexes –

(i) a master index of patients;
(ii) an operating index;
(iii) a disease index;
(iv) a staff index.

Occupational Safety and Health Act. c. 99:09

43. (1) The administrator of every hospital shall ensure that one or more health and safety representatives are chosen from amongst the staff in the hospital in accordance with the provisions of the Occupational Safety and Health Act.

(2) No person shall be employed by a hospital unless the person has been medically examined by a medical practitioner provided by the hospital and found fit for employment.

Quality assurance.

44. (1) In addition to the by-laws referred to in regulation 37, every hospital shall have by-laws that establish a quality assurance programme for the hospital that evaluates the quality of care being provided to patients of the hospital on an on-going basis against a prevailing and accepted standard of professional care.

(2) Every quality assurance programme referred to in paragraph (1) shall –

(a) ensure that all patient care services are efficiently rendered, readily available and properly documented;

(b) ensure that all hospital staff are ethically, professionally, competent and duly qualified for their particular duty in the hospital;

(c) establish a system to evaluate the hospital's facilities, manpower, necessary drug supply and physical safety of workers;

(d) establish protocols to investigate and resolve problems that could negatively impact on the quality of patient care;

(e) establish a system of setting priorities to deal with quality assurance issues to ensure that the problems are investigated and resolved so that the issues may not negatively impact on the quality of patient care; and

(f) establish a system of monitoring, evaluating and documenting the results of the hospital quality assurance programme.

Housekeeping.

45. (1) All floors of the hospital shall be washed at least once a day with cleaning agents recommended or consistent with the recommendations of the manufacturer of the flooring.

(2) Dry sweeping shall not be permitted except in areas meant for out-patients.

(3) Every hospital shall have suitably protective clothing available for staff who may have to come into contact with highly infectious patients or materials.

PART VII
OUT-PATIENT CLINICS

Out-patient

46. Every licensee of a health facility that is licensed

clinics to comply with Part VII.

as an out-patient clinic and every person who operates an out-patient clinic under section 5 of the Act shall ensure that the requirements of this Part are met.

Policies and procedures.

47. (1) Every out-patient clinic shall exhibit at a conspicuous place the names and qualifications and specializations, if any, of the medical practitioners who are available at the clinic and the times at which they are available.

(2) Every out-patient clinic shall have written policies governing visiting of patients at the clinic.

(3) Every out-patient clinic of a hospital shall be under the directions of its medical director or a designated medical practitioner of the hospital.

PART VIII
MATERNITY WARDS IN HOSPITALS AND HEALTH CENTRES

Maternity wards to comply with Part VIII.

48. Every licensee of a health facility that is licensed as a hospital or health centre that operates a maternity ward and every person who operates a maternity ward under section 5 of the Act shall ensure that the requirements of this Part are met.

Staff.

49. (1) Every maternity ward in a hospital shall be under the supervision and direction of a medical practitioner.

(2) Every maternity ward in a health centre shall be under the supervision and direction of a medical practitioner or a medex or a staff nurse or a midwife.

Competent staff to manage maternity care.

50. (1) The patients in labour in a maternity ward shall be managed by a staff nurse or midwife under the direct supervision of the medical practitioner or medex who is

responsible for the care of patients.

(2) Where the medical practitioner or medex referred to in paragraph (1) is not specially trained in obstetrics, the facility shall, where feasible, have an established written agreement with an obstetrician to provide twenty-four hours of direct consulting access for the physician referred to in paragraph (1).

(3) Nursing and maternity care in a hospital shall be set out in an organisational chart and the maternity ward shall meet the following criteria –

(i) Evidence of current registration of all nurses and midwives shall be available on request.

(ii) A roster of nurses and midwives on various shifts within each twenty-four hour period for the week shall be available upon request.

(iii) Vital signs of each patient shall be observed and recorded on each patient's chart at least once in 24 hours or as often as is required in the circumstances.

Accommodation.

51. Every maternity ward shall have and maintain at all times –

(a) at least one delivery room; and

(b) operable resuscitation equipment including a supply of oxygen and suction apparatus commensurate with the number of patients in the facility.

Surgical operations.

52. Every maternity ward in which surgical operations are performed shall meet the requirements of Part XII (Surgical Centres).

PART IX
MEDICAL LABORATORIES

Medical laboratories to comply with Part IX.

53. (1) Every licensee of a health facility that is licensed as a medical laboratory shall ensure that the requirements of this Part are met.

(2) Every licensee of a health facility that contains a medical laboratory and person who operates a medical laboratory under section 5 of the Act shall ensure that the requirements of this Part are met.

Staff.

54. (1) Every medical laboratory shall be under the supervision and direction of a medical practitioner.

(2) Every medical laboratory shall have on staff medical laboratory technicians who are qualified to perform the procedures undertaken by the laboratory.

(3) At least one medical laboratory technologist shall be available on the premises of a medical laboratory during all hours when laboratory tests are performed.

Scope of service.

55. Every medical laboratory shall display a list of all tests that are carried out by the facility along with the details of fees chargeable for each test and those tests that are carried out by any other facility on behalf of the laboratory.

Collection of specimen.

56. (1) The collection of specimens shall only be performed under the general supervision of the laboratory director or a medical laboratory technologist.

(2) Every medical laboratory shall post in a conspicuous place in the laboratory, written instructions for

the handling, timings of collection of samples or specimen, preservation, storage arid transportation of specimens and timing of delivery of test reports.

Records and

57. (1) Every medical laboratory shall keep records

of all tests undertaken at the health facility and
e carried out by any other health facility on
aboratory. (2) True copies of all records and reports of tests performed including the reports received from another laboratory, shall be kept on the premises of the requesting laboratory and the laboratory that performed the tests, for a period of ten years.

(3) The records and reports referred to in this regulation may be kept in electronic form provided they can be reproduced in a readable form at any time during the period of retention in terms of paragraph (2).

(4) The records and reports referred to in this regulation shall be made available to an inspector upon request.

Policies and procedures.

58. (1) Every medical laboratory shall have written policies and procedures that address the following matters –

(i) quality system requirements;
(ii) organization;
(iii) purchasing of equipment and supplies;
(iv) complaints against the laboratory;
(v) review of requests;
(vi) control of non-conforming work and corrective and preventive action;
(vii) control of records and documents;
(viii) quality assurance and management

reviews;
(ix) safety;
(x) personnel;
(xi) accommodation and environmental conditions;
(xii) test methods and sampling;
(xiii) equipment;
(xiv) handling of tests and calibration of instruments;
(xv) assuring quality of test results and reporting of test results.

(2) A medical laboratory shall not to be used unless it is certified by the Guyana Bureau of National Standards as meeting the requirements of paragraph (1).

Reportable disease.

59. (1) Every medical laboratory shall report to the Ministry of Health the particulars of those tests that a medical practitioner is required to report under the existing laws.

(2) A medical laboratory reporting under paragraph (1) shall ensure the confidentiality of all information reported.

Accommodation.

60. (1) All medical laboratories shall be well ventilated and, where possible, air conditioning that is independent from the rest of the facility shall be used.

(2) In every medical laboratory which uses toxic and volatile chemicals, fume hoods that safely vent out toxic and vapors shall be installed.

(3) At the premises of every medical laboratory fire blankets with instructions for proper use shall be kept on.

(4) In every medical laboratory written fire control and evacuation plans together with clearly marked fire escape routes shall be posted in one or more conspicuous places.

(5) Every medical laboratory that uses electronic equipment requiring electrical power shall have emergency power available during a power failure to provide for refrigeration of those things required to be refrigerated under this regulation and to supply heat, if required in the circumstances.

PART X
ONCOLOGY CLINICS

Oncology clinics to comply with Part X.

61. Every licensee of a health facility that is licensed as an oncology clinic shall ensure that the requirements of this Part are met.

Requirement of medical practitioner and staff.

62. (1) A health facility that is licensed as an oncology clinic and every person who operates an oncology clinic under section 5 of the Act shall be under the supervision and direction of a medical practitioner with specialty training in oncology.

(2) A clinic in which medical oncology is provided shall be under the supervision and direction of a medical practitioner with specialty training in medical oncology and shall also have on staff, registered nurses with specialty training in medical oncology.

(3) A health facility that is licensed as an oncology clinic shall have on duty during the hours of operating, at least one member of staff who is a medical practitioner with specialty training in oncology or a registered nurse with special training in oncology.

Examination of tissues.

63. (1) The tissue that is removed from a patient in an oncology clinic shall be sent to a pathologist for an examination.

(2) If on examination of the tissue, the pathologist

finds any malignancy, it shall be reported to the oncology clinic and the oncology clinic shall place a copy of the report in the record of the patient and report the fact to the Ministry of Health.

Administration of chemotherapeutic agents.

64. (1) Every health facility in which chemotherapy is administered shall have written policies and procedures with respect to the preparation of drugs that ensures the safety of the members of the staff and patients.

(2) Specimen preparation shall only be carried out by a medical practitioner, a pharmacist, or a registered nurse who has specialty training in oncology and in the administration of chemotherapy drugs.

(3) Every health facility in which chemotherapy is administered shall have written policies and procedures for the management of adverse effects of such treatment on patients.

(4) Every health facility in which chemotherapy is administered shall obtain a written consent from the patient or a legal representative of the patient before administering chemotherapy drugs.

(5) Where a patient is receiving chemotherapy drugs at home, the health facility shall provide instructions to the patient or, where applicable in the circumstances, to any other person who may be assisting the patient or administering the drugs to the patient.

PART XI
PATHOLOGY AND CLINICAL LABORATORY FACILITIES

Pathology and clinical laboratories to

65. Every licensee of a health facility that is licensed as a pathology and clinical laboratory facility and every

comply with Part XI.

person who operates a pathology and clinical laboratory under section 5 of the Act shall ensure that the requirements of this Part are met.

Accommodation.

66. Every pathology and clinical laboratory facility shall designate separate areas for the procurement and storage of specimens and placing of infectious waste for disposal.

Tracings.

67. Every pathology and clinical laboratory facility shall ensure that abnormal ECG tracings shall be confirmed by an internist or a cardiologist.

PART XII
SURGICAL CENTRES

Surgical centres to comply with Part XII.

68. Every licensee of a health facility that is licensed as a surgical centre and every hospital that operates a surgical centre and every person who operates a surgical centre under section *5* of the Act shall ensure that all the requirements of this Part are met.

Supervision and staff.

69. (1) Every surgical centre shall be under the supervision and direction of a medical practitioner.

(2) Every surgical centre where general intravenous or any other type of a regional anesthesia is being administered shall have on staff an anesthesiologist, a nurse and an anesthetist or a medical practitioner with specialty training in anesthesiology.

Policies and procedures.

70. (1) Where surgical procedures are provided in an ambulatory care setting, the surgical centre shall have written policies and procedures that are consistent with those applicable to in-patient surgery, anesthesia, and post-operative recovery.

(2) The policies and procedures referred to in paragraph (1) shall include –

(a) the types of elective operative procedures that may be performed in the centre and the locations where they may be performed;

(b) the scope of anesthesia services that may be performed in the centre and the locations where such anesthesia services may be administered;

(c) the available pre-operative and post operative transportation;

(d) the available post-operative care including post anesthesia recovery;

(e) standardized procedures for operating and maintaining operating rooms and instruments;

(f) procedures for cleaning and disinfecting surgical areas between operations; and

(g) protocols for regular microbiological testing of the surgical area.

(3) Every patient in a surgical centre who receives anesthesia, other than local anesthesia, shall be examined before discharge and shall be accompanied home by a person designated by the patient or the person taking care of the patient.

(4) The examination referred to in paragraph (3)

shall be performed by a medical practitioner or a dental surgeon, as the case requires.

(5) When a patient is discharged from a surgical centre, the centre shall provide written instructions for follow up care to the patient or other person providing care to the patient including directions for obtaining an appropriate medical practitioner or dental surgeon for post-operative problems.

(6) Whenever feasible, a family member shall be available to pediatric patients during the pre-operative and post-operative periods.

Physical requirements.

71. (1) In every surgical centre, the surgical areas shall be separate and distinct from the rest of the health facility.

(2) A site separate from the surgical area shall be set aside for use of the surgical staff and nursing staff for washing and hanging of clothes.

(3) Every surgical centre shall have emergency power supply available during power failures.

Patient's history to be recorded.

72. (1) Before a patient is submitted to any anesthetic or undergoes any surgical operation, the patient's history, the results of any physical examination and a written pre-operative diagnosis shall be recorded in the patient's record by the operating surgeon or any medical practitioner so authorized by the surgeon.

(2) Where in the opinion of the operating surgeon, compliance with subsection (1) would result in delay and detrimental to the patient, the surgeon shall so state in writing and shall record and sign only the pre-operative diagnosis.

Description of operation in

73. Every operation performed in a surgical centre

patient's medical record.

shall be concisely described in medical writing by the operating surgeon or his assistant and such written description shall form part of the patient's medical record.

Operations register.

74. Every surgical centre shall keep an operation register showing the name of the patient, the date and nature of the operation, the name of the surgeon, the name of the anesthesiologist or nurse anesthetist given and the time the operation began and was completed.

Anaesthetic.

75. The anesthesiologist or nurse anesthetist shall furnish to the surgical centre, a record showing the type of anesthetic given, the amount used, the length of time the anesthetic was administered to the patient and the condition of the patient following the operation.

Surgical procedures.

76. An accurate and completed description of the techniques and findings of every operative procedure performed at a surgical centre shall be dictated or written immediately following surgery by the surgeon who performed the operation.

Examination of tissues.

77. (1) Any tissue removed from a patient during an operation or during oral surgery shall be set aside, preserved and labeled by the operating surgeon and sent to a Medical Laboratory for examination by a pathologist.

(2) The report of the pathologist received by the Surgical Centre shall become part of the patient's medical record and all abnormal findings reported by the pathologist shall be reported to the Chief Medical Officer.

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Reg. 5(2), 5(3)

FORM I

APPLICATION FOR ISSUANCE OF A LICENCE TO ESTABLISH AND OPERATE/CONTINUE TO OPERATE A HEALTH FACILITY UNDER THE HEALTH FACILITIES LICENSING ACT (Cap. 33:03)

To
The Minister of Health,
Guyana, Georgetown.

I /We hereby apply on behalf of ……(name of the person/company/firm) for issuance of a licence under the Health Facilities Licensing Act to establish and operate/continue to operate the following health facility:-

Diagnostic Imaging Facilities
Dialysis Centres or Dialysis Clinic
Health Centres
Hospitals
Human Tissue Banks
Maternity Wards
Medical Laboratories
Nursing Homes
Oncology Clinics with Radiation Therapy
Pathology and Clinical Laboratory
Surgical Centres
Any other health facility as prescribed under section 2 of the Act:

I/We furnish the following information relating to the proposal:

1. Full Name of the applicant and in case the applicant is an individual, his qualifications and

occupation:

2. Postal address of the applicant with telephone number(s):

3. Name of the health facility:

4. Date from which the health facility has been established/proposes to be established:

5. Particulars of the business and professional experience of the person(s) submitting the proposal:

6. Description of the location and postal address of the building(s) where the health facility is situated or proposed to be established:

7. A statement of the interest of the applicant in the building in respect of which the licence to establish and operate/continue to operate a health facility is applied for:

8. Details including nature and cost of the services to be provided in the health facility:

9. Details of physical requirements of the proposed Health facility:

10. Projected planning, capital and operating cost of the health facility:

11. Revenue source (s) of the costs:

12. Financial viability of the health facility:

13. Role of the proposed health facility and services

proposed to be offered in it in the context of the National Health Plan and other Action Plans of the Ministry of Health:

14. Details of the system that will be established to ensure the monitoring of the results of the service(s) to be provided in the health facility:

15. Details of the nature, source and training of the professional staff proposed for the health facility:

16. Detailed drawing/ sketch plan of the building and other structures of the health facility proposed to be utilized:

17. Date from which the health facility is proposed to be established and operated:

18. A statement of sanitary arrangements, ventilation and water supply of the building:

19. A statement as to the arrangements, if any, for feeding of patients:

20. A statement on the fire escapes of the building and the facilities provided for use in case of fire:

21. If it is proposed to offer services in surgery, gynaecology or obstetrics, a statement as to the type of surgery, gynaecology or obstetrics to be performed and as to the facilities and equipment which are to be provided in the building for these purposes including facilities for anaesthesia:

22. The number of professional and administrative staff of the facility and the qualification of each member of such staff (existing and proposed to be

filled up separately):

23. Any other information relevant to the requirements and limitations specified in the request for the proposal determined by the Minister of Health:

24. A statement as to the classes of patients, if any, proposed to be admitted:

25. Details of payment of prescribed fee for licence:

26. Any other information which the applicant considers relevant for the proposal:

27. List of enclosures:

I/We hereby certify that the above particulars are correct and best to my/our knowledge.

……..(A)
Place: (Signature)
Date:

.....…….(B)
(Signature)

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Reg. 7(3), 7(4)

FORM II

(National Emblem)

LICENCE TO ESTABLSH AND OPERATE/CONTINUE TO OPERATE HEALTH FACILITY UNDER THE HEALTH FACILITIES LICENSING ACT (Cap. 33:03)

Provisional/Final Licence is granted to

…….

to establish and operate/continue to operate a health facility of…….. from ……..20 … to 20….

(here specify the relevant prescribed category of health facility) in accordance with the Health Facilities Licensing Act subject to the following terms and conditions and to such additional conditions as may be endorsed on the back of this licence:

Terms and conditions:

Place:

Date : Signature and seal of Licensing Authority.

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