L.N. 161 of 1995

MEDICAL AND KINDRED PROFESSIONS ORDINANCE (CAP. 31)

Private Medical Clinics (Licensing) Regulations, 1995

IN exercise of the powers conferred by section 98 (2) of the Medical and Kindred Professions Ordinance, the Minister for Social Development has made the following regulations:—

Title.

1. These regulations may be cited as the Private Medical Clinics (Licensing) Regulations, 1995,

Interpretation.

2. In these regulations, unless the context otherwise requires —

"authorised person" means a person authorised by the Minister to exercise powers under regulation 13 of these regulations;

"clinic" means a private medical clinic;

"Department" means the Department of Health;

"Minister" means the Minister responsible for health;

"Ministry" means the Ministry responsible for health;

"the Ordinance" means the Medical and Kindred Professions Ordinance;

"private medical clinic" includes a private hospital and a day care medical clinic, but does not include a medical practitioner's consulting room;

"Superintendent" means the Superintendent of Public Health.

Clinic to comply with the provisions of these regulations.

3. A licence for the opening or carrying on of a clinic under section 98 of the Ordinance may only be granted or renewed provided such clinic complies with the provisions of these regulations.

Licensing.

4. (1) An application for a licence for a clinic shall be made to the Minister in writing and sent or delivered to the Ministry:

Provided that where an application for a licence is already pending before the coming into force of these regulations, such application shall be deemed to have been made under these regulations.

(2) In making an application for a licence for a clinic, an applicant shall furnish such particulars as are specified in the First Schedule to these regulations and such other information as the Minister may require.

(3) Any application for a licence, including the renewal of a licence, for a clinic shall be accompanied by a fee payable to Government as the Minister may from time to time by notice in the Gazette prescribe.

Refusal of licence.

5. (1) The Minister may refuse to issue or renew, or may withdraw a licence in respect of a clinic if he is satisfied —

(a) that the applicant, or any person employed or proposed to be employed by the applicant to assume responsibility for the clinic is not of good conduct; or

(b) that for reasons connected with the physical location, construction, state of repair, accommodation, staffing or equipment, the clinic is not fit to be used as a clinic; or

(c) that the clinic is, or any premises used in connection therewith are, used, or proposed to be used, for purposes which are not related to the clinic or which are in any way improper, unethical or not lawful; or

Act No. I of 1992.

(d) that the clinic or any premises to be used in connection therewith consist of or include works executed in contravention of the Development Planning Act, 1992; or

(e) that the arrangements for the management and control of the services provided at the clinic are not adequate.

(2) Where a licence has been refused or is not renewed or has been withdrawn, the applicant or licensee, as the case may be, may within thirty days of receipt of notice of refusal, non-renewal or withdrawal of licence, appeal to a Tribunal to be appointed by the President of Malta and made up of a person who has, for at least seven years, been in possession of a warrant to practise the legal profession in Malta as Chairman, and two other members, one from among the medical profession and the other who shall be a representative of the Department.

Licence to specify number of patients to be kept.

6. (1) The licence certificate shall specify the number of inpatient beds which may be kept at the clinic.

(2) The type of surgical operations which can be carried out in a clinic shall be those listed in the Second Schedule to these regulations and subject to any conditions specified therein.

(3) The licence certificate issued under the Ordinance in respect of any clinic shall be kept affixed in a conspicuous place in the clinic.

(4) The tariff of fees chargeable at the clinic in respect of services, other than professional services provided at the clinic, shall be kept affixed in a conspicuous place in the clinic.

(5) It shall be the duty of the licensee to ensure that all patients asking for or receiving a service are informed of the fees chargeable at the clinic and can receive a copy of the relative fees charged, which copy shall be given to any person on request.

Licence conditions.

7. (1) Where the licence for a clinic is issued on behalf of a company, it shall be the duty of the licensee to inform the Minister in writing of any change in the name of the persons running the company with seven days from such change.

(2) (a) No licence for the running of a clinic shall be granted, transferred or renewed unless the clinic is in the charge of a medical practitioner or a registered nurse, hereinafter referred to as "the person in charge".

(b) It shall be the duty of the licensee to make adequate arrangements, to the satisfaction of the Superintendent, for the running of the clinic while he, or, if he is not the person in charge of the clinic, the person in charge is absent from such clinic, and moreover to ensure that the name of any person at any time in charge of such clinic is fixed at all times in a conspicuous place and visible to the public when the clinic is providing a service. This information is to be communicated forthwith to the Superintendent.

(c) If at any time during the absence of the person in charge there is no person designated as being in charge, the clinic shall during such time be deemed to have been operated without a licence.

(d) It shall be the duty of the licensee to inform forthwith the Superintendent in writing, and where possible and practicable in advance, of any change, other than aforesaid, of the person in charge of the clinic.

(e) There must be a clear distinction and definition of the roles and responsibilities of the person in charge and the licensee in all those instances where these functions are not carried out by the same person.

Presence of medical practitioner.

8. It shall be the duty of the licensee to ensure that at all times in-patients are receiving treatment at the clinic, there is available resident medical coverage for such patients to the satisfaction of the Superintendent, taking into consideration the number and condition of such patients and the service being provided at the clinic:

Provided that where the surgical operations to be carried out at the clinic are limited to those listed in Part I of the Second Schedule to these regulations, the presence of a registered nurse shall be sufficient.

Duties incumbent on licensee.

9. (1) It shall be the duty of the licensee to ensure that there are present at all times at the clinic a sufficient number of nurses to ensure proper care of the patients in the clinic taking into consideration the following:

(a) the number and category of patients accommodated;

(b) the number of floors and the number of patients on each floor;

(c) the overall layout of the building;

(d) the facilities provided;

(e) the number of additional part time staff and of other staff capable of providing nursing support.

(2) (a) Without prejudice to the generality of the above and to the provisions of paragraph (5) of this regulation, there shall be at least one registered nurse on duty in each ward or special unit at all times patients are receiving a service in such ward or special unit.

For the purposes of this paragraph, no ward or special unit shall be considered as one such ward or unit unless it is wholly situated on one floor.

(b) If a children's ward or special unit is incorporated within the clinic there shall be at all times children are receiving treatment, a registered sick children's nurse or a registered nurse with significant experience in the nursing of children.

(c) Where, in any clinic, surgery is carried out there must additionally be present at all times such surgery is carried out and, for a reasonable period before and after such event, a registered nurse with operating theatre experience:

Provided that patients recovering from an anesthetic shall be attended to by a qualified anesthetist or by a suitably trained registered or enrolled nurse.

(3) (a) No patient may be left in the sole charge of a person who is not authorised to practise as a nurse.

(b) The number of temporary or casual nurses on duty shall not exceed the number of permanently employed nurses on duty and no temporary or casual nurse shall be in sole charge of a patient unless a permanently employed registered nurse is present on the premises and can be called upon immediately.

(4) The person in charge of a clinic shall maintain a roster of duties of nurses and such roster shall be available to nurses and on request to an authorised person.

(5) It shall be the duty of the licensee, having regard to the number, age, sex and condition of patients treated at the clinic, to —

(a) provide adequate professional, technical, ancillary and other supporting staff,

(b) provide for each patient in the clinic adequate accommodation and space, including, where appropriate, day room facilities;

(c) provide adequate furniture, bedding, curtains and where indicated, suitable bed screens and floor coverings in rooms occupied or used by patients;

(d) provide adequate medical, surgical and nursing equipment and adequate treatment facilities, including an efficient nurse/patient call system;

(e) provide for the use of patients adequate wash hand basins and baths or, where acceptable, showers, supplying hot and cold water and a suitable number of water closets and sluicing facilities;

(f) provide adequate lighting, heating and ventilation in all parts of the clinic occupied or used by patients;

(g) keep all parts of the clinic, in good structural repair, clean and reasonably decorated;

(h) ensure that adequate facilities exist, and take adequate precautions, against the risk of fire including the provision of adequate means of escape in the event of a fire, as well as make adequate arrangements for detecting, containing and extinguishing a fire, for notices regarding procedure to be used in case of fire and for the giving of warnings, for the evacuation of the patients and staff, for the maintenance of fire fighting equipment, and for such other arrangements as may in any case be required by law, and in the absence of any such law, as may at any time, be directed by the Commissioner of Police;

(i) provide adequate kitchen equipment, crockery and cutlery and adequate facilities for the preparation and storage of food;

(j) supply adequate food for every patient in accordance with such patient's dietary requirements;

(k) arrange appropriate laundering facilities;

(l) make adequate arrangements for the disposal of swabs, soiled dressings, instruments and similar substances and materials as well as for any other hazardous wastes;

(m) make adequate arrangements, as may be indicated, in respect of long stay patients;

(n) make adequate arrangements for the recording, safekeeping, handling and disposal of drugs;

(o) provide adequate arrangements for the prevention of infection, toxic condition, or the spread of infection in the clinic;

(p) take adequate precautions against the risks of accidents;

(q) provide for adequate insurance coverage of patients treated, and of employees working, at the clinic and for insurance of third parties in each case in respect of accident or other mishap.

(6) The number of domestic staff shall be sufficient to ensure a high standard of cleanliness in all parts of the premises and the licensee shall ensure that such staff is supervised by a person with knowledge of cleaning methods and materials applicable to a clinic.

(7) There shall be a supply of wholesome drinking water at suitable points.

(8) Every clinic shall be provided with adequate telephone facilities. Similar facilities shall also be available for private use by patients.

(9) (a) In respect of operations listed under Part I of the Second Schedule, the facilities and resources as well as the condition or medical fitness of the patient shall be such as to enable such operations to be carried out under conditions of good surgical and medical practice, as recommended by academic colleges of anesthesiologists and of surgeons recognised by the Superintendent.

(b) No surgical operations as are listed or referred to in Part II of the Second Schedule may be carried out at a clinic unless there are adequate operating theatre facilities, as are specified in the Third Schedule to these regulations, to the satisfaction of the Superintendent.

(c) Where in any clinic, surgical operations are undertaken or a life support system is used, there shall be available adequate facilities for immediate electrical supply in case of interruption of the public supply as is needed to safeguard the lives of the patients.

(10) In this regulation,

(a) "to provide" includes, where applicable, to maintain; and

(b) where any question arises as to suitability, acceptability or adequacy, it shall be deemed to be suitable, acceptable or adequate, as the case may be, if so considered in the opinion of the Superintendent.

Natal care.

10. Where antenatal, intranatal or postnatal care is given at a clinic, the following provisions shall moreover apply:

(1) A registered midwife shall be in charge of all midwifery services and may, in respect of midwifery services only, act as person in charge for the purposes of regulation 5 of these regulations. In any case a practising midwife shall be present on duty at all times maternity care is provided.

(2) (a) The person-in-charge should make certain that adequate general and specialist medical cover is provided as needed.

(b) Adequate arrangements shall exist for obtaining obstetric, paediatric, anesthetic and any other necessary help in an emergency situation.

(c) Where epidural anesthesia is to be offered to women in labour, this should be carried out by an anesthetist trained in this procedure.

(3) (a) Where maternity beds are provided in a clinic they shall be so designated and shall not, unless these are single rooms, be used to accommodate any other type of patient. Maternity patients shall not share rooms with patients who are not in the clinic for obstetric care.

(b) No mentally disordered patient, alcoholic or drug abuser may be accommodated in the section reserved for maternity patients unless such patient requires maternity care; in such case she shall be given separate accommodation.

(c) Adequate sanitary and bathroom facilities reserved for the sole use of maternity patients shall be provided. Grab rails and nurse call systems shall be included, and where practicable showers and bidets.

(d) Nursery accommodation shall be made available as well as adequate facilities for the preparation as may be necessary of infant formula or other breast milk substitute.

(e) Single rooms shall be present for maternity cases which have special needs.

(f) Delivery rooms shall be adequately sound-proofed.

(g) Emergency electrical supplies shall extend to delivery rooms, nurseries and to any operating theatre.

(4) (a) Resuscitation equipment for new-born babies shall be provided.

(b) When deliveries are being conducted, anesthetic and suction machines shall be available.

(c) Each infant shall have its own cradle of approved design, thermometer and bath.

(d) Each patient shall be provided with a comfortable nursing chair.

(5) The licensee shall in addition to the records referred to under paragraph (1) of regulation 11 of these regulations, keep a case record of each child born to a patient in the clinic, which record shall include the following particulars:

(a) details of the weight and condition of child at birth;

(b) a daily statement of the child's health;

(c) details of each of any of the following paediatric examinations, if carried out:

(i) examination for congenital abnormalities;

(ii) measurement of circumference of the head of the child;

(iii) measurement of the length of the child;

(iv) screening for phenylketonuria or other screening for congenital disorder.

(6) The following additional particulars shall be included on the register of patients kept at the clinic in respect of maternity patients:

(a) the date and time of delivery of each patient, the number of children born to the patient, their sex and whether born alive or dead;

(b) the estimated period of gestation prior to delivery;

(c) the name and qualifications of the person who delivered the patient;

(d) the date and the time of any miscarriage occurring in the clinic, including the period of gestation prior to miscarriage;

(e) the date on which any child born to a patient in the clinic left the clinic: and

(f) if any child born to a patient died in the clinic, the date, time and cause of death.

(7) The provisions of paragraphs (2), (3), (4) and (5) of regulation 11 of these regulations shall *mutatis mutandis* apply to these records.

(8) The provisions of this regulation and, as applicable, of the other regulations. shall apply to any premises licensed as a maternity home.

Registers, receipts, case records.

11. (1) Proper records are to be kept of patients treated at the clinic:—

(a) in respect of each patient, in a register showing:

— the name, address, date of birth and identity card number of the patient and where the patient has no identity card, the passport number shall be included together with the country of issue, if such patient has a passport;

— the name, address, identity card number and telephone number of the patient's next of kin or of any person authorised to act on the patient's behalf;

— the name and address of the patient's medical practitioner;

— the date when and the time during which the patient was admitted and the date of discharge or transfer to a clinic or other place as may be applicable;

— if the patient died in the clinic, the date, time and cause of death;

— in the case of a child, where applicable, the name and address of the school he attends or has attended before being admitted to the clinic;

(b) a separate register of all surgical operations performed in the clinic: such register shall include in respect of each operation, the date and time of such operation, the patient's name, the identity card or passport number as may be applicable or as provided for under the preceding sub-paragraph, the clinic case history number, the name of the medical or dental practitioner who performed the operation, and where applicable, the name of any other practitioner assisting him, as well as the name of the anesthetist in attendance;

(c) a separate case record of every patient which shall contain an adequate updated statement of the patient's health and condition and a note of any investigation and details ot surgical operations carried out and treatment given, including the anaesthetic record sheet.

(d) a record of each member of the staff employed, which record shall include the name, date of birth, identity card number, grade and dates of employment at the clinic, and in respect of nursing staff, details of their qualifications. Such records shall as far as reasonably practicable include the times when individual members of the nursing staff as well as the person or persons in charge were on duty;

(e) a record of the following:

— all fire practices;

— all fire alarm tests, results and action taken where applicable;

— the maintenance carried out on medical, surgical and nursing equipment in the clinic;

(f) such other records as the Minister may, from time to time, require to be kept.

(2) All records referred to in paragraph (1) of this regulation, other than patient case records, shall be retained for a period of not less than two years after the last entry made therein, and shall be open for inspection by an authorised officer or by such authority as may have such power under any law.

(3) Patient case records shall be retained and shall not be destroyed except with the approval of the Minister.

(4) It shall be the duty of the person in charge of the clinic to ensure proper keeping and storage of records and, subject to the provisions of these regulations and to any other law relating to confidentiality of records, to limit disclosure only to persons entitled to access of such information.

(5) All records shall be legibly entered in full and in proper order. Any alterations, corrections or deletions shall be initialled by the person making such alteration, correction or deletion.

(6) Notwithstanding the provisions of the preceding paragraphs, computer records may, under such conditions as the Minister may impose in the licence certificate, be acceptable provided always that a hard copy of the day's entries are made each day and filed in chronological order:

Provided that such alternative shall not, in the case where the Minister directs that a copy of the entries be sent regularly to the Ministry and/or the Department, be construed as any acceptance of any irregularity carried out at the clinic on the pretext that the Ministry and/or the Department had been regularly informed.

Work by Government personnel.

12. (1) No medical practitioner, dental surgeon, nurse, midwife, pharmacist, pharmacy technician or any other person to whom Part IX of the Ordinance refers, and who is also in the employment of Government, may, during those hours in which he is contracted to provide his services to Government, work in any medical clinic unless he is on approved leave of absence. Any breach of this provision by any such medical practitioner, dental surgeon, nurse, midwife, pharmacist, pharmacy technician or other person shall be deemed to be an offence. It shall be the duty of the licensee of such clinic to take all reasonable steps to ensure that this provision is complied with.

(2) The licensee shall require all persons to whom Part IX of the Ordinance refers to register their attendance at the medical clinic, indicating date and time and whether entering or leaving the clinic, immediately on entering and immediately before leaving the clinic, in a register kept for the purpose. The licensee shall transmit the contents of such register to the Ministry or Department in such manner as may be specified by the Minister. The provisions of paragraph (6) of regulation 11 of these regulations shall also apply to the register referred to in this provision.

(3) It shall be an offence for any licensee or person in charge of a clinic to permit on the premises any person to whom paragraph (1) of this regulation refers unless the conditions of the last preceding paragraph have been complied with.

(4) Where, except in an emergency, any licensee or person in charge of a clinic is in wilful breach of any preceding provision of this regulation, such clinic shall be deemed to have been operating without a licence.

Inspections.

13. (1) Subject to the following provisions of this regulation, any authorised person, on producing if asked to do so, a duly authenticated document showing that he is so authorised, may enter and inspect any premises which are used, or which he reasonably believes to be used as a clinic and may require the production of and may inspect any register or records maintained or retained in pursuance of these regulations.

(2) Any authorised person may require the licensee or his representative to furnish information in relation to the clinic in respect of any matters mentioned in the First Schedule to these regulations and such other information as may reasonably be required for the purposes of inspection:

Provided that nothing in this regulation shall be deemed to authorise any person who is not a medical officer to inspect any clinical record relating to a patient in the clinic.

(3) The licensee shall permit any authorised person to interview in private any person in the clinic.

(4) The clinic shall be open for inspection by any authorised person with a view to ensuring full compliance with the provisions of these regulations.

(5) Every clinic licensed under these regulations shall be inspected at least twice in every period of twelve months. The inspecting officer or officers shall conduct a systematic review of facilities and services with a view to ensuring compliance with these regulations and with the conditions of the licence, and shall submit a report to the Minister on the results of his inspection.

Staff members' names.

14. The Ministry is to be informed of the names, addresses and qualifications of each member of the staff employed on date of issue, renewal or transfer of the licence and of any changes in staff subsequent thereto.

Notice of death.

15. If a patient, or a child born to a patient dies in the clinic, the licensee shall give notice to the Superintendent forthwith and shall report to him in writing within 24 hours after such death. Such notice shall include full particulars of the patient, the circumstances and cause or suspected cause of death, and any other information which may be relevant.

Receipt for services at the clinic.

16. For each service carried out on payment at the clinic, an official itemised receipt shall be issued from the clinic to the person in respect of whom such service was provided. The licensee shall moreover ensure that a register of financial accounts of the clinic is kept.

Serving.

17. Nothing in these regulations shall be deemed to exempt any applicant or licensee from any requirement of the law regarding any other licences which may be needed in respect of any facility or service provided at the clinic.

Repeals L.N. 110 of 1981.

18. The Medical Clinics (Licensing) Regulations, 1981 are hereby repealed, without prejudice to anything which may have been done under any of the provisions hereby repealed.

FIRST SCHEDULE

Regulation 4(2)

Matters in respect of which a Health Authority may require information to be furnished by an applicant for a licence

1. The full name and address, and professional or technical qualifications (if any) of the applicant.

2. Where the application is made by a company, society, association or body, the address of its registered office or principal place of business and the full names and addresses and technical qualifications (if any) of the directors or partners.

3. The address of any other clinic in which the applicant has or had a business interest and the nature and extent of his interest.

4. The situation of the clinic and its form of construction (plan to be attached).

5. The accommodation available, and the equipment and facilities provided or to be provided in the clinic.

6. The date on which the clinic was established or is to be established.

7. Whether any other business is or will be carried on in the same premises as the clinic.

8. The type of clinic services to be provided including list of operations proposed to be carried out.

9. The number of patients (excluding staff) for whom it is proposed to be used distinguishing between different categories of patients and indicating the age-range of patients in each category.

10. The full names, ages, qualifications and experience of persons employed or proposed to be employed in the management of the clinic.

1. The arrangements for the management and control of the clinic.

12. The full names and qualifications of any employed medical practitioners.

13. The full names and (where appropriate) qualifications and grades of the nursing and other professional, technical, administrative and ancillary staff (other than staff included under paragraph 12 above) employed or proposed to be employed in the clinic.

14. The details of arrangements made or proposed to be made in respect of the provision of facilities and services.

15. The arrangements made for the supply of blood and blood products.

16. The arrangements made for the provision of pathology and radiology services.

17. The arrangements made for the insurance of patients, staff and third parties against accidents and other mishaps.

18. Whether the clinic is intended to operate as a day care clinic only (i.e. with no overnight stay) or as a clinic with overnight stay of patients.

SECOND SCHEDULE

Regulation 9(9)

Part I

The following operations may be carried out in a clinic, as referred to in paragraph (9) of regulation 9, provided that the facilities and resources, as well as the condition or medical fitness of the patient are such as to enable such operations to be carried out under good medical, surgical and anesthetic practice in line with guidelines established by international academic colleges of surgeons and anesthesiologists recognised by the Superintendent.

Where day surgery is carried out this generally demands a high standard of expertise, and should be undertaken only, or supervised, by experienced practitioners. Such operations should be clean and elective surgical procedures and should normally require a relatively short general anesthesia and should not carry the risk of post-operative complications that normally require overnight stay in a clinic and the patient is expected to recover sufficiently to return home in the early evening. In particular haemostasis must be strictly ensured and where an operation requires drainage, it may not always be suitable to be performed on a day care basis. It is understood that the facilities should be similar to those required for in-patient surgery with ward area near the operating theatre suite (including anesthetic room and recovery room of the high dependency type) and without prejudice to the generality of this requirement must have adequate lighting, basic equipment, piped gases and gas scavenging devices. Basic equipment includes anesthetic machine and monitoring apparatus, operating table, diathermy machine, dressing trolleys, scrub facilities as well as other equipment required in accordance with good surgical and anesthetic practice for specific operations.

The elderly and infants are normally excluded and the arrangements for post-operative care outside the clinic must be satisfactory. In particular the patient must have adult attendance and it must be ensured that such patient is in close reach of the telephone for emergencies. After discharge from the clinic, the patient must be given appropriate instructions following discharge and be accompanied home.

If the patient is deemed to be unfit for discharge from the clinic on the same day either on anesthetic or surgical grounds it shall be the responsibility of the person in charge of the clinic to make appropriate arrangements for in-patient admission to a clinic where overnight stay is allowed.

In every case the prudent exercise of clinical judgement by the surgeon and the anesthetist, faced with an individual problem and particularly when faced with non-ideal facilities, is mandatory.

A. **Paediatric Surgical Operations**

(i) General

Examination under anesthesia
Repair of inguinal/umbilical/femoral/epigastric hernia
Varicocele
Ligation of communicating hydrocele
Orchidopexy (unilateral or bilateral), excluding second stage operations or cases of high non-palpable testis
Laparoscopy
Circumcision, meatotomy
Minor hypospadias
Cystoscopy
Division of tongue tie
Proctoscopy, sigmoidoscopy, anal stretch, examination under anesthesia
Excision of local skin lesions, including biopsy
Lymph node biopsy
Branchial sinus, thyroglossal cyst
Correction of prominent ears
Excision of accessory auricles and digits
Correction of syndactyly
Minor revision following cleft lip and palate surgery
Biopsy/excision/destruction of lesions, or removal of excess mucosa, of mouth
Removal of calculi from salivary ducts

(ii) Orthopaedic

Arthroscopy
Manipulations, closed reductions of simple fractures/dislocations
Change of plaster
Release of trigger finger
Excision of ganglion

(iii) Dental

Extractions/conservation dentistry
Supernumerary or impacted teeth
Biopsy of oral lesions, including excision
Lingual or labial frenectomy
Removal of fixators
Enucleation of simple cysts

(iv) Ear, Nose and Throat

Examination under anesthesia and removal of foreign body from ear, nose and throat
Myringotomy and insertion/removal of tympanostomy tube
Electro-cochleography
Reduction for fractured nose
Electro-cautery for bleeding of nose
Submucosal diathermy
Simple nasal polypectomy
Antral puncture and washout

(v) Ophthalmic

Correction of squint
Electro-diagnostic tests
Examination under anesthesia for ophthalmic conditions

B. **Adult Surgery**

(i) General

Excision of lesions of skin and subcutaneous tissue, including rodent ulcer
Cautery/cryotherapy of skin
Removal of foreign body in deeper tissue
Dermabrasion
Skin suture
Insertion/removal of skin expander into tissue
Repair of simple inguinal, femoral, umbilical or epigastric hernia
Anal fissure, anal stretch, sphincterotomy
Excision of anal fistula
Removal of anal warts
Repair of anal trauma
Rectal polypectomy
Haemorrhoidectomy
Diagnostic Laparoscopy
Needle biopsy of liver
Oesophagoscopy and dilatation
Biopsy breast, lymph node, skin, lesions of mouth
Removal of salivary calculus
Ligation, stripping of/other operations for, varicose veins
Excision of thyroglossal cyst
Excision of branchial sinus
Incision and drainage of abscess , drainage of haematoma
Microdochotomy

(ii) Orthopaedic

Note: Facilities for image intensification and application of plaster casts where necessary should be available

Arthroscopic procedures, including biopsy and operation on articular cartilage
Manipulation of joints, closed reduction of simple fractures/ dislocations
Removal of pins, plates or screws, external fixator
Excision of ganglia, synovial cysts and benign synoviomata
Decompression of carpal tunnel
Decompression of peripheral nerve
De Quervain's release
Removal of neuroma, e.g. on the hand
Correction of minor deformity of hand/foot
Minor amputation of the fingers and toes
Operation on ingrowing toe nails
Subcutaneous tenotomy
Tendon transposition
Primary repair of peripheral nerve
Ulnar styloidectomy
Excision of exostoses
Interphalangeal fusion of the toes
Hallus valgus and osteotomy of metatarsals
Release of trigger finger
Simple excision of palmar fascia in Dupuytren's contracture
Removal of foreign bodies
Scar revision
Biopsy, excision of small lesion, limited repair, of muscle

(iii) Urinary System

Note: Uncatheterised patients should not be sent home before they have passed urine.

Percutaneous nephrostomy fine needle biopsy of kidney
Nephroscopic operations on ureter
Ureteroscopic extraction of calculus of ureter
Endoscopic examination/insertion/removal of prosthesis, ureter
Endoscopic retrograde pyelography
Operations on ureteric orifice
Endoscopic destruction of lesion of bladder
Endoscopic hydrostatic distention of bladder
Endoscopic extraction of bladder calculus or foreign body
Endoscopic dilatation of, or operations on, outlet of female bladder
Repair of epispadias
Endoscopic operations on urethra
Endoscopic examination of urethra/ removal of foreign body
Dilatation of urethra
Endoscopic biopsy of prostate

(iv) Genital System

External meatotomy of urethral orifice
Orchidectomy and excision of spermatic cord
Orchidopexy
Correction of hydrocele
Excision of epididymal cyst, scrotal lesion
Biopsy testis
Operations on varicocoele
Division of preputial adhesions
Circumcision
Vasectomy

(v) Ophthalmic Operations

Cataract surgery
Corneal transplant surgery
Procedures on the eyelid or tarsal plate
Operations on the lachrymal apparatus
Correction of squint
Surgery for refraction
Laser surgery
Keratoplasty
Iridectomy

(vi) Ear, Nose and Throat

Endoscopy of nasal cavity, sinuses, pharynx, larynx, including biopsy
Removal of foreign body from the nose or ear canal
Removal of impacted wax
Excision of lesion of external ear
Myringotomy/insertion/removal of tympanostomy tube
Removal of simple nasal polyps
Reduction of fracture nasal or malar bone
Electro-cautery of the nasal septum
Submucosal diathermy of the inferior turbinates
Antral puncture and washout
Removal of vocal polyp
Diagnostic laryngoscopy, pharyngoscopy and oesophagoscopy

(vii) Endoscopic/Laparoscopic procedures of gastro intestinal tract

Oesophagoscopy/oesophagostro duodenoscopy, including biopsy/ removal/laser or diathermy destruction of lesion
Endoscopy and removal of foreign body/insertion of prosthesis/ dilatation/recanalisation of tumour mass
Sigmoidoscopy including biopsy/removal/destruction of lesion
Fibreoptic colonoscopy including excision/biopsy/destruction of lesion
Endoscopic retrograde cholangiopancreatography

(viii) Plastic Surgery

Excision of skin lesion: direct closure, split skin or full thickness graft, local flaps (other than grafts to the lower limbs)
Scar revision and soft tissue contouring
Separation and inset of certain flaps
Debulking and revision of flaps

Insertion and distension of tissue expanders
Operations for axillary hyperhidrosis
Laser and cryosurgery
Excision of tattoos
Blepharoplasty
Rhinoplasty
Mastopexy
Limited Liposuction

(ix) Gynaecologyical Operations

Note: Uncatheterised patients should not be sent home before they have passed urine

Examination under anesthesia and curettage
Colposcopy, cystoscopy, diagnostic hysteroscopy/laparoscopy, including biopsy and minor laparascopic surgery
Biopsy/cautery of cervix, removal of cervical polyp
Hormone implants
Excision of vulval warts and other minor procedures to the vulva and vagina
Marsupialisation of Bartholin's cyst
Endometrial ablation with laser or resectoscope
Hysteroscopic resection of uterine septum
Hysteroscopic myomectomy
Laser treatment of cervical and vulval lesions
Tubal ligation
Biopsy of ovary or peritoneum
Coagulation of mild endometriosis
Aspiration of small ovarian cysts
Lysis of mild to moderate adhesions
Coagulation of moderate endometriosis
Exploration of small ovarian cysts
Uterine ventrosuspension
Salpingectomy
Salpingectomy for ectopic pregnancy

(x) Oral and Maxillofacial Surgery

Excision of uncomplicated impacted teeth and buried roots
Exposure of unerupted teeth for orthodontic treatment
Biopsy of hard and soft tissues
Enucleation of small cysts of jaw
Division of pedicles
Removal of direct bone plates and wires
Minor soft-tissue surgery
EUA for suspected malignancy
Cryoblockade of paripheral nerves
Laser and cryosurgery of small lesions
Reduction of nasal and malar fractures
Temporomamlibular arthroscopy
Salivary ductoplasty and removal of calculi

(xi) Other

Bronchoscopy, including biopsy and/or removal of foreign body
Oesophagoscopy and dilatation
Removal of pectus bar
Mediastinoscopy
Chest drainage

(xii) Interventional Radiology

CT Scan using contrast
Isotope scanning
Arteriography using small arterial catheters

(xiii) Pain Relief

Epidural injections - cervical, lumbar or thoracic
Peripheral nerve lesion - using injection, radiofrequency, cryoprobe or phenol.

Part II

The following operations may be carried out in a clinic where patients are kept overnight subject to the facilities referred to under regulation 9(9)(b) being available at the clinic:

1. **All operations listed under Part I of this Schedule.**

2. **Any other surgical intervention other than —**

Neonatal surgery
Intracranial operations
Major laryngeal surgery
Surgery for kyphosis and scoliosis
Cardiac surgery
Aortic surgery
Transthoracic oesophageal resection and other thoracic surgery excluding lobectomy and simple chest drainage
Surgery for portal hypertension

Any other operation or procedure, including any operation referred to in Parts I of this Schedule where there is a probability of the patient requiring intensive care after surgery or where significant amounts of blood loss are anticipated, if intensive care facilities, to the satisfaction of the Superintendent, are not available;

unless such operations are specifically approved by the Minister and a note to this effect is entered in the licence.

THIRD SCHEDULE

Regulation 9(9)

Operating Theatre facilities

(1) Facilities must include:.

(a) two operating tables;

(b) a separate anesthetic room for each theatre;

(c) a recovery room or area;

(d) a cleansing room;

(e) a sterilising room, including facilities for sterilising equipment which cannot be autoclaved;

(f) a plant room or area which may or may not be integrated with the remainder of the suite;

(g) storage space;

(h) a rest/refreshments room;

(i) toilets, wash basins and showers;

(j) barrier zone;

(k) a theatre control office;

(l) facilities for intra-operative radiography including on the spot development of X-Ray films.

(2) The floor area of the operating theatres shall be of an area not less than 37 square metres, and that of the anesthetic rooms of an area not less than 16.5 square metres.

(3) The ceilings, floors and applied wall finishes of the operating suite shall be smooth, impervious and jointless. The floor of the operating theatre shall be similarly covered with material and have appropriate antistatic properties. All finishes shall be able to withstand daily cleansing with water and disinfectants.

(4) (i) The operating suite shall be mechanically ventilated by a satisfactory system which shall be capable of providing and maintaining:

(a) temperatures (user adjustable) within a range of 15°C and 25°C;

(b) relative humidity of the atmosphere within the range 40% — 60%. Only steam injection type humidifiers are permissible;

(c) sufficient fresh air for the requisite temperature and humidity control, dilution of airborne bacterial contamination and control of air movements between clean and less clean areas — see 4(ii)(b);

(d) filtration of the incoming air as specified in the CO4 specifications of 4(ii)a;

(e) positive pressures in the operating theatre relating to other parts of the operating suite, with different pressures as applicable for different rooms — see 4(ii)(b).

(ii) For the purposes of the above provisions, "satisfactory system" means a system acceptable by the international standards recognised by the Superintendent.

(iii) An approved system should be included for the removal of exhaust anesthetic gases in accordance with specifications "BS 6834: 1987 Active Anesthetic Gas Scavenging Systems" or equivalent specifications.

(5) (i) The operating theatre shall have clinical quality lighting capable of rendering not less than 400 lux (excluding the illumination from operating lamp). The preparation, scrubbing and recovery areas shall have lighting of not less than 250 lux while the anesthetic areas should have an illumination of not less than 300 lux. The remaining parts of the suite should have an illumination of not less than 200 lux.

(ii) Essential lighting and power shall be provided in the theatre suite. These shall be fed from an automatic standby power source which shall assume the load after a period of not more than 10 seconds.

(iii) Emergency lighting fed from a D.C. Source shall also be available for the essential parts of the operating theatre suite. There shall be ensured a no break supply to the operating theatre lamps.

(6) Clinics carrying out surgery or admitting acutely ill medical patients shall require a cardiac monitor, a pulse oximeter, a defibrillator, a fully equipped resuscitation trolley and oxygen and suctions in all areas where acutely ill patients may be kept. More than one set of equipment may be required in hospitals handling large numbers of patients.

(7) Qualified and fully trained staff able to react and operate the cardiac emergency equipment, if so required, have to be on duty 24 hours a day.

Ippubblikat mid-Dipartiment ta' l-Informazzjoni – Kastilja – Published by the Department of Information - *Castille*

Mitbugħ fl-Istamperija tal-Gvern – *Printed at the Government Printing Press*

Prezz 22c – *Price 22 c*