



**TURKS AND CAICOS ISLANDS**  
**HEALTH REGULATION ORDINANCE 2016**

**(Ordinance 22 of 2016)**

*Assent*.....28<sup>th</sup> June 2016

*Publication in Gazette*.....1<sup>st</sup> July 2016

*Commencement*.....in accordance to section 1

**AN ORDINANCE** TO PROVIDE FOR THE ESTABLISHMENT OF A HEALTH REGULATION AUTHORITY; FOR THE REGULATION OF HEALTH FACILITIES; AND FOR CONNECTED PURPOSES.

**ENACTED** by the Legislature of the Turks and Caicos Islands.

**PART I**

**PRELIMINARY**

**Short title and commencement**

**1.** This Ordinance may be cited as the Health Regulation Ordinance 2016 and shall come into operation on such day as the Governor may appoint by Notice published in the *Gazette*, and different dates may be appointed for different provisions and different purposes.

**Interpretation**

**2.** In this Ordinance—

“Authority” means the Health Regulation Authority established under section 3;

“Appeals Tribunal” means the Health Appeals Tribunal established under the Health Appeals Tribunal Ordinance;

“Board” means the Board of the Authority established under section 7;

“Chairperson” means the person appointed as chairperson of the Board under section 7;

“clinical trial” means—

(a) subject to paragraph (b), an investigation or series of investigations consisting of the administration of one or more medicinal products or of one or more treatments of a particular description—

(i) by or under the direction of a registered practitioner to one or more of his patients; or

(ii) by or under the direction of two or more registered practitioners, each product being administered by or under the direction of one or other of those registered practitioners to one or more of his patients,

where (in any such case) there is evidence that medicinal products or treatments of that description have effects which may be beneficial to the patient or patients in question and the administration of the product or treatment is for the purpose of ascertaining whether, or to what extent, the product or treatment have those or any other effects, whether beneficial or harmful; but

(b) a clinical trial does not include—

(i) the administration of any medicinal product in respect of which there is a product licence in force in the United Kingdom, provided that administration is carried out in accordance with the conditions of the licence;

(ii) the administration of any medicinal product in respect of which a licence equivalent to that referred to in subparagraph (i) has been issued by the appropriate authority in the United States of America, Canada or Jamaica and is in force and that administration is carried out in accordance with the conditions of that licence; or

(iii) the administration of any medicinal product approved by the World Health Organisation;

“health care facility” means premises at which health services are provided by a registered practitioner; and “facility shall be construed accordingly;

“Health Registrar” has the same meaning assigned under the Health Professions Ordinance;

“health services” includes clinical services such as clinical examination, nursing care, dental care, provision of blood and blood products, diagnostic procedures, provision of medical and surgical services, provision of pharmaceuticals, advice or counselling and any such other service as is provided by a registered practitioner under this Ordinance; and a therapeutic service such as physiotherapy or chiropractic shall be construed as a health service;

“inspector” means a person specified in section 41(1);

“licence” means a licence issued under section 29;

“licensee” means a person issued a licence under this Ordinance;

“manager”, in relation to a health care facility, includes owner;

“member” means a member of the Board specified or appointed under section 7;

“Minister” means the Minister responsible for health;

“Ministry” means the Ministry responsible for health;

“Permanent Secretary” means the Permanent Secretary responsible for health; and

“registered practitioner”, in relation to any health profession, means a person registered under the Health Professions Ordinance.

## PART II

### HEALTH REGULATION AUTHORITY AND BOARD

#### **Health Regulation Authority established**

**3.** (1) There is established an Authority to be known as the Health Regulation Authority.

(2) The Authority shall be a body corporate with perpetual succession and a common seal, capable of suing and being sued in its own name, and subject to the provisions of this Ordinance, shall do or perform such acts or things as bodies corporate may, by law, do or perform.

### **Seal of Authority**

4. (1) The seal of the Authority shall be a device which shall be determined by the Authority and shall be kept by the Chief Executive Officer.

(2) The affixing of the seal shall be authenticated by the Chairperson and the Chief Executive Officer, or any other person authorised in that behalf by a resolution of the Board.

(3) Any contract or instrument which if entered into or executed by a person who is not a body corporate is not required to be under seal, may be entered into or executed without a seal by the Chairperson, the Chief Executive Officer or any person authorised by the Board in that behalf.

### **Functions of Authority**

5. (1) The functions of the Authority shall be to—

- (a) licence and regulate health care facilities and to ensure that health services are provided to the highest standards in quality and safety;
- (b) advise the Minister on policy relating to health practice and regulation in the Islands;
- (c) advise the Director responsible for planning and any other relevant authority on applications for the development of health care facilities;
- (d) certify, inspect and investigate health care facilities and health services;
- (e) provide advice and guidance to the Government on the performance of health care facilities contracted by the Government to provide medical services in the Islands;
- (f) research, collect and maintain information on the provision of health care facilities in the Islands; and
- (g) provide for and ensure there is protection of patient information.

(2) The Authority may issue written standards relating to physical facilities, equipment, personnel, healthcare products, medical technologies, health services, clinical services, procedures at health care facilities, health and patient information management and protection.

(3) The standards issued under subsection (2) shall accord with any relevant guidelines in regulations made by the Minister under this Ordinance.

### **Powers of Authority**

6. (1) In carrying out its functions the Authority has power to—

- (a) collaborate with any person it considers necessary, in the collection, compilation and publication of statistics relating to provision of health care services in the Islands; and
- (b) with the approval of the Minister, enter into arrangements with any department of government for the use of personnel, facilities and services of that department to any extent not incompatible with that department's operation or the provisions of this Ordinance.

(2) A publication of statistics or information under subsection (1)(a) shall not contain any particulars identifying any individual.

### **Board of Authority**

7. (1) The Board shall consist of the following members—

- (a) the Permanent Secretary responsible for health;
- (b) the Director of Health Services;
- (c) the Chief Nursing Officer;
- (d) the Director of Planning or his designate;
- (e) the Chief Environmental Health Officer; and
- (f) three members appointed by the Minister from the private sector.

(2) The Chief Executive Officer and the Health Registrar shall be *ex-officio* members of the Board, but shall not have a right to vote or be counted for the purpose of constituting a quorum.

(3) The Minister shall appoint a Chairperson and Deputy Chairperson of the Board from amongst the members.

(4) Subject to section 9(2) and (3), an appointed member shall hold office for a term not exceeding three years, and shall be eligible for reappointment

(5) To ensure that the terms of appointed members do not expire at the same time, the Minister shall make an appointment in a manner that the tenure does not expire at the same time.

### **Functions of Board**

- 8.** (1) The Board is the governing body of the Authority.
- (2) The principal functions of the Board are—
- (a) to consider applications for, and issue licences to persons who make an application to operate a health care facility;
  - (b) to monitor and oversee the management of the affairs and business of the Authority; and
  - (c) perform such other functions as are conferred on it by virtue of this Ordinance or any other law.

### **Disqualification, removal and resignation of member**

**9.** (1) A person shall not be appointed as a member of the Board if—

- (a) he has in terms of any law in force in any country or in the Islands—
  - (i) been adjudged or otherwise declared bankrupt or insolvent and has not been rehabilitated or discharged; or
  - (ii) made an assignment, arrangement or composition with his creditors, which has not been rescinded or set aside;
- (b) within a period of ten years immediately preceding the date of his proposed appointment, has been convicted—
  - (i) in the Islands, of a criminal offence; or
  - (ii) outside the Islands, of an offence which if committed in the Islands would have been a criminal offence,  
and sentenced by a court of competent jurisdiction to imprisonment for six months or more without the option of a fine, whether that sentence has been suspended or not, and for which he has not received a free pardon; or
- (c) he is incapacitated by reason of physical or mental illness;

(2) The Minister may by notice in writing, remove an appointed member from office—

- (a) in the event of the occurrence of anything which would render the member ineligible for appointment in terms of subsection (1);
- (b) where the member has been absent from three consecutive meetings of the Board without reasonable excuse and leave from the Chairperson;
- (c) where the member contravenes the provisions of this Ordinance or otherwise misconducts himself to the detriment of the objectives of the Board and of the Authority, or of the public interest;
- (d) where the member fails to comply with sections 16, 17 and 18; or
- (e) where the member is otherwise unable or unfit to discharge the functions of member of the Board.

(3) An appointed member may at any time resign his office by writing to the Chairperson, who shall forthwith cause the written resignation to be forwarded to the Minister.

(4) For purposes of subsection (2)(c), “misconduct” includes any act done without reasonable excuse by a member which—

- (a) amounts to failure to perform in a proper manner any duty imposed on the member;
- (b) is prejudicial to the efficient conduct of the Board;  
or
- (c) tends to bring the Board into disrepute.

### **Vacation of office**

**10.** The office of an appointed member shall become vacant—

- (a) in the event of the occurrence of anything which would render the member ineligible for appointment in terms of section 9(1);
- (b) upon the death of a member;
- (c) if the member has been removed from office in terms of section 9(2); or
- (d) upon delivery of written resignation by the member in terms of section 9(3).

### **Filling of vacancy**

**11.** (1) Where the Minister is satisfied that an appointed member is temporarily incapacitated by illness, absence or other cause from satisfactorily performing the duties of his office, the

Minister may in terms of section 9(1), appoint another person to act temporarily in his place for a period not exceeding six months, as the Minister may specify.

(2) On the death of, or vacating of office by an appointed member, the Minister shall in terms of section 9(1), appoint another person to be a member in place of the member who vacates office, for the remaining period of office of that member.

### **Directions by Minister**

**12.** (1) The Minister may give general and lawful direction in written form, of the policy which is to be followed by the Board in the performance of its functions, and the Board shall give effect to the directions.

(2) Any direction given or decision made by the Minister which affects the members of the public and which is not of an internal or administrative nature shall be published in the *Gazette*.

(3) A direction made under this section shall not apply to a matter pending before the Board on the day on which the direction is published.

### **Committees of Board**

**13.** (1) The Board shall establish committees it considers necessary to assist it in the exercise of its functions, and may delegate to the committees, any functions it considers necessary or appropriate.

(2) The Board may appoint to the committees, at least two members of the Board and such other number of persons as it considers appropriate, and the persons shall hold office for such period as may be determined by the Board.

(3) Subject to special or general directions of the Board, a committee may regulate its own procedure.

(4) Meetings of a committee shall be held at such place, day and time as a committee may determine, or as the Board may direct.

(5) A committee shall keep records of its meetings and report to the Board on its activities.

(6) The Board may by resolution, adopt or reject a report made to it by any committee, either wholly or with any modifications, additions or adaptations as the Board may see fit.

### **Remuneration, allowances and expenses**

**14.** An appointed member of the Board or committee, or any person co-opted to attend any meeting of the Board or committee,



shall be paid such remuneration, allowances and travelling expenses incurred in connection with service on the Board, as the Minister may determine.

### PART III

#### MEETINGS AND PROCEEDINGS OF BOARD

##### **Meetings of Board**

**15.** (1) Subject to this Ordinance, the Board shall regulate its own procedure.

(2) The Board shall meet as often as is necessary or expedient for the discharge of its functions, but in any case, at least four times a year, and a meeting shall be held at such place, day and time as the Chairperson in consultation with the Chief Executive Officer may determine.

(3) A meeting shall be called by the Chairperson upon giving written notice of not less than seven days.

(4) The Chairperson may call a special meeting—

(a) by giving a shorter notice where the urgency of any matter does not require the giving of notice in terms of subsection (3); or

(b) within five days on written request addressed to him by any three members.

(5) There shall preside at any meeting of the Board—

(a) the Chairperson;

(b) in his absence, the Deputy Chairperson; or

(c) in the absence of the Chairperson or Deputy Chairperson, a member elected by the members present at a meeting for purposes of presiding over that meeting.

(6) A quorum at any meeting of the Board shall be four members, one of whom shall be an appointed member.

(7) A decision of the Board shall be passed by a simple majority of the members present and voting, and in the case of an equality of votes, the person presiding shall cast a vote in addition to his deliberative vote.

(8) The minutes of a meeting of the Board—

(a) shall be kept in a proper form, and shall be confirmed by the person presiding as soon as

practicable after any meeting, and before any subsequent meeting of the Board; and

(b) after being confirmed under paragraph (a), shall be sent to the Minister by copy.

(9) The Board may co-opt any person whose presence it considers necessary to assist or advise at any deliberation of the Board, but the person shall not form part of the quorum or have any right to vote.

### **Disclosure of interest**

**16.** (1) Where a member of the Board or committee is present at a meeting of the Board or committee, at which meeting a matter which is the subject of consideration is one in which the member has any pecuniary interest, directly or indirectly, in a contract, proposed contract, licence or other matter, the member shall as soon as practicable after the commencement of the meeting and before the matter is discussed, disclose his interest and shall leave the meeting for the duration of and not take part in any consideration or discussion of any question touching upon that matter.

(2) A disclosure of interest made under subsection (1) shall be recorded in the minutes of the meeting at which it is made.

(3) Where a member of the Board or committee fails to disclose his interest in terms of subsection (1) and a decision by the Board or committee is made benefiting the member, the decision shall be null and void to the extent to which it benefits that member.

(4) A member of the Board or committee who fails to comply with subsection (1) commits an offence and is liable—

(a) on summary conviction to a fine not exceeding \$20,000 or to imprisonment for a term not exceeding two years, or to both; or

(b) on conviction on indictment to a fine not exceeding \$50,000 or to imprisonment for a term not exceeding three years, or to both.

### **Pecuniary interest**

**17.** (1) For the purposes of section 16, a member of the Board or committee shall be treated as having an indirect pecuniary interest in a contract, proposed contract, licence or other matter if—

- (a) the member, or any nominee of his, is a member of a company or other body which has a direct or indirect pecuniary interest in the contract, proposed contract, licence or other matter under consideration;
- (b) the member is a partner, or in the employment of a person with whom the contract was made or is proposed to be made, or who has a direct or indirect pecuniary interest in a contract, proposed contract, licence or other matter under consideration;
- (c) the member or any partner of his is a professional advisor to a person who has a direct or indirect pecuniary interest in a contract, proposed contract, licence or other matter under consideration; or
- (d) the member's spouse or child has a direct or indirect pecuniary interest in a contract, proposed contract, licence or other matter under consideration.

(2) Subsection (1) does not apply to membership of, or employment by, any public body.

(3) The Minister may, subject to such conditions as he may determine, appoint a person to act as a member for any specified period, in any case in which the number of members disabled by section 16 at any one time would be so great a proportion of the whole, as to impede the transaction of business of the Board.

### **Confidentiality**

**18.** (1) A member of the Board or committee, officer or employee of the Authority, or any person assisting the Board or Authority shall observe and preserve the confidentiality of all matters coming before the Board, committee or Authority, and such confidentiality shall subsist even after the termination of the term of office or the mandate.

(2) A member of the Board or committee, officer or employee of the Authority, or any person to whom confidential information is revealed through working with the Board, committee or Authority shall not disclose that information to any person, unless he is required to do so in terms of any law or for purposes of any judicial proceedings.

(3) A person who contravenes this section commits an offence and is liable—

- (a) on summary conviction to a fine not exceeding \$20,000 or to imprisonment for a term not exceeding two years, or to both; or
- (b) on conviction on indictment to a fine not exceeding \$50,000 or to imprisonment for a term not exceeding three years, or to both.

### **Submission of particulars for declaration**

19. A member shall comply with the provisions of the Integrity Commission Ordinance, and shall submit all particulars required by that Ordinance to identify the member's assets, holdings, beneficial income and other relevant interests.

### **Validity of decisions**

20. The validity of any act or proceedings of the Board or committee shall not be affected by any vacancy among its members, or by any defect in the appointment of a member.

## **PART IV**

### **CHIEF EXECUTIVE OFFICER AND STAFF OF AUTHORITY**

#### **Chief Executive Officer**

21. (1) There shall be a Chief Executive Officer for the Authority who shall be appointed by the Minister on the recommendation of the Board, and upon such terms and conditions and for such period as may be determined by the Minister and specified in the instrument of appointment.

(2) A person shall not be appointed as a Chief Executive Officer unless the Minister is satisfied that the person possesses the appropriate qualifications and experience to undertake the duties, and the person demonstrates that he is competent to carry out the functions of the Authority.

(3) The Chief Executive Officer shall be a full time officer and employee of the Authority, and shall render his services exclusively to the Authority.

(4) The Chief Executive Officer shall be answerable to the Board for his actions and decisions.

(5) In the Chief Executive Officer's absence or inability to fulfil his functions, the Board may appoint a senior officer of the Authority to discharge the functions of the Chief Executive Officer during the period of absence or disability.

### **Functions of Chief Executive Officer**

**22.** (1) Subject to the directions on matters of policy as may be given by the Board, the Chief Executive Officer shall be responsible for—

- (a) the day-to-day management of the affairs of the Authority;
- (b) the discharge of the Board's functions and the exercise of its powers; and
- (c) the discharge of such functions and exercise of such powers as may be assigned to, or conferred on him by this Ordinance, or that may be delegated to him by the Board.

(2) The Chief Executive Officer may delegate to any senior officer of the Authority, any powers that he is authorised to exercise under this Ordinance.

### **Staff of Authority**

**23.** (1) The Board shall appoint the senior officers of the Authority and the Chief Executive Officer shall appoint such officers and employees as may be necessary for the proper discharge of the functions of the Authority.

(2) The terms and conditions of the staff of the Authority shall be determined by the Board, in consultation with the Minister.

### **Secretary**

**24.** (1) There shall be a Secretary of the Board who shall be appointed by the Chief Executive Officer, with the approval of the Board, on such terms and conditions as may be specified in the instrument of appointment.

(2) The Secretary shall, in addition to any function that may be assigned to him by the Board or the Chief Executive Officer—

- (a) attend all meetings of the Board but shall not vote on any matter or question before the Board;
- (b) prepare minutes of the meetings of the Board;
- (c) keep a record of the proceedings and decisions of the Board;
- (d) receive applications for licences for and on behalf of the Board and review whether they are in order before submitting to the Board for consideration; and

(e) attend to other duties as the Chairperson may require.

(3) The Secretary shall attend all meetings of the Board, but shall not have a right to vote on any matter before the Board.

(4) In the absence of, or vacancy of the position of Secretary, the Chief Executive Officer may appoint any member of the staff of the Authority to perform the functions of the Secretary, until the Secretary resumes office or the vacancy is filled, as the case may be.

(5) In the performance of his duties, the Secretary shall be responsible to the Chief Executive Officer.

(6) The Chief Executive Officer may, with the approval of the Board, in writing, terminate the appointment of the Secretary, on such grounds referred to in the instrument of appointment.

## PART V

### FINANCIAL PROVISIONS

#### **Funds of Authority**

**25.** The Funds of the Authority shall consist of—

- (a) sums of moneys as may be appropriated by the House of Assembly for the purposes of the Authority;
- (b) fees that the Authority may charge for services rendered by it or those received for licences; and
- (c) any other moneys to which it may be entitled in terms of this Ordinance.

#### **Financial year**

**26.** The financial year of the Authority shall be a period of twelve months commencing from 1 of April and ending on 31 March of every year.

#### **Annual report, accounts and audit**

**27.** (1) The provisions of the Public Finance Management Ordinance and the National Audit Ordinance in relation to the preparation of estimates, accounts and audits and reporting of a statutory body shall apply to the Authority.

(2) In addition to submitting a report of its governance arrangements and finances as required by the Public Finance Management Ordinance, the Authority shall prepare a written

report of its activities and operations during the last preceding year and furnish that report to the Minister within six months after the end of each financial year.

### **Reserve fund**

**28.** (1) The Authority shall build up and maintain a reserve of funds equal to expenditure of the Authority for a period of three months, and such reserve shall be placed on deposit in such reputable bank or financial institution as the Authority may from time to time determine.

(2) The Authority shall expend money from the reserve fund only for the purposes of the Authority.

(3) If, on the last working day of any quarter within a financial year, the monies standing to the credit of the reserve fund exceed the expected three months of the annual budgeted recurrent expenditure needs of the Authority, the Authority shall, within fourteen days of the last working day of the quarter, pay a sum equal to the excess to the Government for payment into the Consolidated Fund.

## **PART VI**

### **HEALTH CARE FACILITIES**

#### **Licences to operate health care facilities**

**29** (1) A person may make an application to the Board for a licence to operate a health care facility.

(2) An application under subsection (1) shall be made in such form as may be prescribed and accompanied by a prescribed fee.

(3) An application made to the Board in this section shall be submitted to the Secretary who shall forward the application to the Board for consideration.

(4) An applicant shall provide the Board, any further information that the Board may require in considering the application.

(5) The Board may require an applicant or his representative to attend personally before the Board and, if the applicant fails to attend, the Board may refuse the application.

(6) If the Board is satisfied that the applicant meets the requirements, the Board shall issue a licence.

(7) A licence shall be subject to the provisions of this Ordinance and to any terms and conditions the Board considers

appropriate or as may be prescribed, including a condition that a person shall not provide any health service or operate a health care facility, otherwise than as specified in the licence.

(8) A person who operates a health care facility without a licence, or who provides a health service not specified in the licence, commits an offence and is liable—

- (a) on summary conviction to a fine not exceeding \$50,000 or to a term of imprisonment not exceeding two years, or to both; or
- (b) on conviction on indictment to a fine not exceeding \$100,000, and a further fine of \$1,000 for every day during which the facility is operated without a licence.

### **Duration of licence**

**30.** A licence shall be for a fixed period not exceeding three years, and may be renewed.

### **Display of licence**

**31.** The licensee shall display the licence in a conspicuous place at the health care facility.

### **Renewal of licence**

**32.** (1) A person may make an application for renewal of a licence at least three months before the expiration of the licence, in such form as may be prescribed and accompanied by a prescribed fee.

(2) If the Board is satisfied that the applicant continues to meet the requirements for the issue of a licence, the Authority shall renew the licence.

(3) If an application for renewal of a licence has been made before the expiry of the licence but has not been dealt with by the Board when the licence is due to expire, the licence continues in force until the application for renewal is dealt with, and the renewal shall be taken to have commenced from the day when the licence would have expired, but for the renewal.

### **Refusal of licence**

**33.** (1) When the Board is considering the refusal of an application for, or renewal of a licence or the issue of a licence subject to a limitation or condition that is adverse to the applicant or is inconsistent with the terms of the application, the Board shall inform the applicant—



- (a) of its intention and the reasons for it;
- (b) of his or its right to an oral hearing; and
- (c) of his or its right to make written representations to the Board,

before the Authority makes a final decision on the application.

(2) An oral hearing shall take place within twenty-one days of the applicant being informed of the Board's intention.

(3) Any written representations shall be made by the applicant within thirty days after being informed of the Authority's intention.

(4) The Board shall have regard to any representations made by the applicant before making its decision.

### **Licence of body corporate**

**34.** (1) Where the licensee is a body corporate, a registered health practitioner must hold the majority of shares in the company or be a member of the company.

(2) Subsection (1) does not apply to—

- (a) a hospital; and
- (b) a business whose sole purpose is not to operate a health care facility or provide health services, but operates a health care facility as part of or on the premises of the major business.

(3) If the licensee who is a body corporate referred to in subsection (1), undergoes change at any time in the body corporate—

- (a) in the persons who are directors of that body corporate; or
- (b) in the persons in accordance with whose directions or instructions the directors of that body corporate are accustomed to act,

the secretary or another assigned person of the body corporate shall not later than fourteen days of the change, serve a notice to the Authority giving particulars of the change.

(4) A body corporate which fails to comply with subsection (3) commits an offence and is liable on summary conviction to a fine of \$10,000.

### **Revocation of licence and appeal**

**35.** (1) The Board may revoke a licence to operate a health care facility—

- (a) if the manager of the health care facility fails to comply with a notice under section 42 or 43, or it is found that the premises are unsatisfactory for the purposes for which they are licensed;
- (b) on the ground that the licence or renewal fee is due and unpaid;
- (c) if the licensee is a registered practitioner and that practitioner has been removed from the register in accordance with the Health Professions Ordinance;
- (d) if the licensee provides a health service in the health care facility, other than that specified in the licence;
- (e) on the ground that any condition stipulated in the licence has not been complied with; or
- (f) on any other ground which in the opinion of the Board makes the licensee unfit to hold a licence.

(2) If the Board intends to revoke a licence to operate a health care facility, the Board shall give notice in writing to the licensee, of the intention and reasons for the revocation and invite the licensee to show cause why the Board should not proceed as intended.

(3) A notice under subsection (2) shall state that within a period of twenty-one days of service, the licensee may make representations in writing or in person, to show cause to the Board concerning the matter, and the Authority shall not determine the matter without considering any submissions or representations received within that period, or any longer period the Board may allow.

### **Health care facility continuing pending determination**

**36.** If the Board is considering any submissions on representations made under section 34 regarding the revocation of a licence, the Board may, before determining the matter—

- (a) by notice to the licensee, permit the health care facility to continue in operation pending its determination; or
- (b) order the closure of the facility within a period of time it considers just.

### **Management of health care facility**

**37.** (1) Clinical services at a health care facility shall be managed by a person who is a registered practitioner.

(2) Non-clinical services at a health care facility may be managed by a person who is not a registered practitioner.

### **Clinical trials**

**38.** (1) The manager of a health care facility shall not permit a person to carry out clinical trials in a health care facility without the prior written consent of the Authority.

(2) The Authority shall consult the National Research Ethics Committee established in the Ministry before giving consent on any clinical trials.

(3) A manager who contravenes subsection (1) commits an offence and is liable—

(a) on summary conviction to a fine not exceeding \$50,000 or to a term of imprisonment not exceeding two years, or to both; or

(b) on conviction on indictment to a fine not exceeding \$100,000 or to a term of imprisonment not exceeding three years, or to both.

### **Insurance**

**39.** (1) A person who operates a health care facility shall—

(a) provide indemnity cover or malpractice or negligence insurance approved by the Authority for every registered practitioner employed by the health care facility;

(b) ensure that the health care facility is covered by adequate liability insurance; and

(c) ensure that a person who works at the facility under a contract of services with the health care facility has adequate malpractice or negligence, and other relevant insurance.

(2) Regulations shall prescribe minimum requirements for a policy of insurance under subsection (1), including the minimum amount of cover to be provided or any exemptions.

(3) A person who operates a health care facility in contravention of subsection (1) commits an offence and is liable on summary conviction to a fine not exceeding \$50,000 and a further fine of \$1,000 for every day during which the facility is operated without insurance.

PART VII  
ENFORCEMENT

**Power to investigate and inspect**

**40.** The Authority shall have power to investigate any health care facility or provision of health care services—

- (a) on its own motion—
  - (i) where it has reasonable suspicion that a health care facility is not operating or kept in accordance with the standards set under this Ordinance;
  - (ii) where it has reasonable suspicion that a health service is provided contrary to the standards set under this Ordinance; or
  - (iii) if it is satisfied that there are reasonable grounds to carry out an investigation in the public interest; or
- (b) where a complaint is made by a person who claims to have suffered mistreatment by a health care facility in the provision of any health service, whether by negligence or otherwise.

**Inspection of health care facilities**

**41.** (1) An inspector shall be an officer of the Authority and any other person appointed in terms of subsection (2) or (3).

(2) The Permanent Secretary, on the request of the Chief Executive Officer, may assign any public officer having suitable qualifications, as he thinks necessary, as an inspector for the purposes of this Ordinance.

(3) The Minister may, on the request of the Chief Executive Officer, where there are insufficient inspectors or in the absence of a person with the requisite skills to be appointed an inspector under subsection (1) or (2), appoint an inspector from the private sector.

- (4) An inspector may—
  - (a) at any reasonable time, enter, inspect and examine any health care facility in order to ensure that—
    - (i) the premises are being kept in accordance with the standards set by the Authority under section 5(2); or

- (ii) the health service being provided in the health care facility is that authorised in the licence;
- (b) when entering any premises, take with him any equipment and materials considered necessary for the purpose of inspection and examination;
- (c) make any examination and investigation as may in the circumstances be necessary; and
- (d) require any person to afford him such facilities and assistance on any matter or thing within the person's control or in relation to which that person has responsibilities, necessary to enable the inspector to exercise any of the powers conferred by this section.

(5) An inspector shall be provided with an identification card bearing a photograph of himself, indicating that he is an inspector.

(6) An inspector shall produce his identification card for inspection to any person in relation to whom the inspector is about to exercise, is exercising or has exercised a power under this Ordinance.

(7) An inspector who intends to inspect any premises in accordance with this section may give reasonable notice of not more than three days of his intention to inspect the premises, to the manager of the premises.

(8) An inspector, when exercising a power under this section, may be accompanied by any other person whose assistance the inspector considers necessary, and that person may do anything that is reasonably necessary to assist the inspector in the performance of his functions.

### **Improvement notices**

**42.** (1) If an inspector is of the opinion that premises which have been inspected are in an unsatisfactory condition, he shall notify the manager in writing, setting out his findings and giving the manager such period of time as the inspector considers necessary to remedy the situation.

(2) If the manager fails to comply with the notice under subsection (1) within the period of time stated in the notice, the inspector shall report the non-compliance to the Chief Executive Officer.

(3) The Chief Executive Officer may, if he agrees with the report made under subsection (2), serve the manager of the premises a notice ("an improvement notice") stating that the

Chief Executive Officer agrees with the report and the reasons, and requiring the manager to remedy the situation within a period stated in the notice.

### **Prohibition notices**

**43.** (1) If a health service which is not specified in the licence is provided at a health care facility, or any activity is carried out on the premises, and the inspector is of the opinion that the activity involves a risk or serious injury or harm to a patient or to the user of the premises, the inspector shall report the matter to the Chief Executive Officer, and the Chief Executive Officer may, if he agrees with the report, serve the manager of the premises with a prohibition notice.

(2) A prohibition notice shall—

- (a) set out the findings of the inspector;
- (b) specify the matters which, in the opinion of the Chief Executive Officer, give rise to the risk; and
- (c) direct that the activities or services to which the notice relates shall not be carried on at the premises, unless the matters specified in the notice in accordance with paragraph (b) have been remedied.

(3) A direction contained in a prohibition notice under subsection (2)(c) shall take effect—

- (a) at the end of the period specified in the notice; or
- (b) if the notice specifies, immediately.

### **Provisions supplementary to notices**

**44.** An improvement notice or a prohibition notice may include directions on the measures to be taken to remedy the matter to which the notice relates, and such directions may be framed to afford the person on whom the notice is served a choice between different ways of remedying the matter.

### **Emergency action**

**45.** (1) Notwithstanding the procedure set out under sections 41, 42 and 43, the Authority may close a health care facility without notice where there is an emergency and a delay or observance of the procedure set out under these sections may be harmful to the public.

(2) In exercising the emergency power under subsection (1), the Authority shall ensure that the health care facility is not unnecessarily prejudiced and in any case, shall not close the

facility for a period of more than five days without making an application to the court for an order to continue the closure of the facility whilst investigations are being carried out.

### **Appeal against notices**

**46.** (1) In this section—

“notice” means an improvement notice or prohibition notice.

(2) A person on whom a notice is served may within a period of twenty-eight days, appeal by notice to the Appeals Tribunal.

(3) The Appeals Tribunal on consideration of an appeal may—

(a) cancel or affirm the notice; and

(b) if it affirms the notice, do so either in its original form or with any modifications it thinks fit.

(4) If an appeal under this section is brought against a notice, then—

(a) in the case of an improvement notice, the bringing of the appeal has the effect of suspending the operation of the notice until the appeal is finally disposed of or, if the appeal is withdrawn, until the withdrawal of the appeal; and

(b) in the case of a prohibition notice, the bringing of the appeal has the same effect as in paragraph (a), only if the appellant so applies and the Appeals Tribunal directs.

## **PART VIII**

### **MISCELLANEOUS PROVISIONS**

#### **Exemption from licence fees**

**47.** The Minister may by Order published in the *Gazette*, exempt certain public health care facilities from the payment of fees under this Ordinance.

#### **Indemnity**

**48.** No matter or thing done or omitted to be done by a member of the Board or committee, officer or employee of the Authority shall, if the matter or thing is done or omitted to be done in good faith and without negligence, in the course of the operations of the Authority, render a member of the Board or

committee, officer or employee of the Authority, or any person acting by his direction, personally liable to an action, claim or demand.

### **Offence against illegal operations**

**49.** (1) A person who is not a registered practitioner who provides services tantamount to health services commits an offence.

(2) A person who commits an offence under this section is liable on conviction on indictment to a fine not exceeding \$150,000 or to a term of imprisonment not exceeding five years, or to both.

### **Offences and penalties**

**50.** (1) A person who wilfully obstructs any officer or employee of the Authority in the performance of his functions under this Ordinance commits an offence.

(2) A person who without reasonable excuse, fails to comply with any requirement lawfully imposed by the Board for—

(a) his attendance before the Board;

(b) the giving of evidence; or

(c) the production of documents,

commits an offence.

(3) A person who wilfully makes or produces or causes to be made or produced, either verbally or in writing, any declaration, licence or representation which he knows to be false or fraudulent, commits an offence.

(4) A person who commits an offence under this section is liable on summary conviction to a fine not exceeding \$10,000 or to a term of imprisonment not exceeding six months, or to both.

### **Regulations**

**51.** (1) The Minister may make regulations prescribing anything under this Ordinance which is to be prescribed or which is necessary or convenient to be prescribed for the better carrying out of the objects and purposes of this Ordinance, or to give force and effect to its provisions.

(2) Without prejudice to the generality of subsection (1), the Minister may make regulations to provide for—



- (a) the records, books, reports and returns to be made in respect of health care facilities and the production to and inspection by the Board, or any person authorised by the Board, of the records, books, reports and returns;
- (b) the submission of reports and returns by health care facilities to the Board;
- (c) the submission of reports and returns by the Board to the Minister;
- (d) the use of any information acquired by the Authority for research and statistical purposes;
- (e) the criteria of issue of licences and the types and forms of licences;
- (f) the scope of operation of health care facilities, including the control, management and conduct of such health care facilities;
- (g) the standards for health care facilities, personnel and delivery of health services;
- (h) patient information management and protection;
- (i) the classification and grades of health care facilities;
- (j) the construction, establishment, alteration, safety, equipment, maintenance and repair of health care facilities;
- (k) the services to be provided in health care facilities;
- (l) the admission, treatment, care of, discharge of patients and the control of admission of any class of patient;
- (m) minimum requirements for insurance under section 39; and
- (n) fees required under this Ordinance.

(3) Regulations may make provision for offences and impose administrative penalties and general penalties of up to a fine of \$150,000 or imprisonment for a term of five years, or to both.

### **Transitional provisions**

**52.** (1) If immediately before the coming into operation of this Ordinance a private medical establishment or health care facility is licensed under the Health Practitioners Ordinance, that licence, whatever the length of its unexpired term, shall extend

until six months after the coming into force of this Ordinance and shall be construed as a licence to operate a health care facility under this Ordinance during that period.

(2) Sections 12 and 13(*d*) of the Health Practitioners Ordinance shall continue to apply to a licence extended under subsection (1).

(3) If a licence for a private medical establishment or health care facility has been extended in accordance with subsection (1), any person who wishes to operate a health care facility at those premises shall, sixty days before the termination of the licence, apply for a licence under this Ordinance.

(4) A person who operates a health care facility, shall within twelve months of commencement of this Ordinance, obtain an insurance cover as required under section 39.

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