

HEALTHCARE OPERATORS REGULATION

REGULATION NUMBER (4) OF 2013

STATEMENT

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Part One Preliminary and Key Provisions

1 Title

This Healthcare Operators Regulation is to be referred to as the DHCC Healthcare Operators Regulation No. (4) of 2013 (the “Healthcare Operators Regulation”).

2 Issue of Regulation

This Healthcare Operators Regulation is issued in accordance with the Law.

3 Repeal of Regulation

This Healthcare Operators Regulation repeals and replaces the DHCC Healthcare Operators Regulation No. (4) of 2008.

4 Hierarchy

- (1) If there is any conflict between the provisions of this Healthcare Operators Regulation and any other Regulation approved by the Chairperson, the provisions of the Governing Regulation shall prevail.
- (2) In the event of any inconsistency between an earlier version of a Regulation and an amended version of the same Regulation, the most recently amended version of the Regulation shall prevail.

5 Commencement

This Healthcare Operators Regulation comes into force on the date of its issuance by the Chairperson.

6 Background

The vision of DHCC is to be the internationally recognized location of choice for quality Healthcare Services and an integrated center of excellence for clinical and wellness services, medical education and research. To assist in achieving this vision, there needs to be a strong and transparent governance framework relating to the regulation of Healthcare Operators within DHCC. No Entity or person may conduct Clinical Activities within DHCC without a Clinical Operating Permit issued in accordance with this Healthcare Operators Regulation and the applicable Rules, Standards and Policies.

7 Purpose

- (1) The purpose of this Healthcare Operators Regulation is to:
 - (a) govern all Entities and Licensed Healthcare Operators providing or intending to provide Healthcare Services in DHCC;
 - (b) set out the framework under which Licensed Healthcare Operators may operate within DHCC, including but not limited to the general criteria and procedures under which Healthcare Operators may obtain and maintain Clinical Operating Permits to provide Healthcare Services within DHCC;
 - (c) promote the safe provision of Healthcare Services to patients receiving such Healthcare Services within DHCC;



- (d) enable the establishment of consistent and reasonable standards for providing Healthcare Services to patients receiving such Healthcare Services within DHCC;
 - (e) encourage Healthcare Operators to take responsibility for the safe provision of Healthcare Services; and
 - (f) encourage Licensed Healthcare Operators providing Healthcare Services to improve the quality of such Healthcare Services continuously.
- (2) This Healthcare Operators Regulation provides a framework to ensure safeguards are in place to ensure:
- (a) the safe provision of Healthcare Services in DHCC;
 - (b) the provision of Healthcare Services in DHCC is regulated under this Healthcare Operators Regulation; and
 - (c) there are DHCC Standards or other Standards recognized by the Quality Council for the Commissioning and accreditation of healthcare operators, Provisional Approval Letter Holders and Licensed Healthcare Operators.

8 Requirement to comply with Regulation

All Entities intending to provide or providing Healthcare Services in DHCC shall comply with all of the applicable requirements of this Regulation and the applicable Rules, Standards and Policies

9 Amendment of Regulations

The Chairperson may, from time to time, approve amendments to this Healthcare Operators Regulation in accordance with the provisions of the Governing Regulation.

10 Provision of services in accordance with Regulations

- (1) No person or Entity may operate as a Licensed Healthcare Operator conducting Clinical Activities within DHCC unless it is an Entity and has obtained and maintains a Clinical Operating Permit, , in accordance with this Healthcare Operators Regulation and the applicable Rules, Standards and Policies.
- (2) No person or Entity may provide Healthcare Services within DHCC except in accordance with this Healthcare Operators Regulation and any other applicable Regulations, Rules, Standards and Policies.
- (3) Failure to comply with subsections (1) or (2) may result in:
 - (1) a Penalty being imposed as provided by the Healthcare Operators Regulations;
 - (2) the imposing of conditions, suspension, revocation, refusal to renew, or termination of the Licensed Healthcare Operator's Clinical Operating Permit within DHCC as provided by the applicable Regulations; or
 - (3) eviction of the person or Entity operating within DHCC without a License.

11 Healthcare Operators Regulation to be read in conjunction with other Regulations

This Healthcare Operators Regulation shall be read in conjunction with the following Regulations and any amendments to such Regulations:

- (1) Commercial Services Licensing Regulation;
- (2) Company Regulation;



- (3) Complementary and Alternative Medicine Professionals Regulation;
- (4) Education Regulation;
- (5) Governing Regulation;
- (6) Health Data Protection Regulation;
- (7) Healthcare Professionals Regulation;
- (8) Medical Liability Regulation;
- (9) Research Regulation; and
- (10) Any other Regulation approved by the Chairperson under the Law.

12 Responsibility for administration of Regulations

The DHCC Board of Directors and the Executive Body of the DHCA are responsible for ensuring proper administration of this Healthcare Operators Regulation and any Rules, Standards and Policies made under this Healthcare Operators Regulation.

13 Savings and Transitional Provisions

- (1) Every person and Entity who is licensed under the repealed DHCC Healthcare Operators Regulation No. (4) of 2008 immediately before the date upon which this present Healthcare Operators Regulation comes into force shall upon that date be deemed to be licensed under the provisions of this Healthcare Operators Regulation.
- (2) This Healthcare Operators Regulation shall not apply to any investigation, inquiry, review, appeal or other similar proceedings commenced before the date upon which this present Healthcare Operators Regulation comes into force and the repealed DHCC Healthcare Operators Regulation No. (4) of 2008 shall continue to apply to that investigation, inquiry, review, appeal or proceedings as if this Healthcare Operators Regulation has not been enacted.
- (3) Where on the date upon which this present Healthcare Operators Regulation comes into force, any investigation, inquiry, review, appeal or other similar proceedings is in process, the relevant committee or panel carrying out that investigation, inquiry, review, appeal or proceedings shall continue to exist to complete the investigation, inquiry, review, appeal or other similar proceedings and may make such order, ruling or direction as it could have made under the powers of the repealed DHCC Healthcare Operators Regulation No. (4) of 2008.
- (4) A person who was appointed as a member of any Agency, committee or panel before the date upon which this present Healthcare Operators Regulation comes into force, and whose term has not expired by that date, shall continue to be a member of such Agency, committee or panel until the expiry of his term.



Part Two Interpretation

14 Definitions

Capitalized terms not defined in this Healthcare Operators Regulation shall have the meanings ascribed to them in the Governing Regulation.

Words in the singular include the plural and words in the plural include the singular.

Unless it is specifically stated otherwise in another Regulation or unless the context otherwise requires:

Academic and Research Council means the Academic and Research Council established by Part Five of the Governing Regulation;

Agency means each or any of the boards, councils, registries and similar Entities established under the Governing Regulation and includes the Appeals Board, Central Governance Board, Licensing Board, Planning Council, Quality Council, Academic and Research Council, Professionals Council, Registry of Companies and CPQ ;

Appeals Board means the Appeals Board as established by Part Six of the Governing Regulation;

Applicant means the applicant as defined in the specific Regulations that submits an Application;

Application means an application for a License, a Provisional Approval Letter, or a Miscellaneous Permit made under the specific Regulations;

Approved Continuing Healthcare Education Program, means a Continuing Healthcare Education Program that has been approved by the Registry of Companies;

Approved Continuing Medical Education Program, means a Continuing Medical Education Program that has been approved by the Registry of Companies;

Approved Education Operator means an Entity licensed by the Registry of Companies to conduct Education Programs in accordance with the Education Regulation and the applicable Rules, Standards and Policies;

Approved Non-Degree Granting Healthcare Program means a Non-Degree Granting Healthcare Program that has been approved by the Registry of Companies;

Approved Research Operator means an Entity holding a Research Permit duly issued by the Registry of Companies in accordance with the Research Regulation and the applicable Rules, Standards and Policies;

Approved Professional Indemnity Insurance means professional indemnity insurance that shall be obtained and maintained by a Licensee in accordance with the applicable Regulations, Rules, Standards and Policies;

Associated Person means with regard to an Applicant, any other person, including an Entity, that is Closely Linked with such Applicant;

Branch means the branch of a company or any other Entity or body formed outside DHCC under the laws and regulations applicable in its place of incorporation and authorized to conduct business through this branch inside DHCC;

Building Regulations means those laws, regulations, rules or standards of general applicability to the design, construction and safety of buildings in DHCC, whether clinical in nature or not, enforced in DHCC from time to time;



Business Category means a line of clinical business, as determined in accordance with Schedule One of the Healthcare Operators Regulation in at least one of which a Licensed Healthcare Operator engages in DHCC;

Central Governance Board means the Central Governance Board established under Part Five of the Governing Regulation;

Chairperson means the Chairperson of the DHCA appointed under Article (8) of the Law;

Clinical Activity means a Healthcare Service that falls within a Business Category;

Clinical Affairs Department means the department set up within CPQ to monitor and improve the quality of Healthcare Services within DHCC, and to oversee the accreditation processes of healthcare institutions within DHCC;

Clinical Operating Permit means the authorization issued by the Registry of Companies to a healthcare operator allowing it to conduct one or more Clinical Activities;

Clinical Operating Permit Request means a request by a Provisional Approval Letter Holder to convert its Provisional Approval Letter to a Clinical Operating Permit;

Closely Linked, with reference to the relationship between a person and an Applicant, means that such person:

- (1) directly or indirectly, is a Controller of such an Applicant;
- (2) directly or indirectly, is controlled by such an Applicant;
- (3) directly or indirectly, is under common control with such an Applicant; or
- (4) is a person in accordance with whose directions or instructions the directors of the Applicant are accustomed to act;

Commercial Services means services provided by a Licensed Commercial Company;

Commercial Services Licensing Regulation means the DHCC Commercial Services Licensing Regulation No. (9) of 2013 as in force from time to time;

Commissioning means the process of verifying and documenting that the Provisional Approval Letter Holder and all of its systems and assemblies are planned, designed, installed, tested, operated and maintained to meet the required Standards so that a License may be granted;

Committee means the committees established under the specific Regulation;

Company Regulation means the DHCC Company Regulation No. (8) of 2013, as in force from time to time;

Complementary and Alternative Medicine Professionals Regulation means the DHCC Complementary and Alternative Medicine Professionals Regulation No. (3) of 2013, as in force from time to time;

Continuing Healthcare Education Program, means a program of continuing education for Licensed Healthcare Professionals but does not include a Continuing Medical Education Program;

Continuing Medical Education Program means a program of continuing education for Licensed Healthcare Professionals;

Controller with reference to the relationship between a person and an Applicant, means a person who, either alone or with any of its Associated Persons:

- (1) holds more than 50 percent (%) of the economic interests in the Applicant or of another person of which the Applicant is a subsidiary company;
- (2) is entitled to exercise, or control the exercise of, more than 50 percent (%) of the voting power of the Applicant or of another person of which the Applicant is a subsidiary company; or

- (3) is able to exercise significant influence over the management of the Applicant or of another person of which the Applicant is a subsidiary company, with such influence being manifested by such indicia as the Controller being a person in accordance with whose directions or instructions the directors of the Applicant are accustomed to act.

CPQ means the Center for Healthcare Planning and Quality established by Part Four of the Governing Regulation;

CPU means the Customer Protection Unit, a department set up within CPQ to manage and investigate complaints against Licensees as set out in Part Eight of the Governing Regulations and other applicable Regulations;

Degree Granting Healthcare Program means an Education Program that refers to the period of didactic and if appropriate clinical experience in a healthcare setting culminating in certification, certificate, diploma or degree;

Design and Construction Guidelines means, as of the applicable time, (1) the then most current edition of the American Institute of Architects' Guidelines for Design and Construction of Hospital and Health Care Facilities, (2) DHCC Healthcare Facility Projects – The Planning, Design and Construction Guidelines and such other guidelines of general professional acceptance that apply to specific Business Categories, provided that any such additional guidelines have been specifically identified as applicable by the Registry of Companies and adequate advance notice is provided that such guidelines may no longer be applicable;

DHCA means the Dubai Healthcare City Authority established under Article (4) of the Law, and comprises the Chairperson, the DHCC Board of Directors and the Executive Body;

DHCA Services means the services provided by the DHCA in carrying out the objectives and functions of the DHCA and include the services provided by the Agencies, and any Entity established by the DHCA for the purposes of providing such services;

DHCC means the Dubai Healthcare City established in the Emirate of Dubai under Law No. (9) of 2003;

DHCC Board of Directors means the board established under Article (10) of the Law;

Document and Documentation means information stored in any form of writing, code or visual depiction and the manner in which such information is stored is irrelevant for the purpose of deeming the information to constitute a "document" for the purpose of this definition. A "document" includes summons, notice, order or other legal process and registers;

Education Permit means the authorization issued by the Registry of Companies to an Entity under the Education Regulation and the applicable Rules, Standards and Policies allowing it to conduct one or more Education Programs in DHCC;

Education Program means a program to educate or train persons in one or more areas, including a:

- (1) Post-Graduate Medical Education Program;
- (2) Post-Graduate Healthcare Education Program;
- (3) Continuing Medical Education Program
- (4) Continuing Healthcare Education Program;
- (5) Degree Granting Healthcare Program;
- (6) Non-Degree Granting Healthcare Program;
- (7) High School Education Program; and
- (8) Pre-School Education Program.

Education Regulation means the DHCC Education Regulation No. (5) of 2013, as in force from time to time;

Effective Date means the date upon which a Provisional Approval Letter or a License becomes effective;

Electronic Record means a record generated, communicated, received or stored by electronic, magnetic, optical or other means in an information system or for transmission from one information system to another;

Electronic Signature means any letters, characters, numbers or other symbols in digital form attached to or logically associated with an Electronic Record, and executed or adopted with the intention of authenticating or approving the Electronic Record;

Entity means an organization, institution, or corporation other than a natural person;

Executive Body means the Executive Body of the DHCA established under Article (12) of the Law and is presently known as Dubai Healthcare City Regulatory Authority (“**DHCR**”);

Facilities Committee means the committee set up under the purview of the Registry of Companies to carry out the day-to-day administrative functions of the Registry of Companies;

Fit and Proper Person is a determination made under the Governing Regulation or any other applicable Regulation with respect to a natural person who is to serve as a Controller, director, Associated Person or Manager with regard to an Entity, with such determination being made by consideration of such person’s probity, competence and soundness of judgment for fulfilling the responsibilities of the particular position, the diligence with which he is fulfilling or likely to fulfill those responsibilities and whether the interests of patients, vendors, investors, or the Agencies are, or are likely to be, in any way negatively impacted by his holding such position;

Fitness to Practice Panel means the Fitness to Practice Panel established by Part Eight of the Governing Regulation;

Governing Regulation means the DHCC Governing Regulation No. (1) of 2013, as in force from time to time;

Health and Safety Rules

Health Safety and Environment Regulations means those laws, regulations, rules or standards of general applicability to the health, safety and environment of buildings in DHCC, whether clinical in nature or not, enforced in DHCC from time to time;

Health Data Protection Regulation means the DHCC Health Data Protection Regulation No. (7) of 2013, as in force from time to time;

Healthcare Operators Regulation means the DHCC Healthcare Operators Regulation No. (4) of 2013, as in force from time to time;

Healthcare Professionals Regulation means the DHCC Healthcare Professionals Regulation No. (2) of 2013, as in force from time to time;

Healthcare Services means the healthcare and medical services provided by Licensed Healthcare Professionals, Licensed Complementary and Alternative Medicine Professionals and Licensed Healthcare Operators, and includes, but is not limited to, diagnosis, treatment, advice, service or goods provided in respect of the physical or mental health of a person;

High School Education Program means any high school education for children provided by qualified teachers and professionals, culminating in certification, certificate or diploma.

Home Jurisdiction means the jurisdiction outside of DHCC in which the Parent of a Branch has been incorporated, established or formed;

Law means Dubai Healthcare City Law No. (9) of 2011, issued by the Ruler of Dubai, establishing Dubai Healthcare City Authority, and any amendments or variations to that Law;



License means a license issued by the Licensing Board with regard to healthcare professionals and Complementary and Alternative Medicine professionals or a license or permit issued by the Registry of Companies with regard to commercial companies, including Clinical Operating Permits, Non-Clinical Operating Permits, Research Permits and Education Permits;

Licensed Commercial Company means a company registered under the Company Regulation and licensed under the Commercial Services Licensing Regulation to provide Commercial Services within DHCC;

Licensed Complementary and Alternative Medicine Professional means a natural person engaged in the provision of Complementary and Alternative Medicine holding a License duly issued by the Licensing Board in accordance with the Complementary and Alternative Medicine Professionals Regulation and the applicable Rules, Standards and Policies;

Licensed Healthcare Operator means a hospital, clinic, laboratory, pharmacy or other Entity providing Healthcare Services in DHCC, holding a Clinical Operating Permit duly issued by the Registry of Companies in accordance with the Healthcare Operators Regulation and the applicable Rules, Standards and Policies;

Licensed Healthcare Professional means a natural person engaged in a healthcare profession holding a License duly issued by the Licensing Board in accordance with the Healthcare Professionals Regulation and the applicable Rules, Standards and Policies;

Licensee means a Licensed Healthcare Professional, a Licensed Complementary and Alternative Medicine Professional, a Licensed Healthcare Operator, an Approved Education Operator, an Approved Research Operator, a Licensed Commercial Company, or a Non-Clinical Operating Permit Holder;

Licensing Board means the Licensing Board as established by Part Six of the Governing Regulation;

Licensing Department means the department set up under the purview of the Licensing Board, to carry out the day-to-day administrative functions of the Licensing Board, to assist the Academic and Research Council in carrying out their functions, and to undertake the review and approval of advertising and promotional materials by clinical and non-clinical facilities within DHCC;

Location means the site within DHCC, including the physical facility or facilities associated therewith, at which a Licensed Healthcare Operator, an Approved Education Operator, an Approved Research Operator, or a Non-Clinical Operating Permit Holder conducts or proposes to conduct activities under its License;

Manager means the person who is appointed by a Licensee or Miscellaneous Permit Holder to be its principal representative in all dealings with external parties and authorities;

Medical Liability Regulation means the DHCC Medical Liability Regulation, Regulation No. (5) of 2005, as in force from time to time;

Miscellaneous Permit means the authorization issued by the Registry of Companies to an Entity or a person allowing it to conduct one or more activities that is not a Healthcare Service, research activity, or education activity on a short-term basis;

Miscellaneous Permit Holder means a person or Entity holding a Miscellaneous Permit;

Non-Clinical Operating Permit means the authorization issued by the Registry of Companies to a Licensed Commercial Company allowing it to conduct one or more activities that are not Healthcare Services, research activities, or education activities, and includes a public health permit;

Non-Clinical Operating Permit Holder means an Entity holding a Non-Clinical Operating Permit;



Non-Degree Granting Healthcare Program means an Education Program that refers to the period of didactic and if appropriate clinical experience in a healthcare setting which does not culminate in certification, certificate, diploma or degree, and includes a residency training program and a house-officer training program;

Parent means, with respect to a Branch, an Entity that has been legally formed outside DHCC, under the applicable law of the jurisdiction of formation, of which the Branch is a division, provided that a Branch is not a legal Entity separate from the Parent;

Penalty means the penalty imposed on a Licensee in accordance with the applicable Regulations;

Plan has the meaning set out in section 65(8) of the Governing Regulation;

Planning Council means the Planning Council as established by Part Five of the Governing Regulation;

Policy means a defined course of action determined by the DHCA and adopted in accordance with the provisions of the Governing Regulation, on the position, strategy or standing on a subject that shall be followed by those identified within the policy;

Post-Graduate Healthcare Education Program means the period of didactic and clinical training in a healthcare specialty that follows the completion of a recognized undergraduate healthcare education program and which prepares the Trainee for the independent practice of a healthcare specialty, but does not include a Post-Graduate Medical Education Program;

Post-Graduate Medical Education Program means the period of didactic and clinical training in a medical specialty that follows the completion of a recognized undergraduate medical education program and which prepares the Trainee for the independent practice of a medical specialty;

Pre-School Education Program means any non-compulsory pre-school education for children provided by qualified teachers and professionals with the primary objective of promoting structured educational experiences based on learning through play and social interaction;

Professional Practice means with respect to any Licensed Healthcare Professional or Licensed Complementary and Alternative Medicine Professional, the provision of Healthcare Services and the performance of functions within the scope of his License, as provided in the Healthcare Professionals Regulation, the Complementary and Alternative Medicine Professionals Regulation and the applicable Regulations, Rules, Standards and Policies;

Professionals Council means the Professionals Council as established by Part Five of the Governing Regulation;

Provisional Approval Letter means the approval issued to an Entity by the Registry of Companies to enable that Entity to:

- (1) commence the activities required to meet the requirements of the Commissioning; and
- (2) obtain a License in accordance with the specific Regulations;

Provisional Approval Letter Holder means an Entity holding a Provisional Approval Letter;

Quality Council means the Quality Council as established by Part Five of the Governing Regulation;

Registry of Companies means the Registry of Companies established by Part Seven of the Governing Regulation;

Regulation means any regulation approved by the Chairperson under the Law, including any amendments to any such regulation;



Renewal Application means an application to renew a License under the specific Regulation;

Renewal Date is the date as provided in the specific Regulations by which a Licensee shall renew its License, to enable it to continue operating within DHCC;

Research Permits means the authorization issued by the Registry of Companies to an Entity under the Research Regulation and the applicable Rules, Standards and Policies allowing it to conduct one or more research activities in DHCC;

Research Regulation means the DHCC Research Regulation No. (6) of 2013, as in force from time to time;

Rules mean the rules approved by the Chairperson or DHCC Board of Directors as provided for under the Governing Regulation and any other Regulation, and include the rules as in force from time to time;

Standard means a specification that defines materials, methods, processes or practices and that is used to provide a basis for determining consistent and acceptable minimum levels of quality, performance, safety and reliability;

Trainee means a person who is participating in an Approved Post-Graduate Medical Education Program, an Approved Post-Graduate Healthcare Education Program or an Approved Non-Degree Granting Healthcare Program;

UAE means the United Arab Emirates;

Zoning Regulations means those laws, Regulations, Rules or Standards of general applicability to zoning and the use of real estate enforced in DHCC from time to time.

15 **Regulations include amendments**

References in this Healthcare Operators Regulation, or any other Regulations, to the Regulations are to be read as references to any of such Regulations as in force from time to time.

16 **Headings**

The headings used in this Healthcare Operators Regulation are included for convenience of reference only and shall be ignored in the construction or interpretation of this Healthcare Operators Regulation.

17 **Time periods**

References in Regulations to time periods are to be construed in accordance with the Gregorian calendar. Whenever Regulations refer to a period of time, such period shall include every calendar day, except that:

- (1) when the last day of the period falls on a Friday or a Saturday, the period shall end instead on the next Sunday; and
- (2) when the last day of the period falls on a UAE or Dubai public holiday, the period shall end instead on the next day that is not a UAE or Dubai public holiday.

18 **Gender**

Pronouns indicating male gender are used to refer to persons of both genders.

19 **Documents in languages other than English**

A person who wishes to submit an original document, a photocopy or an electronic version of a document written in a language other than English shall also submit a notarized



translation into English of such document prepared by a legal translation service acceptable to the officer, employee or agent providing the DHCA Services to whom the document is submitted.

20 Documents in writing

- (1) Unless otherwise specifically stated, references in the Regulations to any requirement for a document or notice to be submitted to the Registry of Companies, the Licensing Board or any other Agency in writing shall be satisfied if such document or notice is submitted in the form of an Electronic Record.
- (2) Unless otherwise specifically stated, references in the Regulations to any requirement for a signature on any document or notice to be submitted to the Registry of Companies, the Licensing Board, or any other Agency is to be construed as being satisfied by an Electronic Signature that may be proved in a manner satisfactory to the Registry of Companies.

21 Meaning of Person

Unless the context otherwise requires, any reference in the Regulations to a “person” includes a reference to a natural person, and to a body corporate, limited liability company, association or partnership and to the legal or personal representatives, legal successors and lawful assigns of any such person.

22 Reference to sections

Unless otherwise specifically stated, references in a Regulation to a section and subsection mean the section and subsection of that Regulation.



Part Three

General Provisions relating to Provisional Approval Letters and Clinical Operating Permits

23 Eligibility

- (1) Only an Entity which is registered or intending to be registered under the Company Regulation and the Commercial Services Licensing Regulation may submit an Application for a Provisional Approval Letter.
- (2) The Entity submitting an Application for a Provisional Approval Letter or a Clinical Operating Permit under this Healthcare Operators Regulation shall be the eventual Licensed Healthcare Operator conducting the Clinical Activities for which the said Applications are filed.

24 Requirements

- (1) Only an Entity which is registered under the Company Regulation and the Commercial Services Licensing Regulation may become a Provisional Approval Letter Holder.
- (2) No person may obtain a Clinical Operating Permit unless it is an Entity and has first obtained a Provisional Approval Letter, in accordance with this Healthcare Operators Regulation and the applicable Rules, Standards and Policies.
- (3) No person may obtain a Clinical Operating Permit or a Provisional Approval Letter unless he has been granted the relevant in-principle approvals from the Clinical Affairs Department and Licensing Board.

25 Provisional Approval Letter Holder not entitled to provide Healthcare Services

A Provisional Approval Letter Holder is not entitled to conduct any Healthcare Services within DHCC under the authority of the Provisional Approval Letter.

26 Requirement for Provisional Approval Letter Holders and Licensed Healthcare Operators to comply with Regulations

Both Provisional Approval Letter Holders and Licensed Healthcare Operators shall comply with all of the applicable requirements of this Healthcare Operators Regulation and any other applicable Regulations, Rules, Standards and Policies.

27 Responsibilities of Provisional Approval Letter Holders

Each Provisional Approval Letter Holder shall ensure that when undertaking the design and construction of its facilities under its Provisional Approval Letter, that the Location at which it proposes to provide Clinical Activities, upon issuance of a Clinical Operating Permit, complies with all applicable provisions of the:

- (1) Building Regulations and Zoning Regulations;
- (2) Design and Construction Guidelines;
- (3) Health Safety and Environment Regulations; and
- (4) the applicable Rules, Standards and Policies.



28 Responsibilities of Licensed Healthcare Operators

Each Licensed Healthcare Operator shall ensure that all Locations at which it provides Clinical Activities shall at all times comply with all applicable provisions of the:

- (1) Building Regulations and Zoning Regulations;
- (2) Design and Construction Guidelines;
- (3) Health, Safety and Environment Regulations; and
- (4) the applicable Rules, Standards and Policies.

29 Provision of Clinical Activities within Business Category

A Licensed Healthcare Operator may only engage in or conduct any Clinical Activity:

- (1) that is encompassed within the Business Category for which its Clinical Operating Permit has been issued; and
- (2) where the Licensed Healthcare Operator has employed or engaged a Licensed Healthcare Professional or a Licensed Complementary and Alternative Medicine Professional whose Professional Practice covers the provision of the Clinical Activity specified in the Clinical Operating Permit.

30 Exceptions from requirement to hold a Clinical Operating Permit

- (1) A person or Entity who owns or leases land in DHCC or any building in DHCC in which a Clinical Activity is conducted or intended to be conducted, but does not himself conduct or manage such Clinical Activity on that land or in that building, shall not be required to obtain a Provisional Approval Letter or a Clinical Operating Permit under this Healthcare Operators Regulation.
 - (1)
- (2) In such cases the person or Entity shall provide information to the Registry of Companies about:
 - (a) the Business Categories and the Clinical Activities that the building is to be used for, and
 - (b) the manager or operator of the Clinical Activities.

31 Licensed Healthcare Operators may only employ or engage Licensed Healthcare Professional or Licensed Complementary and Alternative Medicine Professional

A Licensed Healthcare Operator may only employ or engage a person to engage in Clinical Activities in DHCC if the person is a Licensed Healthcare Professional or Licensed Complementary and Alternative Medicine Professional whose Professional Practice covers the Clinical Activities provided by the Licensed Healthcare Operator.

32 Licensed Healthcare Operators responsible for certification

- (1) A Licensed Healthcare Operator may employ or engage a person to provide support services such as a health care assistant or an assistant providing support services to a Licensed Healthcare Professional or a Licensed Complementary and Alternative Medicine Professional related to the provision of Healthcare Services.
- (2) Where the Licensed Healthcare Operator employs or engages such a person, the Licensed Healthcare Operator shall be required to provide details of such a



person to the Registry of Companies prior to such employment or engagement for the purposes of seeking certification from the Registry of Companies.

- (3) The Registry of Companies may issue guidelines, from time to time, setting out the process for certification.

33 Jurisdiction of Licensed Healthcare Operator

- (1) A Licensed Healthcare Operator is only licensed to provide within DHCC those Clinical Activities for which its Clinical Operating Permit has been issued.
- (2) Except as specifically provided in this Healthcare Operators Regulation, any Licensed Healthcare Operator intending to provide services outside of DHCC shall be solely responsible for meeting any standards or other requirements of that other jurisdiction.
- (3) For the purposes of this Regulation, any medical treatment that is rendered in an emergency situation while transporting a patient back to DHCC in an ambulance shall be deemed to be a Healthcare Service provided within DHCC and shall be performed in accordance with this Healthcare Operators Regulation and any other applicable Regulations, Rules, Standards and Policies.

34 Provision of Healthcare Services by a locum Licensed Healthcare Professional or Licensed Complementary and Alternative Medicine Professional

- (1) A Licensed Healthcare Operator may utilize a locum to provide any of its Clinical Activities provided that person is a Licensed Healthcare Professional or Licensed Complementary and Alternative Medicine Professional whose Professional Practice covers the Clinical Activities provided by the Licensed Healthcare Operator.
- (2) The Licensed Healthcare Operator remains responsible for any Clinical Activities provided under any locum arrangement.

35 No assignment or transfer of Provisional Approval Letter or Clinical Operating Permit

- (1) Neither a Provisional Approval Letter Holder nor a Licensed Healthcare Operator may transfer or assign its Provisional Approval Letter or Clinical Operating Permit.
- (2) For the avoidance of doubt, where there is a change of Controller this shall be considered to be an assignment or transfer and subject to subsection (1).

36 Compliance with requirements of Agencies

Each Licensed Healthcare Operator shall comply with all requirements that any of the Agencies may from time to time establish regarding data requirements and disease reporting, and shall ensure that each employee that it engages shall also comply with such requirements.

37 Exemption from certain requirements

- (1) The Registry of Companies, upon the recommendation of the relevant Agency, may provide a waiver (in such terms and conditions as it deems appropriate) to an Applicant, a Provisional Approval Letter Holder or a Licensed Healthcare Operator for the otherwise applicable requirements of the:
 - (a) Building Regulations; or
 - (b) Design and Construction Guidelines,

insofar as this is permitted under the applicable laws.

- (2) Such a waiver may only be granted if the Registry of Companies, together with the relevant Agency, both agree that:
 - (a) doing so is in the public interest;
 - (b) requiring compliance with the particular provision would create an undue hardship on the Applicant; and
 - (c) granting such waiver or waivers would not impair or endanger the health, safety or welfare of any person, including any patient of a Licensed Healthcare Operator.

38 Fees

The ROC shall publish from time to time the applicable fees that are to accompany all Applications, Renewal Applications and other submissions to the Registry of Companies provided for under this Healthcare Operators Regulation.



Part Four Provisions relating to Provisional Approval Letters

39 Fee to be paid at time Application for Provisional Approval Letter is submitted

The Applicant shall pay the applicable fee at the time the Application for a Provisional Approval Letter is submitted to the Registry of Companies.

40 Withdrawal of Application for Provisional Approval Letter

- (1) An Applicant may withdraw his Application at any time.
- (2) The Registry of Companies shall retain a record of the Applicant's withdrawal of the Application together with a copy of all the information provided by the Applicant or otherwise obtained during the course of consideration of the Application up until the time the Application is withdrawn.
- (3) Any fee submitted shall not be refunded.

41 Role of Applicant's Manager in Application process

The Applicant's Manager shall be the first point of contact with regard to any matters that arise during the Application process.

42 Form of Application

- (1) An Applicant shall submit an Application in the form and manner as may be required by the Registry of Companies.
- (2) An Application for a Provisional Approval Letter shall be considered only if it meets the following requirements:
 - (a) it is in English;
 - (b) it is typewritten or written in a legible manner;
 - (c) all data, information, and signatures required under this Healthcare Operators Regulation and the applicable Rules, Standards and Policies are supplied;
 - (d) the appropriate application form is utilized; and
 - (e) the applicable fee is submitted.

43 Information to be provided with Application for Provisional Approval Letter

The Applicant shall provide together with the completed application form:

- (1) documentation indicating that the Applicant is registered to carry on business or is intending to be registered in DHCC under the Company Regulation and the Commercial Services Licensing Regulation;
- (2) a description of the Business Category for which the Applicant is seeking a Provisional Approval Letter and the Clinical Activity or Activities that it will undertake upon conversion of its Provisional Approval Letter to a Clinical Operating Permit;
- (3) a detailed business plan and functional brief and space utilization plan as per the requirements of the Design and Construction Guidelines for the Clinical Activity or



Activities that the Applicant will undertake upon conversion of its Provisional Approval Letter to a Clinical Operating Permit;

- (4) the intended Location or Locations of where the Clinical Activity or Activities is to be carried out, including, unless otherwise agreed by the Registry of Companies, evidence of the Applicant's legal right to the use of each Location as of the Effective Date;
- (5) A proposed space utilization plan identifying number of clinical rooms and support areas, medical equipment, and mechanical, electrical and plumbing ("MEP") service requirements;
- (6) Applications for Licenses to be granted to healthcare professionals comprising the key personnel of the Applicant, as may be stipulated by the Registry of Companies from time to time;
- (7) information regarding any disciplinary action or adverse action taken in any jurisdiction against any Associated Person or Controller of the Applicant, including, if the Applicant is a Branch, of the Applicant's Parent;
- (8) details of all Controllers, directors and Associated Persons relating to the Applicant;
- (9) details of the Manager who is appointed by the Applicant to be the principal representative in dealings with the DHCA;
- (10) sufficient documentation, to the satisfaction of the Registry of Companies, that the Applicant is capable of satisfying all requirements established under this Healthcare Operators Regulation and the applicable Rules, Standards and Policies; and
- (11) a written declaration that the Applicant shall promptly notify the Registry of Companies of any modifications or changes to the information or documentation contained in its Application that occur subsequent to the filing; and
- (12) any such other information or particulars, and verified in such manner, as the Registry of Companies or the relevant Agencies may require.

44 Declaration by Applicant

The Application shall be accompanied by:

- (1) a written declaration confirming the accuracy of the statements included in the Application and any accompanying documents;
- (2) an authorization for the Registry of Companies to verify the accuracy of any information provided and to conduct reference checks with any Entity or authority that the Applicant has had dealings with, and, subject to the Governing Regulation, to share such information and documentation with any party as the Registry of Companies considers necessary for purposes of such verification or checks.

45 Provision of incomplete Application for Provisional Approval Letter

- (1) It is the responsibility of the Entity making the Application to submit a completed Application form and to ensure the accuracy of all information provided.
- (2) In the case of incomplete Applications, the Registry of Companies shall notify the Entity identifying the information that has not been provided and the timeframe within which the Application may be resubmitted.
- (3) The Registry of Companies shall specify a reasonable period of time within which the Application may be resubmitted with the required information.



- (4) The Applicant shall not be required to pay an additional fee for resubmitting the Application within the specified timeframe.
- (5) If the Application is not submitted within the time specified, the Application shall be considered to be withdrawn and the Applicant shall need to submit a new Application together with the applicable fee.

46 Requirement to provide further information in Application for Provisional Approval Letter

- (1) At any time after an Application is submitted to the Registry of Companies and before action on it is taken, the Registry of Companies and/or any relevant Agency may, by written notice to the Applicant and/or relevant party, require the provision of such additional information or documents as the Registry of Companies and/or any relevant Agency deems reasonable and necessary to review the Application, in such form and within such time period as required.
- (2) Such additional information may include:-
 - (a) financial information regarding the Applicant and any Associated Person or Controller of the Applicant sufficient to assess the Applicant's financial capability to undertake the Clinical Activity or Activities proposed;
 - (b) details of all Controllers, directors and Associated Persons relating to the Applicant.
- (3) Subsection (1) also applies to any person who is:
 - (a) identified in the Application as a director, Controller or Manager of the Applicant;
 - (b) identified in the Application as being intended to be a director, Controller or Manager of the Applicant; or
 - (c) identified as the key personnel of the Applicant as may be stipulated by the Registry of Companies from time to time.

47 Failure to provide further information in Application for Provisional Approval Letter

- (1) If the Applicant fails to comply with the requirement to provide further information or resubmit the Application in accordance with section 46, the Registry of Companies may consider the Application withdrawn on the basis of insufficient information.
- (2) If the Registry of Companies considers an Application withdrawn, in accordance with subsection (1) on the basis of insufficient information, the Registry of Companies shall notify the Applicant and any fee paid by the Applicant shall not be refunded to the Applicant.

48 All information to be provided before Application for Provisional Approval Letter reviewed

- (1) An Application shall not be considered complete until all information required under this Healthcare Operators Regulation has been submitted to the Registry of Companies for its review.
- (2) The Registry of Companies shall not take any action on an Application until it has determined that the Application is complete based on the requirements set out in this Healthcare Operators Regulation and any applicable Rules, Standards and Policies.

49 Requirement to notify changes in Application for Provisional Approval Letter

- (1) At any time during the review of an Application and prior to the Registry of Companies issuing a Provisional Approval Letter, the Applicant shall promptly notify the Registry of Companies of any modification or change to the information or documentation contained in its Application.
- (2) Failure of an Applicant to notify the Registry of Companies of any such changes in accordance with subsection (1) shall result in the Application being considered incomplete and withdrawn in accordance with section 46.
- (3) If the notification of changes is received after the Registry of Companies has completed its review of the Application, the Applicant shall pay the applicable fee before the Registry of Companies undertakes a further review of the revised Application.

50 Information from other sources

At any time during the process of reviewing an Application, the Registry of Companies may inquire of the DHCA as to the information that the DHCA holds with regard to the capability of the Applicant to provide the Clinical Activity or Clinical Activities proposed in the Application.



Part Five Review of Applications for Provisional Approval Letters

51 Evaluation of facilities by Registry of Companies

In preparation for a review of the Application for a Provisional Approval Letter, the Registry of Companies may arrange for an on-site evaluation of the Entity's facilities.

52 Matters Registry of Companies takes into account

In considering an Application, the Registry of Companies may take into account any matters relating to:

- (1) the need to protect the public and the reputation of DHCC, Dubai and UAE;
- (2) any other factors identified in the applicable Regulations and Rules, Standards and Policies as appropriate to consider;
- (3) any person who is or shall be employed by or associated with the Applicant for the purposes of any of the Applicant's Clinical Activities if a Clinical Operating Permit is issued to the Applicant;
- (4) any person that is an Associated Person, director, Controller or proposed Manager of the Applicant;
- (5) the financial resources available to the Applicant to undertake and maintain the proposed Clinical Activity or Activities;
- (6) in the case of an Applicant that is a Branch, the length of time the Branch's Parent has been conducting Clinical Activities prior to the Branch submitting its Application under the Healthcare Operators Regulation;
- (7) the likelihood that the Applicant shall be capable of complying with the requirements of this Healthcare Operators Regulation and the applicable Rules, Standards and Policies;
- (8) the proposed name of the facility and whether it reflects the Applicant's Clinical Activities if a Clinical Operating Permit is issued to the Applicant.

53 Action on Application for Provisional Approval Letter

Upon the completion of its review, the Registry of Companies may:

- (1) approve the Application;
- (2) approve the Application subject to conditions or restrictions, as it considers necessary and proper to be included in the Provisional Approval Letter; or
- (3) deny the Application.

54 Approval of Application for Provisional Approval Letter by the Registry of Companies

The Registry of Companies shall not approve an Application unless it determines that:

- (1) the Applicant satisfies all relevant criteria contained in this Healthcare Operators Regulation and the applicable Rules, Standards and Policies with regard to the type of Clinical Activities the Applicant proposes to undertake;
- (2) the Clinical Activity or Clinical Activities the Applicant proposes to undertake are consistent with the Plan in effect from time to time in DHCC;



- (3) the Applicant is capable of completing all of the steps required by this Healthcare Operators Regulation and the applicable Rules, Standards and Policies to convert its Provisional Approval Letter to a Clinical Operating Permit;
- (4) the Licensed Healthcare Professionals and Licensed Complementary and Alternative Medicine Professionals identified to be the key personnel employed or engaged by the Applicant to carry out the Clinical Activities, possess the clinical competence to implement all Clinical Activities proposed in the Application in a manner consistent with all applicable Rules, Standards and Policies;
- (5) all Controllers, directors, Associated Persons and Managers identified in the Application are Fit and Proper Persons;
- (6) no facts have been found that would constitute grounds for the Registry of Companies to deny a Provisional Approval Letter;
- (7) in-principle approval has been granted by the Clinical Affairs Department; and
- (8) in-principle approval has been granted by the Licensing Board.

55 Grounds for denying Application for Provisional Approval Letter

The Registry of Companies may deny an Application if it determines that:

- (1) any statements, information or documents submitted by the Applicant are false, misleading or deceptive or are likely to mislead or deceive;
- (2) there has been a modification or change in the circumstances relating to the information or documentation contained in the Application subsequent to its filing, and the Applicant has failed to notify the Registry of Companies of any such modification or change in a timely manner;
- (3) the Applicant has failed to satisfy any of the requirements in section 5454; or
- (4) the Registry of Companies is not satisfied that the Applicant shall comply with the provisions of this Healthcare Operators Regulation and the applicable Rules, Standards and Policies, if it were to hold a Clinical Operating Permit.

56 Applicant to be notified of Registry of Companies' decision

- (1) The Registry of Companies shall notify the Applicant of its decision to:
 - (1) approve the Application and issue the Provisional Approval Letter;
 - (2) impose conditions and/or restrictions on the issue of such Provisional Approval Letter; or
 - (3) deny the Application for a Provisional Approval Letter.
- (9) The Registry of Companies shall also notify the Applicant of:
 - (a) the details of the Clinical Activities covered by the Provisional Approval Letter and any conditions or restrictions imposed; and
 - (b) the Effective Date.

57 No right of appeal of decision of Registry of Companies

The Applicant has no right to seek an appeal of the Registry of Companies' decision to deny an Application or to impose conditions or restrictions on the Provisional Approval Letter.



58 Restriction on submitting new Application for Provisional Approval Letter

If the Registry of Companies denies an Application, unless otherwise agreed by the Registry of Companies, the Applicant may not file a new Application for a Provisional Approval Letter to provide the same Clinical Activity or Clinical Activities as those proposed in the denied Application for a period of six (6) months or such period as may be determined by the Registry of Companies following the Applicant's receipt of notice from the Registry of Companies under section 56.

59 Details contained in Provisional Approval Letter

A Provisional Approval Letter shall contain the following details:

- (1) the name of the Provisional Approval Letter Holder;
- (2) the name and Location of the facility;
- (3) the Effective Date of the Provisional Approval Letter;
- (4) the term of the Provisional Approval Letter;
- (5) the name of the Provisional Approval Letter Holder's Manager;
- (6) the Business Category within which the Provisional Approval Letter Holder intends to provide Clinical Activity or Clinical Activities;
- (7) the Clinical Activity or Clinical Activities proposed to be undertaken under a Clinical Operating Permit; and
- (8) such other matters, including but not limited to any terms, conditions or restrictions included in the Provisional Approval Letter, as may be specified by the Registry of Companies.

60 Term of Provisional Approval Letter

Subject to the provisions of the applicable Rules, Standards and Policies or any terms, conditions or restrictions imposed by the Registry of Companies, a Provisional Approval Letter shall be valid for a period of:

- (1) 2 years in the case of a Provisional Approval Letter for a hospital;
- (2) 1 year in the case of all other Provisional Approval Letters,

or such further term as may be extended under section 73.

61 Abandonment of Clinical Activities

- (1) Unless otherwise agreed to by the Registry of Companies, a Provisional Approval Letter Holder shall be deemed to have abandoned its intent to implement one or more Clinical Activities encompassed by its Provisional Approval Letter if the Provisional Approval Letter Holder does not commence, within 6 months of receipt of the notice from the Registry of Companies under section 56, steps necessary for the eventual filing of an Application.
- (2) The Registry of Companies shall make arrangements for the Applicant to be notified in writing of its decision regarding:
 - (a) the revised scope of the Clinical Activities covered by the Provisional Approval Letter due to abandonment of one or more Clinical Activities; or
 - (b) the withdrawal of the Provisional Approval Letter due to abandonment of all Clinical Activities.

62 Restriction on submitting new Application for Provisional Approval Letter following abandonment

If the Applicant is deemed to have abandoned one or more Clinical Activities under section 61, the Applicant may not file a new Application for a Provisional Approval Letter to provide the same Clinical Activity or Clinical Activities for a period of 6 months following its receipt of notice from the Registry of Companies under section 61(2) unless agreed otherwise by the Registry of Companies.



Part Six

Obligations of Provisional Approval Letter Holders

63 Conditions imposed to ensure progress

Following issuance of its Provisional Approval Letter, each Provisional Approval Letter Holder shall:

- (1) make good faith efforts and continuing progress toward filing an Application;
- (2) report to the Registry of Companies on its actions and continuing progress every 3 months or as requested by the Registry of Companies; and
- (3) comply with all terms, conditions or restrictions imposed on its Provisional Approval Letter.

64 Designs plans and specifications

The Registry of Companies shall make arrangements for the designs, plans and specifications to be reviewed based on the applicable sections of the Design and Construction Guidelines, including fit-outs, modifications, minor works and new building constructions.

65 Final design and construction documentation

- (1) Unless agreed otherwise by the Registry of Companies, the Provisional Approval Letter Holder shall submit the design and construction documents for its Location to the Registry of Companies by no later than:
 - (1) 12 months following the Effective Date in the case of a Provisional Approval Letter Holder that is a hospital; or
 - (2) 2 months following the Effective Date in the case of all other Provisional Approval Letter Holders.
- (2) The documents referred to in subsection (1) shall demonstrate that the construction at such Location shall meet all applicable requirements of the Registry of Companies and the Central Governance Board, including the applicable Building Regulations, Zoning Regulations, Health and Safety Rules, and the Design and Construction Guidelines.

66 Commencement of construction

The Provisional Holder may not commence construction at its Location until it has received a fit-out permit from the Registry of Companies.

67 Access to Location

- (1) During the term of the Provisional Approval Letter, the Provisional Approval Letter Holder shall allow the Registry of Companies and any other associated Entities identified by the Registry of Companies involved in monitoring the construction, fit out and health and safety issues, access to each Location, to monitor the progress being made in completing physical construction at each such Location.
- (2) Any Entity seeking access shall provide the Provisional Approval Letter Holder with reasonable notice of such.



68 Requirement to notify the Registry of Companies of modifications to an Application

The Provisional Approval Letter Holder shall promptly notify the Registry of Companies of any modification or change to the information or documentation contained in its Application for the Provisional Approval Letter.

69 Requirement to notify of changes in personnel

The Provisional Approval Letter Holder shall promptly notify the Registry of Companies of any changes as to the identity of all those persons who shall be Associated Persons, Controllers and directors, and the Manager during the term of the Provisional Approval Letter.

70 Modification or changes to Provisional Approval Letter Holders which are Branches

When the Registry of Companies issues a Provisional Approval Letter to an Applicant that is a Branch, the Provisional Approval Letter Holder that has received such Provisional Approval Letter, shall notify the Registry of Companies in writing of any modification or change to the licensure, registration or equivalent authorization that it reported in its Application, together with the date of the occurrence of such modification or change, by no later than 20 days following any such modification or change.

71 Continuation of legal existence of Parent in Home Jurisdiction

During the term of the Provisional Approval Letter and prior to an Application for a Clinical Operating Permit, the Provisional Approval Letter Holder shall provide the Registry of Companies on each anniversary of the Provisional Approval Letter's Effective Date, a certificate issued by the relevant authority in the Parent's Home Jurisdiction that proves the continuation of the legal existence of the Parent in the Home Jurisdiction and the validity of its licensure, registration or equivalent authorization with such authority.

72 Request for extension of term of Provisional Approval Letter

- (1) A Provisional Approval Letter Holder may request in writing for the Registry of Companies to extend the term of the Provisional Approval Letter.
- (2) The request shall specify the:
 - (1) period of time for the extension of the Provisional Approval Letter;
 - (2) outstanding requirements to be completed; and
 - (3) details of any circumstances beyond the reasonable control of the Provisional Approval Letter Holder which have presented a substantial obstacle to the timely completion of the steps needed to make a Clinical Operating Permit Request.
- (3) Any such request shall be made no later than 60 days prior to the expiration of the Provisional Approval Letter, and submitted together with the applicable fee.

73 Extension of term of Provisional Approval Letter

- (1) Where the Provisional Approval Letter Holder makes such a request under section 72, and the Provisional Approval Letter Holder has made substantial progress during the term of its Provisional Approval Letter towards converting its Provisional Approval Letter to a Clinical Operating Permit, the Registry of Companies may extend the time for such Provisional Approval Letter Holder to file its Application.



- (2) In considering the request under section 72, the Registry of Companies may take into account any advice provided to the Registry of Companies by the Facilities Committee regarding the progress of the Provisional Approval Letter Holder.

74 Period of extension

The Registry of Companies shall consider the request to extend the term of the Provisional Approval Letter no later than 30 days prior to the expiration of the Provisional Approval Letter and may extend the term for a further period of up to:

- (1) 2 years, in the case of Provisional Approval Letter Holders that are hospitals; and
- (2) 1 year, in the case of all other Provisional Approval Letter Holders.

75 Notification of decision regarding request for extension of term

The Registry of Companies shall notify the Applicant in writing of its decision regarding the request for the extension of the term of the Provisional Approval Letter including:

- (1) whether the request is granted;
- (2) whether the request is denied and the reasons for denying the request; and
- (3) the expiry date of the Provisional Approval Letter.

76 No right of appeal of decision of Registry of Companies

The Applicant has no right to seek an appeal of the Registry of Companies' decision to deny the request for an extension of the term of the Provisional Approval Letter.

77 Failure to apply for Clinical Operating Permit during term of Provisional Approval Letter

If a Provisional Approval Letter Holder fails to apply for a Clinical Operating Permit prior to the expiration of its Provisional Approval Letter, such Provisional Approval Letter shall automatically terminate on the expiry date specified in the Provisional Approval Letter.



Part Seven

Revocation and Suspension of Provisional Approval Letter

78 Grounds for suspension or revocation of Provisional Approval Letter

The Registry of Companies may suspend or revoke a Provisional Approval Letter on the grounds that the Provisional Approval Letter Holder has breached its obligations as set out in Part Six of this Healthcare Operators Regulation or on the same grounds on which the Registry of Companies could have denied an Application for a Provisional Approval Letter under section 55.

79 Opportunity to rectify breach

Prior to suspending or revoking the Provisional Approval Letter, the Registry of Companies shall give the Provisional Approval Letter Holder an opportunity to rectify the breach within a period of time stipulated by the Registry of Companies.

80 Provisional Approval Letter Holder to be notified of suspension or revocation

- (1) The Registry of Companies shall notify the Applicant in writing of:
 - (a) its decision to suspend or revoke the Provisional Approval Letter; and
 - (b) the reasons for its decision; and
 - (c) in the case of suspension, any requirements that the Provisional Approval Letter Holder shall meet before the suspension will be lifted.
- (2) The Registry of Companies shall also provide the Licensed Healthcare Operator with:
 - (a) a written statement of the reasons for its decision; and
 - (b) details of its right to seek an appeal of the decision.

81 Right of appeal of decision of Registry of Companies

- (1) The Applicant has the right to seek an appeal of the Registry of Companies' decision to suspend or revoke the Provisional Approval Letter.
- (2) Any appeal shall be carried out in accordance with Part Thirteen of this Healthcare Operators Regulation.

82 Suspension of Provisional Approval Letter

Where the Registry of Companies suspends or revokes the Provisional Approval Letter, the affected Provisional Approval Letter Holder's Provisional Approval Letter shall be suspended until the Registry of Companies' appeal process under Part Thirteen of this Healthcare Operators Regulation is completed.

83 Lifting of suspension

- (1) Where the Provisional Approval Letter has been suspended subject to the meeting of certain requirements, the Provisional Approval Letter Holder may request the Registry of Companies to lift the suspension when those requirements have been met.

- (2) The Registry of Companies may request any information it considers necessary from the Provisional Approval Letter Holder to enable it to consider the request to lift the suspension.



Part Eight

Provisions relating to Applications for Clinical Operating Permits

84 Requirements to convert Provisional Approval Letter to Clinical Operating Permit

For a Provisional Approval Letter Holder to convert its Provisional Approval Letter to a Clinical Operating Permit it shall:

- (1) complete the Commissioning as determined by the Registry of Companies from time to time; and
- (2) have been granted the relevant in-principle approvals from the Clinical Affairs Department and the Licensing Board.

85 Provisional Approval Letter Holder responsible for submitting Application for Clinical Operating Permit

The Provisional Approval Letter Holder is responsible for submitting an Application for a Clinical Operating Permit to the Registry of Companies within the term of the Provisional Approval Letter together with the applicable fee.

86 Information to be provided with Application for Clinical Operating Permit

- (1) The Application shall contain such information as the Registry of Companies may reasonably require, consistent with the provisions of this Healthcare Operators Regulation and the applicable Rules, Standards and Policies.
- (2) Each Provisional Approval Letter Holder making an Application for a Clinical Operating Permit shall specify in its Application, the Clinical Activity or Clinical Activities that it proposes to carry on and the Business Category within which it will conduct its Clinical Activity or Activities, if different from the information contained in its Application for a Provisional Approval Letter.

87 Preparation for Commissioning

In preparation for Commissioning, the Provisional Approval Letter Holder shall develop policies and procedures for the provision of the Clinical Activity or Activities included in its Provisional Approval Letter in accordance with the applicable Rules, Standards and Policies.

88 Commissioning

- (1) A Provisional Approval Letter Holder shall undergo the Commissioning to ensure that it complies with the applicable Rules, Standards and Policies and any other standards that an Agency specifies are required to be met prior to issuing a Clinical Operating Permit.
- (2) Following the submission of an Application for a Clinical Operating Permit, the Registry of Companies shall undertake, or arrange for the undertaking of the Commissioning which shall include, but is not limited to:
 - (a) a review of the final versions of all of the Provisional Approval Letter Holder's written policies then required to be in place;
 - (b) a comprehensive on-site inspection and/or assessment of the Location at which the Provisional Approval Letter Holder proposes to conduct its Clinical Activity or Activities;



- (c) the review of information that supports the conclusion that the Provisional Approval Letter Holder shall be able to satisfy all provisions of this Regulation and the applicable Rules, Standards and Policies; and
 - (d) the provision of documented evidence that the Provisional Approval Letter Holder has received all licenses and other approvals required under the applicable Building Regulations and Zoning Regulations.
- (3) In undertaking the Commissioning, the Registry of Companies shall also determine if the Controllers, directors and Associated Persons of the Provisional Approval Letter Holder, as well as any Managers identified by the Provisional Approval Letter Holder, are all Fit and Proper Persons.
 - (4) On completion of the Commissioning, the Registry of Companies shall provide the Provisional Approval Letter Holder with a report on the preparedness of the Provisional Approval Letter Holder to provide its Clinical Activity or Clinical Activities.

89 Requirement to provide further information towards Application for Clinical Operating Permit

The Provisional Approval Letter Holder shall provide any such other information as the Registry of Companies may reasonably request within the timeframe specified by the Registry of Companies, in preparation for the Registry of Companies to review the Application for a Clinical Operating Permit.

90 Review of Application for Clinical Operating Permit by the Registry of Companies

- (1) The Registry of Companies shall consider the Clinical Operating Permit Request together with the report on the Commissioning and the in-principle approvals from the Clinical Affairs Department and Licensing Board, if any.
- (2) In considering the information provided under subsection (1), the Registry of Companies shall take into account any applicable Regulations, Rules, Standards and Policies.

91 Action on Application for Clinical Operating Permit

Upon review, the Registry of Companies may:

- (1) approve the Application;
- (2) approve the Application subject to conditions or restrictions as it deems necessary and proper to be included in the Clinical Operating Permit; or
- (3) deny the Application.

92 Approval of Application for Clinical Operating Permit

The Registry of Companies shall not approve an Application unless it determines that:

- (1) the Applicant satisfies all relevant criteria contained in this Regulation, and applicable Rules, Standards and Policies with regard to the type of Clinical Activities the Applicant proposes to undertake;
- (2) the Clinical Activity or Clinical Activities the Applicant proposes to undertake are consistent with the Plan in effect from time to time in DHCC;
- (3) the Applicant has completed or is capable of completing all of the steps required by this Regulation and the applicable Rules, Standards and Policies to convert its Provisional Approval Letter to a Clinical Operating Permit;



- (4) the Licensed Healthcare Professionals and Licensed Complementary and Alternative Medicine Professionals identified to be the key personnel employed or engaged by the Applicant to carry out the Clinical Activities, who possess the clinical competence to implement all Clinical Activities proposed in the Application;
- (5) all Controllers, directors, Associated Persons and Managers identified in the Application are Fit and Proper Persons;
- (6) no facts have been found that would constitute grounds for the Registry of Companies to deny an Application;
- (7) in-principle approval has been granted by the Clinical Affairs Department; and
- (8) in-principle approval has been granted by the Licensing Board.

93 Grounds for denying Application for a Clinical Operating Permit

The Registry of Companies may deny an Application if it determines that:

- (1) any statements, information or documents submitted by the Applicant are false, misleading or deceptive or are likely to mislead or deceive;
- (2) there has been a modification or change in the circumstances relating to the information or documentation contained in the Application subsequent to its filing, and the Applicant has failed to notify the Registry of Companies of any such modification or change in a timely manner;
- (3) the Applicant has failed to satisfy any of the requirements in section 92; or
- (4) the Registry of Companies is not satisfied that the Applicant will comply with the provisions of this Healthcare Operators Regulation, and the applicable Rules, Standards and Policies, if it were to hold a Clinical Operating Permit.

94 Applicant to be notified of Registry of Companies' decision

- (1) The Registry of Companies shall notify the Applicant in writing of its decision to:
 - (a) approve the Application and issue the Clinical Operating Permit;
 - (b) impose conditions or restrictions on the issue of such Clinical Operating Permit; or
 - (c) deny the Application and the reasons for denying the Application.
- (2) The Registry of Companies shall also provide the Applicant with:
 - (a) a written statement of reasons for its decision; and
 - (b) details of its right to seek an appeal of the decision under section 95.

95 Right of appeal from decision of Registry of Companies

- (1) The Provisional Approval Letter Holder has the right to seek an appeal of the Registry of Companies' decision to deny an Application or impose conditions or restrictions on the Clinical Operating Permit.
- (2) Any appeal shall be carried out in accordance with Part Thirteen of this Healthcare Operators Regulation.

96 Right to be referred to as a Licensed Healthcare Operator

Where the Application is approved by Registry of Companies, the Applicant shall be entitled to:



- (1) refer to itself as a Licensed Healthcare Operator; and
- (2) provide the Clinical Activities within DHCC in accordance with its Clinical Operating Permit.

97 Details contained on Clinical Operating Permit

A Clinical Operating Permit shall contain the following details:

- (1) the name of the Licensed Healthcare Operator;
- (2) the Effective Date of the Clinical Operating Permit;
- (3) the name of the Licensed Healthcare Operator's Manager;
- (4) the Clinical Activity or Clinical Activities the Licensed Healthcare Operator intends to conduct; and
- (5) such other matters, including any terms, conditions or restrictions included in the Clinical Operating Permit, as may be specified by the Registry of Companies.

98 Display of Clinical Operating Permit

A Licensed Healthcare Operator shall at all times prominently post a copy of its Clinical Operating Permit at each Location at which it is conducting a Clinical Activity under its Clinical Operating Permit, in such a manner that the Clinical Operating Permit is visible to clients and patients receiving Healthcare Services at such Location.

99 Term of Clinical Operating Permit

- (1) The term of the Clinical Operating Permit shall be specified in accordance with this Healthcare Operators Regulation and applicable Rules, Standards and Policies except to the extent limited by a condition or restriction imposed on the Clinical Operating Permit by the Registry of Companies.
- (2) Unless otherwise provided in a specific Rule, Standard or Policy or as required by the Registry of Companies:
 - (1) the term of the initial Clinical Operating Permit issued to a Licensed Healthcare Operator shall be 2 years thereafter, expiring on the anniversary date of its issue;
 - (2) each Licensed Healthcare Operator shall renew its Clinical Operating Permit in accordance with the provisions of Part Ten of this Healthcare Operators Regulation on the expiration of the initial term and then every 2 years, effective in each case as of the anniversary date of the initial issue of the Clinical Operating Permit; and
 - (3) each second anniversary date shall be the "Renewal Date".

100 Details of Clinical Operating Permit to be recorded on Register

At the time the Clinical Operating Permit is issued, the details of the Clinical Operating Permit, including any conditions, or restrictions being included in the Clinical Operating Permit, shall be added to the Registry of Companies' Register in accordance with the Governing Regulation.

101 Unsuccessful Provisional Approval Letter Holder may submit subsequent Application

- (1) Subject to subsection (2) and (3), where the Registry of Companies declines an Application, the Provisional Approval Letter Holder may submit a subsequent Application.

- (2) Any subsequent Application for a Clinical Operating shall be made within the term of the Provisional Approval Letter.
- (3) Any subsequent Application may not be submitted within a period of 3 months or such period as may be determined by the Registry of Companies following the Applicant's receipt of notice from the Registry of Companies under section 94.



Part Nine Obligations and Roles of Licensed Healthcare Operators

102 Compliance with Regulations

Each Licensed Healthcare Operator shall comply with all applicable requirements of this Healthcare Operators Regulation, and all other applicable Regulations, Rules, Standards and Policies.

103 Change of name, address and other details

- (1) A Licensed Healthcare Operator shall ensure that the information contained in the register is up to date and shall notify the Registry of Companies of any changes as soon as practicable after the date of change.
- (2) The Registry of Companies may require the Licensed Healthcare Operator to provide evidence to support any such change.

104 No addition or change of Clinical Activities

- (1) No Licensed Healthcare Operator may conduct a Clinical Activity not encompassed within its already issued Clinical Operating Permit or substantially change an Clinical Activity encompassed within its already issued Clinical Operating Permit without first obtaining the Registry of Companies' approval.
- (2) Where a Licensed Healthcare Operator intends to change the Clinical Activities that have been approved within its Clinical Operating Permit, the Licensed Healthcare Operator shall submit a new Application before it is able to provide such Clinical Activities.

105 Licensed Healthcare Operators required to obtain and maintain accreditation

All Licensed Healthcare Operators shall obtain accreditation by an accreditation organization approved by the Clinical Affairs Department within such time as may be stipulated, and maintain such accreditation throughout the term of its Clinical Operating Permit.

106 Restrictions on Licensed Healthcare Operators

No Licensed Healthcare Operator may, without first obtaining the Registry of Companies' approval:

- (1) substantially modify the physical facilities at its Location; or
- (2) acquire major capital equipment.

107 Quality Assurance Committees

- (1) Every Licensed Healthcare Operator that carries out any surgical or invasive procedures, as may be stipulated in Rules and Standards issued from time to time, shall establish quality assurance committees to monitor and review the quality of the services provided by the Licensed Healthcare Operator.
- (2) Such quality assurance committee shall:



- (a) evaluate the quality and appropriateness of the services provided by the Licensed Healthcare Operator;
 - (b) identify and resolve problems that may have arisen in connection with any service provided by the Licensed Healthcare Operator;
 - (c) review incidents involving mortality, disabilities or other injuries associated with the services provided by the Licensed Healthcare Operator;
 - (d) make recommendations to improve the quality of the services provided by the Licensed Healthcare Operator and to ensure compliance with their policies, procedures or credentialing requirements;
 - (e) monitor the implementation of such recommendations; and
 - (f) pursue opportunities for the improvement of the patient care and other services that are provided by the Licensed Healthcare Operator.
- (3) Such quality assurance committees shall consist of such Licensed Healthcare Professionals and any other administrative or ancillary staff employed by the Licensed Healthcare Operator.
 - (4) The Manager of each Licensed Healthcare Operator shall report to the Clinical Affairs Department the activities, findings, and recommendations of each quality assurance committee or such information as may be required within such time and in such manner as may be stipulated by the Clinical Affairs Department.

108 Cooperation with regard to on-site assessment

- (1) The Licensed Healthcare Operator shall comply with any reasonable requirements identified by the Clinical Affairs Department in the notice under subsection (2) related to an on-site assessment.
- (2) The Clinical Affairs Department may at any time during the term of a Clinical Operating Permit, serve the Licensed Healthcare Operator a written notice to undertake an on-site assessment which includes:
 - (1) an on-site assessment of the Location that is subject to the Clinical Operating Permit and the manner in which the Licensed Healthcare Operator is providing the Clinical Activity or Activities for which it has received its Clinical Operating Permit;
 - (2) a review of all of the Licensed Healthcare Operator's policies and procedures then in effect, to ensure that they remain in compliance with the requirements of this Healthcare Operators Regulation and all other applicable Regulations, Rules, and Standards and Policies.

109 Provision of information

Each Licensed Healthcare Operator that is a Branch shall:

- (1) provide the Registry of Companies, on each anniversary of the issuance of the Branch's Clinical Operating Permit, a certificate issued by the Home Jurisdiction of the Parent that proves the continuation of the legal existence in such Jurisdiction of the Parent and the validity of its licensure, registration or equivalent authorization with such authority; and
- (2) notify the Registry of Companies in writing of any modification or change to its Parent's licensure, registration or equivalent authorization that it reported in its Application, together with the date of the occurrence of such modification or change, by no later than 20 days following any such modification or change.



110 Notification of termination of Clinical Activities

- (1) A Licensed Healthcare Operator shall promptly notify the Registry of Companies if it decides not to proceed with implementation of any of the Clinical Activities for which its Clinical Operating Permit has been issued;
- (2) Immediately upon the submission of a notification required by subsection (1), the Clinical Operating Permit issued to such Licensed Healthcare Operator shall become null and void as it relates to any such Clinical Activity and the Registry of Companies may issue a revised Clinical Operating Permit.

111 Notification of changes to business

In addition to the information that a Licensed Healthcare Operator is otherwise required to provide under this Healthcare Operators Regulation or any other applicable Rules, Standards or Policies, each Licensed Healthcare Operator shall provide notice to the Registry of Companies of the occurrence of any of the following:

- (1) changes in the nature of any other business it carries on in conjunction with any of its Clinical Activities;
- (2) any proposal of the Licensed Healthcare Operator to alter the nature or extent of any business that it carries on;
- (3) changes to its Manager, Controllers, directors and Associated Persons; and
- (4) changes to the facility and medical equipments requiring design approvals and fit-out permits to be issued in accordance with the Design and Construction Guidelines.



Part Ten Renewal of Clinical Operating Permit

112 Renewal of Clinical Operating Permit

- (1) Each Licensed Healthcare Operator shall renew its Clinical Operating Permit every 2 years, effective as of the anniversary of the issuance of its Clinical Operating Permit.
- (2) Each date on which a Licensed Healthcare Operator's Clinical Operating Permit is to be renewed is the "Renewal Date".

113 Submission of Renewal Application

- (1) A Licensed Healthcare Operator shall submit to the Registry of Companies a completed Renewal Application and the applicable fee no later than sixty (60) days prior to each Renewal Date.
- (2) The Registry of Companies may, at its discretion, allow a Renewal Application to be filed later than the date provided for in subsection (1), but any such extension shall be for no longer than sixty (60) days.
- (3) Any extension granted under this section is subject to any Penalty that may be imposed by the Registry of Companies pursuant to section 121.

114 Information to be provided with Renewal Application for Clinical Operating Permit

The Renewal Application shall include such information as the Registry of Companies determines is reasonable and appropriate relating to the Licensed Healthcare Operator, including, but not limited to, the details of the following:

- (1) disciplinary action taken or proposed to be taken by another licensing body or governmental agency against the Licensed Healthcare Operator;
- (2) criminal charges or civil proceedings instituted against the Licensed Healthcare Operator;
- (3) evidence that the Licensed Healthcare Operator's Approved Professional Indemnity Insurance remains in effect and may reasonably be expected to be in effect for the renewal period of the Clinical Operating Permit;
- (4) evidence that the Licensed Healthcare Operator is duly accredited as required by this Healthcare Operators Regulation and the Rules, Standards and Policies applicable to the Business Category associated with such Licensed Healthcare Operator's Clinical Operating Permit, or has otherwise satisfied a quality survey periodically undertaken by the CPQ; and
- (5) any other information that the Registry of Companies requires.

115 Registry of Companies to review the Renewal Application for Clinical Operating Permit

- (1) The Registry of Companies shall review the Renewal Application at its next scheduled meeting provided that such meeting is more than 7 days after receipt of the Renewal Application.



- (2) If the next scheduled meeting of the Registry of Companies is less than 7 days after receipt of the Renewal Application, the Renewal Application shall be considered at the meeting following the next meeting.

116 Notification of Registry of Companies' decision

- (1) The Registry of Companies shall notify the Licensed Healthcare Operator in writing of its decision to:
 - (a) approve the Renewal Application;
 - (b) approve the Renewal Application and impose conditions or restrictions on a Clinical Operating Permit; or
 - (c) deny the Renewal Application.
- (2) The Registry of Companies shall also provide the Licensed Healthcare Operator with:
 - (a) a written statement of reasons for its decision; and
 - (b) details of its right to seek an appeal of the decision.

117 Right of appeal of decision of Registry of Companies

- (1) The Licensed Healthcare Operator has the right to seek an appeal of the Registry of Companies' decision to deny the Renewal Application or place conditions or restrictions on the Clinical Operating Permit.
- (2) Any appeal shall be carried out in accordance with Part Thirteen of this Healthcare Operators Regulation.

118 Request for extension of term of Clinical Operating Permit

- (1) If a Licensed Healthcare Operator is unable to file a Renewal Application for its Clinical Operating Permit in accordance with section 113, the Licensed Healthcare Operator may request in writing for the Registry of Companies extend the term of its Clinical Operating Permit.
- (2) The request shall specify:
 - (a) the period of time for the extension of the term of the Clinical Operating Permit; and
 - (b) the reasons for the extension of the term of the Clinical Operating Permit.
- (3) Any such request shall be made no later than 14 days prior to the Renewal Date together with the applicable fee.

119 Extension of term of Clinical Operating Permit

- (1) The Registry of Companies shall consider the request to extend the term of the Clinical Operating Permit and may, at its discretion, extend the term of the Clinical Operating Permit for a period not exceeding 60 days.
- (2) The Registry of Companies shall notify the Licensed Healthcare Operator of its decision in writing prior to the expiry of the term of the Clinical Operating Permit.
- (3) Any extension granted under this section is subject to any Penalty that may be imposed by the Registry of Companies pursuant to section 121.
- (4) The Licensed Healthcare Operator has no right of appeal from a decision of the Registry of Companies under this section.

120 Failure to file a Renewal Application

If a Licensed Healthcare Operator fails to file a Renewal Application for its Clinical Operating Permit in accordance with section 113 or within the extended term granted in accordance with section 119, its Clinical Operating Permit shall automatically terminate upon the expiry of its term or extended term as the case may be, and the Licensed Healthcare Operator shall immediately cease providing any or all Clinical Activities under the Clinical Operating Permit.

121 Penalty for late filing of Renewal Application

If a Licensed Healthcare Operator files a Renewal Application for its Clinical Operating Permit later than what is permitted in this Part of this Healthcare Operators Regulation, the Registry of Companies may impose the applicable Penalty for the delay in filing.



Part Eleven

Actions by Clinical Affairs Department Following On-site Assessment

122 Non-compliance following on-site assessment

- (1) Subject to section 125, following an on-site assessment under section 108, the Clinical Affairs Department shall notify the Licensed Healthcare Operator if it finds non-compliance with the requirements of the:
 - (1) Licensed Healthcare Operator's Clinical Operating Permit;
 - (2) any of the applicable requirements of this Healthcare Operators Regulation, or
 - (3) any other applicable Regulations, Rules or Standards and Policies.
- (2) Where a Licensed Healthcare Operator is found to be non-compliant under subsection (1), it shall:
 - (a) if required by the Clinical Affairs Department, file a plan of correction to rectify the breaches and implement this plan within such period of time as the Clinical Affairs Department may require; and
 - (b) in any case, comply with any requirements as directed by the Clinical Affairs Department to rectify the breaches within such period of time as the Clinical Affairs Department may require.

123 Further on-site assessment

The Clinical Affairs Department shall undertake, or arrange to be undertaken, a further on-site assessment to monitor the rectification of the breaches.

124 Notification to CPU of failure to rectify breaches

If the Licensed Healthcare Operator fails to comply with section 122(2) or if the Clinical Affairs Department is not satisfied that the breaches have been rectified, the Clinical Affairs Department may notify CPU.

125 Notification to CPU of serious and imminent risk

- (1) If following an on-site assessment under section 108, the Clinical Affairs Department identifies a serious and imminent risk to the health or safety of its employees, patients or the public, the Clinical Affairs Department shall notify CPU immediately.
- (2) The Clinical Affairs Department may include, in its notification to the CPU, a request for an immediate interim restriction or suspension to be imposed on the Clinical Operating Permit, or if applicable, the relevant Clinical Activities under the Clinical Operating Permit, if they consider that there is reasonable cause to believe that it is necessary because:
 - (1) action or inaction by such Licensed Healthcare Operator poses a serious and imminent risk to the health or safety of its employees, patients or the public;
 - (2) the on-site assessment undertaken by the Clinical Affairs Department under section 108 indicates a serious and imminent risk to the health or safety of its employees, patients or the public; or

- (3) the Licensed Healthcare Operator no longer has Approved Professional Indemnity Insurance in effect.



Part Twelve

Imposition of Conditions, Suspension and Revocation of a Clinical Operating Permit

126 CPU to act on information from Clinical Affairs Department

- (1) Where the CPU has received a notification from the Clinical Affairs Department pursuant to section 124 or 125, CPU shall act in accordance with the provisions of this Part of this Healthcare Operators Regulation.
- (2) For purposes of this Part of this Healthcare Operators Regulation, any such notification shall be referred to as a complaint from the Clinical Affairs Department.

127 Initial assessment

- (1) After receipt of a complaint, the CPU shall carry out an initial assessment.
- (2) The CPU shall as soon as reasonably practicable send a copy of the complaint to the Licensed Healthcare Operator concerned and require him to submit his written explanation to the complaint within a stipulated time.
- (3) At any time, the CPU may refer a complaint for mediation in accordance with section 128.
- (4) At any time, the CPQ may take steps to obtain further information as it deems necessary pursuant to its powers as provided for in sections 136 to 143 of the Governing Regulation.
- (5) After its initial assessment, CPU may refer the complaint to a Fitness to Practice Panel for review.
- (6) Upon making its decision on its course of action, the CPU shall as soon as reasonably practicable serve a written notification to the Licensed Healthcare Operator and the complainant, and in the case of the Licensed Healthcare Operator, provide it with a copy of the complaint.

128 Mediation

- (1) Where the CPU has referred the matter for mediation, the CPU shall notify the Licensed Healthcare Operator and the complainant.
- (2) Both the Licensed Healthcare Operator and the complainant must consent to the mediation before the mediation can proceed.
- (3) Upon obtaining such consent from the Licensed Healthcare Operator and the complainant, the CPU shall appoint a mediator to carry out the mediation.
- (4) If no such consent has been obtained from:
 - (a) the Licensed Healthcare Operator, the CPU shall refer the matter to the Fitness to Practice Panel;
 - (b) the complainant, the CPU may dismiss the complaint.
- (5) Upon the conclusion of mediation, the mediator shall submit a report to the CPU, including the terms of any amicable resolution of the matter reached.
- (6) In the event that the complainant and/or the Manager of the Licensed Healthcare Operator refused or failed without reasonable cause to attend the mediation, the mediator may recommend the following:



- (a) refer the matter to Fitness to Practice Panel; or
 - (b) dismiss the complaint.
- (7) In the event that there is no amicable resolution of the matter, the CPU may, after consideration of the report submitted by the mediator, make the following orders:
- (a) dismiss the complaint; or
 - (b) refer the matter to the Fitness to Practice Panel.

129 Interim restriction or suspension

- (1) Where the CPU has received a request from the Clinical Affairs Department pursuant to section 125(2) to impose an immediate interim restriction or suspension on the Clinical Operating Permit, or if applicable the relevant Clinical Activities under the Clinical Operating Permit, the CPU shall inform the chairperson of the Complaints Panel immediately.
- (2) The chairperson of the Complaints Panel shall review the complaint to determine whether an immediate interim restriction or suspension should be made.
- (3) The chairperson of the Complaints Panel may be assisted by a legal assessor in his review of the complaint.
- (4) The chairperson of the Complaints Panel shall provide the Licensed Healthcare Operator with a copy of the complaint and request it to provide its explanation as to whether an immediate interim restriction or suspension should be made, either in writing or at a hearing. If the Manager of the Licensed Healthcare Professional is called upon to attend a hearing, he shall attend the hearing alone, unless the chairperson of the Complaints Panel allows otherwise.
- (5) The chairperson of the Complaints Panel may impose an interim restriction or suspension on the Clinical Operating Permit.
- (6) The chairperson of the Complaints Panel shall immediately serve a written notification of its decision under subsection (5) above to the Licensed Healthcare Practitioner, and such decision shall take effect from the date of receipt of such notification.
- (7) Such interim restriction or suspension shall remain in place until directed otherwise by the Fitness to Practice Panel following the completion of the review by the Fitness to Practice Panel.
- (8) Where an interim restriction or suspension has been imposed under subsection (5) above, sections 146 and 147 of this Healthcare Operations Regulation shall apply.
- (9) For the avoidance of doubt, Part Twelve shall continue to apply to a Licensed Healthcare Operator whose Clinical Operating Permit is the subject of an interim restriction or suspension imposed by the chairperson of the Complaints Panel pursuant to subsection (5).

130 Referral to Fitness to Practice Panel

- (1) Where the CPU has made its decision to refer the complaint to the Fitness to Practice Panel, the chairperson of the Complaints Panel shall appoint a Fitness to Practice Panel in accordance with section 135 of the Governing Regulation.
- (2) The Fitness to Practice Panel shall review the complaint against the Licensed Healthcare Operator to determine whether an order to impose conditions on, suspend or revoke the Clinical Operating Permit should be made.



131 Obtaining legal advice

The Fitness to Practice Panel may obtain legal advice from a legal assessor to assist in its review.

132 Preparation for Fitness to Practice Panel's review

- (1) The Fitness to Practice Panel may, at any time before its review commences, require:
 - (a) the Licensed Healthcare Operator to provide any additional information; or
 - (b) the Manager of the Licensed Healthcare Operator to meet with a member of the Fitness to Practice Panel to identify and clarify the nature of the issues that shall be considered or determined during the review.
- (2) The Fitness to Practice Panel shall provide the Licensed Healthcare Operator with guidance concerning the conduct of the review prior to the commencement of the review.

133 Notification of Fitness to Practice Panel's hearing

When a Fitness to Practice Panel hearing is to be held, the Fitness to Practice Panel shall:

- (1) within 3 days following its appointment, serve notice on the Licensed Healthcare Operator that states:
 - (a) the nature of the hearing and of any allegations made against the Licensed Healthcare Operator or the issues that have been identified;
 - (b) the time and place of the hearing;
 - (c) that the Licensed Healthcare Operator has the right to make submissions at the hearing, through the Manager and/or counsel; and
 - (d) that the hearing shall be held in private unless required otherwise by the Fitness to Practice Panel.
- (2) fix a time and place for the hearing to be held, which time shall be no earlier than 21 days and no later than 45 days following notification to the Licensed Healthcare Operator under subsection (1) above.

134 Procedures for hearing

- (1) At the Fitness to Practice Panel hearing:
 - (a) the Fitness to Practice Panel shall hear and determine the matter before it;
 - (b) the Licensed Healthcare Operator is entitled to be present, by way of the Manager and/or legal counsel, to make submissions, to call witnesses and to undertake cross-examination; and
 - (c) the proceedings are to be closed to the public unless the Fitness to Practice Panel determines otherwise;
- (2) Subject to the other provisions of this section and any relevant Standards and Policies, the Fitness to Practice Panel:
 - (a) may regulate its own procedure;



- (b) shall conduct the proceedings with as little formality and technicality as the requirements of this Healthcare Operators Regulation and the proper consideration of the matter reasonably permit;
- (c) is not bound by rules of evidence but may inform itself in any way that is reasonable; and
- (d) is bound by the rules of natural justice.

135 Decision of Fitness to Practice Panel

- (1) At the conclusion of the review, the Fitness to Practice Panel may:
 - (a) impose conditions or restrictions on a Licensed Healthcare Operator's Clinical Operating Permit;
 - (b) suspend the Clinical Operating Permit for a period stipulated by the Fitness to Practice Panel;
 - (c) revoke the Clinical Operating Permit;
 - (d) remove or modify conditions or restrictions previously included in a Licensed Healthcare Operator's Clinical Operating Permit;
 - (e) impose a Penalty in accordance with the schedule of prescribed fines issued by the Registry of Companies from time to time; or
 - (f) take no further action.
- (2) Further to subsection (1), the Fitness to Practice Panel may order the Licensed Healthcare Operator concerned to pay such sums as it thinks fit in respect of costs and expenses of and incidental to any proceedings before the Fitness to Practice Panel, and where applicable, the chairperson of the Complaints Panel. Such costs and expenses shall include:-
 - (a) the costs and expenses of any legal assessor appointed to assist the Fitness to Practice Panel in its review;
 - (b) such reasonable expenses as the Fitness to Practice Panel may pay to witnesses; and
 - (c) such reasonable expenses as are necessary for the conduct of proceedings before the Fitness to Practice Panel and the chairperson of the Complaints Panel.

136 Grounds for imposing conditions or restrictions, suspending or revoking a Clinical Operating Permit

- (1) Grounds for the Fitness to Practice Panel imposing conditions or restrictions, suspending or revoking a Clinical Operating Permit in full or in part include, but are not limited to, where the Licensed Healthcare Operator:
 - (a) has substantially contravened a provision of this Healthcare Operators Regulation, any other applicable Regulations, Rules, Standards and Policies or the terms, conditions or restrictions included in its Clinical Operating Permit;
 - (b) has failed to obtain or maintain accreditation;
 - (c) has failed to satisfy a material obligation to which it is subject to by virtue of this Healthcare Operators Regulation, or any other applicable Regulations, Rules, Standards or Policies or the conditions or restrictions included in its Clinical Operating Permit or no longer meets



- the relevant applicable criteria under which its Clinical Operating Permit was granted;
- (d) has repeatedly failed to correct deficiencies identified to it by the Agencies or the Clinical Affairs Department, upon the Agency's or the Clinical Affairs Department's periodic review, even if individually any one such deficiency would not by itself constitute grounds for revocation of a Clinical Operating Permit;
 - (e) no longer holds a License to carry on business in DHCC under the Company Regulations;
 - (f) in the case of a Licensed Healthcare Operator that is a Branch, its Parent no longer has the right to carry on a business in its Home Jurisdiction;
 - (g) fails to maintain Approved Professional Indemnity Insurance, if applicable;
 - (h) provides Healthcare Services through the use of any healthcare professional or Complementary and Alternative Medicine professional who is required to hold a License from the Licensing Board to engage in his Professional Practice in DHCC and who does not possess the required License;
 - (i) has furnished fraudulent, misleading, deceptive or inaccurate information to the Registry of Companies or CPQ under or for the purposes of any provision of this Healthcare Operators Regulation, any other applicable Regulations, Rules, Standards and Policies;
 - (j) has not commenced one or more of the Clinical Activities for which its Clinical Operating Permit was granted within 90 days of such grant, or within such other period as may reasonably have been specified by the Registry of Companies;
 - (k) has not completed implementing all of the Clinical Activities for which its Clinical Operating Permit was granted within 6 months following the issuance of the Clinical Operating Permit, unless otherwise agreed by the Registry of Companies;
 - (l) has not paid any applicable fee, including any Penalty, due and payable in respect of a Clinical Operating Permit, or has not paid any other amounts due to the Registry of Companies;
 - (m) has ceased to provide any Clinical Activity without written notice for which its Clinical Operating Permit was granted;
 - (n) is carrying on, purportedly under its Clinical Operating Permit, a Clinical Activity or Activities in a Business Category different from that for which its Clinical Operating Permit was granted; and
 - (o) has assigned the benefit and control of the Clinical Activity or Activities of the Licensed Healthcare Operator to a third party.
- (2) The Fitness to Practice Panel may also impose conditions or restrictions on, suspend or revoke a Clinical Operating Permit:
- (a) on the order of a court or tribunal having jurisdiction in DHCC; or
 - (b) on any other ground that the applicable Rules, Standards and Policies may specify as a proper and reasonable ground for the imposition of conditions or restrictions, suspension or revocation of a Clinical Operating Permit.



- 137 Licensed Healthcare Operator to be notified of Fitness to Practice Panel's decision**
- (1) The Fitness to Practice Panel shall notify the Licensed Healthcare Operator in writing of its decision.
 - (2) The Fitness to Practice Panel shall also provide the Licensed Healthcare Operator with:
 - (a) a written statement of reasons for its decision; and
 - (b) details of its right to seek an appeal of the decision.
- 138 Right of appeal of decision of Fitness to Practice Panel**
- (1) The Licensed Healthcare Operator has the right to seek an appeal of the Fitness to Practice Panel's decision.
 - (2) Any appeal shall be carried out in accordance with Part Thirteen of this Healthcare Operators Regulation.
- 139 Registry of Companies may suspend or revoke Clinical Operating Permit in summary manner**
- (1) The Registry of Companies may suspend or revoke a Clinical Operating Permit of a Licensed Healthcare Operator in a summary manner where —
 - (a) the License(s) of Licensed Healthcare Professional(s) who are identified to be key personnel of the Licensed Healthcare Operator have been revoked or suspended; or
 - (b) the Licensed Healthcare Operator is not covered by the applicable insurance in accordance with section 156 while providing Healthcare Services.
 - (2) Before suspending or revoking the Clinical Operating Permit under subsection (1), the Registry of Companies shall —
 - (a) give to the Licensed Healthcare Operator notice in writing of its intention to do so; and
 - (b) in such notice, call upon the Licensed Healthcare Operator to show cause within such time as may be specified in the notice as to why its Clinical Operating Permit should not be suspended or revoked.
 - (3) If the Licensed Healthcare Operator —
 - (a) fails to show cause within the period of time given to him or such extended period of time as the Registry of Companies may allow; or
 - (b) fails to show sufficient cause, as to why the Clinical Operating Permit should not be suspended or revoked,the Registry of Companies shall give notice in writing to the Licensed Healthcare Operator of the date from which the suspension or revocation of the Clinical Operating Permit is to take effect and where applicable, the period of suspension.
 - (4) Sections 146 and 147 of this Healthcare Operators Regulation shall apply in the same manner as if the Clinical Operating Permit was suspended or revoked by the decision of the Fitness to Practice Panel as set out in Part Twelve of this Regulation.



Part Thirteen Appeal Process

140 Appeal against decision of Registry of Companies or Fitness to Practice Panel

Where a right of appeal against a decision of the Registry of Companies or Fitness to Practice Panel has been provided in this Healthcare Operators Regulation, the appeal process shall follow the provisions of this Part.

141 Registry of Companies' and Fitness to Practice Panel's orders shall not take effect pending appeal

Unless otherwise ordered by the Fitness to Practice Panel or the Registry of Companies, where the Applicant, Provisional Approval Letter Holder or Licensed Healthcare Operator has filed an appeal against the Registry of Companies' or Fitness to Practice Panel's orders, the orders shall not take effect until the conclusion of the appeal and the Appeals Board has made a decision under section 144.

142 Right to provide further information upon appeal

- (1) Where the Applicant, Provisional Approval Letter Holder or Licensed Healthcare Operator files an appeal against the Registry of Companies' or Fitness to Practice Panel's decision, the Applicant, Provisional Approval Letter Holder or Licensed Healthcare Operator shall provide the Appeals Board with:
 - (a) a written notification of its intention to appeal the relevant decision;
 - (b) a written response to the statement of reasons set out in the notification; and
 - (c) such additional and supplemental information as it deems appropriate.
- (2) The information provided in subsection (1) above shall be provided to the Appeals Board within 30 days of receipt of the notification of the Registry of Companies or the Fitness to Practice Panel's decision.

143 No right to be heard

- (1) The Applicant, Provisional Approval Letter Holder or Licensed Healthcare Operator has no right to be heard by the Appeals Board, unless his attendance has been requested by the Appeals Board under subsection (2).
- (2) The Appeals Board may invite the Applicant, Provisional Approval Letter Holder or Licensed Healthcare Operator to attend the meeting of the Appeals Board where the matter is to be considered.

144 Decision of Appeals Board

- (1) Following consideration of the matter together with the further information provided under section 142, the Appeals Board shall either:
 - (a) approve the Application;
 - (b) approve the Application subject to conditions or restrictions;
 - (c) deny an application for a Provisional Approval Letter;
 - (d) deny an Application;

- (e) suspend a Clinical Operating Permit or part of a Clinical Operating Permit for a stipulated period of time;
 - (f) revoke a Clinical Operating Permit or part of a Clinical Operating Permit;
 - (g) remove or modify conditions or restrictions previously included on a Licensed Healthcare Operator's Clinical Operating Permit;
 - (h) impose a Penalty in accordance with the schedule of prescribed fines issued by the Registry of Companies from time to time; or
 - (i) take no further action.
- (2) Further to subsection (1), the Appeals Board may order the Licensed Healthcare Operator concerned to pay such sums as it thinks fit in respect of costs and expenses of and incidental to any proceedings before the Appeals Board. Such costs and expenses shall include:-
- (a) the costs and expenses of any legal assessor appointed to assist the Appeals Board in its review;
 - (b) such reasonable expenses as the Appeals Board may pay to witnesses; and
 - (c) such reasonable expenses as are necessary for the conduct of proceedings before the Appeals Board.
- (3) The Appeals Board shall make its decision by a majority vote.

145 No right of appeal

The Applicant has no right to seek an appeal of the Appeals Board's decision.



Part Fourteen Termination of Activities

146 Actions following refusal to renew or revocation of Clinical Operating Permit License

- (1) Following a refusal by the Registry of Companies to renew the Licensed Healthcare Operator's Clinical Operating Permit, a decision of the Fitness to Practice Panel or the Appeals Board to revoke the Licensed Healthcare Operator's Clinical Operating Permit, or a decision of the chairperson of the Complaints Panel to impose an interim restriction or suspension on the Licensed Healthcare Operator's Clinical Operating Permit, the Registry of Companies shall determine the duration of an orderly wind down period for the Clinical Activity or Activities provided by the Licensed Healthcare Operator under the Clinical Operating Permit.
- (2) In determining the duration of an orderly wind down period, the Registry of Companies shall give due consideration to, among other relevant factors, the need for proper notice to clients and patients, especially those clients and patients already scheduled at the time to receive Healthcare Services from the Licensed Healthcare Operator, and the time required to ensure that inpatients are properly discharged or transferred to the care of other qualified Licensed Healthcare Operators and Licensed Healthcare Professionals and/or Licensed Complementary and Alternative Medicine Professionals.
- (3) Where the Licensed Healthcare Operator has obtained a license to operate outside of DHCC in compliance with section 33(2), it shall notify the relevant authority of the revocation, refusal to renew, or the interim suspension or revocation of its Clinical Operating Permit.
- (4) In the situation described in subsection (3), the Registry of Companies may also disclose the revocation, refusal to renew, or the interim suspension or revocation of the Licensed Healthcare Operator's Clinical Operating Permit to the relevant authority.
- (5) The obligations in this section shall take effect upon the expiry of the 30 day period provided for the notification of an appeal to the Appeals Board.

147 Ceasing activities

Upon the completion of the orderly winding down of the Licensed Healthcare Operator's Clinical Activity or Clinical Activities, the affected Licensed Healthcare Operator shall immediately cease providing all Clinical Activities under its Clinical Operating Permit and shall no longer be entitled to refer to itself as a Licensed Healthcare Operator.



Part Fifteen

Voluntary Termination of Clinical Activities

148 Written notice to be provided

A Licensed Healthcare Operator may, at any time, provide written notice to the Registry of Companies that it intends to cease providing one or more Clinical Activities under its Clinical Operating Permit as of a date or dates specified in the notice.

149 Information to be provided

The Licensed Healthcare Operator shall include with the written notice under section 148 a plan for the orderly winding down of the Clinical Activity or Clinical Activities that it proposes to cease providing including the date that the Licensed Healthcare Operator expects to complete the winding down of the Clinical Activities.

150 Advice from Registry of Companies, other Agencies and CPQ

The Registry of Companies may seek the advice of the other Agencies with regard to the voluntary termination of Clinical Activities on a permanent and temporary basis and in particular the adequacy of the plan submitted under section 149.

151 Sufficient time required to wind down Clinical Activities

- (1) The date or dates specified in a notice provided under section 148 shall be sufficient to provide such time as is reasonable for the Licensed Healthcare Operator to provide for the orderly winding down of each Clinical Activity identified in such notice.
- (2) In determining whether sufficient time has been provided for an orderly wind down period, due consideration shall be given to, among other relevant factors, the need for proper notice to clients and patients, especially those clients and patients already scheduled at the time to receive Healthcare Services from the Licensed Healthcare Operator, the time required to ensure that inpatients are properly discharged or transferred to the care of other qualified Licensed Healthcare Operators and Licensed Healthcare Professionals and/or Licensed Complementary and Alternative Medicine Professionals, and the transfer and/or destruction of medical records of the clients and patients.

152 Registry of Companies may require extension of time

Following a review of the information under section 149, the Registry of Companies may require that any date specified in a notice under section 148 be extended if it determines that more time is required in order to ensure that the Clinical Activities are terminated in an orderly fashion.

153 CPQ may direct winding down

If the Registry of Companies considers a plan submitted under section 149 to be insufficient, or otherwise determines that the affected Licensed Healthcare Operator is not itself able adequately to arrange for the orderly closure of any of the affected Clinical Activities, it may direct CPQ or an organization appointed by CPQ to enter the Location at

which the Licensed Healthcare Operator has been conducting such Clinical Activities solely to provide for an orderly winding down of all such Clinical Activities.

154 Termination of Clinical Operating Permit

Upon the date specified in the notice under section 148 or any other date that may be stipulated by the Registry of Companies, the Clinical Operating Permit shall be terminated and the Registry of Companies shall issue a revised Clinical Operating Permit if necessary.

155 Notice to temporarily cease provision of Healthcare Services

- (1) A Licensed Healthcare Operator may temporarily cease the provision of one or more Clinical Activities upon the approval of the Registry of Companies.
- (2) The Licensed Healthcare Operator shall provide written notice to the Registry of Companies:
 - (a) at least 30 days prior to the cessation of each Clinical Activity to which it refers, unless such cessation must occur urgently, in which case such notice shall be provided as close as possible prior to the cessation of the Clinical Activity;
 - (b) specifying the period of time during which the Licensed Healthcare Operator shall cease providing the Clinical Activity, which period shall be no longer than 6 months without the approval of the Registry of Companies; and
 - (c) specifying the steps to be taken by the Licensed Healthcare Operator to ensure alternative care for persons scheduled to receive care in conjunction with such Clinical Activity as of the time such notice is given.



Part Sixteen Approved Professional Indemnity Insurance

156 Requirement to have insurance

- (1) A Licensed Healthcare Operator shall not conduct any Clinical Activity unless it is covered by the required Approved Professional Indemnity Insurance, public liability insurance and/or any other form of insurance, where applicable.
- (2) Such insurance under subsection (1) is to be obtained and maintained in such amounts and on such terms and conditions as the Central Governance Board may reasonably specify from time to time and/or as required under other applicable laws, Regulations, Rules, Standards or Policies in force from time to time in DHCC.

157 Approval by CPQ of insurers

- (1) Such insurance is to be obtained from carriers that have been approved by CPQ based on CPQ's assessment of their financial solvency and other characteristics that CPQ deems reasonable and relevant to assuring the ability of such carriers to meet their obligations under policies issued for Licensed Healthcare Operators in DHCC.
- (2) A list of such approved carriers shall be published by CPQ from time to time.

158 Professional Indemnity Insurance required in addition to other insurance

The Approved Professional Indemnity Insurance shall be in addition to any other insurance that the Licensed Healthcare Operator is required to obtain and maintain under other applicable laws, Regulations, Rules, Standards or Policies in force from time to time in DHCC.

159 Restriction on granting Clinical Operating Permit

The Registry of Companies:

- (1) shall not issue a Clinical Operating Permit to a Provisional Approval Letter Holder unless it is satisfied that the Provisional Approval Letter Holder shall, while conducting a Clinical Activity, be covered by Approved Professional Indemnity Insurance; and
- (2) may revoke, suspend or refuse to renew the Clinical Operating Permit of a Licensed Healthcare Operator if it is satisfied that the Licensed Healthcare Operator is not covered by Approved Professional Indemnity Insurance while conducting a Clinical Activity.

Schedule One Business Categories

1 Business Categories

- (1) General hospitals;
- (2) Specialty hospitals;
- (3) Pharmacies;
- (4) Outpatient surgery centers;
- (5) Private medical practices;
- (6) Outpatient multi-specialty clinics;
- (7) Diagnostic centers;
- (8) Laboratories;
- (9) Nursing homes;
- (10) Outpatient physical therapy centers;
- (11) Home care agencies;
- (12) Geriatric care centers;
- (13) Long-term care centers; and
- (14) Dental clinics.
- (15) Any other category of healthcare operators as determined from time to time by the DHCA and set out in the applicable Rules, Standards and Policies.