

EXTRAORDINARY  
GOVERNMENT



REGISTERED NO. PIII

**G A Z E T T E**

## **KHYBER PAKHTUNKHWA**

Published by Authority

**PESHAWAR, MONDAY, 12TH JULY, 2016**

### **KHYBER PAKHTUNKHWA HEALTH CARE COMMISSION**

Bungalow No 25-D, Circular Road University Town, Peshawar.  
Phone: 091-9216922-3 Fax 091-9216921 [www.kphra.gov.pk](http://www.kphra.gov.pk)

#### **NOTIFICATION**

Dated: 5<sup>th</sup> April, 2016

**No. HCC/4532/4.** In exercise of the powers conferred by the section 31 of the Khyber Pakhtunkhwa Health Care Commission Act, 2015, the Khyber Pakhtunkhwa Health Care Commission has been pleased to approve it's below mentioned regulation in its 6<sup>th</sup> meeting dated 30.03.2016 held at main Khyber Pakhtunkhwa Health Care Commission office:

#### **KHYBER PAKHTUNKHWA HEALTH CARE COMMISSION CONDUCT OF BUSINESS REGULATIONS 2016**

- (1) Regulation of Procedures.
- (2) Registration and Licensing Regulations.
- (3) Complaint Management and Patients' Rights Regulations.
- (4) Human Resource Management Regulations.
- (5) Financial Regulations.

#### **ANNEXURE-A**

Health Care Commission Services Regulations 2016.

#### **ANNEXURE-B**

ADOPTION BY THE COMMISSION, OF HEALTH CARE STANDARDS, PROCUREMENT RULES AND LAWS /RULES RELATED TO THE HEALTH CARE SYSTEMS

**Sd/-x-x-x**  
**Chief Executive Officer/Secretary,**  
**Khyber Pakhtunkhwa Health Care**  
**Commission.**

**Acronyms**

CEO	Chief Executive Officer
CFO	Chief Financial Officer
DFID	Department for International Development, UK
DOH	Department of Health
HCC	Health Care Commission
HCE	Health Care Establishment
HRA	Health Regulatory Authority
HRM	Human Resource Management
HSRU	Health Sector Reform Unit
IMR	Infant Mortality Rate
JD	Job Description
KP	Khyber Pakhtunkhwa
KPHCC	Khyber Pakhtunkhwa Health Care Commission
LHW	Lady Health Workers
MSDS	Minimum Standards of Service Delivery
TRF+	Technical Resource Facility+
U5MR	Under 5 Mortality Rate

## 2. REGISTRATION AND LICENSING REGULATIONS

In exercise of powers conferred under Section 32 of the Khyber Pakhtunkhwa Health Care Commission Act, 2015, the Commission is pleased to make following regulations:

1. **Short Title and Commencement:** (1) These regulations may be called the Khyber Pakhtunkhwa Health Care Commission Registration, Licensing and Complaints Management regulations, 2016.
  - (2) These regulations should extend to all healthcare establishments of Khyber Pakhtunkhwa both in the Public and Private sector.
    - (a) owned, managed or administered by Government or non-profit organizations, charities, trusts, corporate sector or by any person, or group of persons incorporated or not; and
    - (b) Operated and managed under allopathic system, complementary and alternative medical treatment system recognized in Pakistan.
  - (3) These regulations shall come into force at once.
2. **Definitions:** In these regulations, unless there is anything repugnant in the subject or context, the following terms shall have the meanings given as under
  - a) "Act" means Khyber Pakhtunkhwa Health Care Commission Act, 2015.
  - b) "Applicant" means healthcare establishment and / or healthcare service provider who has applied for license or its renewal as the case may be.
  - c) "Employee" means such service providers who have been rendering services at the Healthcare Establishments, including but not limited to doctors, consultants, nurses, paramedics and administrative staff, whether serving under written or un-written agreement(s) for service or of service.
  - d) "Fee" means the amount of money fixed by the Commission of Khyber Pakhtunkhwa Health Care Commission for the purposes of granting registration and licenses to Healthcare Establishments keeping in view factors, including but not limited to, the services to be rendered thereat, their bed strength as well as for the purposes of servicing the provisions of the Khyber Pakhtunkhwa Act, 2015 and includes such additional fee(s) as fixed by the Members of the Commission, from time to time, for the particular purpose(s), specified herein.
  - e) "Licensee" means any person or Healthcare Establishment who holds a regular license issued by the commission.
  - f) "Quality Assurance and Compliance Committee" means such a Committee as is established by a Healthcare Establishment and/or Healthcare Service Provider, as the case may be, and entrusted with the responsibility and capacity to ensure compliance with the governing law and the instructions, corrective orders issued by the Commission in accordance with the Act and Rules/regulations.
  - g) "Reference Manual" means such manuals as prepared by the Commission from time to time for achieving purposes of the Act, containing sets of guidelines for the Healthcare Establishments relating to implementation of the standards.
  - h) "Regulations" means Khyber Pakhtunkhwa Health Care Commission Licensing Regulations, 2016.
  - i) "Standards" means the standards set by the Commission for the primary and secondary level of care and any other standards, manuals etc. as set out by the Commission from time to time.
  - j) "Aggrieved person" means a patient/client who is not satisfied with the services rendered to him/her by the Healthcare Establishment and includes his next of kin or any other person duly authorized by him.
  - k) "Case" means any such matter which is taken up by the Commission to probe and take further necessary action, within the scope of the Act and has not been filed before it as a Complaint. The word "Case" and "Complaint", as the context may require, are being used interchangeably in these regulations/rules.

- l) "Case Worker" includes any competent authority or an officer of the Commission who is authorized to investigate and/or process complaints.
  - m) "Complainant" means any "aggrieved person" or "aggrieved Healthcare Service Provider" who makes a Complaint to the Commission.
  - n) "Complaint" means grievance occurring in respect of any of such instances, including but not limited to those as contained in regulation 47 and submitted by an Aggrieved Person or an Aggrieved Healthcare Service Provider or any information brought into the knowledge of the Commission through a third source, as the case may be.
  - o) "Expert" means a person with appropriate degree of skill and knowledge in a particular subject, who has relevant and up to date expertise with regard to issues in the case and having qualification and experience in the relevant field or specialty, as the case may be.
  - p) "False Complaint" means a frivolous Complaint made with an intention to harass, defame, embarrass and/or to pressurize the party complained against and is so proved to be false, after the investigation by the Commission.
  - q) "Hearing" includes proceedings before the Competent Authority or the Case Worker, as the case may be, in order to ascertain facts or issues arising in a Complaint by involving one, any or all involved parties to reach a settlement of the complaint under review.
  - r) "Inspection" means but is not limited to the process of examining any apparatus, appliance, equipment, instrument, product, goods, food supplies, systems or items used or found in, or any practice or procedure being carried out or otherwise connected with fulfilling the requirements as set out in the Standards to ensure quality of care, at a Healthcare Establishment.
  - s) "Maladministration" means poor or failed administration by a Healthcare Establishment and includes.
    - i. A decision, process, recommendation, act of omission or commission, which is contrary to law, rules/regulations, is a departure from established practice or procedure, unless it is bonafide and for valid reasons; is pervasive, arbitrary, or unreasonable, unjust, biased, oppressive, or discriminatory; or is based on irrelevant grounds;
    - ii. Neglect, inattention, delay, incompetence, inefficiency, and/or ineptitude, in the administration or discharge of duties and responsibilities including but not limited to, administrative irregularities, abuse of power, incorrect action or failure to take any action, failure to foresee and take comprehensive precautionary measures against possible mishaps, failure to provide requisite information, failure to investigate, failure to reply, misleading or inaccurate statements, inadequate liaison, corrupt behaviour, incorrect or illegal administration of a drug to a patient/client, incorrect or incomplete entry in a document or violation of human rights.
  - t) "Malpractice" includes improper, unskilled, immoral, illegal, or unethical professional conduct by a Healthcare Service Provider or a person working at a Healthcare Establishment and being the proximate cause of injury or harm to another person.
  - u) "Medical Record" including but not limited to, comprehensive medical history, examination(s), investigation(s) and treatment of the patient/client along with the progress notes.
  - v) "Notice" means any information communique sent to a concerned party by the Competent Authority or Case Worker or any authorized officer, as the case may be.
  - w) "Penalties" mean such penalties as may be prescribed by the Commission from time to time under the provisions of the Act.
3. All other words and expressions used in these regulations but not defined herein shall have the same meanings as are assigned to them in the Act, Standards, Reference Manual or guidelines for the Healthcare Establishments and/or such other instructions or orders including but not limited to any other directives relating to the improvement of healthcare services and/or healthcare service delivery systems, as developed and issued by the Commission, from time to time, for achieving the purposes of the Act.

## **DIRECTORATE OF REGISTRATION AND LICENSING**

- 4. Licensing Management System:** (1) The Commission shall have an internal Registration and Licensing Management System under the Directorate of Registration and Licensing for registration and licensing, renewal, cancellation and suspension of registration and of license of healthcare establishments and performing such other tasks for the purposes of ensuring that the healthcare services are rendered in accordance with the provisions of the Act, Rules/regulations, Standards, Reference Manuals and corrective orders etc.
- (2) All Health care Establishments/Healthcare Service Providers, as the case may be, shall establish their own Quality Assurance and Compliance Committees or a person for the purposes of interacting on their behalf with the Commission and shall be responsible for all steps involved in the process of being registered and obtaining the requisite license.
- (3) The Quality Assurance and Compliance Committee of the Commission may consist of one member or more surveyors as considered appropriate by the Members of the Commission, keeping in view the size and capacity of Healthcare Establishment. Such a Committee should be duly authorized to undertake and/or commit to the Directorate/Commission, as the case may be, for ensuring compliance with the Act and these regulations, on behalf of the said Health care Establishment.
- 5. Decisions by the Members of the Commission:** Any HCE or representative thereof having concerns with the processing of the registration and licensing matters can file a dispute to be addressed by the Members of the Commission, which will be resolved by the Members of the Commission in meetings.
- 6. Decisions by Directorate of Registration and Licensing:** Except for the matters as specified in the Rule 5, all other matters pertaining to registration, inspection and licensing shall be decided by the Directorate of Registration and Licensing.

## **REGISTRATION AND IMPLEMENTATION**

- 7. Responsibility for compliance.** (1) It shall be the responsibility of every new private Healthcare Establishment/Healthcare Service Provider to apply for Registration to the Commission through the Directorate of Registration and Licensing within the time as set out by the Commission.
- (2) The public sector Healthcare Establishment shall be considered as registered Healthcare Establishment and regulated by assessment for Licensing in accordance with the regulations for Licensing under these regulations.
- (3) A Healthcare Establishment already registered under the Khyber Pakhtunkhwa Medical and Health Institutions and Regulation of Health Care Services Ordinance, 2002 (Khyber Pakhtunkhwa Ord. No XLV of 2002), shall register itself under Khyber Pakhtunkhwa Health Care Commission Act, 2015 and shall renewed its registration in accordance with the provisions of the Act and Rules/regulations as the case may be.
- 8. Unregistered Healthcare Establishment/Healthcare Service Provider.** An unregistered Healthcare Establishment/Healthcare Service Provider found to be providing healthcare services without having applied for Registration, shall be liable to pay a fine, which may extend up to Rupees Five Hundred Thousands (Rs. 500,000/-).

**9. Application for Registration.** (1) Every existing Healthcare Establishment/Healthcare Service Provider shall apply for registration with the Commission in accordance with the registration forms as specified by the Commission from time to time.

(2) The Commission if it deems appropriate may combine the application form for Registration and Licensing. The healthcare establishment would get a receipt of acknowledgement on receiving the Application for Registration and Licensing.

(3) Every new private Healthcare Establishment/Healthcare Service Provider shall, either prior to commencement of operations or as soon as such a provider is registered with Pakistan Medical and Dental Council, Council for Tibb, Council for Homeopathy or Nursing Council, whichever is earlier, apply for registration with the Commission, in accordance with the form specified by the Commission.

(4) All the public sector Healthcare Establishments shall be considered as registered Healthcare Establishment and regulated by assessment for Licensing in accordance with these Regulations.

(5) The Directorate of Registration and Licensing shall maintain a register of all the Healthcare Establishments/Healthcare Service Provider providing healthcare services in the province of Khyber Pakhtunkhwa containing such details and information as considered necessary by the Commission. This will include but will not be limited to the employees, equipment, facilities, etc.

(6) The Director of the Directorate of Registration and Licensing shall be the competent authority to issue Registration Certificate under the provisions of the Act and these Regulations.

#### **LICENSING AND IMPLEMENTATION**

**10. Compliance Responsibility.** It shall be the responsibility of every Healthcare Establishment, either in the capacity of being an Applicant or a Licensee, as the case may be, to apply for License in accordance with the provisions of the Act and these regulations.

**11. Application for Licenses.** The healthcare service provider shall make an application for a license to the Commission in the prescribed form which shall be accompanied by such particulars, documents and fees as the Commission may prescribe.

**12. Combined application for Registration and License.** (1) The Commission if it deems appropriate may combine the application form for Registration and Licensing. The healthcare establishment would get a receipt of acknowledgement on receiving the Application for Registration and Licensing.

(2) The HCE shall be visited for the purposes of inspection by the HCC any time within 6 months or any other timeline as deemed appropriate by the Commission, from the date of receipt of the application form for Registration and Licensing.

**13. Unlicensed Healthcare Establishments.** No person, including but not limited to association of persons, authority, body, company, corporation, firm, individual, partnership, proprietorship or other entity, nor any Government, or Local Government shall establish, operate, conduct and/or maintain, as the case may be, in the Province of Khyber Pakhtunkhwa, any Healthcare Establishment for human beings without a License issued by the Commission in accordance with the criteria laid down by the Commission for Licensing.

**14. License not transferrable.** A License issued under these regulations shall neither be assignable or transferrable, unless a written permission is granted by the Commission, in accordance with these regulations, with reasons recorded in writing, pertaining to issues of merger, acquisition or change of proprietorship of the HCEs.

**15. Display of License.** A License issued by the Commission shall be visibly posted at the Healthcare Establishment at a prominent location.

**16. Types of Licenses.** (1) A *Provisional License* shall be issued by the Commission to such an Applicant whose application is complete in all respects, in accordance with the provisions of these Regulations.

(2) A *Conditional License* shall be issued by the Commission to such an applicant who has already been granted a Provisional License and, after the inspection, has achieved overall compliance of 60% or more (aggregated score) provided no indicator score is less than 50%.

(3) A *Regular License* shall be issued by the Commission to such an Applicant whose application is accepted by the Commission after inspection and finding that the Applicant fully complies with the provisions of the Act, regulations as well as the standards specified by the Commission. The Regular License will be time bound and the Commission will prescribe the term from time to time.

**17. Licensing Procedure.** (1) A Healthcare Establishment shall apply for a License on the prescribed form and relevant documents. Either prior to the commencement of the operation of a Healthcare Establishment, or six (6) months prior to the expiry of the existing License, the Applicant must file an application for License or renewal thereof, as the case may be, on the Forms specified by the Commission

(2) The Commission shall, on receipt of an application, complete with all required documents issue a provisional license to the healthcare establishment and shall prepare a plan for inspection.

(3) The Commission, before issuing the Regular or Conditional License, will inspect the healthcare establishment, which is to be licensed, or cause such healthcare establishment to be inspected by an inspection team.

(4) Applicants must demonstrate satisfactory evidence of compliance with all the laws and the regulations as applicable in this regard, from time to time.

(5) The Applicant shall retain a copy of the application and its attachments as submitted to the Directorate of Registration and Licensing.

(6) The Commission will have the right to seek further information before issuing a Provisional License.

(7) A Regular or the Conditional License, as the case may be, based on the inspection of the Healthcare Establishment by the Commission, must be issued within time as may be fixed by the Commission, from the date of acceptance of the application. The Applicant will inform the Commission about the fulfilment of the condition after which the Commission will undertake an inspection and then issue a Regular License.

(8) The Commission may reject the Application for License or its renewal, as the case may be, if, despite Notice issued by the Directorate, the Applicant fails to provide the requisite information and/or supporting documents required by the Directorate, within the timeline given by it.

(9) An Applicant whose application has been rejected, may re-apply after complying with all the requisite requirements, as prescribed. The inspection process will have to be undertaken before the license can be issued.

(10) Subject to categories and timelines for the initial Licensing as laid down by the Commission, an unlicensed Healthcare Establishment shall be liable to pay a fine, which may extend up to Rupees Five Hundred Thousand (Rs. 500,000/-), if found to be providing healthcare services without having applied for the requisite License or without having a License, as the case may be.

**18. Refusal to issue a License.** The Commission may refuse to issue a License to the Applicant if it finds misrepresentation, materially incorrect or insufficient information on the application, or the premises does not meet the requirements for issuing a license

**19. Term of Licenses.** (1) The term of the Provisional License shall be for a period of six (6) months, within which time the HCE shall upgrade itself to meet the standards set by the HCC and request for inspection for the Regular License. In case the HCE cannot meet the Standards within six months, it may seek extension in the term of the Provisional License for another three months. Failing to meet this timeline, the HCE will not be allowed to operate and the HCC may seal the HCE altogether.

(2) The term of the Conditional License shall be for a maximum period of six (6) months within which the Healthcare Establishment shall be responsible to become fully compliant with the Act, Rules/regulations, the Standards and the necessary orders passed by the Commission in this regard. In case the HCE cannot meet the Standards within six months, the HCC may fully or partially seal the HCE, depending on the nature of the Condition.

(3) For the purposes of issuance of the Regular License to the Healthcare Establishment which has been given Conditional License on initial inspection, shall only be entitled to have a maximum of three (3) inspections within the period of six (6) months.

(4) If the Healthcare Establishment holding Conditional License fails to get a Regular License in the period prescribed in these regulations, the Conditional License shall be withdrawn and the said Healthcare Establishment shall be deemed to have Provisional License and the HCC may fully or partially seal the HCE, depending on the nature of the Condition, and / or impose fines and penalties as deemed appropriate.

(5) If the Healthcare Establishment fails to qualify for a Regular License in a period of one (1) year, following inspections by the Commission, the Commission will have the powers to pass directions regarding the cessation of services and closure of the said Healthcare Establishment and imposition of fines and penalties.

(6) A Healthcare Establishment closed by the Commission under the provisions in these regulations, may re-apply for the License after an undertaking on Affidavit that it has met the requisite standards as identified by the Commission, upon which an inspection will be commissioned by the HCE and the licensing process will be followed ab initio.

(7) The Regular License issued to the Healthcare Establishment shall be valid for a fixed period of five (5) years. The Applicant, to whom Regular License has been issued, shall re-apply for Renewal six (6) months prior to the completion of the five (5) year period.



(8) The Healthcare Establishment completing the five (5) year period of Regular License, will be inspected and re-assessed. If the Commission concludes on re-assessment that the said Healthcare Establishment does not meet the requisite Standards, the Commission may issue Conditional Licence as deemed appropriate, to the Applicant. Upon renewal of the Regular License, its term shall be for a period of five (5) years from the date of renewal.

**20. Geographical Specification of the License.** (1) The License issued by the Commission shall only be for the premises identified in the application.

(2) Healthcare Establishments operated by the same Applicant or Licensee on different grounds (Geographically apart) shall have separate Licenses which are to be applied separately.

(3) One License shall be issued to the Applicant or Licensee who has separate facilities located in physically separated structures on the same ground (within the same boundary wall).

**21. Specifications of the License.** Any kind of License shall specify the following clearly but is not limited to:

- (1) Name of the Healthcare Establishment;
- (2) Name(s) of the owner;
- (3) The location and address of the building(s);
- (4) The total number of beds;
- (5) The effective date, Type and Term of License as specified
- (6) The services being provided at the Healthcare Establishment
- (7) The name of the Chief Executive Officer / Administrator / Manager of the HCE (if different from the owner)
- (8) The name of the Complaints Officer of the HCE with the phone number and email for receiving complaints

**22. Changes in scope of services, structures and ownership of the Licensed Healthcare Establishments.** (1) Any change in the Licensed capacity including but not limited to the services rendered at the already Licensed Healthcare Establishment, shall not be implemented without the Applicant or the Licensee having prior written approval, permission and/or the requisite License for the same from the Commission, as the case may be.

(2) Any change in the structure/construction or new construction, addition or alteration in any manner, as the case may be, shall got approved from the competent authority and notified to the Commission. This does not apply to minor alterations and the routine maintenance and repairs that do not affect the scope of the services and the primary functional operations or the number of beds.

(3) Any change in the ownership of the private Healthcare Establishments and change of in-charge, administrator or the Chief Executive Officer (in case of the public sector facilities), must be reported to the Commission as soon as possible but within 30 working days.

(4) Any change in the personnel in terms of their qualifications, competencies or departing from / joining the HCE must be reported to the Commission as soon as possible but within 30 working days.

(5) An amended license shall be issued in this regard by the Commission on application of the Applicant, on terms and conditions as deemed appropriate by the Commission, including but not limited to payment of additional fee(s) as fixed by the Commission, for the said particular purpose(s), from time to time.

**23. Verification by the Commission.** (1) Before issuing a Regular License, the Commission shall verify or require the verification of the following:

- (i) Approvals regarding construction documents, if any
- (ii) Approvals/certifications from other related authorities, including but not limited to the fire and environment etc, as the case may be;
- (iii) Application to be complete in all respects;
- (iv) Deposit of full License Fee;
- (v) Compliance with the instructions issued after the on-site survey conducted by the Commission or the Inspection Team, as the case may be;
- (vi) Compliance with the Act, regulations, Standards, any instructions and/or corrective orders passed by the Directorate of Registration and Licensing or the Commission, as the case may be, while processing and/or considering the Application keeping in view the survey and/or the inspection report, as the case may be.

(2) The Commission shall also review the Annual Healthcare Establishment Update Information documentation and on its acceptance, issue the Regular License.

- (i) Details of all the employees, who are and/or have been rendering services at the Healthcare Establishment during the last one year from the date of Application for issuance of License.
- (ii) Any other information relating to the working of the Healthcare Establishment, as considered necessary or appropriate by the Directorate for the purposes of enhancing clinical governance.

(3) The Commission may deny to issue or renew a License when it finds that the Applicant has failed or refused to comply with the provisions of the Act and/or these regulations, as the case may be, for the purposes of obtaining the said License.

**24. Amending, Modifying or refusing to renew a License.** The Commission may Amend, Modify or refuse to renew a License in accordance with the Act, regulations, Standards, Reference Manual and/or instructions or directions passed by the Commission, as the case may be, for reasons to be recorded in writing, setting out which requirements have not been fulfilled by the HCE.

**25. Grounds for Suspension and/or Revocation of License.** The Commission may revoke and/or suspend a License in accordance with the provisions of the Act and these regulations. The Healthcare Establishment whose License is suspended or revoked may re-apply for the License after an undertaking on Affidavit that it has met the requisite standards as identified by the Commission, upon which an inspection will be undertaken before the License can be issued by the Commission.

**26. Emergency Suspension of service(s).** If the Commission at any time, on inspection of a Healthcare Establishment, observes that a particular condition(s) can be an immediate threat to the health and safety of the patients at the Healthcare Establishment, or lead to an emergency, the Commission by its duly authorized employees may, issue orders for emergency suspension of such services or facilities as deemed appropriate by the Commission and adjust for the duty of care of any patients under treatment in that healthcare establishment.

**27. Cancellation of the Conditional License.** The Commission shall have the powers to cancel the Conditional License, if the Healthcare Establishment fails to meet any of the condition(s), instructions directions etc issued by the Commission, upon personal service of the written notice to the Applicant, or, if the Applicant cannot be reached for personal service, by personal service to the person in charge.

**28. Sealing/De-sealing of the Healthcare Establishment.** The Commission shall have the powers to seal a Healthcare Establishment if it finds that the Healthcare Establishment has violated the Act, Rules/regulations, Standards, Reference Manual and/or instructions or directions passed by the Commission, as the case may be, despite notices by the Commission. The Healthcare Establishment may re-apply for the License after providing an undertaking on Affidavit that it has met the requisite standards as identified by the Commission, and the Commission after verification on inspection of the sealed Healthcare Establishment, shall decide on de-sealing of the said Healthcare Establishment.

**29. Hearing opportunity for the Healthcare Established before cancellation of License.** Before passing the orders for cancellation of the Conditional or the Regular License, the Healthcare Establishment shall be given the opportunity of being heard.

**30. Appeals.** (1) Any person who is aggrieved by any order of the Commission including the:

- (a) Refusal of the Commission to issue or renew a license;
- (b) Decision of the Commission to suspend or revoke a license;
- (c) Order of closing down of a Healthcare Service Provider or Healthcare Establishment, as the case may be, or making improvements in the Healthcare Establishment;
- (d) Order relating to equipments, apparatus, appliances, or other things at a Healthcare Service Provider or Healthcare Establishment; or
- (e) Imposition of fine and penalties by the Commission.

may, within thirty days from the date of communication of the order of the Commission, prefer an appeal in writing to the District and Sessions Judge.

(2) Healthcare Service Providers shall provide legal aid to a person, working in the Healthcare Establishment, pertaining to the matters related to this Act.

**31. Building Lease and Plans.** (1) In case, the building of the Healthcare Establishment is not owned by the Applicant or it is taken on lease, the Healthcare Establishment shall clearly show which party to the agreement is responsible for repair and maintenance of the property. The Commission shall be notified in five (5) working days of any changes to the lease agreement that may alter the responsibility for repair and maintenance, and compliance with these regulations.

(2) For all practical purposes, the owner / administrator / manager / CEO of the HCE will be held responsible for ensuring that the conditions are met. In case, the conditions are not fulfilled, the Commission will have a right to take corrective action in terms of partially or fully closing down the HCE as appropriate.

(3) A set of building plan and specifications for each building used in the provision of the healthcare services, drawn to scale, must be provided to the Commission. Building plans and specifications for alteration in the physical environment or utilities of the Healthcare Establishment, that materially affect patient care, must be duly approved by the Competent authority and submitted to the Commission prior to the implementation of the proposed changes.

**32. Number of Beds.** The Healthcare Establishment must clearly indicate the number of beds for each of the service rendered or to be rendered, as the case may be. This information should be provided at the time of filing the application. The Application form should require these details from the HCE.

**33. Water supply and Sanitation.** The Applicant or the Licensee must provide evidence that the water supply and Sanitation facilities at the Healthcare Establishment are in accordance with all the applicable laws, rules/regulations and regulations pertaining to water supply and Sanitation.

**34. Fire safety inspection.** Prior to the issuance of the Regular License, and annually thereafter, the Commission must receive a written statement signed by the Competent authority (Civil Defence Officer or the Municipal Official designated to make fire safety inspections), to the effect that the premises comply with fire safety standards.

**35. Construction and Renovation.** (1) Any construction of new buildings for occupancy as a Healthcare Establishment and/or additions, renovations, alterations or repairs of existing buildings must comply with the local laws and the copies of the relevant record in this regard shall be properly maintained by the Healthcare Establishment.

(2) Upon completion of the project and prior to occupancy, the following information must be received by the Commission before a license is issued;

- (a) Architect's Letter of certification, as applicable, that the construction conforms to the certified drawings and specifications that were prepared according to the authorisation granted for the same by the Competent Authority.
- (b) Approval from Fire Safety Department
- (c) All such documentation evidencing that the requirements under the Act, Rules, regulations, Standards, Reference Manual, any other instructions or orders passed by the Commission have been fulfilled; and
- (d) Copies of policies and procedures, contractual agreements, staffing plans, or material(s) necessary to ascertain compliance with these regulations

**36. Fees.**

- (1) The Registration and License fee(s) shall be as prescribed by the Commission, from time to time, and shall be non-refundable.
- (2) The Registration and License fee is to be submitted along with the application for the Registration and shall be for a fixed period of five (5) years.
- (3) The Healthcare Establishment granted with a Conditional License, shall pay the License fee as prescribed by the Commission.
- (4) The additional fee(s) may be charged for every change(s) and/or amendments to a license(s) as prescribed by the Commission, from time to time.

**37. Laws and Codes.** The applicant must provide evidence from the appropriate municipal or other relevant authorities, indicating compliance with all laws and/or codes, as the case may be, relating to the type of Health Care Services for which the license is being applied for.

**38. Accreditation Credentials.** A copy of the latest accreditation Certificate by an accrediting body, for any purpose, must be on file with the Commission, if the Applicant/Licensee has been so accredited.

### **INSPECTION**

**39. Inspections.** (1) All inspections shall be carried out as prescribed under the Section 14 of the Act and these regulations. The Commission may, by order in writing, appoint an inspector or an inspection team to perform the functions and exercise the powers of the Commission in relation to inspections under the Act and these regulations subject to such conditions and limitations as the Commission may specify in this behalf.

(2) The inspections will be conducted for issuance, renewal and amendment of a License, on receipt of a complaint, for de-sealing a healthcare establishment or for suspected violation of the Act, Rules, regulations, Standards, Reference Manual, any other instructions or orders passed by the Commission.

(3) The HCC will inform the HCE about the dates of the inspection at least one week in advance in case of issuance or amendment of the license. But in cases of inspections carried out in response to a complaint or suspected violation of the Act, Rules, regulations, Standards, Reference Manual, any other instructions or orders passed by the Commission, shall be carried out without any notice to the Concerned Healthcare Establishment.

(4) In case no complaint is received against a licensed HCE, or there is no other cause to undertake mid-term inspection, a Licensed Healthcare Establishment shall be inspected at least once in every three (3) years, unless otherwise decided by the Commission.

(5) **Statement of Deficiencies.** The Commission shall issue a statement of deficiencies as a consequence of determination that a deficiency, omission, or violation of the Act, Rules, regulations, Standards, Reference Manual, any other instructions or orders, including but not limited to a plan of correction, passed by it has occurred. The Commission shall also issue a timeline to comply with the same.

(6) **Remedial action.** The Commission may, in the event of deficiencies of the Healthcare Establishment, issue directions to implement its plan of action, or take additional corrective actions as specified by it.

(7) **Response of the Applicant/Licensee.** Within ten (10) days of receipt of the Statement of Deficiencies, the Applicant or the Licensee, may request for a meeting to provide evidence to dispute the findings of the Inspection Team, if the Applicant/Licensee disagrees with the Statement of Deficiencies by the Commission.

**40. Inspection Team.** (1) The Commission will engage a team of qualified professionals as Inspectors who will report to the Director of Registration and Licensing. No inspection will be conducted by a single inspector under any circumstances.

(2) The Commission will draw upon a Panel of Experts including the renowned subject specialists comprising of the niche medical, surgery, allopathic, homeopathic, tibb, paramedical disciplines and will also include general engineers, equipment engineers, building engineers, legal experts who will be included in the inspection team to support the HCC Inspectors in verifying if an HCE fulfils the Standards and requirements as set out by the Commission. This Panel of Experts will not be permanent employees of the Commission but will be engaged as expert consultants and advisors on the basis of an agreed compensation / honoraria as decided by the Commission from time to time.

**41. Right of Entry.** (1) An Application for a License or its renewal pursuant to these regulations would constitute a permission for complete acquiescence to any entry or inspection for which the license is sought in order to facilitate verification of the information submitted on, or in connection with, such an application.

(2) The Commission and/or any duly designated representative shall have the right to enter upon and into premises of the Applicant or a Licensee, as the case may be, pursuant to these regulations at any time without threat of injury, verbal abuse, or harassment and in the spirit of mutual cooperation in order to determine the status of compliance with the Act, Rules, regulations, Standards, Reference Manual, any other instructions or orders passed by the Commission. In case any person tries to interfere with the inspection process, the Commission will have a right to impose a fine of Rupees 500,000/-.

(3) Right of Entry shall entitle Commission and/or its authorized personal full access to all the relevant records, documents and reports at the said premises, as required for the purpose of these Regulations or other applicable law.

(4) Right of Entry gives the Commission authorization to copy records, documents and reports either manually or by photocopy unless otherwise protected by law, at no expense to the Commission.

(5) The Inspection Team may inspect any apparatus, appliance, equipment, instrument, product, goods or item used or found in, or any practice or procedure being carried out at a Healthcare Establishment or by a Healthcare Service Provider.

(6) Where, in the opinion of the Inspection Team, the use of any apparatus, appliance, equipment, instrument, product, goods or item; or the carrying out of any practice or procedure in a Healthcare Establishment, is dangerous or detrimental to any person therein or otherwise unsuitable for the purpose for which it is used or carried out, it shall immediately report the matter in writing to the Commission along with the necessary details. On receipt of report the Commission may act according to the provisions in the Act and these regulations.

(7) The Commission may impose a fine which may extend to fifty thousand rupees (Rs. 50,000/-) upon a health care establishment who,-

- (a) Refuses or fails, without reasonable cause, to furnish any information to the inspection team;
- (b) Gives any false or misleading information to the inspection team.
- (c) Obstructs the authorised person in conducting the inspection for the purposes of the Act and as prescribed in the Rules/regulations.

**42.** Except in the case of a prosecution for an offence under this Act, a member of the Inspection Team shall not be bound to give evidence in any proceedings in respect of, or to produce any document containing, any information which has been obtained from any Healthcare Service Provider or a Healthcare Establishment in the course of carrying out any investigation, inspection, enquiry or performing any duty or function under the Act and these Regulations.

**43.** A member of the Inspection Team shall not disclose any information at any forum which is contained in the medical record, or which relates to the condition, treatment or diagnosis, of any person, as may have come to his knowledge in the course of carrying out any investigation, inspection, enquiry or performing any duty or function under the Act and these regulations unless allowed in writing by the Commission. In case the authorised officers undertake misconduct in his regard, they shall be processed against as prescribed in the Human Resource Management regulations and relevant policies of the Commission.