

# **Khyber Pakhtunkhwa Health Care Commission**

## **(Registration and Licensing) Regulations, 2022**

### **CHAPTER I PRELIMINARY**

#### **1. Short Title, Application and Commencement**

- (1) These Regulations shall be called as the Khyber Pakhtunkhwa Health Care Commission (Registration and Licensing) Regulations, 2022.
- (2) These Regulations shall extend to the whole Province of Khyber Pakhtunkhwa and apply to all Health Care Establishments (HCEs), whether public or private:
  - (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 systems recognized in Pakistan.
- (3) These Regulations shall come into force at once.

#### **2. Definitions**

- (1) In these Regulations, unless the context otherwise requires, the following expressions shall have the meanings hereby respectively assigned to them, as given below:
  - (a) "Act" means the Khyber Pakhtunkhwa Health Care Commission (KP HCC) Act, 2015;
  - (b) "Applicant" means health care establishment and/or health care service provider who has applied for registration and/or licence or its renewal, as the case may be;
  - (c) "Board" means the Board of Health Care Commission, constituted under the Khyber Pakhtunkhwa Health Care Commission Act, 2015;
  - (d) "Commission" means the Khyber Pakhtunkhwa Health Care Commission, established under section 3 of the Act and includes the Board and the Executive of the Commission. The former is the policy formulation forum and the latter is the execution body;
  - (e) "Case" means any such matter which is taken up by the Commission for inquiry and further necessary action, within the scope of the Act and these Regulations;
  - (f) "Complaint" means any application or plea of grievance by any aggrieved person, received by the Commission under the Act and these Regulations and includes a complaint received manually or online, through the Pakistan Citizen's Portal or the online complaint portal maintained by the Commission;
  - (g) "Competent Authority" unless otherwise provided in these regulations, Competent Authority for the purpose of these regulations, means the Director Licensing/Registration, or any other officer of the Commission, specifically authorized in this regard, exercising delegated authority of the Board through the Chief Executive Officer;
  - (h) "Directorate" means any Directorate of the Commission, established and authorized under these regulations and headed by a Director, duly appointed or designated by the Board;
  - (i) "Executive" means the execution body of the Commission, headed by the Chief Executive Officer, and includes the Directors/Chief Financial Officer and their subordinate staff;
  - (j) "Expert" means a person with relevant knowledge and skills in a particular subject, with regard to issues in the case;

- (k) "Fee" means the amount of money approved by the Board for the purpose of granting registration and licence to health care establishments keeping in view factors, including but not limited to, the size, category, and services under the provisions of the Act;
- (l) "Health Care Establishment" means a hospital, diagnostic center, blood bank, medical clinic, nursing home, maternity home, dental clinic, homeopathic clinic, tibb clinic, acupuncture, physiotherapy clinic, aesthetic clinic, rehabilitation centres or any other premises or conveyance:
  - i. Wholly or partly used for providing health care services in public or private sector; and
  - ii. Declared by the Commission as health care establishment.
- (m) "Health Care Services" means services provided in public and private sectors for diagnosis, treatment or care of persons suffering from any physical or mental disease, injury or disability, including procedures that are similar, to forms of medical, dental or surgical care but are not provided in connection with a medical condition, and includes any other service notified by Government;
- (n) "Health Care Service Provider" means a person who provides health care services duly registered by the Pakistan Medical Dental Council, National Council for Tibb, Council for Homeopathy, Nursing Council or any other relevant council/body of the Government. Such person may or may not be the owner or in charge of a health care establishment;
- (o) "Inspection" means the process of examining any apparatus, appliance, equipment, instrument, product, goods or items used or found in, or any practice, process or procedure being carried out, at health care establishment (may be alternatively called as assessment);
- (p) "Inspection Team" means a team of experts and/or officials of the Commission for the purpose of inspection of a particular health care establishment (may be alternatively called as assessment team);
- (q) "Licence" means licence issued by the Commission under section 12 of the Act for the use of any premises or conveyance as a health care establishment and "Licensing" shall be construed accordingly;
- (r) "Licencee" means a health care establishment or conveyance which holds a licence issued by the Commission;
- (s) "Maladministration" means poor, dishonest or inefficient administration or mismanagement by a health care establishment and includes:
  - i. A decision, process, recommendation, act, omission or commission which is contrary to law, rules or regulations or is a departure from established practice, procedure, and standard, unless it was done in good faith and required in the circumstances of that particular case; and/or is perverse, arbitrary or unreasonable, unjust, biased, oppressive, or discriminatory; and/or is based on irrelevant grounds; and/or involves the exercise of powers and the failure/refusal to do so; and/or;
  - ii. Neglect, in-attention, delay, incompetence and inefficiency 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 the requisite information, failure to investigate, failure to reply, misleading or inaccurate statements, inadequate liaison, corrupt behaviour, 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 health care service provider or a person working at a health care establishment and being the proximate cause of injury or harm to another person;
  - (u) "Notice" means any information communicate sent to a concerned party by the competent authority, appellate authority or any other authorized staff of the Commission, as the case may be;
  - (v) "Penalties" mean such penalties as prescribed by the Act or these Regulations or other laws and regulations of the Commission enforced from time to time;
  - (w) "Proprietor" means such person(s) who owns the premises at which the health care services are provided and includes any such person who may also be the in charge or service provider of the health care establishment. The proprietor of the premises and the owner of the health care establishment may not be the same person;
  - (x) "Quality Assurance" means the responsibility and capacity of a Health Care Establishment and/or health care service provider, as the case may be, to ensure compliance with the governing laws, instructions, standards, guidelines and corrective orders issued by the Commission in accordance with the Act and Rules/Regulations;
  - (y) "Quality Assurance Committee" means a committee established by a health care establishment and entrusted with the responsibility, to ensure compliance with the governing laws, instructions, standards, guidelines and corrective orders issued by the Commission in accordance with the Act and Rules/Regulations;
  - (z) "Reference Manual" means any such manual(s) prepared by the Commission, from time to time, for regulating the health care sector and achieving the purposes of the Act, containing sets of guidelines for the health care establishments relating to implementation of the standards;
  - (aa) "Registration" means registration granted by the Commission under section 12 of the Act, for the use of any premises or conveyance as a health care establishment;
  - (bb) "Regulations" means the Khyber Pakhtunkhwa Health Care Commission (Registration and Licensing) Regulations, 2022;
  - (cc) "Standards" mean the health care standards for all categories of health care establishments, duly notified by the Commission, from time to time.
- (2) All other words and expressions used in these regulations but not specifically defined herein shall have the same meanings as are assigned to them in the Act, other laws for the time being in force, rules, regulations, reference manuals of standards or guidelines for the health care establishments and/or such other instructions or order relating to the improvement of health care services and/ or health care service delivery systems, as prepared and issued by the Commission, or the Government from time to time, for achieving the purpose of the Act.

## **CHAPTER II**

### **REGISTRATION AND LICENSING MANAGEMENT SYSTEM**

For registration and licensing management, the Commission shall establish two Directorates; namely, the Directorate of Licensing and the Directorate of Quality, and any other directorate as deemed appropriate.

#### **3. Directorate of Licensing/Registration**

- (1) The Commission shall establish a Directorate of Licensing/Registration, headed by a director and assisted by as many employees of the Commission, as are necessary for discharge of its functions under the Act and Regulations, and as decided by the Board, from time to time;
- (2) The Directorate of Licensing or any other officer of the Commission shall use delegated authority of the Board through the Chief Executive Officer to register and issue licences to the health care establishments and/or renew and modify, and suspend the registration and/or licences, granted by the Commission;
- (3) It may suspend registration and/or licence, issue show cause notices and temporarily seal health care establishments in case of violation of the provisions of the Act, Regulations, Reference Manuals for standards and any other orders or instruction issued by Commission, from time to time;
- (4) The Directorate of Licensing/Registration shall perform such other tasks for the purposes of ensuring that the health care services are rendered in accordance with the provisions of the Act and these Regulations;
- (5) The Directorate of Licensing/Registration shall perform all the functions of the Commission as assigned to it by the Commission from time to time.

#### **4. Directorate of Quality**

- (1) The Commission shall establish a Directorate of Quality, headed by a director and assisted by as many employees of the Commission, as are necessary for discharge of its functions under the Act and Regulations, and as decided by the Board, from time to time;
- (2) The Directorate of Quality shall be the custodian of Minimum Service Delivery Standards (MSDS), and shall be responsible to keep it updated and available to HCEs;
- (3) The Directorate shall provide the available and relevant literature to and arrange training for the managers, service providers and nominated staff of the health care establishments on the Minimum Service Delivery Standards;
- (4) The Directorate of Quality shall provide assistance to the health care establishment for implementation of minimum service delivery standards through target setting and supportive supervision, depending upon the availability of staff and requirement of the HCEs;
- (5) Directorate of Quality shall be responsible for awareness of various segments of the society, including health managers, health care service providers, patients and their attendants, and general public, on quality of health care services and their rights and responsibilities;
- (6) It shall work in close coordination with all other Directorates of the Commission, particularly the Directorate of Licensing/Registration, to improve quality of health care services;
- (7) The Directorate of quality shall perform all the functions of the Commission as assigned to it by the Commission from time to time.

**5. Registration and Licensing Authority**

The respective director shall use delegated authority of the Board through the Chief Executive Officer to issue registration certificates and licences to eligible health care establishments.

**6. Categorization of Health Care Establishments**

For the Purpose of registration and licensing under the Act and these Regulations, and implementation of the Minimum Service Delivery Standards (MSDS), all health care establishments in the Khyber Pakhtunkhwa shall be categorized as per **first schedule**, of these regulations.

**CHAPTER III  
REGISTRATION**

**7. Compulsory Registration of Health Care Establishments**

- (1) All the private health care establishments in the Khyber Pakhtunkhwa, including trusts, charities, associations, foundations and cooperative societies providing health care services, shall apply to the Commission for registration and no private health care establishment, shall provide health care services, if not registered with the Khyber Pakhtunkhwa Health Care Commission;
- (2) The public sector health care establishment shall be considered as registered;
- (3) Any new private health care establishment shall register itself with the Commission before commencement of health care services;
- (4) A health care 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 get registered through online portal, under Khyber Pakhtunkhwa Health Care Commission Act, 2015;
- (5) Health care establishments operating under the same name/banner/owner, but located separately, shall be considered as separate entities and shall be registered accordingly.

**8. Procedure for Registration**

- (1) Every health care establishment shall apply for registration with Commission on the prescribed form and submit all the documents mentioned in the form, along with the nature of premises whether rented or personal etc., and its documentary proof to the Commission;
- (2) The health care establishment shall provide all the information and documentary evidence relevant to the scope and extent of health care services being/to be provided, as required by the Commission;
- (3) The health care establishment shall also deposit the prescribed registration fee;
- (4) The Commission shall issue Registration Certificate in the name of the health care establishment and not in the name of the owner or in-charge, except in the case of health care service providers in medical, dental, homeopathic and tibb clinic, falling in category 3, where the establishment has no trade name;
- (5) The proprietor or in-charge of the health care establishment shall also furnish an affidavit that he/she has made no attempt to use same, identical, resembling or similar name of a registered HCE, and that the name is not inappropriate or undesirable;
- (6) The health care establishments shall apply through online registration portal of the Commission and fulfill all the requirements;

- (7) The Commission shall either complete the process and issue a Certificate of Registration to the applicant or communicate the decision of rejection, if the health care establishment does not meet the essential criteria for registration, within 30 days of the receipt of application;
- (8) The applicant would be at liberty to re-apply for registration if the criteria is subsequently fulfilled, and the Commission is satisfied that the health care establishment is eligible for registration.

#### **9. Registration Fee**

- (1) The Commission shall charge fee for registration of health care establishments as determined by the Board, from time to time;
- (2) Registration fee shall be deposited in the designated bank account of the Commission and cash payment shall not be accepted;
- (3) Registration fee shall be non-refundable.

#### **10. Certificate of Registration**

- (1) The competent authority shall, after it is satisfied that all due formalities as per section 8 ibid regulation have been fulfilled, issue a "Certificate of Registration" to the concerned Health Care Establishment, on the format as prescribed by the Commission;
- (2) The certificate so issued under section 10(1) ibid shall contain the scope and extent of the services provided i.e., category and sub-category, as the case may be;
- (3) The registration certificate once issued shall be valid for life. However, if the health care establishment desires to modify the scope and extent of services and/or nomenclature so registered, it shall apply to the Commission for modification, in the same manner as provided for registration and the Commission shall adopt the same procedure before issuing a modified registration certificate;
- (4) The respective directorate shall maintain a register (database) of all the registered health care establishments providing health care services in the province of Khyber Pakhtunkhwa, containing such details and information as considered necessary by the Commission;
- (5) A list of all registered HCEs shall be posted on the Commission's website.

#### **11. Procedure for Registration of Unregistered Health Care Establishments**

- (1) The Commission shall issue notice to all the unregistered health care establishments, not falling under the definition of quack, directing them to get registered, within a specified time. The time so specified by the Commission may be extended for securing the best public interest and giving an opportunity to all the health care establishments to secure their registration certificates;
- (2) If, at the end of specified period or the extended period, as the case may be, a health care establishment fails to register, such health care establishment shall be temporarily sealed and a show cause notice shall be served upon it, as to why it may not be permanently sealed;
- (3) The respective director shall, on report of the sealing officer, take cognizance of the case, and submit it to the Review Committee;
- (4) The Review Committee(s) shall be constituted by the Chief Executive Officer, from time to time, consisting of at least three members and chaired by an officer of the Commission not below the rank of deputy director;
- (5) The Review Committee shall provide right of hearing to the proprietor/owner/ in-charge of the health care establishment or his/her nominee or the relevant service

provider or his/her nominee and may, subject to operation of law, impose any or all of the below mentioned penalties against the health care establishment:

- (a) Permanently seal the premises; and/or;
- (b) Impose fine which may extend to rupees one million; and/or;
- (c) Refer the case to other law enforcement agencies for appropriate action under the relevant law.

Provided that imposition of penalty against any health care establishment would not bar registration of such health care establishment and it may, subject to payment of fine, apply for registration of the establishment. The Directorate of Licensing/Registration while considering application for registration of such health care establishment under penalty, shall not be prejudiced by the penalty so imposed and decide the same on merit.

## **12. Provision of Incorrect Information**

If the information furnished by the proprietor/owner/in-charge of the HCE, under an affidavit duly stamped and notarized, is found to be incorrect, the HCE shall be temporarily sealed on the spot. In order to permanently seal and/or impose fine and or/refer the case to other law enforcement agencies, an opportunity of hearing shall be afforded to the proprietor/owner/in charge by the Review Committee.

## **CHAPTER IV LICENSING**

## **13. Compulsory Licensing of Health Care Establishments**

- (1) It shall be the responsibility of every health care establishment, whether in public or private sector to apply for Licence in accordance with the provisions of the Act and these Regulations;
- (2) No entity, 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 health care establishment for human beings without a Licence issued by the Commission in accordance with the criteria laid down by the Commission for Licensing;
- (3) All health care establishments shall, after being registered, make an application for a licence to the Commission on the prescribed form, which shall be accompanied by such particulars, documents and fee as the Commission may prescribe;
- (4) The Commission, if it deems appropriate, may combine the application form for registration and licensing;
- (5) Health Care Establishments operating under the same name/banner/owner but located separately, shall be considered as separate entities and need to be licensed accordingly.

## **14. Types of Licence**

The Khyber Pakhtunkhwa Health Care Commission shall issue two types of licence:

- (1) A **Provisional Licence** shall be issued by the competent authority to such HCE, which has submitted an application and its staff is trained on the relevant MSDS;
- (2) A **Full Licence** shall be issued by the competent authority to such provisionally licensed HCE whose assessment shows compliance with the provisions of the Act, Regulations as well as the standards specified by the Commission.

## 15. Procedure for Licensing

- (1) The registered health care establishments shall make an application to the Commission for issuance of licence on the prescribed form;
- (2) The unregistered HCEs may submit a combined application for registration and licence, on the prescribed form;
- (3) The application form must be accompanied by the relevant documents, evidences, statements and fee as determined by the Commission;
- (4) Once the application is complete in all respects and the requisite fee is deposited, the Directorate of Quality shall be informed which shall provide the available literature and arrange a training for the managers and health care service providers of the concerned establishment on the Minimum Service Delivery Standards;
- (5) The Directorate of Quality shall, as soon as possible, arrange the training for staff of the establishment. At least two staff members of category 1 and 2 health care establishments, and one of category 3 shall be trained. The HCE shall be directed to disseminate the literature and MSDS to other staff members for implementation;
- (6) Upon the directives of the Directorate of Quality, all category 1 and 2 health care establishments shall establish Quality Assurance Committee for the purpose of interaction with the Commission and shall be responsible for implementation of the Minimum Service Delivery Standards. Category 3 HCEs shall designate Quality Assurance Manager for the same purpose;
- (7) Upon completion of training and issuance of certificates by the Directorate of Quality, the Directorate of Licensing shall award Provisional Licence to the health care establishment and issue directions to the proprietor/in charge to complete all the requirements for a licence within the stipulated time;
- (8) The health care establishment shall have three months, from the date of issuance of provisional licence, to implement the minimum standards. During this period the Directorate of Quality may provide assistance to the health care establishment for implementation of minimum service delivery standards through target setting and supportive supervision, as and when required;
- (9) The health care establishment under the provisional licence shall upgrade itself to meet the minimum standards set by the Commission or rectify the deficiencies pointed out by the Directorate of Quality;
- (10) The Directorate of Licensing shall arrange final inspection of the HCE for licence through expert independent assessors and the KP HCC staff may accompany for assistance, if required;
- (11) The HCE shall pay fee for the first inspection for licence, at the rate prescribed by the Board from time to time;
- (12) If, as a result of inspection, the health care establishment fulfils the minimum criteria and gets the required score, Full Licence shall be awarded;
- (13) In case the HCE is unsuccessful in the first inspection for licence, a warning and Statement of Deficiencies shall be issued along with reasonable extension in the term of provisional licence;
- (14) On completion of the extended period or even earlier, second inspection shall be scheduled and the health care establishment shall be assessed on the deficient indicators only, and if it fulfils the criteria, full licence shall be awarded;
- (15) The HCE shall pay fee for the second inspection for licence, at the rate prescribed by the Board from time to time;
- (16) If the health care establishment is unsuccessful in the second attempt also, a warning and Statement of Deficiencies shall be issued along with reasonable extension in the term of provisional licence;
- (17) The staff of the HCE shall be trained again at the fee prescribed by the Board from time to time;
- (18) The HCE shall pay fee for third inspection for licence, at the rate prescribed for second inspection by the Board from time to time;
- (19) During third inspection the health care establishment shall be assessed on the deficient indicators only, and if it fulfils the criteria, full licence shall be awarded;

Provided that in case of failure, the registration and provisional licence shall stand cancelled. The HCE shall be sealed, forthwith, for the purposes of health care service provision;

Provided that the HCE shall be allowed to work on the upgradation to meet the minimum service delivery standards.



Provided further that such an HCE shall be considered as a new case for registration and licensing.

**16. Review:**

- (1) If the health care establishment has reservation about the assessment for licence, it shall have the right of appeal to the review committee;
- (2) The review committee shall provide the opportunity of hearing and provision of evidences in support of its reservations;
- (3) The committee may also call the assessors for their version on the assessment for licensing, if it deems appropriate.

**17. Panel of Trainer for MSDS**

- (1) The Commission shall develop a pool of qualified professional trainers for MSDS;
- (2) Advertisement shall be made in at least two newspapers to invite applications for enrolment as member of panel of trainers for MSDS. The advertisement shall be made once and shall remain open for the whole year. Scrutiny and interviews of the shortlisted candidates shall be conducted on quarterly basis/need basis, by a committees constituted by the Chief Executive Officer and consisting of at least two Directors/Senior Officers. Such numbers of trainers, as deemed expedient by the Commission, shall be enrolled in the pool to act as trainer for MSDS;
- (3) On case to case basis, trainers shall be nominated by the Director Quality from the said panel. An officer of the Commission shall coordinate with the trainers and facilitate them during training on MSDS;
- (4) The Directorate of Quality shall frame guidelines for training and ensure that those are followed in letter and spirit;
- (5) Members of the panel of trainers shall not be employees of the Commission, and shall act as consultants of the Commission for that particular case and shall be provided with such honorarium/fee as determined by the Board, from time to time.

**18. Licensing Fee**

- (1) The Khyber Pakhtunkhwa Health Care Commission shall charge fee for Licensing of health care establishments, as approved by the Board, from time to time;
- (2) For every subsequent renewal, the health care establishment shall pay licence fee again, on such rates as approved by the Board and prevalent at that time;
- (3) Licence fee shall be deposited in the designated bank account of Khyber Pakhtunkhwa Health Care Commission and cash payment shall not be accepted;
- (4) Licence fee once deposited, shall be non-refundable.

**19. Term of Licence**

- (1) Provisional Licence  
The term of provisional licence shall be three months for implementation of Minimum Service Delivery Standards;
- (2) Full Licence  
The Full Licence of health care establishment shall be valid for three years.

Provided that, irrespective of the terms of licence, in case of change in scope or extent of services and/or nomenclature, the proprietor/owner or in charge of the HCE shall apply for a new licence according to its category.

**20. Renewal of Licence**

- (1) The health care establishments shall apply for renewal of their licences, six months prior to the completion of the three-year period;
- (2) For the purpose of renewal of licence, the health care establishments shall be inspected again and re-assessed on the same criteria as for issuance of the new licence;

- (3) The competent authority may refuse renewal of licence, if the health care establishment has not maintained its standard and does not meet the requisite minimum service delivery standards, at the time for renewal of licence;
- (4) In case of refusal under regulation (3) *ibid*, the competent authority shall downgrade it to the category of provisional licence, on such terms and conditions as it deems appropriate, including directions to improve its standards within the term of provisional licence.

**21. Licences to be Non-transferrable**

A licence issued under these Regulations shall neither be assignable nor transferrable, unless a written permission is granted by the competent authority, in accordance with these Regulations, with reasons to be recorded in writing, pertaining to issues of merger, acquisition or change of proprietorship etc., of the HCE.

**22. Refusal to Grant, Renew or Amend Licence**

- (1) The competent authority may refuse to grant, renew or amend the licence, if it is satisfied that:
  - (a) The applicant has made misrepresentation, and presented materially incorrect or insufficient information on the application;
  - (b) The applicant has not supplied the requisite information and evidences to the competent authority;
  - (c) The applicant, after the issuance of provisional licence and sufficient time being given for the purpose has not improved and maintained the minimum service delivery standards;
  - (d) The applicant has failed to comply any other directives of the Commission issued in this behalf.
- (2) For the purpose of these regulation, satisfaction of the competent authority shall be objective, and the order of refusal must be in writing, mentioning sufficient reasons for refusal.

**23. Suspension of Licence**

The competent authority may either on its own motion or on the recommendation of review committee or other directorates of the Commission, suspend the licence of any health care establishment, temporarily seal the premises and issue a show cause notice for cancellation of licence, if it is satisfied that:

- (1) The establishment is involved in maladministration, malpractice or any other illegal activities;
- (2) The licence was obtained by way of fraud, misrepresentation and concealment of fact(s);
- (3) The establishment is involved in quackery;
- (4) The establishment has violated the terms and conditions of licence and was used for unauthorized purposes;
- (5) The establishment was adjudged by the inquiry or review committee, guilty of medical negligence, quackery or any other violation of the Act, Regulations, reference manuals for standards and any other orders or instruction issued by Commission from time to time;

Provided that except in case the licence was suspended upon the recommendation of the review committee, the health care establishment shall have the right to file representation before the review committee, within 30 days of suspension. The review committee may, on such terms and conditions as it deems appropriate, including the imposition of fine which may extend to one million rupees, order restoration of licence,

either provisional or full, and order removal of the deficiencies reported against the establishment;

Provided further that during the period under review, the licence shall remain suspended and the premises shall remain temporarily sealed.

**24. Cancellation of Licence**

(1) All the cases of suspension of licence, temporary sealing the premises and issuance of show cause notice for cancellation of licence, shall be submitted to the review committee;

Provided that except in case where the licence was suspended upon the recommendation of the review committee.

Provided further that the aggrieved HCE shall also have the right to file representation before the review committee, within 30 days.

(2) The review committee may decide the case, on such terms and conditions as it deems appropriate, including the imposition of fine which may extend to one million rupees, order restoration of licence, retaining suspension of licence till rectification of the irregularities, order removal of the deficiencies reported against the establishment, cancellation of licence, and/or permanently sealing the HCE;

Provided that during the period under review, the licence shall remain suspended and the premises shall remain temporarily sealed.

**25. Opportunity of Hearing:**

The Review Committee shall provide an opportunity of hearing to the health care establishment during proceedings and before taking final decision.

**26. Shifting of Health Care Establishment:**

(1) In case of shifting of a health care establishment, from one premises to another, the health care establishment shall seek prior approval from the competent authority and if the approval is granted, the licence so issued earlier shall remain valid for the remaining period with change in address, on payment of prescribed fee for change of address;

(2) For the purpose of approval to shift the HCE, the competent authority shall arrange an inspection of the premises, on payment of fee equal to second inspection fee, and shall take decision on the basis of inspection and fitness report.

**27. Change in Infrastructure, Services and Ownership:**

(1) Any change in the services rendered at the already licensed health care establishment shall not be implemented without prior written approval and issuance of an amended licence, as the case may be, by the competent authority;

(2) Any major change in the infrastructure, including addition and/or alteration in any manner shall be made in conformity to the relevant laws/rules and under intimation to the competent authority and amended licence shall be issued, if required;

(3) Any change of proprietor of a private health care establishment shall be reported to the Commission within thirty days of such change, and an amended licence shall be acquired.

**28. Display of Licence**

The licence issued to a health care establishment, shall be visibly displayed at the reception or any other prominent place in the establishment.

**29. Re-application**

An HCE whose application has been rejected or the licence, once issued, has been cancelled, or any penalty imposed upon it, may re-apply for licence, after complying with all the requirements, as prescribed. The competent authority while deciding such

applications, shall not be prejudiced by any previous decisions and decide the application on merit.

- 30. Register of Licensed Health Care Establishments:** The Directorate of Licensing shall maintain a register (database) of all the licensed health care establishments providing health care services in the province of Khyber Pakhtunkhwa, containing such details and information as considered necessary by the Commission.

## **CHAPTER V INSPECTIONS**

### **31. Inspections for Licensing**

- (1) The competent authority shall, before issuance, renewal and amendment of licences to the health care establishment, conduct inspections (may be alternatively called as assessment), of the health care establishment through an inspection team of experts (may be alternatively called as assessment team), duly selected on the basis of qualification and expertise;
- (2) Inspection shall be conducted by a team of at least two members, to be nominated through rotational plan, by the competent authority;
- (3) The inspection team shall during the inspection, exercise all the powers and functions as provided in the Act, Regulations, Standard Operating Procedures or defined by the Commission from time to time;
- (4) All inspections shall be carried out in the manner prescribed by the Act, Regulations, Standard Operating Procedures or other directives of the Commission;
- (5) For the purpose of inspection under these Regulation, the Directorate of Licensing shall inform the health care establishment about the dates of inspection at least one week before the date of inspection;
- (6) The inspection team shall inspect the HCE in light of the requirements for licensing and furnish its report in writing to the Commission along with such proforma, checklist or score sheet as may be prescribed, not later than the last day of inspection;
- (7) The competent authority shall, based on the inspection report, issue a statement of deficiencies as a consequence of determination that a deficiency, omission, or violation of the Act, Regulations, reference manuals for standards, any other instructions or orders passed by it has occurred. The competent authority shall also specify a timeline for removal of the deficiencies, if any;
- (8) The competent authority may, in the event of deficiencies of the health care establishment, issue directions to implement its plan of action, or take additional corrective actions as specified by it. The Directorate of Quality may provide guidance to the health care establishment regarding removal of the deficiencies, if required;
- (9) In case the applicant disagrees with the Statement of Deficiencies, he/she may submit written response within ten days of receipt of the Statement of Deficiencies to the review committee;
- (10) The review committee shall consider the written statement of applicant as per 31(9) and shall decide on merit the next steps including, agreeing with all or portion of the response of the applicant and advising the competent authority to issue a revised statement of deficiencies, or rejecting the written response. Such decision shall be communicated to the applicant within seven days;
- (11) Follow up inspection shall be conducted on, as and when required, basis.

**32. Panel of Independent Assessors for Inspection of Licensing**

- (1) The Commission shall engage a pool of qualified professional assessors for inspection;
- (2) Applications for enrolment as member of panel of independent assessors for inspections shall be invited through advertisement in at least two newspapers and the application process shall remain open for a year. Scrutiny and interviews of the shortlisted candidates shall be conducted on quarterly basis, by committees constituted by the Chief Executive Officer and consisting of at least two Directors/Senior Officers. Such numbers of experts, as deemed expedient by the Commission, shall be enrolled in the pool to act as member inspection team;
- (3) On case to case basis, inspection teams shall be nominated by the competent authority from the said panel on rotational basis. An officer of the Commission shall coordinate with the inspection team and may accompany it during inspection of the health care establishments;
- (4) The competent authority shall frame terms of reference and guidelines for the inspection team and ensure that those are followed in letter and spirit;
- (5) Members of the panel of assessors shall not be employees of the Commission and shall act as consultants. They shall be provided with such honorarium/fee as determined by the Board, from time to time.

**33. Yearly Inspection**

- (1) In case no complaint is received against a licensed health care establishment, or there is no other cause to undertake mid-term inspection, the Directorate of Licensing shall conduct at least one inspection of all the licensed health care establishments in a year, unless otherwise decided by the competent authority;
- (2) The officer/team inspecting the establishment shall furnish a detailed report of inspection to the competent authority, on the prescribed scoring sheet;
- (3) The competent authority shall issue Statement of Deficiencies, if any, with the concerned HCE, along with an action plan and timeline for corrective action;
- (4) The competent authority shall take appropriate action as prescribed in the case of inspection for licensing.

**34. Routine Inspections**

The competent authority, in consultation with the Chief Executive Officer, may carry out routine inspections through its own staff for ensuring compliance with the provisions of the Act, Regulations, Reference manuals of Standards, and instructions issued. Such inspections may be with or without prior intimation to the concerned health care establishment, as the competent authority may decide.

**35. Emergency Suspension of Service(s)**

If the Commission, at any time, on inspection of a health care establishment, observes that a particular condition(s) can be an immediate threat to the health and safety of the patients, health care providers, staff, attendants at the health care establishment, or lead to an emergency, the Commission, through its duly authorized employee(s), may issue orders for emergency suspension of such services or facilities as deemed appropriate and adjust for the duty of care of any patients under treatment in that health care establishment.

**36. Right of Entry**

- (1) The inspection team or any other officer of the Commission on duty and duly authorized by the Commission in this behalf, shall have the right to enter into premises of any health care establishment 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, Regulations, Reference Manuals for standards, any other instructions or orders passed by the Commission;

- (2) Right of entry shall authorize the inspection team or the authorized officer of the Commission to have 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;
- (3) Right of entry shall authorize the inspection team or the authorized officer of the Commission to copy records, documents and reports either manually or by photocopy, and take photographs and record videos through electronic devices, unless otherwise protected by law;

Provided that the records, documents, photos and videos so recorded shall be confidential and not shared with any person other than the authorized staff of the Commission. Breach of confidentiality, in the case of panel of experts, shall amount to malpractice, and in case of employee of the Commission, shall be considered as misconduct and liable to disciplinary action.

- (4) 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 health care establishment;
- (5) 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 health care 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 competent authority along with the necessary details. On receipt of report the competent authority may act according to the provisions of the Act and these Regulations.

### **37. Interference with the Inspection**

- (1) In case any person tries to interfere with the inspection process and hinders the inspection, the matter shall be reported to the competent authority;
- (2) The competent authority shall forward the complaint to the Directorate of legal Affairs in accordance with the complaints management regulations 2022, or the review committee constituted under these regulations, which shall proceed as per regulations, and issue such directions, including payment of fine, as may be provided and considered just in the circumstances;
- (3) Complaint under clauses (1) & (2) ibid shall be furnished on any of the following grounds namely:
  - (a) Refusal or failure, without reasonable cause, to furnish any information to the inspector/inspection team;
  - (b) Providing any false or misleading information to the inspector/inspection team;
  - (c) Denying the lawful right to entry;
  - (d) Obstructs the authorised person in conducting the inspection for the purposes of the Act and as prescribed in these Regulations.

### **38. Power to Impose Penalty:**

The Review Committee shall have the power to impose penalties upon the health care establishments and/or the service providers as per Act and regulations.

### **39. Appeal:**

Any person aggrieved by the final order of Directorate of Licensing, Directorate of Legal affairs and/or Review Committee, with regard to registration, licensing and/or any disciplinary or legal proceedings under these regulations may, within 30 days of the decision, prefer an appeal in writing before the court of District and Sessions Judge.

## **CHAPTER VI MISCELLANEOUS**

### **40. Indemnity**

All the acts of employees of the Commission and/or consultants and inspection teams under these regulations shall be presumed to have been done in good faith and no suit, prosecution or legal proceedings before any court of law, tribunal or executive authority shall lie against any act done under these regulations.

### **41. Authorities to Act in Aid of the Commission**

All law enforcement agencies and/or any other executive authorities shall act in aid of the Commission for carrying into effect the implementation of regulations and provide assistance to the Commission, whenever deemed necessary, as per KP HCC Act.

### **42. Removal of Difficulties**

- (1) The Board of Khyber Pakhtunkhwa Health Care Commission may issue such instructions, directions or amend these Regulations, in public interest keeping in view the purpose of the Act, or for the purposes of removing any difficulties that may arise in implementing these Regulations.
- (2) The Chief Executive Officer shall approach the Board for its guidance and/or for further necessary action, if so deemed necessary for implementation of these Regulations.
- (3) The Board may amend or repeal these Regulations.

### **43. Office Procedures**

The Executive of the Commission may make office procedures, with the approval of the Chief Executive Officer, not inconsistent with the provisions of the Act, Rules and these Regulations.

### **44. Overriding Effect**

Notwithstanding anything to the contrary contained in any other regulations, the provisions of these Regulations shall have an overriding effect and the provisions of any such regulations on the subject, to the extent of inconsistency to these Regulations shall cease to have effect.

### **45. Repeal**

The Khyber Pakhtunkhwa Health Care Commission Registration and Licensing Regulations, 2016 are hereby repealed.

**FIRST SCHEDULE**

**Categories of Health Care Establishments for the purpose of implementation of Minimum Service Delivery Standards**

CATEGORIES OF HEALTH CARE ESTABLISHMENTS		
Level 1	Level 2	Level 3
<b>In-Patient HCEs</b>	<b>Category 1</b>	
	Hospitals	Hospital with 300 and above bed
		Hospital with 100 to 299 bed
		Hospital with 50 to 99 bed
	<b>Category 2</b>	
		Hospital with 31 to 49 bed
		Hospital upto 30 bed
	Rehabilitation Center (as per bed strength)	Drug Rehabilitation Center
		Physical Medicine & Rehabilitation
		Physiotherapy Center
		Prosthetic / Orthotic Center
		Autism Centre
		Psychotherapy Centre
		Occupational Therapy
		Speech Therapy
		Other
	Thalassemia Centre with in-patient facility (as per bed strength)	
Dental Hospital with in-patient facility (as per bed strength)		
<b>Out-Patient HCEs</b>	<b>Category 3</b>	
	General Practitioner Clinic	-
	Dental Clinic	-
	Maternity Home (Only for normal deliveries run by a doctor)	-
	CMW Clinic (Only for normal deliveries run by a CMW)	-
	Homeopathic Clinic	-
	Tibb Clinic	-
	Nursing Home (Old age people centre)	-
	Dialysis Center	-
	Lithotripsy Centre (Without inpatient facility)	-
	Specialist Clinic	Cardiac Surgery
		Cardiology
		Clinical Hematology
		Dermatology (Skin)
		Endocrinology
		Gastroenterology
		General Medicine Clinic
		General Surgery Clinic
		Nephrology



	Neurology
	Neurosurgery
	Nuclear Medicine (Oncology)
	Obstetrics and Gynecology
	Ophthalmology
	Orthopedic
	Otorhinolaryngology (ENT)
	Pain Medicine
	Pediatric Surgery
	Pediatrics
	Psychiatry
	Pulmonology
	Rheumatology
	Thoracic Surgery
	Urology
	Other
Rehabilitation Center (Without inpatient facility)	Drug Rehabilitation Center
	Physical Medicine & Rehabilitation
	Physiotherapy Center
	Prosthetic / Orthotic Center
	Autism Centre
	Psychotherapy Centre
	Occupational Therapy
	Speech Therapy
	Other
Aesthetics Clinics (Without inpatient facility)	Aesthetic Medical Clinic
	Aesthetic Surgical Clinic (Only hair transplant clinic)
	Aesthetic Surgical Clinic (Other than hair transplant)
	-
Clinical Pathology Laboratory	Main Clinical Pathology Laboratory
	Collection Center of Clinical Pathology Laboratory
Radiological Diagnostic Centre	X-Ray and/or
	Ultrasonography (Ultrasound) and/or
	Computed Tomography (CT) Scan and/or
	Magnetic Resonance Imaging (MRI) and/or
	Electrocardiography (ECG) and/or
	Echocardiography (Echo) and/or
	Angiography and/or
	Flouroscopy and/or
	Mamography and/or

	Other
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