



**THE BALOCHISTAN HEALTHCARE COMMISSION
LICENSING AND ANTI-QUACKERY
REGULATION, 2024**

**GOVERNMENT OF BALOCHISTAN
LAW & PARLIAMENTARY AFFAIRS DEPARTMENT
(CODIFICATION SECTION)
(BALOCHISTAN – QUETTA)**

**THE BALOCHISTAN HEALTHCARE COMMISSION
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REGULATION, 2024**

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**¹THE BALOCHISTAN HEALTHCARE COMMISSION
LICENSING AND ANTI-QUACKERY
REGULATION, 2024**

NOTIFICATION

[07th October 2024]

Regulation No.I/BHCC/LAQ/962-969 In exercise of the powers conferred under Section 47 read with Sections 4, 15, 16, 17, 18, 19, 20 and 21 of the Balochistan Healthcare Commission Act, 2019² (Act XII of 2019), the Commission is pleased to make the following Regulations: -

**THE BALOCHISTAN HEALTHCARE COMMISSION
LICENSING AND ANTI-QUACKERY
REGULATION, 2024**

**CHAPTER I
INTRODUCTION**

1. Short Title and Commencement: (1) These Regulations may be called the Balochistan Healthcare Commission Licensing and Anti-Quackery Regulations, 2024.

(2) These Regulations shall extend to the whole of the Balochistan.

(3) These Regulations shall come into force at once.

2. Interpretation: - (1) In these Regulations, the following rules of interpretation shall apply.

(2) Unless the context requires otherwise:

- (a) words in the masculine gender are to be read as including the feminine gender (and vice versa)
- (b) words in the singular are to be read as including the plural (and vice versa), and

¹ These regulation have been issued by the Health Department, Government of Balochistan, vide its Regulation No.I/BHCC/LAQ/962-969, dated 07th October 2024, and published in the Balochistan Gazette (Extraordinary) No. 168, dated 07th October 2024.

² Act No. XII of 2019, passed by the Provincial Assembly of Balochistan on 18th November 2019, assented to by the Governor of Balochistan on 10th December 2019, and published in the Balochistan Gazette (Extraordinary) No. 204, dated 16th December 2019.

- (c) references to a numbered Chapter, Regulation or sub-Regulation are to the provision bearing that number within these Regulations.

(3) The words ‘including’ and ‘in particular’ indicate a list of examples and should not be read as limiting the scope of the words that occur before them.

(4) Any reference to another Policy, Standard, Law, Rule or other legal instrument is to be read as a reference to that legal instrument as it may be revised or reissued.

(5) Where these regulations require any duty to be complied with by a specified time, and where the duty has not been complied with by that time, that duty shall continue to be binding until it has been satisfied and the continuing failure to comply with it shall be treated as an ongoing and repeated breach of these Regulations

3. 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 the Balochistan Healthcare Commission Act, 2019¹.
- b) “Applicant” means a healthcare service provider and/or a healthcare establishment requesting for registration, grant of license or renewal thereof and/or accreditation, as the case may be, in accordance with the provisions of the Act.
- c) “Authorized Officer” means a person appointed or designated by the Commission to exercise powers and perform duties under the Act and these Regulations, specifically in relation to Licensing and anti-quackery activities.
- d) “Bed” means such beds which are maintained and staffed for the care of admitted patients for overnight stay and shall include the following: -
 - (a) beds in all departments/ wards/ rooms/ cots for sick babies and whether occupied or un-occupied
- (ii) Exclusion Criteria;
 - (a) surgical tables, recovery trolleys/ beds, emergency stretchers, beds for same day care, cots for healthy infants, labor room beds

¹ Act No. XII of 2019, passed by the Provincial Assembly of Balochistan on 18th November 2019, assented to by the Governor of Balochistan on 10th December 2019, and published in the Balochistan Gazette (Extraordinary) No. 204, dated 16th December 2019.

- (b) beds in wards/ rooms/ store which were closed for any reason, and temporary beds
- e) “Category” means categorization of Healthcare Establishments based on the number of beds as notified by the Commission from time to time: [Schedule -I].
- f) “Charter” means such Charter(s) as issued by the Commission from time to time, relating to the rights and responsibilities of patients/clients and others, as well as that relating to the rights and responsibilities of the healthcare establishments.
- g) “Competent Authority” means such officer(s), or Committee(s) comprising of one or more member, as nominated by the Commission, from within its staff, from time to time, authorized to take necessary action under the provisions of the Act and the Regulations made thereunder, and also to pass such orders, including but not limited to interim orders, as deemed necessary, and exercise all or any such powers as provided for in the Act, including but not limited to issuing directions for complying with the Standards, closure of services/sealing of the healthcare establishment(s) and penalties;
- h) “Committee” means Continuous Quality Improvement Committee of the Commission established under Section 12(c) of the BHCC Act, 2019.
- i) “Directorate” means Directorate of Licensing and Anti-quackery as established under Regulation 3.
- j) “Employee” means any staff member of the healthcare establishment, whether serving under written or un-written agreement(s) for service or of service.
- k) “Extended Inspection” means a follow-up inspection conducted by the Commission, solely for the purpose of assessing the deficient areas identified during the preceding routine inspection. Such Extended Inspection shall only be permitted in respect of Healthcare Establishments those achieved a score of 60% or higher in the preceding inspection.
- l) “Fee” means such sum(s) of money which is prescribed by the Commission from time to time for the purposes of granting registration, license and/or accreditation to a healthcare establishment and includes such additional fee(s) as may be prescribed by the Commission, for any particular purpose(s), specified herein: [Schedule -II]

- m) “Healthcare Personnel” means and includes such healthcare provider(s) which are or have been rendering any kind of services at the healthcare establishment, including but not limited to doctors, consultants, nurses, Allied Health Professionals, homoeopathic doctors and hakims, serving under written agreement(s) for, or of service.
- n) “Healthcare Management Personnel”: means the CEO, the Executive Board Members, Medical/Clinical Director, and Service Managers Responsible for day-to-day operations and Facility Management.
- o) “Incident” means any or all of the following occurrences which must be reported to the Commission within forty-eight hours;
 - (1) fires causing injury to patient(s);
 - (2) fires requiring evacuation of patient(s);
 - (3) fires requiring moving patient(s);
 - (4) emergency evacuation of patient(s) from all or parts of a healthcare establishment and
 - (5) violation of any law(s) relating to the healthcare establishment or healthcare service provider by patients or their attendant as the case may be.
- p) “Misleading Advertisement” means any promotional material that provides false or unverified information about the efficacy, safety, or quality of a medical product or treatment;
- q) “Proprietor” means such person who owns the premises at which a- quack is rendering health services and includes any such person who may also be the Owner, Manager, Incharge of the Healthcare, Establishment;
- r) “Quality Assurance & Compliance Committee” means Committee established by a healthcare establishment or healthcare service provider, as the case may be, and entrusted with the responsibility and capacity to ensure compliance with the governing law, standards, the instructions and/or corrective orders issued by the Commission from time to time in accordance with the Act and the Regulations;
- s) “Quack” means a pretender providing health services without having registration of the Pakistan Medical & Dental Council, Council for Tib, Council for Homeopathy or the Pakistan Nursing Council;

- t) “Quackery” includes such forms and methods of practices, including but not limited to different forms of treatments which are unsubstantiated and lack scientific plausible rationale; or are rendered, performed or undertaken, by persons who are not authorized to render, perform or undertake the same as per the governing laws, as well as standards of ethics etc., as the case may be, whether or not being so rendered, performed or undertaken by a quack as defined under the Act or herein;
- u) “Quackery Outlet” refers to a Healthcare Establishment that offers healthcare services without proper licensing or authorization, promotes unverified and scientifically unsupported treatments, engages in deceptive practices, posing a risk to public health and safety, in violation of BHCC Act;
- v) “Reference Manual” means the manual containing set of guidelines for healthcare establishments relating to implementation of the Standards as prepared by the Commission from time to time, for achieving the purposes of the Act.
- w) “Registration” means where the context so requires, either Registration as provided for under the provisions of clause (pp) of Section 2 or that of the Healthcare Service Provider as provided for under Section 15 of the Act.
- x) “Regulatory Requirements” means the provisions of the Act, Regulations, Standards, Reference Manuals, Guidelines, Directives and/or any corrective orders issued by the Commission from time to time;
- y) “Report” means such reports as are submitted to the Commission on the prescribed format, by the various authorized officers and or persons duly authorized by the Commission or on its behalf, from time to time, pertaining to the activities of quacks and those relating to quackery, within the Province of Balochistan.
- z) “Regulations” means the Balochistan Healthcare Commission Licensing and Anti-quackery Regulations, 2024.
- aa) “Remote Inspection”: means a remote inspection of Healthcare Establishment using smart devices, through a live audio-visual call that connects the Commission’s health professionals in the office, with the management personal in the inspected Healthcare Establishment.

- bb) “Routine Inspection” means standard routine inspection of healthcare establishments conducted by the Commission for assessment of compliance with standards as part of the Licensing process;
- cc) “SOPs” refer to the Standard Operating Procedures notified by the Commission from time to time for Enforcement and Hearing/Adjudication providing a detailed framework for the efficient working.
- dd) “Special Inspection” means an inspection conducted by the commission for assessment of a special aspect of the services being provided.
- ee) “Standards” include Minimum Service Delivery Standards (MSDS), developed by Commission from time to time.
- ff) “Sentinel Event” means an unexpected occurrence involving death or serious physical or psychological injury or the risk thereof that must be reported to the Commission within forty-eight hours of occurrence along with analysis report and action plan in a manner notified by the Commission from time to time.
- gg) “Committee of the Board” means the Licensing, Accreditation and Anti-quackery Committee of the Board, or such other Committee(s) as may be constituted by the Board, for such specific purpose(s) and given such powers as may be deemed appropriate by it, from time to time, for the purposes of the Act and these Regulations;
- hh) “Type” means classification of healthcare establishments based on the types of services provided and as such notified by the Commission from time to time. Public healthcare establishment Type shall be as designated by the concerned government department. Private healthcare establishments are classified into following types;
 - i) **Aesthetic Clinic** – A healthcare establishment providing aesthetic services as defined by the PMDC through a healthcare personal having appropriate qualification as prescribed by the PMDC, in this regard.
 - ii) **Addiction Treatment Center** – A healthcare establishment providing outdoor and/or indoor services to the addicts;

- iii) Advanced Diagnostic Center – A healthcare establishment where both laboratory and advanced imaging diagnostic services are provided;
- iv) Advanced Imaging Center – A healthcare establishment where advanced Imaging diagnostic services including but not limited to CT scan, MRI, CT Angio, with or without basic imaging services are provided;
- v) Clinical Laboratory – A healthcare establishment where only laboratory diagnostic services are provided;
- vi) Collection Center – A center where only samples are collected for their analysis at a Clinical Laboratory;
- vii) Collection & Imaging Center - A center where only samples are collected for their analysis at a parent Clinical Laboratory and Imaging diagnostic services are provided.
- viii) Cosmetic Surgery Clinic – A healthcare establishment providing specialized cosmetic surgery services through a surgeon having a post-graduate degree and valid registration from Pakistan Medical and Dental Council;
- ix) Dental Clinic – A healthcare establishment providing only outpatient dentistry services through a dental surgeon having valid registration from the Pakistan Medical and Dental Council;
- x) Diagnostic Center – A healthcare establishment where both laboratory and imaging diagnostic services are provided;
- xi) Dialysis Center – A healthcare establishment where only dialysis services are provided under supervision of a medical practitioner having valid registration from Pakistan Medical and Dental Council;
- xii) Family Planning Clinic – A healthcare establishment where only family planning services are provided;
- xiii) General Medical Practitioner Clinic/ Dispensary – A healthcare establishment providing only outpatient services through a general medical practitioner having valid registration from the Pakistan Medical and Dental Council;

- xiv) Hair Transplant Clinic - A healthcare establishment providing only hair transplant services through a surgeon having post-graduate degree and valid registration from Pakistan Medical and Dental Council;
- xv) Homoeopathic Clinic – A healthcare establishment providing only outpatient homoeopathic services through a homoeopathic practitioner having valid registration with National Council for Homoeopathy;
- xvi) Hospital –A healthcare establishment with indoor services; xvii) Imaging Center – A healthcare establishment where only Imaging diagnostic services are provided;
- xviii) Maternity Home – A healthcare establishment providing outpatient and midwifery services through a doctor, Nurse Midwife, Lady Health Visitor, Midwife and/or Community Midwife;
- xix) Mobile Clinics - Customized vehicles that provide preventive and curative healthcare services through a qualified practitioner having valid registration from the Pakistan Medical and Dental Council;
- xx) Mobile Vaccination Van – Customized vehicle that provide vaccination to the children in hard-to-reach areas through a qualified or trained vaccinator having valid registration from the Balochistan Medical Faculty or training certificate issued from the Immunization Program;
- xxi) Nursing Home - A healthcare establishment for people such as the aged or chronically ill who do not need to be in a hospital but cannot be cared for at home;
- xxii) Poly Clinic – A healthcare establishment providing only outpatient services of multiple types of the same system of treatment including but not limited to the combinations of General Medical Practitioner, dentistry, Lab services, imaging services, specialists etc.
- xxiii) Single Specialty Clinic – A healthcare establishment providing only outpatient services in a particular specialty through a specialist having valid registration from the Pakistan Medical and Dental Council;
- xxiv) Tib Clinic – A healthcare establishment providing only tib services on outpatient basis through a Hakim/Tabib

having valid registration from the National Council for Tib;

- xxv) Home Healthcare Service- Facility service engaged in arranging and providing medical care services at the patient's home. This service can be licensed either independently or as a sub-service to other service provider such as hospital, polyclinic, specialty clinic etc.
- xxvi) Convalescence Home- Provides residence services for 24 hours or more for stable patients who are undergoing treatment for diseases, injuries, deformities, or any abnormal physical or mental condition or lack of self-reliance to perform daily activities of life or for the purpose of convalescence in the post-medical treatment period, or in a need for continuous care that does not need an overnight stay in hospitals.
- xxvii) Patient Transfer Services- Center provides services of transferring patients from health facilities or home according to request of the client. The service may cover Vehicle, air and/or water ambulance transportation;
- xxviii) Blood Bank- A place where blood is collected from donors, typed, separated into components, stored, and prepared for transfusion to recipients. A blood bank may be a separate freestanding facility or part of a larger laboratory in a hospital.
- xxix) Pharmacy- As defined in the Provincial Drugs Rules;
- xxx) Tele-health Center- A facility that utilizes telecommunications technologies Such as multimedia, e-mail and smart applications, by health facilities or practitioners, so as to enable safe and direct communication between the patients and health practitioners to assess their medical conditions and provide necessary treatment.

4. 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, any other directives relating to the improvement of healthcare services and/or healthcare service delivery systems, as prepared and issued by the Commission, from time to time, for achieving the purposes of the Act.

CHAPTER II

GENERAL

5. Directorate of Licensing and Anti-Quackery: The Commission shall establish a Directorate to manage its Licensing and Anti-quackery functions manned with essential workforce and entrusted with functions as provided in the Human Resource Management Policies and Procedure Manual.

6. Licensing and Anti-Quackery Management System: The Commission shall establish and maintain an internal Licensing Accreditation and Anti-quackery Management System within the Directorate, tasked with receiving and processing applications for registration, granting licenses and accreditations, and issuing, suspending, and/or revoking registrations, licenses, and accreditations and taking actions against quacks. The system shall also perform any additional functions necessary to ensure that healthcare services are rendered in accordance with the provisions of the Act, Regulations, Standards, Reference Manuals, and any corrective orders issued by the Commission from time to time.

7. Register of Healthcare Providers and Establishments: The Directorate shall maintain a comprehensive register of all healthcare service providers and healthcare establishments operating within the province of Balochistan. This register shall include all details and information deemed necessary by the Commission.

8. Decisions by the Board: All decisions pertaining to the issuance, suspension, and/or revocation of licenses and accreditations for healthcare establishments shall be made by the Board during a duly convened meeting.

9. Provisional License Requirement: All new healthcare establishments are required to obtain a provisional license from the Commission prior to commencing the provision of health services.

10. Issuance of Licenses: The Commission shall issue licenses contingent upon compliance with relevant laws, regulations, standards, manuals, guidelines, and the payment of all applicable licensure fees.

11. Non-Refundable Fees: Fees paid to the Commission are non-refundable, except under exceptional circumstances as approved and in accordance with the specified terms and conditions.

12. Compliance with License Conditions: Healthcare establishments must adhere to all conditions or restrictions imposed under the terms of the license issued by the Commission.

13. Service Provision Restrictions: Healthcare establishments shall not provide services under the following conditions:

- (1) The healthcare establishment's license is suspended.
- (2) The healthcare establishment or its related specialty is temporarily or permanently closed.
- (3) The healthcare establishment's license has expired and has not been renewed in accordance with these regulations.
- (4) Services at the healthcare establishment, in whole or in part, are suspended.

14. Temporary Closure Due to Staff Unavailability: The absence of licensed professional staff at a healthcare establishment will result in its temporary closure. However, such temporary closure does not preclude the renewal of the establishment's license.

15. Maximum Period of Temporary Closure: The maximum allowable period for the temporary closure of a healthcare establishment shall not exceed six months.

CHAPTER III REGISTRATION

16. Responsibility to apply for Registration: It shall be the responsibility of healthcare service provider to apply, to the Commission through the Directorate, for his registration in accordance with the provisions of section 15 of the Act.

17. Unregistered Healthcare Service Provider: (1) A healthcare service provider shall not provide healthcare services without being registered with the Commission.

(2) The Commission may impose a fine which may extend to ten hundred thousand rupees and/or order to stop provision of service(s) or seal the premises of a healthcare service provider who is found providing healthcare services without registration, as required under the Act.

(3) The Commission may recover the fines imposed and other dues recoverable under the Act and the Regulations in accordance with section 43 of the Act.

18. Application for Registration: (1) A healthcare service provider, prior to the commencement of operations of his healthcare establishment, shall apply for registration with the Commission through online facility, supported by such documents and fee as may be prescribed by the Commission, from time to time.

(2) Until the online system becomes fully operational, applications shall be submitted on the prescribed form as provided by the Commission. [Schedule-III]

(3) Upon submission of online Application, a system generated application number will be sent to the applicant through an email for future reference.

(4) An application for registration, grant of license or accreditation, not on the prescribed form, shall not be processed and shall be deemed to have been rejected.

- (5) a) The collection centers attached with the Parent Lab situated in the Balochistan province, need not to apply separately, the parent lab will mention all its collection centers with the complete prescribed details while submitting Application for Registration.
- b) The parent lab registered with any other provincial healthcare commission/ Islamabad health regulatory authority and located outside the Balochistan Province, will apply separately for the registration of all its collection centers as separate HCEs.
- c) Notwithstanding what has been stated in clause (a) above, a parent laboratory shall be responsible for compliance of the relevant standards at its collection center(s).

(6) Before issuance of registration certificate, the Commission may carry out verification of information provided in the application by the Applicant. In case the information provided by the Applicant is not verified, the application may be rejected, and action may be taken in accordance with the provisions of the Act.

(7) In case the Commission fails to issue certificate of registration to an applicant within fourteen working days, from the receipt of the application, the Healthcare Service Provider shall be deemed to have been provisionally registered, provided that the application is complete in all respects.

(8) A registration certificate issued under sub-regulation (3) only amounts to enlistment of the healthcare service provider with the Commission and shall not be taken as compliance to the standards, required for issuance of license.

(9) It shall be the responsibility of the healthcare service provider to ensure that he and all his staff/employees, who may be required to be registered with any of the above noted federal councils, is/are so

registered at all times and have valid registration from the relevant council.

(10) The Commission may reject such application for registration wherein the information provided is found to be incorrect or where despite issuance of notice by the Directorate, the healthcare service provider fails to provide the requisite information, supporting documents or other particulars required for registration, within the stipulated time.

(11) An Applicant whose application has been rejected may re-apply for registration after complying with sub-regulations (1) to (4).

19. Registration Fees are non-refundable: Registration fees paid to Commission are nonrefundable.

20. Certificate of Registration not transferable: A certificate of registration issued under these Regulations shall neither be assignable nor transferable, unless a written permission is granted by the Commission, in accordance with these Regulations.

21. Registration number to be displayed: The registration number issued by the Commission shall be conspicuously displayed within and outside the healthcare establishment, from where it is visible to the public.

CHAPTER IV **LICENSING**

22. New Healthcare Establishment License: (1) Within thirty days of the issuance of the certificate of registration, or such other time as may be fixed by the Government, the healthcare service provider shall make an Application for grant of license to his healthcare establishment to the Commission through online facility, supported by such documents and fee as may be prescribed by the Commission, from time to time.

(2) Until the online system becomes fully operational, applications shall be submitted on the prescribed form by the Commission. [Schedule-III]

(3) Upon submission of online Application, a system generated application number will be sent to the applicant through an email for future reference.

(4) On receipt of an application, complete in all respects, including but not limited to documentary evidence regarding compliance of the said healthcare establishment with the Critical Patient Safety Areas as notified by the Commission from time to time, the Commission shall issue a provisional license to the Applicant.

(5) Provided that issuance of a provisional license to a healthcare establishment shall not be taken as compliance to the relevant standards by the said healthcare establishment.

(6) Provided further that the Commission may roll out the requirement pertaining to compliance of the healthcare establishments with the Critical Patient Safety Areas for the purposes of issuance of provisional license, in a phased manner.

(7) The Provisional License will be valid for one year during which the decision will be made about grant of a Regular License.

(8) The decision about grant of regular License will be taken as provided in the Act and prescribed in these Regulations after Inspection for the compliance with Act, Regulations, standards and guidelines.

(9) Verification by the Commission. Before issuing a regular license, the Commission may verify or require verification of the following:

-

- a) Application is complete in all respects
- b) Full license fee is deposited.
- c) Compliance with the Act, Regulations, Standards and any instructions and/or corrective orders passed by the Commission or the Directorate, as the case may be, while processing the application keeping in view the survey and/or the inspection report, as the case may be.

(10) If due to reasons on the part of the Healthcare Service provider, the Regular License could not be acquired in spite of total permissible inspections under these regulations, the service provider shall submit full Licensing fee for a six-month further extension.

(11) Notwithstanding what has been stated in sub-Regulation (9), an Applicant whose application has been rejected may re-apply after fulfilling all the requirements and providing all particulars, documents, fee(s) as notified by the Commission from time to time in this regard.

23. Renewal of Existing License: (1) The Healthcare Service Provider shall apply to the Commission for the renewal of existing license 3 months before its expiry date.

(2) The Applicant shall make an application for renewal of license to his healthcare establishment to the Commission through online

facility, supported by such documents and fee as may be prescribed by the Commission, from time to time.

(3) Until the online system becomes fully operational, applications shall be submitted on the prescribed form by the Commission.

(4) In case the application for renewal of a license is submitted in terms of clause (1) above, the healthcare establishment in respect of which such application is submitted shall be deemed to be provisionally licensed after the expiry of its existing license, till such time that the application is decided by the Commission.

(5) In case the application for renewal of a license is not submitted even after expiry of the existing license, the healthcare establishment shall be considered as unlicensed and the Commission may impose a fine which may extend to ten hundred thousand rupees and/or order to stop provision of service(s) or seal the premises of a healthcare service provider who is found providing healthcare services without submitting application for renewal of license along with prescribed documents and fee, as required under the Act or may remove the name of the healthcare service provider from the register.

(6) The decision about renewal of regular License will be taken as provided in the Act and prescribed in these Regulations after Inspection for the compliance with Act, Regulations, standards and guidelines.

(7) If due to reasons on the part of the Healthcare Service provider, the License could not be acquired in spite of total permissible inspections under these regulations, the Commission may reject the application and remove his name from the Register.

(8) Notwithstanding what has been stated in sub-Regulation (8), an Applicant whose application has been rejected may re-apply after fulfilling all the requirements and providing all particulars, documents, fee(s) as notified by the Commission from time to time in this regard.

24. Temporary Permit: (1) Temporary permits may be issued by the Commission for specific, short-term events designed to provide healthcare services. Such events include, but are not limited to, health awareness campaigns, eye camps, dental screenings, family planning camps, school health awareness programs, and other similar healthcare activities that serve the public interest.

(2) Temporary permits shall be applicable solely to healthcare activities conducted at temporary fixed locations designated for the specific events mentioned above. The permits do not extend to mobile healthcare units or permanent healthcare establishments.

(3) Applications for temporary permits must be submitted in the prescribed format as determined by the Commission along with the fee. The application must include all necessary documentation and information as specified by the Commission to assess the eligibility and appropriateness of the proposed healthcare activity.

(4) Only those healthcare establishments that hold a valid Provisional or Regular license issued by the Commission or the registered NGOs are eligible to apply for a temporary permit.

(5) Temporary permits shall be valid only for the duration specified in the permit. The validity period shall commence on the start date and conclude on the end date as stipulated in the permit. Under no circumstances shall the temporary permit extend beyond the specified period without the express approval of the Commission.

(6) Healthcare establishments granted a temporary permit must comply with all conditions and requirements specified by the Commission.

(7) They must also provide a report upon the conclusion of the event detailing the services provided, the number of beneficiaries, and any other information required by the Commission to ensure transparency and accountability.

(8) The Commission reserves the right to revoke a temporary permit at any time if the healthcare establishment fails to comply with the terms and conditions of the permit, engages in activities beyond the scope of the permit, or violates any applicable laws or regulations.

25. Temporary closure of the Healthcare Establishment: (1) Healthcare Service provider may request to temporarily close his Healthcare establishment for one (1) day or up to a period of six (6) months only.

(2) The Healthcare Service provider may apply for the entire Healthcare Establishment closure or only for a specific specialty.

(3) The temporary closure does not exempt him from other responsibilities like paying renewal fees, extending any expiring licenses etc.

26. Unlicensed Healthcare Establishments: (1) No person, including but not limited to association of persons, authority, body, company, corporation, firm, individual, partnership, proprietorship, any Government, Local Government or other entity, as the case may be, shall operate, conduct and/or maintain, in the province, any healthcare establishment for treatment or otherwise of human beings without

obtaining a license from the Commission in accordance with the criteria laid down by the Commission.

(2) The Commission may impose a fine which may extend to ten hundred thousand rupees and/or order to stop provision of service(s) or seal the healthcare establishment which is found to be operated without a valid license, as required under the Act.

27. Fees: (1) The fee(s) shall be as prescribed by the Commission from time to time and shall be non-refundable [Schedule-II].

(2) The prescribed fee(s) for issuance of a license, renewal thereof and/ or accreditation must be submitted along with the application and shall be for a period of five (05) years, commencing from the date of grant of the license or accreditation to the healthcare establishment.

(3) The additional fee(s), as notified by the Commission from time to time, may be charged for, including but not limited to change(s) and/ or amendment(s) to a registration certificate, license(s) and/ or accreditation certificate.

28. Right of entry: (1) An application for registration, grant of license or its renewal or accreditation, pursuant to the provisions of the Act and/or these Regulations would constitute a permission and/ or complete acquiescence on the part of the Applicant or the licensee, as the case may be, to any entry or inspection by the Commission of the healthcare establishment for the verification of the information submitted on, or in connection with, such application.

(2) A duly authorized officer/representative of the Commission shall have the right to enter upon the premises/healthcare establishment of an applicant or a licensee, as the case may be, 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 of such healthcare establishment with the Act, Regulations, Standards and/ or any other instructions or orders passed by the Commission.

(3) Without prejudice to what has been stated in sub-Regulation (2), a healthcare service provider shall provide full access to the designated officer(s)/representative(s) of the Commission, to all relevant records, documents and reports at his healthcare establishment, as required for the purposes of these Regulations or other applicable laws. The said officer(s)/representative(s) may obtain a copy of records, documents and reports either manually or by photocopy, if deemed necessary, unless otherwise protected by law.

(4) The Commission may impose a fine which may extend to one hundred thousand rupees upon a healthcare service provider who refuses

or fails, without reasonable cause, to furnish any information to the designated officer(s)/representative(s) or the inspection team of the Commission or gives any false or misleading information or obstructs, hinders or impedes such officer(s)/representative(s) or the inspection team, as the case may be, in the performance of their functions or execution of their duties.

29. License not transferable: A license issued under these Regulations shall neither be assignable nor transferable, unless a written permission is granted by the Commission, in accordance with these Regulations.

30. License to be posted: A license issued by the Commission shall be conspicuously posted in the healthcare establishment where it is visible to the public.

31. Term of Licenses: The term of a regular license shall be for a period of five (05) years from the date of its issuance. The Applicant, to whom a regular license has been issued, shall apply for its renewal prior to the expiry of the above term.

32. License to be Premises Specific: The license issued by the Commission shall only be in relation to the premises identified in the application.

33. Specifications of a License: A license must specify the following:-

- (1) name of the healthcare establishment;
- (2) address of the healthcare establishment;
- (3) name of the owner;
- (4) the total number of beds;
- (5) the effective date, kind and term of the license;
- (6) the identification of services being rendered at the healthcare establishment.

34. Distinct parts: (1) A healthcare service provider operating healthcare establishment on different locations shall apply for their registration and license separately.

(2) Where an Applicant has separate facilities located in physically separate buildings, on the same grounds, operated by the same ownership/administration, the Commission shall issue only one registration and license in respect of such facilities.

(3) The Commission may issue a regular license in respect of two or more buildings either situated in the same premises or with in the proximity of 100 meters from each other, if the Applicant: -

- a) meets the requirements as listed in sub regulation (2);
- b) operates the buildings as an integrated system with: -
 - (i) administration by a single authority over all buildings or portions of buildings;
 - (ii) administrative control of the medical staff for all healthcare establishment facilities under the same management; &
 - (iii) application of same policies and procedures for all facilities and departments.
- c) provides for safe and appropriate transport of patients between all facilities and buildings.

(4) Healthcare establishments situated in the same premises but operated by different ownership/administration shall apply for separate registrations and licenses.

(5) Healthcare establishments situated in the same premises having same ownership/administration but providing different systems of treatment shall apply for separate registrations and licenses.

35. Changes in licensing information and/or capacity: (1) No change in the capacity of the healthcare establishment as granted under the license, including but not limited to services being rendered at the said healthcare establishment, shall be implemented/enforced without prior written approval/permission and/or the requisite license, from the Commission, as the case may be.

(2) Any change in the building including but not limited to new construction, additions or alterations in any manner, as the case may be, must be approved by the relevant authority and reported to the Commission in a manner notified by the Commission from time to time in this regard. Provided that sub-regulation (2) shall not be applicable to minor alterations which do not affect the primary operations or the number of beds of the healthcare establishment, or to routine maintenance and repairs as the case may be.

(3) Any change of owner, management personal, other available clinical staff, specific equipment as updated from time to time, name and/or address of the healthcare establishment, as the case may be, shall be reported to the Commission in the manner as notified by the

Commission, at the earliest however, in no case such period shall exceed a maximum of thirty (30) working days.

(4) Upon acceptance of the application in this regard, the Commission may issue amended registration and/or license, on such terms and conditions as deemed appropriate, including but not limited to the inspection, and payment of such additional fee(s) as notified by the Commission from time to time, for the said purpose.

(5) In the event a registration certificate and/or a license issued by the Commission, to a healthcare establishment is lost or damaged, the same shall be reported to the Commission as early as possible but not later than ten (10) working days from the date of such loss or damage. The Commission shall issue a duplicate registration certificate and/or license as the case may be on receipt of an affidavit on stamp paper in this regard and payment of such additional fee(s) as may be notified by the Commission, from time to time, for the said purpose.

(6) The Commission may remove the name of a healthcare service provider from its register, at any time if;

- a) the registration certificate/license has been obtained by fraud or misrepresentation;
- b) the closure of the healthcare establishment is reported or brought to the notice of the Commission by the Applicant or through any other source;
- c) the application for license is rejected;
- d) the healthcare service provider is convicted under the provisions of the Act or the regulations made thereunder.

(7) The healthcare service provider whose name has been removed from the register, may re-apply for registration after complying with sub-regulations (1) to (4) of regulation 8.

36. New services: In order for a license to extend to new service(s), a separate application, in the manner as notified by the Commission, may be submitted to the Commission for approval.

37. Rejecting, Amending, Modifying, or Refusing to Renew a License: (1) The Commission may amend, modify or refuse to renew a license in conformity with the Act, Regulations, Standards, Reference Manual and instructions or directions issued by the Commission, as the case may be.

(2) If deemed appropriate, the Commission may, upon payment of such additional fee(s) as prescribed by the Commission, from time to time in this regard and after the inspection, if required, modify a license on the application of a healthcare establishment, where the ownership and/or the address of the healthcare establishment has been changed.

38. Grounds for suspension and/or revocation: The Commission may revoke and/or All healthcare establishments or healthcare service providers, as the case may be, shall establish their own Quality Assurance & Compliance Committee(s) for the purposes of interacting on their behalf with the Commission and shall be responsible for the compliance of process involved for obtaining the requisite license.

The Quality Assurance & Compliance Committee(s) may consist of one or more members, as deemed appropriate by the healthcare establishment or the healthcare service provider, keeping in view its size and capacity. Such Committee(s) shall be duly authorized by the healthcare establishment or the healthcare service provider to undertake and/or commit to the Directorate/Commission, as the case may be and ensure compliance with the provisions of the Act and these Regulations, on behalf of the said healthcare establishment or healthcare service provider.

CHAPTER V INSPECTION

39. Undertaking an Inspection: (1) All inspections shall be carried out as provided under the Act, and these Regulations.

(2) Inspections may be carried out without any notice to the concerned healthcare establishment in response to a complaint or suspected violation of any Regulatory Requirements. The Commission may in circumstances requiring immediate action and/or emergency, get the inspection carried out through an inspection team or any other executive authorities for violation of any other laws relating to buildings, fire etc. or for other purposes, including but not limited to the licensing process.

(3) For completion of the licensing process, the inspection shall be carried out with prior notice.

(4) The inspection of the Healthcare Establishment may be conducted through one or both of the following modes:

- i. *Physical Inspection:* The inspection team or authorized officer may conduct an on-site visit to the Healthcare Establishment to verify compliance with regulatory requirements.

- ii. *Remote Inspection:* The inspection team or authorized officer may utilize smart devices and digital technologies to conduct a remote inspection of the Healthcare Establishment, as deemed appropriate.

The choice of inspection mode shall be at the discretion of the designated officer in the Directorate keeping in view the availability of facilities at the Healthcare Establishment to be visited, and the Healthcare Establishment shall cooperate fully with the inspection team or authorized officer in facilitating the inspection, regardless of the mode chosen.

(5) Upon inspection, a statement of deficiencies shall be issued by the authorized officer or the inspection team, pertaining to any deficiency, omission or violation of the Act, Regulations, Standards, and any other instructions or orders, including but not limited to a plan of correction, issued by the Commission along with the timeline, if so required.

(6) The authorized officer or the inspection team may, in the event of default by the Applicant or the licensee, as the case may be, issue directions to implement its plan of correction, or take additional corrective action if so required.

(7) If an Applicant or the licensee disagrees with the statement of deficiencies issued by the inspection team, visiting team or the authorized officer, as the case may be, he may request for an informal conference to provide evidence to dispute the findings, within ten (10) working days from the receipt of such statement of deficiencies.

(8) It shall be responsibility of the Applicant or a licensee to ensure compliance to the instruction(s), orders or plan of action, issued by the Commission, within stipulated time and submit the compliance report in the manner notified by the Commission.

(9) It shall be responsibility of the healthcare establishment to attend, at the place and time as specified by the inspection team or the authorized officer, for the purposes of assessment of compliance of the deficiencies identified at the time of inspection.

(10) In case a healthcare establishment fails to qualify for the grant of license after two inspections, the Commission may charge the cost of subsequent inspections at the rates notified by the Commission from time to time.

(11) In the event, a healthcare establishment fails to qualify for the grant of license even after the third inspection, the Commission may

impose fine, order closure of service(s) and/ or reject the application for grant of license along with removal of the healthcare service provider's name from its register.

(12) In case a healthcare establishment fails to qualify for renewal of its license even after two inspections, the Commission may charge the cost of subsequent inspections at the rate(s) notified by it from time to time, impose fine, order **suspension** of service(s) and/ or reject the application for renewal of license along with removal of the healthcare service providers name from its register.

(13) The follow-up inspections conducted by the Commission, for the purpose of assessing the deficient areas identified during the preceding routine inspection may be through extended inspection mode as defined in these regulations.

(14) Within thirty (30) working days from the date of approval of its application by the competent authority, the Commission shall issue a regular license to a healthcare establishment which fully complies with the provisions of the Act, Regulations, and the Standards.

(15) Where during an inspection by an authorized officer/Inspection team of the Commission, such conditions are found to exist at a healthcare establishment that may jeopardize the health and/or safety of the patients at the said healthcare establishment, or create an emergency, which in the estimation of the said officer may not be ably handled at the said healthcare establishment, keeping in view its capacity, the Commission may through its authorized officer(s)/representative(s) issue orders for immediate suspension of such service(s) or facility(ies) as deemed appropriate by the Commission. In addition to the aforesaid suspension, the authorized officer may seal the healthcare establishment or part thereof. To standardise the action to be taken by the authorized officers of the Commission during inspection or field visit, common observations with onsite actions required are detailed in Schedule-V.

(16) All licensed healthcare establishments shall be inspected/visited at least once every three (03) years, unless otherwise decided by the Commission.

CHAPTER VI **ANTI-QUACKERY**

40. Authorization of Anti-quackery Measures: (1) The Commission may delegate all or any of its powers and instruct/direct, any such Executive Authorities and/or the Law Enforcement Agencies, as deemed appropriate, to assist it to check and report to the Commission about the activities and whereabouts of the quack(s) and submit reports regarding

quackery being practiced at any Healthcare Establishment, as the case may be.

(2) The Commission may authorize the Executive Authorities/ law enforcement agencies through written instructions/directions for exercising such powers as may be deemed necessary for visiting such premises which as per the information, with such Executive Authorities or Law Enforcement Agencies or as provided by the Commission, and report quack(s) and other activities relating to quackery to the Commission, directly or through such other officers as directed by the Commission.

41. Visit of the Quackery Outlets: (1) The Commission upon revising a complaint/information regarding practice of Quackery or otherwise may get any suspected premises visited by its own authorized officer(s) or authorized officer(s) of the Executive authorities and/or the law enforcement agencies.

(2) The Authorized officer(s) shall visit the relevant premises to check and verify if the person(s) rendering healthcare services there have the requisite valid registration from any of the following Councils:

- i) The Pakistan Medical and Dental Council
- ii) The Pakistan Nursing Council
- iii) The National Council for Tibb
- iv) The National Council for Homeopathy

(3) The said officer(s) shall also check if the said Healthcare Establishment has the required Certificate of Registration and a valid license from the Commission, under the provisions of Sections 15, 16, 17, 18, and 19 of the Act.

To standardise the action to be taken by the authorized officers of the Commission during the visit with common observations and onsite actions required are detailed in Schedule-VI

(4) The said officer(s) shall seize all or any relevant evidence, which they may deem necessary, including but not limited to prescription slips and medicines being given and/or administered to the patients by persons who do not have valid registration from any of the above-mentioned Councils, and forward the same to the Commission along with the Report. They may also record statements of the patients and/or their attendants who may be willing to appear before the Commission as a witness.

(5) In cases where the statement(s) of a patient or their attendant is recorded, the same shall also be forwarded to the Commission along with the Report.

(6) A recovery memorandum shall also be prepared at the premises/site in the presence of the Owner, Manager, In-charge of the Healthcare Establishment, and the Proprietor, as the case may be. The signatures of the said persons, as may be present at the said premises, shall also be obtained by the said Officer, along with their thumb impressions. In case such person(s) is not willing to do so, it would be sufficient for the said Officer to note their refusal to do so.

(7) The said officer(s) shall also be authorized to seal the said premises in case it is found that the persons rendering any kind of healthcare services threat, do not have a valid registration from either of the above-mentioned councils and/ or, the requisite certificate of registration and the valid license issued by the Commission. The said officer(s) shall accordingly seal the said premises in view of the provisions of the section 15, 16, 17, 18 and 19 of the Act. in public interest in case, it is found that the quackery is taking place at the said premises.

(8) The officer(s) shall prepare a memorandum of sealing the said premises on the prescribed format and obtain signatures of the Owner, Manager, Incharge of the healthcare establishment and the Proprietor, as the case may be on the prescribed format.

(9) The said officer(s) shall ensure, before sealing the said premises that are no such patients at the said premises which may need immediate treatment and the management. In case he is of the opinion that any such patient is so present at the said premises, then the said officer shall make all such necessary arrangements for immediate shifting of such patients in order to safeguard and protect the life of the said patients as the case may be.

(10) The said Officer(s) may also issue such directions regarding any medicines or other perishable items found at the said premises, as he may deem fit for the purposes of protecting the same from expiring or decaying, as the case may be, if so, requested by any person or an employee at the said premises.

(11) The said Officer(s) shall, after locking and sealing the premises with the very keys of the premises, handover the said keys to the Owner, Manager, Incharge of the Healthcare Establishment, or the Proprietor as the case may be. In case the Owner, Manager, Incharge of the Healthcare Establishment, or the Proprietor leaves the premises or abscond himself during or after the visit by the said officer, the keys of the sealed premises shall be submitted to the Commission along with the report.

CHAPTER VII ENFORCEMENT

42. Opportunity of hearing before passing any orders: (1) The Commission may constitute as many committees as required from among its staff to provide opportunity of hearing before passing any orders.

(2) The Committee may issue a notice to the relevant person(s) on the basis of the Report submitted to the Commission, to attend the proceedings of the Committee on a fixed date at a fixed time.

(3) The person(s) so appearing before the Competent Authority shall submit his stance in writing with supporting documents, if any, along with an affidavit duly verified by the Oath Commissioner.

(4) The Competent Authority may require the person(s) appearing before it to produce any other document deemed necessary for the just and proper disposal of the matter.

(5) While proceeding with a matter pending adjudication before it, the Competent Authority may exercise all such powers as provided under section 4(10) of the Act.

(6) The Competent Authority may, if deemed necessary, instruct the concerned officer of the Commission to submit his views/comments in writing, on the stance/response submitted before the Competent Authority.

(7) If the Competent Authority is satisfied that despite service of notice/summon, the relevant person is not attending its proceedings, it may direct the local police or any other Executive Authority or law enforcement agency to produce such person or any other relevant person before it.

43. Grounds for suspension and/or revocation: The Commission may revoke and/or suspend a license in accordance with the provisions of the Act and these Regulations. The decision about suspension or revocation shall be taken by the Board in its meeting.

Provided that the license so suspended may be restored by the Commission upon successful compliance of the instructions issued by the Commission.

44. Powers to pass Orders: (1) Without prejudice to what has been stated in regulation 41 above, the Competent Authority, may pass such orders, including but not limited to the following orders, while recording the reasons thereof, in view of the facts and circumstances of the matter, in order to safeguard the public interest and for achieving the purposes of the Act: -

- 1) issue orders of restraint;
- 2) issue directions to any executive authority and law enforcement agency to act in aid of the Commission as provided under Section 42 of the BHCC Act 2019.
- 3) issue directions to a Healthcare Establishment.
- 4) pass any conditional orders relating to the manner in which healthcare services are being delivered or to improve the healthcare delivery system at any given healthcare establishment;
- 5) issue such instructions, directions or orders as deemed necessary, including but not limited to imposition of fine, closure of services or part thereof, and sealing of healthcare establishment.
- 6) confirm the act/order of sealing of the premises/site or undo the same after hearing the Owner, Manager, In-charge of the healthcare establishment or the Proprietor, as the case may be, in accordance with the procedure notified by the Commission from time to time, in this regard.
- 7) liaison and communicate with the Pakistan Medical and Dental Council, Council for Homeopathy, Council for Tib, Nursing Council or any other authority competent to handle the matter and to assist the Commission in deciding the matter, in the larger public interest.
- 8) The Competent Authority may if deemed necessary and appropriate, refer the case/matter to other law enforcing agencies, for appropriate proceedings under any other relevant laws.
- 9) Any person who is proved to be responsible and/or involved in the act of violating the regulatory requirements, the Committee shall impose a fine upon such a person, which may extend up to ten hundred thousand rupees, depending upon the facts and circumstances of the case and keeping in view the gravity of the offence as contained in the Schedules VI.

Provided that the Competent Authority may also further direct that any of the Orders so passed by it may be for a particular period/duration of time or that the same be

implemented within a particular time frame and that a compliance report be submitted before it.

(2) The Competent Authority shall have the power to issue, amend, alter, affirm or revoke any orders on hearing the concerned person(s) in the matter, after due Notice.

45. Appeals: Any person who is aggrieved of any decision of the Commission, may file an appeal in accordance with the provisions of Section 37 of the Act.

DUTY TO ACT WITH UTMOST GOOD FAITH

46. It shall be the duty of all the persons appearing before the Competent Authority, in any capacity whatsoever, to act with utmost good faith at all times and assist, in performing its duties and also for achieving the purposes of the Act.

CHAPTER VIII MISCELLANEOUS

47. Protection of Whistleblowers: (1) Each healthcare establishment shall prominently and conspicuously post for display in a public area of the healthcare establishment that is readily visible to patients, residents, employees and visitors, a statement that non-employees, employees and staff are protected from discrimination or retaliation for reporting a violation of the governing laws including the Act, Regulations, Standards, reference manual and any other orders or instructions passed by the Commission. The statement shall be in English and such other language(s) as is appropriate to the demographic makeup of the community being served.

(2) A healthcare establishment may not suspend or terminate the employment of, discipline, or otherwise discriminate against an employee for reporting in utmost good faith to the employee's supervisor, an administrator of the healthcare establishment, the regulatory agency, and/or the healthcare service provider, the Commission or any other law enforcing agency, as the case may be, a violation of the governing law including the Act, Regulations, Standards, reference manual and/or any other orders or instructions passed by the Commission. For the purposes of this sub-Regulation, a report shall be deemed to have not been made in utmost good faith if there is not a reasonable factual or legal basis for making the same.

(3) A healthcare establishment may not retaliate against a person who is not an employee for reporting a violation of the governing law including the Act, Regulations, Standards, reference manual and any other orders or instructions passed by the Commission.

ACTIONS TAKEN IN GOOD FAITH

48. No suit, prosecution or other legal proceedings shall lie against the Balochistan Healthcare Commission, its Committees, Reporting Officers or other persons for anything which is done in good faith or intended to be done under these Regulations.

DISSEMINATION OF INFORMATION ABOUT LICENSING OF HEALTHCARE ESTABLISHMENTS AND QUACKERY & QUACKS TO THE PUBLIC

49. The Commission may disseminate all the relevant information about Licensed healthcare Establishments and quackery and quacks found to have been practicing in the province and may through chosen medium provide information to the public at large to keep them informed from time to time. The Commission, however, may also make all such data of status of Licenses of healthcare establishments and quacks available on its official website as may be deemed necessary and in public interest.

REMOVAL OF DIFFICULTIES

50. (1) The Board may issue such instructions, directions or amend these Regulations, in public interest keeping in view the purposes of the Act or for the purposes of removing any difficulties that may arise in implementing these Regulations.

(2) The Directorate, the Competent Authority or the Commission, as the case may be, approach the Board for its guidance and or for further necessary action, if so, deemed necessary for the implementation of these Regulations.

Schedule-I- Categorization of Healthcare Establishments

Number of beds	Category
100 and above	I
50-99	II
25-49	III
<25	IV
Without Indoor beds	V

Schedule-II- Registration and Licensing Fee

Pursuant to the authority vested in the Commission, a fee structure has been established for the registration and licensing of Healthcare Establishments (HCEs). These fees are subject to periodic review and modification as deemed necessary by the Commission. The following outlines the registration and licensing fees, incorporating a tiered system based on bed count for registration and a categorization system for licensing based on the type of HCE.

A. Registration Fee:

- a) To encourage compliance and facilitate a smooth transition, the registration will be free of charge for the first year from the date of enforcement of these regulations.
- b) After the initial one-year period, a registration fee will be applicable. The fee structure is outlined in the table below:

Number of beds	Category	Registration Fee (Rs.)
100 and above	I	10,000
50-99	II	8,000
25-49	III	5,000
<25	IV	2,000
Without Indoor beds	V	1,000
Any change in the already registered HCE	All	1,000

Note. If an HCE upgrades its category, it shall pay the difference between the two registration fees and the fee for change of category.

B. Licensing Fee: The licensing fee for Healthcare Establishments is structured as follows:

- a) **Hospitals:** A flat rate of Rs. 3,000 per bed will be charged for a period of five years. This fee is applicable to all hospitals, regardless of their size or type.
- b) **Healthcare Establishments without Indoor Beds:** The licensing fee for these establishments will vary depending on their specific type as depicted in table below:

Sr. No.	Types of HCEs	Licensing Fee for Five Years (Rs)
1	Hakeem Matab	10,000
2	Homoeopathic Clinic	10,000
3	MCHC/ CMWs/ Nursing/ Maternity Home	25,000
4	Family Physicians/ Single Man (GPs) Clinic	10,000
5	Single Speciality Clinic	40,000
6	Poly Clinic	100,000
7	Dental Clinic (per Chair)	10,000
9	<i>Diagnostic Laboratories</i>	
9.1	Pathology Lab including Static Labs with or without collection center	100,000
9.2	Pathology Lab including Static Labs with Collection center	100,000 for lab +25,000 per collection Center
9.3	Stand alone Collection Centre of the parent lab situated out of the province	50,000
9.4	Collection & Imaging Center	150,000
9.5	X - Ray/ Imaging Centre	100,000
9.6	Pathology Lab/ Imaging centre having CT-Scan/ MRI/ Angio/ other advanced facilities	200,000
10	Asthetic Clinic	200,000
11	Dialysis Center	100,000
12	Mobile Clinics	10,000
13	Mobile Vaccination Van	10,00
14	Nursing Home	10,000
15	Home Healthcare Service	10,000
16	Convalescence Home	10,000
17	Patient Transfer Services	10,000
18	Tele-health Center	10,000
19	Temporary Permit	10,000

Schedule-III- Application for Registration

<u>APPLICATION FOR REGISTRATION WITH BALOCHISTAN HEALTHCARE COMMISSION</u>		For office use: application number _____
IMPORTANT: Please follow the instructions completely. Failure to submit the necessary items/information will delay the processing of your application and may end up with the rejection. Please tick the relevant box: and Identify fee paid (The required fees must accompany the application)		
☐ With Indoor Facility	☐ Complete all sections	
☐ Without Indoor Facility	☐ Complete all sections except section 9	
☐ Change of Ownership	☐ Complete sections 1, 2, 3 and 4	
☐ Change of location	☐ Complete sections 1,2 and 7	
☐ Change of HCE Name	☐ Complete sections 1, 2	
☐ Change of Healthcare Service Provider	☐ Complete sections 1,2, 4 and 6	
☐ Temporary Closure	☐ Complete section 1,2 and 5	

1. HEALTHCARE SERVICE PROVIDER DETAILS	
Name (as it appears in CNIC):	Gender ☐ Male ☐ Female (Please tick)
Previous name (if different from above):	CNIC Number:
Designation:	
Status: ☐ Owner ☐ Manager ☐ In-charge	
Qualification (Highest):	
Valid Registration No. PMDC/PNC/NCH/NCT/ other (if applicable):	
Mailing Address:	
District:	Tehsil:
Building/House No:	Locality:
	Street:
Landline:	
Mobile:	
Email:	

2. HEALTHCARE ESTABLISHMENT	
Name: Name Change: (if applicable)	Date of establishment at present location:
Mailing Address:	
District:	Tehsil: Locality:
Building/House No:	Street:
Is this a changed location: Y/N (circle)	If Yes, Previous location: Mailing Address: District: Tehsil: Locality: Building/House No: Street:
Landline:	
Mobile:	
Is the current HCE licensed: Y/N (circle)	
☐ Premises Leased/Rented ☐ Premises Owned	
Name of lessor/renter: Address: Contact Number: <i>Note: A copy of the lease agreement must accompany this application</i>	

3. OFF SITE COLLECTION CENTERS (CC)		
☐ Yes	☐ No (if yes then complete lower part of this section. If needed use the additional sheet)	
Name of offsite CC	Complete Address	Contact No.
1.		
2.		
3.		
4.		

4. TYPE OF OWNERSHIP (please check the appropriate box)			
Government		Others	
Name of offsite CC	Complete Address	Contact No.	
☐ District Government	☐ Sole Proprietary	☐ Voluntary Non-Profit	
☐ Provincial Government	☐ Partnership	☐ Association	
☐ Federal Government	☐ Corporation	☐ Limited Liability Company (Pvt)	
☐ Autonomous Institution	☐ Trust	☐ Limited Liability Company (Pub)	
Owners Name:	CNIC #:	Contact No.	
Mailing address of the owner			
Is this a changed Owner: Y/N (circle)	If Yes, Previous Owner name: District: Tehsil: Locality: Building/House No. Street: Contact No.		
Signature of current owner		Signature of previous owner	

5. TYPE OF HEALTHCARE ESTABLISHMENT (please check the relevant box)		
A. By System of Treatment a) Allopathic ☐ b) Homeopathic ☐ c) Tibb ☐		
B. By Availability of indoor beds With Indoor beds ☐ Without indoor beds ☐		
C. By Teaching Status a) Teaching ☐ Noni Teaching ☐		
D. Specific Type		
Aesthetic Clinic ☐	Family Planning Clinic ☐	Poly Clinic ☐
Addiction Treatment Center ☐	General Medical Practitioner Clinic/ Dispensary ☐	Single Specialty Clinic ☐
Advanced Diagnostic Center ☐	Hair Transplant Clinic ☐	Tibb Clinic ☐
Advanced Imaging Center ☐	Homoeopathic Clinic ☐	Home Healthcare Service ☐
Clinical Laboratory ☐	Hospital ☐	Convalescence Home ☐
Collection & Imaging Center ☐	Mobile Clinics ☐	Blood Bank ☐
Collection Center ☐	Maternity Home ☐	Patient Transfer Services ☐
Cosmetic Surgery Clinic ☐	Mobile Vaccination Van ☐	Tele-health Center ☐
Dental Clinic ☐	Nursing Home ☐	Dialysis Center ☐
Diagnostic Center ☐	Other Specify ☐	

6. STAFFING SUMMARY			
Indicate number of full time (FT) and part time (PT) employees. (Attach additional pages if necessary). By name list to be enclosed as per Appendix-1			
S. No.	Category	FT	PT
1	Healthcare Management Personal		
2	Consultants		
3	Medical Officers		
4	PG Trainees		
5	House Officers		
6	Nurses		
7	Pharmacist		
8	Allied Health Practitioners		
9	Support staff		
10	Others (specify)		
Total			

7. BUILDING PLANS			
Do you have building plans?	Yes & approved ☐ Yes, but not approved ☐ No ☐		
Are building alteration and remodeling proposed in the next 5 years?			Yes ☐ No ☐
Nos of floors:	Residential accommodation		Yes ☐ No ☐
Nos of Generator:	Parking		Yes ☐ No ☐
Fire Exit	Yes ☐ No ☐	Nos of chillers:	
Offsite locations will include any type of collection centers, laboratories, branch sites etc. Please provide information in terms of sq. ft.			

8. SERVICES PROVIDED BY THE HEALTHCARE ESTABLISHMENT			
Sr. No.	Services	Sr. No.	Services
1	Medicine	17	General Surgery
2	Neonatology	18	Orthopedics
3	Neurology	19	Trauma Management
4	Oncology	20	ENT
5	Rheumatology	21	Eye
6	Pulmonology	22	Gyne & Obs
7	CCU	23	Pediatric Surgery
8	Emergency	24	Cardiac Surgery
9	Blood Bank	25	ICU
10	Laboratory	26	Neurosurgery
11	Radiology & diagnostic Imaging	27	Facio-maxillary
12	Pharmacy Indoor	28	Urology
13	Pharmacy Outdoor	29	Plastic Surgery
14	Physiotherapy	30	Dentistry
15	Speech Therapy	31	Homeopathy
16	Nutrition	32	Tibb

9. BED CAPACITY				
		Total beds	Male	Female
1.	Medical and allied			
2.	Surgical and allied			
3.	ICU			
4.	CCU			
5.	ICU Neonates			
6.	Emergency			
7.	Others			
Total				

10. EXTERNAL VALIDATION

List all applicable external certificate, licenses, accreditation and similar Awards/ Certificates

Agency	_____	Award	_____
Agency	_____	Award	_____
Agency	_____	Award	_____
Agency	_____	Award	_____

11. DECLARATION

I/we, the undersigned, do hereby solemnly affirm and declares that the information provided about HCE _____ are true and correct to the best of my/our knowledge and belief and that nothing has been concealed there from. I/we understand that if any false or incorrect information is provided to the Commission, it may result in rejection of my application for Registration, and I may also be found liable to pay fine to the Commission. I further undertake to inform the Commission in writing, within fifteen days of any addition/alteration made in the services/premises, at any time in future.

Name of Healthcare Service Provider:	Signatures: Date:
Name of the Owner*:	Signatures: Date:

* Only if the services provider is different from the owner

12. CHECKLIST

Please use the checklist to make sure that you have attached all necessary documents.

- ☐ Architectural Drawings
- ☐ Copy of lease agreement (in case of rented building) with the owner of the real estate on which the facility is built or proof of ownership if building owned.
- ☐ Copy of previous license (if applicable).
- ☐ Copy of all approvals obtained from required departments and organizations in the Balochistan Province e.g., Civil defense, fire safety, Local government.
- ☐ Receipt evidencing payment of applicable fees.
- ☐ Other:

Appendix-1
Staffing

Sr. #	Name	Designation	Part Time (PT)/ Full Time (FT)	Council Rgd. # (if applicable)	Contact #
A. Healthcare Management Personnel					
B. Consultants					
C. Mos					
D. PG Trainees					
E. House officers					
F. Nurses					
G. Pharmacists					
H. Allied Health Practitioners					
I. Support staff					
J. Others					

Appendix-2

List of Electromedical Equipment

[illegible]

Appendix-3

List of Machinery

[illegible]

Schedule-IV- Application for License

To,

The Director, Licensing & Anti-Quackery
Balochistan Healthcare Commission.

Subject:- **Formal Request for Issuance of License/Renewal of the License
for [Name of HCE], Registration No. [RGD #]**

Dear Sir/Madam,

I, [Your Full Name], authorized Healthcare Service Provider of [Name of HCE], located at [Address of HCE], and registered under Registration No. [Reg.#], submit this formal request for the issuance/renewal of the license for the aforementioned HCE.

In compliance with the Balochistan Healthcare Commission's provisions and regulatory requirements, I have deposited the requisite licensing fee of Rs. [amount in Rs]. Please find the documentary evidence of said payment enclosed and have started the implementation of applicable MSDS.

To maintain legal compliance and ensure uninterrupted healthcare services, I respectfully request that your esteemed office expedites the processing of this application for the issuance/ renewal of the license. The timely approval and issuance of the requisite license are crucial for the lawful operation of the HCE.

I trust that this matter will receive prompt and diligent attention. Please do not hesitate to contact me if additional documentation or clarification is required to facilitate the process.

Thank you for your anticipated cooperation

Yours faithfully,

[Your Full Name]

[Your Address]

[Contact No.]

Date: [Date]

Schedule-V- Samples of Registration Certificate, Provisional and Regular License

A. Sample Registration Certificate

Logo of BHCC

Registration Certificate

Registration No. (#)

Date of Issuance (D/M/Y)

WHEREAS, Healthcare Service Provider of [Name of HCE] has submitted an application to the Balochistan Healthcare Commission (hereinafter referred to as “the Commission”) for registration as a Healthcare Service Provider under the Balochistan Healthcare Commission Act, 2019 (hereinafter referred to as “the Act”) and Regulations framed thereunder;

AND WHEREAS, the Commission has scrutinized the application and supporting documents;

NOW, THEREFORE, in exercise of the powers conferred under Section 15 of the Act, the Commission hereby Registers [Name of Healthcare Service Provider] as a Healthcare Service Provider of the above-mentioned Healthcare Establishment, subject to the terms and conditions specified herein;

PARTICULARS OF REGISTRATION

- **Name of HCE:** [Name of HCE]
- **Category:** [Cat of HCE]
- **Number of Beds:** [# of beds]
- **Sector:** [Private or Public]
- **Type of HCE:** [Specific as selected in application]
- **Registration Number:** (R-#)

CONDITIONS OF REGISTRATION

1. This Registration is granted solely based on the submitted information and documents and does not imply compliance with the standards required for the issuance of a License.
2. The Healthcare Service Provider shall apply for a License within 30 days from the date of this registration, accompanied by the prescribed fee and requisite documents.
3. The Healthcare Service Provider shall comply with the Licensing and Anti-quackery Regulations 2024 of the Commission.

NOTE

This registration does not constitute a License and shall not be construed as such. The Commission reserves the right to revoke or suspend this registration if the HCE fails to comply with the terms and conditions specified in the Act, Regulations and herein.

Director Licensing & Anti-quackery
Balochistan Healthcare Commission

SEAL OF THE COMMISSION

B. Sample Provisional License

Logo

Provisional License

Provisional License No. #

Date of Issuance (D/M/Y)

WHEREAS, Healthcare Service Provider of [Name of HCE] has submitted an application to the Balochistan Healthcare Commission (hereinafter referred to as "the Commission") for License of his/her Healthcare Establishment under the Balochistan Healthcare Commission Act, 2019 (hereinafter referred to as "the Act") and Regulations framed thereunder;

AND WHEREAS, the Commission has scrutinized the application and supporting documents;

NOW, THEREFORE, in exercise of the powers conferred by Section 16 of the Act, the Commission hereby grants Provisional License to [Name of HCE] subject to the terms and conditions specified herein.

PARTICULARS OF PROVISIONAL LICENSE

- Name of HCE: [Name of HCE]
- Category: [Cat of HCE]
- Number of Beds: [# of beds]
- Sector: [Private or Public]
- Type of HCE: [As selected indicated in application]
- Date of Issuance: [D/M/Y]
- Date of Expiration: [D/M/Y]
- PL Number: (PL-#)

CONDITIONS OF PROVISIONAL LICENSE

1. This Provisional License is granted solely based on the submitted information and documents and does not imply compliance with the standards required for the issuance of a License.
2. The HCE shall fulfil all the requirements and get Regular license before date of expiration of the Provisional License.
3. The HCE shall comply with the Licensing and Anti-quackery Regulations 2024 of the Commission.

NOTE

This Provisional License does not constitute a Regular License and shall not be construed as such. The Commission reserves the right to revoke or suspend this PL if the HCE fails to comply with the terms and conditions specified herein.

**Director Licensing & Anti-quackery
Balochistan Healthcare Commission**

C. Sample Regular License

Regular License No. #

Date of Issuance (D/M/Y)

WHEREAS, Healthcare Service Provider of [Name of HCE] has submitted an application to the Balochistan Healthcare Commission (hereinafter referred to as “the Commission”) for License of his/her Healthcare Establishment under the Balochistan Healthcare Commission Act, 2019 (hereinafter referred to as “the Act”) and Regulations framed thereunder;

AND WHEREAS, the Commission has scrutinized the application and supporting documents;

NOW, THEREFORE, in exercise of the powers conferred by Section 16 of the Act, the Commission hereby grants Regular License to [Name of HCE] subject to the terms and conditions specified herein.

PARTICULARS OF REGULAR LICENSE

- Name of HCE: [Name of HCE]
- Category: [Cat of HCE]
- Number of Beds: [# of beds]
- Sector: [Private or Public]
- Type of HCE: [As defined in application]
- Date of Issuance: [D/M/Y]
- Date of Expiration: [D/M/Y]
- PL Number: (PL-#)

CONDITIONS OF REGULAR LICENSE

1. The Licensed HCE shall operate strictly in accordance with the terms and conditions set forth by the Commission.
2. Any operation or use of the HCE that contravenes the condition shall render both the licensee and the superintendent liable to prosecution and penalties under the applicable laws and regulation framed thereunder. The HCE shall ensure timely application for the renewal of the License, in strict adherence to the procedures and timelines prescribed in the Regulations.

NOTE

The Commission reserves the absolute right to revoke or suspend the License if the HCE fails to adhere to the stipulated terms and conditions.

**Director Licensing & Anti-quackery
Balochistan Healthcare Commission**

**Schedule-VI- Observations and Required Actions During Inspection/Field Visits
and Associated Penalties**

This schedule delineates the observation and actions during the inspection and field visits and associated penalties enforceable by the Commission for various non-compliances identified within the HCEs. Each listed observation represents a specific infraction of the established healthcare standards and regulations. The corresponding actions range from formal notices and advisories to the cessation of services and the sealing of facilities, accompanied by financial penalties.

Sr. No.	Observations	Action	Penalty
1	Cat-III HCE except Labs, Diagnostics, Aesthetic centers not registered with BHCC but applied for registration and run by a legitimate healthcare personnel	Report/Notice	Warning/ Advice
2	Cat-III HCE not registered with BHCC nor applied for registration but run by a legitimate healthcare personnel	Stoppage of services	200,000
3	Cat-III HCE registered or unregistered with BHCC with evidence of quackery	Sealing	200,000-400,000
4	Labs within a registered Hospitals/clinics performing specialized tests or tests of walk-in patients without Pathologist	Stoppage of services	200,000
5	Standalone Lab unregistered but being run by a Pathologist	Stoppage of services	200,000
6	Standalone Lab Registered with BHCC but being run without pathologist	Sealing	400,000
7	Standalone Lab unregistered and without Pathologist	Sealing	600,000
8	Unregistered collection center only doing sample collection	Sealing	200,000
9	Unregistered collection center and performing tests	Sealing	400,000-600,000
10	Registered collection center performing tests	Sealing	400,000
11	Standalone Radiological centre Unregistered but being run under supervision of Radiologist	Stoppage of services	200,000
12	Standalone Radiological Centre Registered with BHCC but no evidence of being run under supervision of Radiologist	Sealing	400,000
13	Standalone Radiological Centre unregistered and without supervision of Radiologist	Sealing	600,000
14	Acupuncture services at registered HCE	Sealing	200,000

15	Acupuncture services at unregistered HCE	Sealing	300,000
16	Standalone Acupuncture center	Sealing	300,000
17	Hajjama at registered HCE other than Hakeem	Sealing	200,000
18	Hajjama at un-registered HCE other than Hakeem	Sealing	300,000
19	Standalone Hajjama center other than Hakeem	Sealing	300,000
20	Aesthetic Centre registered with BHCC but not supervised by a qualified practitioner	Sealing	400,000
21	Aesthetic Centre unregistered with BHCC but functioning under supervision of a qualified practitioner	Stoppage of services	200,000
22	Aesthetic Centre unregistered with BHCC and not supervised by a qualified practitioner	Sealing	600,000
23A	Unregistered Hospital		400,000
23B	Other observations irrespective of registration status:		
23B.I	Inadequate 24/7 Medical coverage	Stoppage of indoor services	200,000
23B.II	Non availability of qualified consultants against the claimed services	Stoppage of relevant service	800,000
23B.III	Inadequate infection control measures at OT	Suspension of OT services	600,000
23B.IV	Unauthorized blood transfusion services	Report/Notice	400,000
23B.V	Expired Medicine/ Reagents/ disposables	Sealing of Hospital Pharmacy/Lab	400,000
23B.VI	Inadequate HWM arrangements	Report/Notice	200,000
23B.VII	No PNRA License	Stoppage of imaging services	200,000
23B.VIII	Cath Lab being run without permission of BHCC, unregistered interventional cardiologists, unregistered with CROP, without PNRA license	Stoppage of services	200,000-800,000
Note: Total amount of the fine should not exceed 1,000,000			
24	Special deficiencies in category- I Hospitals:		
24.I	Non availability of Emergency services	Report/Notice	200,000
24.II	Emergency beds less than 5% of total hospital beds	Report/Notice	200,000
24.III	Inadequate staff in emergency	Report/Notice	200,000
24.IV	Non availability of emergency medicine	Report/Notice	200,000

24.V	Non availability of ICU	Report/Notice	200,000
25	Violation of Directions regarding stoppage of services	Sealing of the concerned section	Cat-1: 600,000 Cat-II: 300,000 Cat-III: 100,000-200,000
Note: The proposed penalties at Sr. No. 25 would be in addition to penalties for original violations and will be dealt as second offense			
26	Seal breaking, before hearing and de-sealing orders from BHCC	Resealing and FIR on case-to-case basis	Cat-I: 1,000,000 Cat-II: 600,000 Cat-III: 200,000-400,000
27	Seal breaking, after hearing without payment of fine	Resealing and FIR case to case basis	200,000-400,000
28	Seal breaking after payment of fine but without de-sealing orders from BHCC	Report/Notice	Warning
29	Seal breaking after fine set aside by the court but without desealing orders from BHCC	Report/Notice	Warning
30	Change in category, services, ownership, address and or HCP/Personnel without informing the commission	Report/Notice (Lic)	Up to 400,000
31	Non-payment of cost of inspection	Report/Notice	50% of the inspection cost
32	Violation of Statement of Declaration regarding CPSA	Report/Notice	200,000-400,000 and Rescission/Withdrawal of PL on case to case basis
33	Deregistered/HCEs with rejected applications found functional, but has applied for new registration	Stoppage of services	200,000
34	Deregistered/HCEs with rejected applications found functional, but not applied for new registration	Sealing	600,000
35	HCE not qualified after five inspections	Stoppage of services	200,000 and other legal actions as mentioned in these Regulations
36	Qualified HCE scoring less than 80% score in any inspection after qualification	Report/Notice	Up to 1,000,000 fine and Rescission/Withdrawal of license and other legal actions as mentioned in the Licensing regulations on case to case basis

Note: i) *These observations/actions are not exhaustive. If any further violations of applicable laws, regulations, standards, or guidelines are identified, those will be addressed according to the severity of the infraction, as determined by the authorized officers.*

- ii) *Penalties imposed shall be followed strictly when passing orders. Any deviations from the specified amounts must be supported by detailed reasons in the final order.*
- iii) *The given penalties are supplementary to any additional fees which may be required under these regulations.*