

**A
Bill**

to provide for the regulation of health care services on sound physical and technical footings in the public and private sectors and to establish the Khyber Pakhtunkhwa Health Care Commission

WHEREAS it is expedient to provide for the regulation of health care services on sound physical and technical footings in public and private sectors, make provisions for the safe and high quality health care services to the people of the Khyber Pakhtunkhwa and to set out actions needed to achieve the vision of excellent quality health care services in the Province of the Khyber Pakhtunkhwa;

AND WHEREAS to promote and improve patient safety and health care service quality in public and private sectors, it is necessary to provide mechanism for banning quackery in all its forms and manifestations and to establish the Khyber Pakhtunkhwa Health Care Commission to regulate health care establishment in public and private sectors and for matters connected therewith and ancillary thereto;

It is hereby enacted as follows:

**CHAPTER I
INTRODUCTORY**

1. Short title, application and commencement.---(1) This Act may be called the Khyber Pakhtunkhwa Health Care Commission Act, 2015.

(2) It shall apply to all the health care establishments in public and private sectors,-

- (a) owned, managed or administered by Government or non-profit organizations, charities, trusts, corporate sector or by any person, or group of persons incorporated or not; and
- (b) operated and managed under allopathic system, complementary and alternative medical treatment system recognized in Pakistan.

(3) It shall come into force at once.

2. Definitions.---In this Act, unless the context otherwise requires, the following expressions shall have the meanings hereby respectively assigned to them, that is to say,-

- (a) "Commission" means the Khyber Pakhtunkhwa Health Care Commission, established under section 3 of this Act;
- (b) "Chairperson" means the Chairperson of the Commission or the Search and Nomination Council, as the case may be;
- (c) "Chief Executive Officer" means the Chief Executive Officer of the Commission;

- (d) “Council” means Search and Nomination Council constituted under section 8 of this Act;
- (e) “Council for Homeopathy” means the National Council for Homeopathy, established under the Unani, Ayurvedic and Homoeopathic Practitioners Act 1965 (II of 1965);
- (f) “Council for Tibb” means the National Council for Tibb, established under the Unani, Ayurvedic and Homoeopathic Practitioners Act 1965 (II of 1965);
- (g) "Fund" means the Health Care Commission Fund, established under section 24 of this Act;
- (h) “Government” means the Government of the Khyber Pakhtunkhwa;
- (i) “healthcare establishment” means a hospital, diagnostic centre, blood banks, medical clinics, nursing home, maternity home, dental clinic, homeopathy clinic, Tibb clinic, acupuncture, physiotherapy clinic or any other premises or conveyance-
 - (a) wholly or partly used for providing healthcare services in public and private sectors; and
 - (b) declared by the Commission as a health care establishment.
- (j) “health care services” mean 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;
- (k) “health care service provider” means an owner, manager or in charge of a healthcare establishment and includes a person registered by the Medical and Dental Council, Council for Tibb, Council for Homeopathy or Nursing Council;
- (l) “Inspector” means a person or expert having relevant qualification and experience commissioned by the Commission for assessing compliance to standards, protocols, guideline prescribed by rules or regulations;
- (m) “inspection team” means a team comprising more than two experts having relevant qualification and experience commissioned by the Commission for assessing compliance to standards, protocols, guideline prescribed by rules or regulations;

- (n) “prescribed” means prescribed by rules or regulations made under this Act;
- (o) “Quackery” means any person who does not qualify to be registered or licensed by the Commission and also includes registered or licensed persons/ institutions in public and private sectors that are providing services other than licensed.
- (p) “regulations” mean the regulations made under this Act; and
- (q) “rules” mean the rules made under this Act.

CHAPTER II ESTABLISHMENT, FUNCTIONS AND POWERS OF THE COMMISSION

3. Khyber Pakhtunkhwa Health Care Commission.---(1) As soon as, after the commencement of this Act, Government shall by notification, establish a Commission to be known as the Khyber Pakhtunkhwa Health Care Commission.

(2) The Commission shall be a body corporate having perpetual succession and a common seal, with powers to acquire and dispose of property both movable and immovable and shall be the said name sue and be sued.

(3) The main office of the Commission shall be at Peshawar and shall have such other regional offices as Government may establish.

4. Composition of the Commission.---(1) The Commission shall consist of ten members with three of its members as official members and seven members shall be from private sector as non-official members.

(2) The official members of the Commission shall include representatives from Health Department, Home Department and Pakistan National Accreditation Council.

(3) The non-official members shall be technical and professional people of the field, retired senior civil service officers related to quality and patient safety, medical professionals with contribution to healthcare quality and patient safety, health management experts, quality assurance experts, law, finance and economics professionals, and representatives of consumer or patient association, which shall be appointed and notified by Government on the recommendation of the Search and Nomination Council.

(4) Non-official members shall hold office for a term of three years and shall be eligible for re-appointment.

(5) In case of a casual vacancy of a non-official member, Government shall appoint a person as member for the remainder of the term of the member, who has died, resigned or disqualified under this Act; provided that the vacancy shall not be filled if remaining period is less than four (4) months.

(6) The Chairperson shall be elected by the non-official members through voting from amongst its non-official members, who shall preside over the Commission meetings. In case of his absence, the Chairperson may nominate a Commission member as acting Chairman or if he has not done so, the members present shall elect an acting Chairperson for that meeting.

(7) No person shall be, or shall continue to be, the Chairperson or a member who,-

- (a) has tendered resignation and not withdrawn it within a period of thirty days;
- (b) is, or at any time has been, adjudicated as insolvent;
- (c) is found to be of unsound mind by a court of competent jurisdiction;
- (d) is, or has at any time been, convicted of any offence which, in the opinion of Government, is an offence involving moral turpitude;
- (e) absents himself from four consecutive meetings of the Commission; and
- (f) is an employee, advisor or consultant of a healthcare service establishment.

(8) The Commission shall prescribe the remuneration payable to a member for attending a meeting of the Commission.

(9) A decision of the Commission shall not be valid if decided in a meeting without quorum.

5. Meetings of the Commission.---(1) The Chairperson shall convene meetings of the Commission on quarterly basis for the conduct of the business of the Commission.

(2) Extra ordinary meetings of the Commission may be convened as and when required. The Extraordinary meeting may be called by the Chairman or on the request of three or more members in writing for reasons specified there.

(3) Two-third of the total members shall constitute quorum for a meeting of the Commission.

(4) All decisions in the meeting shall be taken on majority of votes; provided that in the case of equality of votes, the Chairperson shall have a second or casting vote.

6. Powers and functions of the Commission.---(1) The Commission shall perform such functions and exercise such powers as may be required to ensure the safety of patient and health staff and to improve quality of public and private healthcare services.

(2) Without prejudice to the generality of the provisions of sub-section (1), the Commission shall,-

- (a) set standards or requirements for registration and licensing of health care establishments that ensure patient and health staff safety;
- (b) registration of all health care establishments and issuance of license defining scope and extent of services to be provided;
- (c) enforce minimum standards of patient and health staff safety in public and private sectors;
- (d) play technical and advisory, educative and disciplinary role to support the registered and licensed health care establishments to improve quality of services;
- (e) regulate the registered and licensed health care establishments in public and private health sectors through health regulation tools; certification, peer review, clinical governance, self-regulation or any other tool nationally or internationally recognized and accepted;
- (f) grant, renew, suspend and cancel licenses in the prescribed manner to health care establishments and to vary terms and conditions and purposes of the license;
- (g) enquire and investigate into mal-administration, malpractice and failures in the provision of private healthcare services and issue consequential advice and orders;
- (h) impose and collect fees and charges on registration, licensing or for any other services rendered to health care establishments, such as trainings on guidelines, standards, etc., under this Act;
- (i) impose and collect fines on violation, breach or non-compliance of the provisions of this Act, rules, regulations and standards;
- (j) advocate rights and responsibilities of recipients and providers of the private health care services;
- (k) hold seminars, conferences and meetings on developing awareness about provision of high quality private healthcare services;
- (l) co-ordinate, liaise and network with any person, agency or institution for the purpose of this Act;
- (m) appoint, engage, authorize and terminate employees, consultants, advisors, attorneys, inspection teams, surveyors, contractors, agents and experts on such terms and conditions as it deems necessary and assign, delegate or entrust them with such functions and powers as are

expedient for the performance of functions of the Commission;

- (n) take measures for the welfare of the employees of the Commission as well as its all registered members;
- (o) devise mechanism to deal with quackery;
- (p) to monitor service performance against prescribed standards;
- (q) perform any other function assigned to it by Government from time to time.

(3) The Commission may exercise the same powers as are vested in a Civil Court under the Code of Civil Procedure, 1908 (V of 1908), in respect of the following matters:

- (a) summoning and enforcing the attendance of any person and examining him on oath;
- (b) compelling the production of documents;
- (c) receiving evidence on affidavits; and
- (d) issuing Commission for the examination of witnesses.

(4) Government may, as and when it considers necessary, advice the Commission on matters of policy.

7. Committees.---The Commission shall establish the following committees and may establish other committees for assistance and advice to the Chief Executive in relation to the performance of functions of the Commission and determine the membership, remuneration of members and terms of reference of each committee:

- (i) Technical Committees;
- (ii) Finance and Grant Committee;
- (iii) Performance Review Committee; and
- (iv) Continuous Quality Improvement Committee.

8. Search and Nomination Council.---(1) Government shall constitute and notify a Search and Nomination Council, for recommendations of persons suitable to be appointed as non-official members which shall consist of-

- (a) Minister for Health; Chairman
- (b) Additional Chief Secretary Planning and Development Department; Vice Chairman
- (c) Secretary to Government, Health Department; Member

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| (d) | Vice Chancellor of the Khyber Medical University; | Member |
| (e) | a philanthropist with substantial contribution to the public health care system to be nominated by Government; | Member |
| (f) | a retired senior person from medical profession to be nominated by Government; and | Member |
| (g) | a representative of civil society to be nominated by Government. | Member |

(2) The Chairman shall chair the meeting of the Council and in his absence, the Vice Chairman shall chair the meeting.

(3) A non-official member shall, unless otherwise directed by Government, hold office for a period of three years and shall be eligible for another term of three years or part thereof as Government may deem appropriate:

Provided that Government may remove a non-official member at any time after giving him an opportunity of being heard.

9. Chief Executive Officer.---(1) The Commission shall appoint a person as a Chief Executive Officer having a minimum of fifteen years of experience in health management, finance, law and regulation or other fields related to service regulation.

(2) The chief executive officer shall, subject to the supervision and control of the commission, manage the affairs of the Commission, and may exercise such powers as are delegated to him by the Commission.

(3) In particular, the chief executive officer may,-

- (a) manage the administration, operations and functions of the Commission;
- (b) act as the principal accounting officer responsible and accountable for the management of the Commission's funds and assets in an efficient and effective manner;
- (c) prepare and present the Commission with strategic and operational plans for its review and appraisal;
- (d) assist the Commission in strategic thinking, planning and leadership and implement its policies;
- (e) protect the financial health of the Commission;
- (f) act as spokesperson and advocate of the Commission;
- (g) provide leadership to the senior management and direction to all staff; and

(4) The Chief Executive Officer shall be Secretary to the Commission with no right of vote and shall prepare and circulate agenda and minutes of the Commission meetings .

10. Disqualifications of Chief Executive Officer.---A person shall not be appointed or hold office as chief executive officer who,-

- (a) is a member of the Federal or Provincial legislature, local council or local body constituted under any law or has contested last general election;
- (b) is employed in any capacity in the service relating to the affairs of the Federation or Province or hold any office for which salary or other remuneration is payable out of public funds;
- (c) is a director, officer or employee of any healthcare service establishment or has an interest or share in any healthcare establishment;
- (d) has been convicted of tax evasion or for an offence involving moral turpitude; or
- (e) is in default of payments for an amount of more than one hundred thousand due from him, for more than one hundred and eighty days, to any bank, financial institution, cooperative society, governmental agency, department or corporation.

11. Delegation.---The Commission may, by general or special order, delegate to the Chairperson or a member or an expert, consultant, adviser, or other officer of the Commission, or any other entity any of its functions or a part thereof of a function under this Act subject to such conditions or restrictions as it may be determined.

CHAPTER III REGULATION OF HEALTH CARE SERVICES

12. Registration and licencing.---(1) The Commission may establish Registration and Licensing Bodies at the divisional level for registration of health care establishment and issue licence defining scope and extent of services to be provided by such health care establishment.

(2) A private health care establishment shall not provide health care services without being registered and licenced under this section:

Provided that a health care establishment in existence on the date coming in to force of this Act may without registration continue to function for a period not exceeding ninety (90) days from such date, and in case an application has been made for registration under the rules, it may continue to function without registration until the application is disposed of:

Provided further that 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 deem to be registered under this Act and shall

renewed its registration in accordance with the provisions of this Act and rules.

(3) The public sector health care establishment shall be considered as a registered health care establishment and shall be regulated in such a manner as may be prescribed.

(4) Government shall from time to time provide a list of public sector health care establishment, with scope and extent of services, to the Commission for regulation.

(5) The registering and licencing body shall register a health care establishment and issue licence in such a manner as may be prescribed by rules.

(6) The rules made under sub-section (3) beside other matter may also provide the procedure for registration and licencing, renewal, cancellation and suspension of registration and of licence of a health care establishment and disqualification of a person to run a health care establishment.

(7) Every licence of a health care establishment shall specify the kind of health care establishment for which it is issued and the purposes of the health care establishment.

(8) The Commission shall maintain a register of all registered health care establishment and may enter in the register any necessary details for other particular of the health care establishment.

CHAPTER IV COMPLAINT, INSPECTION AND INVESTIGATION

13. Complaints.---(1) An aggrieved person may, within sixty days from the date of knowledge of the cause of action, file a complaint against a healthcare service provider or healthcare establishment by submitting an application in writing supported by an affidavit, national identity card number and address of the aggrieved person.

(2) The Commission shall not entertain an anonymous or pseudonymous complaint against a private health care service provider or healthcare establishment.

(3) The Commission shall investigate in a transparent manner, the complaints relating to quality of health services, health services or system and medical negligence.

(4) The Commission shall prescribe the procedure for the conduct of investigation to be carried out by the Commission under this Act.

14. Inspection.---(1) The Commission may, by order in writing, appoint an inspector or an inspection team to perform the functions and exercise the powers of the Commission in relation to inspections under this Act, rules or regulations subject to such conditions and limitations as the Commission may specify in this behalf.

(2) The inspector or inspection team may inspect a health care establishment,-

- (a) at the time of issuance and renewal of license; or
- (b) on receipt of a complaint.

(3) The inspector or 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, the healthcare establishment.

(4) The inspector or inspection team may enquire any case if there has been any instance or allegation of maladministration, malpractice or failure in the provision of private healthcare services against a health care establishment.

(5) The Commission may impose a fine which may extend to fifty thousand rupees upon a health care establishment who,-

- (a) refuses or fails, without reasonable cause, to furnish any information to the inspection team; or
- (b) gives any false or misleading information to the inspection team.

15. Directions as to apparatus, appliance, equipment or products.---Where, in the opinion of the inspector or inspection team,-

- (a) the use of any apparatus, appliance, equipment, instrument, product, goods or item; or
- (b) the carrying out of any practice or procedure in a healthcare establishment,-

is dangerous or detrimental to any person therein or otherwise unsuitable for the purpose for which it is used or carried out, he shall immediately report, the matter in writing to the Commission along with the necessary details. On receipt of report the Commission may act according to the rules, regulations and the procedure prescribed under rules and regulations.

16. Obstructing inspection team.---The Commission may impose a fine which may extend up to fifty thousand rupees on a person who obstructs, hinders or impedes an inspector or an inspection team in the performance of its function or execution of its duty.

17. Protection from liability.---No suit or other legal proceedings shall lie against the Commission and various committees constituted under this Act, Chief Executive Officer, officers, inspection teams, advisors, consultants or agents of the Commission for anything done in good faith in the execution or purported execution of this Act, rules or regulations.

18. Jurisdiction of Commission for adjudication of fine.---(1) Notwithstanding anything contained in any other law, the Commission may, for contravention of a provision of this Act, rules or regulations, impose fine which may extend to one million rupees in accordance with the provisions of this Act.

(2) The Commission shall afford adequate opportunity of hearing and in certain circumstances give specified time for the improvement of the

health care establishment to a person before imposing fine on the person under this Act.

(3) If the complaint, submitted either by an aggrieved person or a healthcare service provider, is proved false, the Commission may impose fine which may extend to two hundred thousand rupees upon the complainant.

19. Immunity.---No suit, prosecution or other legal proceedings related to provision of private health care services shall lie against a health care establishment except under this Act.

20. Bar of jurisdiction.---Save as provided in this Act, no Court other than the Court of the District and Sessions Judge shall have jurisdiction,-

- (a) to question the validity of any action taken, or intended to be taken, or order made, or anything done or purporting to have been taken, made or done under this Act; or
- (b) to grant an injunction or stay or to make any interim order in relation to any proceeding before, or anything done or intended to be done or purporting to have been done by, or under the orders or at the instance of the Commission.

21. Appeal.---(1) A person who is aggrieved by the,-

- (a) refusal of the Commission to issue or renew a license;
- (b) decision of the Commission to suspend or revoke a license;
- (c) order of closing down of a healthcare establishment or making improvements in the healthcare establishment;
- (d) order relating to equipment, apparatus, appliances, or other things at a healthcare establishment; or
- (e) imposition of fine by the Commission;

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

(2) The private health care service provider shall provide legal aid to a person, working in the health care establishment, pertaining to the matters related to this Act.

CHAPTER V EMPLOYEES, FUND, BUDGET AND ACCOUNTS

22. Service of the Commission.---To carry out the purposes of this Act, the Commission may, from time to time, engage such officers, officials, experts, consultants and advisers on such terms and conditions as it may determine.

23. Public servant.---The Chairperson, members and all other employees of the Commission shall be deemed to be public servants within the meaning of section 21 of the Pakistan Panel Code (Act XLV of 1860).

24. Fund.---(1) There shall be a Fund to be known as the Khyber Pakhtunkhwa Health Care Commission Fund.

(2) The Fund shall consist of-

- (a) grant in Aid in lieu of services rendered to public sector health care establishment;
- (b) such sums as Government may grant by way of seed money;
- (c) donations from domestic and international donor agencies and other institutions;
- (d) grants of money and sums borrowed or raised by the Commission for the purposes of meeting any of its obligations or discharging any of its duties;
- (e) fees, penalties or other charges imposed under this Act; and
- (f) all other sums, which may in any manner become payable to or vested in the Commission in respect of any matter incidental to the exercise of its functions and powers.

(3) The Fund established under section 25B of the Khyber Pakhtunkhwa Medical Health Institutions and Regulation of Health Care Services Ordinance, 2002, shall be part and parcel of this Fund.

(4) The Fund shall be utilized for the purpose of the Commission and shall be regulated under the overall supervision of the Commission in such a manner as may be prescribed by the Commission.

25. Annual budget.---(1) The Commission shall prepare and approve annual budget for a financial year in the prescribed manner.

(2) No expenditure shall be made for which provision has not been made in any approved budget except if made from any previously approved contingency funds, unless further approval is sought and obtained from the Commission.

26. Annual report and accounts.---(1) The Chief Executive Officer shall within ninety days from the end of each financial year, prepare a report on the activities and performance of the Commission, and submit a copy of the report to Government, after approval from the Commission.

(2) The Commission shall keep proper accounts and shall, as soon as practicable, after the end of each financial year, prepare a statement of accounts of the Commission through Chief Executive Officer for the financial year which shall include a balance sheet and an account of income and expenditure.

(3) The accounts of the Commission shall be audited by the Auditor General of Pakistan.

(4) The Commission shall, within one hundred and twenty days of the end of each financial year, together with the annual report of the Commission under sub-section (2), send a copy of the statement of accounts of the Commission certified by the auditors and a copy of the auditors' report to Government.

(5) The Commission may invest money not required for immediate expenditure in Government Saving Scheme or in fixed deposit with banks approved by Government.

CHAPTER VI MISCELLANEOUS

27. Assistance to the Commission.---All Law Enforcement Agencies of Government shall provide assistance to the Commission.

28. Offences.---(1) Quackery by person, who does not qualify the provisions of this Act shall be punished with imprisonment, which may extend to six months or with fine, which may extend to one million rupees, or with both.

(2) The offences under this Act shall be non-bailable and cognizable.

29. Recovery of fines and other dues as arrears of land revenue.---The Commission may recover the fines imposed under this Act or other dues recoverable under this Act as arrears of land revenue under the West Pakistan Land Revenue Act, 1967 (W.P. Act No. XVII of 1967).

30. Removal of difficulties.---If any difficulty arises in giving effect to any provision of this Act, Government may make such order not inconsistent with the provisions of this Act as may appear to it to be necessary for the purpose of removing such difficulty.

31. Regulations.---(1) The Commission may make regulations, not inconsistent with the provision of this Act and the rules, for carrying out the purposes of this Act.

(2) The power to make regulations conferred by this section shall be subject to the condition of previous publication and, before making any regulations, the draft thereof shall be published, in the official Gazette, two newspapers of wide circulation and on the website of the Commission, for eliciting public opinion thereon within a period of not less than fifteen days from the date of publication.

32. Rules.---(1) Government may, by notification in the official Gazette, make rules for giving effect to the provisions of this Act.

(2) The power to make rules conferred by this section shall be subject to the condition of previous publication and, before making any rule, the draft thereof shall be published in the official Gazette for eliciting public opinion thereon within a period of not less than fifteen days from the date of publication.

33. Overriding effect.----Notwithstanding anything to the contrary contained in any other law, the provisions of this Act shall have an overriding effect and the provisions of any such law to the extent of inconsistency to this Act shall cease to have effect.

34. Repeal.---(1) The Khyber Pakhtunkhwa Medical Health Institutions and Regulation of Health Care Ordinance, 2002, Ordinance No. XLVII is hereby repealed.

(2) On commencement of this Act,-

- (i) all employees recruited by the Khyber Pakhtunkhwa Health Regulatory Authority under the repealed Act; and
- (ii) all assets and liabilities, including furniture, fixtures, machinery and vehicles etc.

shall stand transferred to the Commission established under this Act.

(3) Notwithstanding the aforesaid repeal, anything done, action taken, rules made, and notification or order issued under the aforesaid Act, shall, so far as it is not inconsistent with the provisions of this Act, be deemed to have been done; taken, made or issued, appointed constituted, given, commenced or taken, under this Act, and shall have effect accordingly.

STATEMENT OF OBJECTS AND REASONS

The objective of this Act is to promote and improve patient safety and health care service quality in private sector in the Province of the Khyber Pakhtunkhwa and to provide mechanism for banning quackery in all its forms and manifestations. Hence, this Bill.

MINISTER-IN-CHARGE