#### **INTRODUCED ON 10-04-2017**

#### [AS INTRODUCED IN THE SENATE]

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#### **BILL**

to provide for the regulation of health care services in the public and private sectors, and to protect the rights of patients

**WHEREAS** it is expedient to provide for the regulation of health care in public and private sectors, make provisions for the safe and high quality health care services in the Islamabad Capital Territory and elsewhere in the country under the Federal Government and to set out actions needed to achieve the vision of excellent quality health care services; and

**WHEREAS** it is expedient to promote and improve patient safety and health care service quality in public and private sectors, to provide mechanism for protection of patient's rights and to establish National Health Care Commission to regulate health care establishments in public and private sectors under the Federal Government 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 National Health Care Act, 2017.
- (2) It shall apply to all the health care establishments in public and private sectors,-
  - (a) owned, managed or administered by Government or nonprofit organizations, charities, trusts, corporate sector or by any person, or group of persons incorporated or not, in the Islamabad Capital Territory; and
  - (b) owned, managed or administered by Government or any department of Government elsewhere in the country.
  - (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) "attending physician" means a physician who determines the diagnosis, procedures, interventions and treatment plan to respond to the patient's illness or health condition for the medical treatment of the patient;
  - (b) "attending relative" means a person who is accompanying the patient and who is his next of kin or any other person who look after the patient for the time being;
  - (c) "Chairperson" means the Chairperson of the Commission;
  - (d) "Chief Executive Officer" means the Chief Executive Officer of the Commission;
  - (c) "Commission" means the National Health Care Commission, established under this Act;
  - (f) "Council for Homeopathy" means the National Council for Homeopathy, established under the Unani, Ayurvedic and Homoeopathic Practitioners Act 1965 (II of 1965);
  - (g) "Council for Tibb" means the National Council for Tibb, established under the Unani, Ayurvedic and Homoeopathic Practitioners Act 1965 (II of 1965);
  - (h) "Emergency" means an unforeseen and sudden change in health which, in the absence of urgent medical care, would endanger the patient's life, or result in severe or permanent health impairment;
  - (i) "Fund" means the Health Care Commission Fund, established under section 24 of this Act;
  - (j) "Government" means the Federal Government;

- (k) "health care" means a set of health care services delivered in connection with the patient's health status;
- (I) "health care establishment" means a site devoted primarily to the maintenance and operation of facilities for the prevention, diagnosis, treatment, and care of individuals suffering from illness, disease, injury, or deformity if in need of medical and nursing care, and includes 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;
- (m) "Health care practitioner" means any physician, dentist, nurse, pharmacist or paramedical and other supporting health personnel, a person with professional qualification, person without qualification involved in delivering health services, including, but not limited to, medical and dental technicians and technologists, nursing aides, therapists, nutritionists trained in health care and, or duly registered and licensed to practice in the Pakistan as well as traditional and alternative health care practitioners.
- (n) "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;
- (o) "health care service provider" means a legal entity, unincorporated organization, natural person, 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, Paramedic Council or Nursing Council;

- (p) "Human Experimentation" means the physician's departure from standard medical practice of treatment for the purpose of obtaining new knowledge or testing a scientific hypothesis on human subjects.
- (q) "Informed Consent" means the voluntary agreement of a person to undergo or be subjected to a procedure or other bodily intervention for treatment based on his understanding of the relevant consequences of receiving that particular treatment, as clearly, truthfully and reasonably explained by the health care provider in a manner and language understandable to the patient.
- (r) "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;
- (s) "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, quideline prescribed by rules or regulations;
- (t) "Intervention" means any physical, chemical, biological or psychological act performed for preventive, diagnostic, therapeutic, rehabilitation or other purposes which will, or may, result in a change in the patient's body and includes procedure related to examinations performed on a corpse and the removal of tissues and organs;
- (u) "Next of kin" includes parents, grandparents, uncles, aunts and their descendants, siblings and their descendants, sons, daughters and their descendants, spouse, in laws;
- (v) "Patient means" a person who avails himself of health and medical care services or is otherwise the subject of such services.
- (w) "Public Health and Safety" means the state of well-being required for health of the population in general;
- (x) "prescribed" means prescribed by rules or regulations made under this Act;

- (y) "regulations" mean the regulations made under this Act;
- (z) "rules" mean the rules made under this Act; and
- (aa) "Traditional and alternative health care" means the sum total of knowledge, skills and practices on health care, other than those embodied in biomedicine, used in the prevention, diagnosis and elimination of physical or menta1 disorder.

### CHAPTER II DECLARATION OF RIGHTS

- **3. Right to appropriate medical care and humane treatment.-** (1) Every patient shall have right to health and medical care of good quality corresponding to his state of health without any discrimination and within the limits of the resources, manpower and competence available for health and medical care at the relevant time.
- (2) Every patient shall have right to receive, in an emergency, life-saving care to prevent serious or permanent impairment to health, as well as to have his pain controlled and his suffering relieved, without any deposit, pledge, mortgage or any form of advance payment for treatment.
- (3) In the course of health care, the human dignity, convictions, integrity, individual needs and culture of the patient shall be respected and he shall be treated humanely.
- (4) Unless otherwise provided by this Act, only the interventions necessary for the care of the patient may be performed.
- (5) A patient may only be made to wait on such grounds and for a duration which are reasonable.
- (6) In the course of health care, the patient's modesty shall be ensured and in no case it shall be violated without reasons medically necessary for the necessary time and to the professionally justified extent.

**4. Right to informed consent.**– (1) Every patient shall have right to a clear, truthful and substantial explanation, in a manner and language understandable to him, of all proposed procedures, whether diagnostic, preventive, curative, rehabilitative or therapeutic; wherein the person who will perform the said procedure shall provide his name and credentials to the patient, possibilities of any risk of mortality or serious side effects, problems related to recuperation, and probability of success and reasonable risks involved:

Provided that, the patient may be subjected to any proposed procedure without his informed consent.-

- (a) in emergency cases, when the patient is at imminent risk of physical injury, decline or death if treatment is withheld or postponed and in such cases, the physician may perform any diagnostic or treatment procedure as good practice of medicine dictates without such consent;
- (b) when the health of the population is dependent on the adoption of a mass health program to control epidemic;
- (c) when the law makes it compulsory for everyone to submit to a procedure;
- (d) when the patient is either a minor, or legally incompetent, in which case, a third party consent shall be required;
- (e) when disclosure of material information to patient will jeopardize the success of treatment, in which case, third party disclosure and consent shall be in order; and
- (f) when the patient waives his right in writing.
- (2) Informed consent shall be obtained from the patient concerned if he is adult and of sound mind:

Provided that if the patient is legally or physically incapable of giving consent, than the consent may be obtained from the spouse or, son or daughter of legal age or, either parent or, brother or sisters of legal age or, guardian or, any other person who has for the time being care of the patient;

Provided further that a Court of Competent jurisdiction, upon the petition of the physician or any person interested in the welfare of the patient, in a summary proceeding may order for medical or surgical procedure, if the persons mentioned in the preceding proviso cannot be found or refuse to give consent to a medical or surgical procedure necessary to save the life or limb of a patient incapable of giving consent.

- **5. Right to choose health care provider and facility.** (1)Every patient shall have right to freely choose the health care provider to serve him as well as the facility except when he is under the care of a service facility or when public health and safety so demands or when the patient expressly or impliedly waives this right.
- (2) Every patient shall have right to choose his attending physician in the healthcare establishment of the level justified by his condition and, unless a legal rule sets forth an exception, the physician so chosen shall provide health care services to the patient.
- (3) Every patient shall have right to discuss his condition with a consultant specialist, at the patient's request.
- (4) Every patient shall have right to seek for a second opinion and subsequent opinions, if appropriate, from another health care provider/practitioner.
- **6. Right to privacy and confidentiality.** (1) Every patient shall have right of privacy and confidentiality which must be ensured at all stages of his treatment and shall be free from unwarranted public exposure:

Provided that the right of privacy and confidentiality may be waived if there is controversy regarding his mental or physical condition and the appropriate court, in its discretion, orders his physical or mental examination by a physician, or when the public health and safety so demand or when the patient waives this right.

(2) Every patient shall have the right to have only those persons present during the course of his examination and medical treatment whose involvement is necessary in delivering such care, or whose presence he has consented, unless otherwise provided by law.

- (3) Every patient shall have the right to have his examination and treatment take place under circumstances whereby it cannot be seen or heard by others without his consent, unless this is unavoidable due to an emergency or critical situation.
- (4) Every patient shall have the right to demand that all information, communication and records pertaining to his care be treated as confidential, and no health care provider or practitioner involved in the treatment of the patient, and all those who have legitimate access to the patient's record shall, without his consent, divulge any information to a third party who has no concern with the care and welfare of the patient, except,-
  - (a) when such disclosure will benefit public health and safety;
  - (b) when it is in the interest of justice and upon the order of a competent court; and
  - (c) when the patient has waived in writing the confidential nature of such information.
- (5) Unless explicitly prohibited by the patient, the attending relatives of the patient shall have right to every information about the status of patient and no attending relative shall be prohibited access to patient except in cases in which such access endangers the life or limb of the patient.
- **7. Right to treatment on time.-** (1) If a patient cannot be given the necessary care warranted by his health condition within the shortest possible period of time, the healthcare provider shall be obliged to inform him of the healthcare provider where the specific healthcare service is available.
  - (2) The patient shall be placed on a waiting list, if,-
  - (a) the specific healthcare service cannot be delivered by another healthcare provider, or
  - (b) in the case under sub-section (1), the patient refuses to be cared for by another healthcare provider.

- (3) Any patient who has been placed on waiting list shall be informed of the reason for waiting, its possible consequences and date on which the patient shall be provided health care services.
- (4) The patients' selection for the waiting list shall be based upon unified, controllable and published professional criteria, in a manner justified by the state of health of the patient without any discrimination.
- (5) Except as warranted by the health condition of the patient or unforeseen adverse situations which renders it impossible, no patient shall be denied the health care services, on the date fixed under this section.
- **8. Right to information.** (1) Every patient shall have right to complete information provided in an individualized form.
- (2) Every patient shall have right to receive detailed information about,-
  - (a) his state of health, including its medical evaluation;
  - (b) the recommended examinations and interventions;
  - (c) the possible benefits and risks of performing or not performing the recommended examinations and interventions;
  - (d) the planned dates for performing the examinations and interventions;
  - (e) his right to decide in respect of the recommended examination or intervention;
  - (f) the possible alternative procedures and methods;
  - (q) the course of care and the expected outcome;
  - (h) additional services; and
  - (i) the recommended lifestyle.

- (3) Every patient shall have right to pose additional questions during information and subsequently.
- (4) Every patient shall have right to be informed of the results or eventual failure, or unexpected outcomes and their reasons, after an examination or intervention has been performed in the course of his care.
- (5) The legally incapable patient or a patient with reduced disposing capacity shall also have a right to information corresponding to his age and mental state.
- (6) Every patient shall have right to know the identity, qualifications and professional status of those directly providing services.
- (7) Every patient shall have right to be informed in a way which is comprehensible for him, with regard to his age, education, knowledge, state of mind and his wish expressed on the matter and subject to its need and possibility, the services of an interpreter or a sign language interpreter shall be supplied for the provision of information.
  - (8) A patient may waive his right to be informed.
- **9. Right to leave the health care facility.-** (1) Every patient shall have the right to leave the healthcare facility at any stage of his treatment:

Provided that this right may be restricted in cases where the patient threatens the physical safety or health of others.

- (2) The patient shall inform his attending physician of his intention to leave, who shall enter this fact in the patient's medical record.
- (3) If the patient has left the healthcare facility without information, the attending physician shall enter this fact in the patient's medical record, and if required by the patient's condition, he shall notify the competent authority or the legal representative of a legally incapable patient or a patient with restricted disposing capacity, that the patient has left the healthcare facility.

- (4) The patient or his attending relative shall be informed of his planned discharge from the healthcare facility in advance, possibly at least twenty four hours prior to such planned discharge.
- (5) In the case of a legally incapable patient, the right defined in subsection (1) may be exercised in consultation with attending relative of the patient.
- (6) No patient shall be detained in any health care institution on the sole basis of his failure to fully settle his financial obligations.
- **10. Enforcement of patient's rights.-** (1) The health care service provider shall inform the patient, upon admission or prior to the actual delivery of care, depending upon his state of health, of the rights of patients, of the possibilities of enforcing such rights and of the house rules of the health care establishment.
- (2) The Government, the health care establishment and all concerned with the patient's care shall make sure the enforcement of the patient's rights.
- **11. Right to religious belief.-** Subject to the limitations prescribed in the proviso of sub-section (1) of section 4, every patient shall have right to refuse medical treatment or procedures which may be contrary to his religious belief.
- **12. Right to refuse participation in medical research.** Every patient shall have the right to refuse or to be advised if the health care provider plans to involve him in medical research, including but not limited to human experimentation, which may be performed only with the written informed consent of the patient.
- **13. Right** to **correspondence and to receive visitors.-** Every patient shall have the right to communicate with relatives and other persons and to receive visitors subject to reasonable limits prescribed by the rules and regulations of the health care establishment.
- **14. Right to have designated person.-** (1) every patient shall have the right to have the person designated by him to stay with him.

- (2) A woman in childbirth shall have the right to designate a person to stay with her continuously during labor and delivery, and after delivery, to have her new-born baby placed in the same room with her.
- **15. Right to express grievances.** (1) Every patient shall have the right to express grievances about the care and services received without fear of discrimination or reprisal and to know about the disposition of such complaints.
- (2) Every patient shall have the right to initiate administrative, civil or criminal proceeding against the person who violated his rights.
- **16. Right to be informed of his rights and obligations as a patient.** (1) Every patient shall have the right to be informed of his rights and obligations as a patient.
- (2) The Government in coordination with health care providers, civil society, media, local governments, shall launch information and education campaign to make known to people their rights as patients, as declared in this Act and such rights and obligations of patients shall be posted in a board conspicuously placed in health care establishments.
- (3) It shall be the duty of health care providers to inform patients of their rights as well as of the establishment's rules and regulations that apply to the conduct of the patient while in the care of such health care providers.
- **17. Right to participate in policy decisions.** The patients shall have right to participate in policy decisions relating to patient's right to health at the community and national levels.

# CHAPTER III DECLARATION OF OBLIGATIONS

**18. Obligations of patient.-** Every patient shall have to fulfill at all times his obligations and responsibilities regarding medical care and his personal behavior and shall ensure that he knows and understands what the patients' rights are and shall exercise those rights responsibly and reasonably.

- **19. Provide accurate and complete information.** Every patient shall provide, *to* the best of his knowledge, accurate and complete information about all matters pertaining to his health, including medications and past or present medical problems, to his health care provider.
- **20. Report unexpected health changes.** It shall be the duty of every patient to report unexpected changes to his condition or symptoms, including pain, to a member of the health care team.
- **21. Understand purpose and cost of treatment.** Every patient shall ensure that he understands the purpose and cost of any proposed treatment or procedure before deciding to accept it.
- **22.** Accept consequences of own informed consent. Every patient shall accept all the consequences of the patient's own informed consent or, if he refuses treatment or do not follow the instructions or advice of the health care provider or practitioner.
- **23. Settle financial obligations.** Every patient shall ensure that financial obligations of his health care are fulfilled as promptly as possible.
- **24. Relation to others.** Every patient shall make sure not to interfere with the well-being or rights of other patients or providers of health care and shall act in a considerate and cooperative manner, respect the rights and property of others and follow the policies and procedures of the health care establishment.

### CHAPTER IV REDRESSAL OF GRIEVANCES AND PENAL PROVISIONS

- **25. Grievances Mechanism.-** (1) The Government shall establish Grievances Redressal Cells in the health care establishments of public sector and shall appoint as many Grievances Redressal Officers, for public sector and private sector health care establishments, as may be required.
- (2) The Government may empower Grievances Redressal Officer of one health care establishment to be Grievances Redressal officer of other establishments, whether in public sector or private sector.

- (3) Health care providers in private sector may also establish their own Grievances Redressal Cells in the establishments.
- (4) The Grievances Redressal Cells shall work on twenty four hour basis and shall redress the grievances within the shortest possible time and shall not take time more than twenty four hours.
- (5) In case the grievances of the complainant not redressed within twenty four hours, the complainant may file complaint with the Commission.
- (6) The Commission upon receiving recommendations of the Grievances Redressal Officer or complaint from any party, shall act on or, decide the same within one month, and shall provide opportunity to the parties to be heard.
- (7) Any party aggrieved from the order of the Commission may file petition in the court of law.
- **26. Grievances Redressal Officers.-** (1) The Government shall by rules prescribe the qualifications and terms of services for the appointment of Grievances Redressal Officers.
- (2) No person shall be appointed as Grievances Redressal Officer who is a health care practitioner as defined in section 2.
- (3) The Grievances Redressal Officer shall; ensure the protection and enforcement of the patient's rights in the health care establishments, direct the concerned quarters to protect and enforce the patient's rights and, recommend action to the Commission against those who violate the rights of the patients defined in this Act.
- **27. Civil liabilities of the health care providers.-** (1) Every health care provider shall be liable to pay damages to the patient if his rights are violated and he suffered any financial loss due to the violation of his rights defined in this Act.
- (2) The patients shall have the right to claim damages for his suffering due to the commission or omission of the health care provider.

- (3) Nothing in this section shall prevent a patient from initiating a criminal proceeding against the person who has committed any offence, defined under this Act, against the patient.
- **28. Emergency health care services**.- (1) A health care provider, health worker or health establishment shall not refuse a person emergency medical treatment for any reason whatsoever.
- (2) Any person who contravenes the provisions of sub-section (1) shall be liable on conviction to a punishment prescribed by the Pakistan Penal Code (Act of 1860) for the offence and the damage, injury or loss caused to the patient.
- (3) Any person who contravenes the provisions of sub- section (1) and no offence under the Pakistan Penal Code (Act of 1860) is made out, than the person shall be punished with imprisonment of either description for a term which may extend to six months, or with fine which may extend to fifty thousand rupees, or with both.
- **29. Woman in childbirth.-** (1) No health care provider, health care practitioner or health care establishment shall refuse a woman in childbirth to designate a person to stay with her continuously during labor and delivery, and after delivery, to have her new-born baby placed in the same room with her.
- (2) Any person who contravenes the provisions of sub- section (1) shall be punished with imprisonment of either description for a term which may extend to one year, or with fine which may extend to one hundred thousand rupees, or with both.
- **30.** Taking away new born from mother. Whoever kidnaps, or steals, or takes away new born child from his mother with intent to, adopt, sell, secretly substitute a male child with a female child, secretly substitute a female child with a male child, secretly substitute children with the same sex, or for any other illegal purpose shall be punished with imprisonment for life and shall also be liable to fine which may extend to three million rupees.
- **31. Removing tissues, blood or blood product.-** Except as provided by law, whosoever, remove tissue, blood or blood product, whether replaceable by natural process or not, from the body of another person for any purpose without his informed consent and without lawful authority shall be punished with imprisonment of either description for a term which may extend to five years but which shall not be less than two years and shall also be liable to fine which may extend to one million rupees.

- **32. Removing organs from human body.-** Except as provided by law, whosoever, entrusted with the duties of health care practitioner, removes organ from human body without his informed consent or in contravention of law, shall be punished with imprisonment for life and shall also be liable to fine which may extend to three million rupees.
- **33. Manipulating genetic materials.-** Whosoever, manipulate any genetic materials, including genetic material of human gametes, zygotes or embryos; or engage in any activity including nuclear transfer or embryo splitting for the purpose of the cloning of human being, import or export human zygotes or embryos, shall be punished with imprisonment for life and shall also be liable to fine which may extend to three million rupees.
- **34. Practice by unqualified person**.- Whosoever, being not registered with the relevant registration authority and not qualified to provide health care services, provides health care services to the patients, be punished with imprisonment of either description for a term which may extend to ten years but which shall not be less than five years and with fine which may extend to one million rupees.
- **35**. **Offences to be non bailable and Cognizable.-** The offences under this Chapter shall be non-bailable and cognizable.

### CHAPTER V NATIONAL HEALTH CARE COMMISSION

- **36. National 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 National 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 by the said name sue and be sued.
- (3) The main office of the Commission shall be at Islamabad and may have such other regional offices as Government may establish.

- **37. Composition of the Commission.-** (1) The Commission shall consist of ten members with four of its members as official members and six members shall be from private sector as non-official members.
- (2) The official members of the Commission shall include representatives from Ministry of National Health Services and Coordination, representative from Ministry of Interior and Narcotics Control, representatives from Pakistan Medical and Dental Council 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 consumers or patients, which shall be appointed and notified by Government.
- (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 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.
- **38. 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 and in the case of equality of votes; the Chairperson shall have a second or casting vote.
- **39. 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) make sure the 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;
- (I) 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) take measures to protect and enforce the rights of the patients;
- (r) create awareness among the public about their rights as patients;
- (s) take action on the complaint of the patient and on the recommended action of the Grievances Redressal Officers; and
- (t) 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, namely:-
  - (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) The Government may, as and when it considers necessary, advice the Commission on matters of policy.
- **40. Committees.-** The Commission shall establish the following committees and may establish other committees for assistance and advice to the Chief Executive Officer 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;
  - (iv) Grievances and Complaints Committee; and
  - (v) Continuous Quality Improvement Committee.
- **41. 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 position of the Commission;
- (f) act as spokesperson and advocate of the Commission; and
- (g) provide leadership to the senior management and direction to all staff.
- (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.
- **42. Disqualifications of Chief Executive Officer.-** A person shall not be appointed or hold office as Chief Executive Officer who,-
  - 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.

**43. 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 VI REGULATION OF HEALTH CARE SERVICES

- **44. Registration and licensing.-** (1) The Commission shall be responsible for registration of health care establishments and shall issue licence defining scope and extent of services to be provided by such health care establishments.
- (2) A private health care establishment shall not provide health care services without being registered and licensed 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 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 any other law shall be deemed to be registered under this Act and shall renew 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 establishments, with scope and extent of services, to the Commission for regulation.
- (5) The registering and licensing 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 licensing, 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 VII COMPLAINT, INSPECTION AND INVESTIGATION

- **45. 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.
- **46. 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.

# **47. 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.

- **48. 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.
- **49. 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.
- **50. 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.
- **51. 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 VIII EMPLOYEES, FUND, BUDGET AND ACCOUNTS

- **52. 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.
- **53. 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).
- **54. Fund.** (1) There shall be a Fund to be known as the National 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 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.
- **55. 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.
- **56. 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 ninety 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 IX MISCELLANEOUS

- **57. Assistance to the Commission.-** All Law Enforcement Agencies of Government shall provide assistance to the Commission.
- **58.** 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).
- **59. 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.
- **60. 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.
- **61. 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.

**62. 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.

#### STATEMENT OF OBJECTS AND REASONS

The regulation of health care services is one of the most important duties of the States. In modern era, no State can absolve from providing quality health care services to the patients. Quality health care service is the fundamental right of every citizen in a State. Unfortunately the health care services in Pakistan have no regulated framework in which the rights of the patient can be protected. Patients become victims of carelessness and criminal negligence of the health care practitioners without having any remedy against them. In some cases, patients even die in the presence of health care practitioners and they don't care for them. In Pakistan, no rights of the patients have been defined. Even there exist no regulatory body in Islamabad which may regulate the health care services, protect the rights of the patients and regulate the health care establishments. This Bill is a comprehensive document consists on the patient's rights, his obligation, grievances redressal mechanism, punishment for offences against the patients and establishment of National Health Care Commission. The Bill will; protect the patients' rights, ensure quality health care services to them and, regulate the health care establishments, health care practitioners and health care providers.

The Bill has been designed to achieve the aforesaid objectives.

**SENATOR MOHAMMAD AZAM KHAN SWATI** 

Member-in-Charge

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