

The Balochistan Clinical Laboratories Regulatory Authority Ordinance, 2001

ORDINANCE XLV OF 2001

An Ordinance to provide for the establishment of Balochistan Clinical Laboratories Authority in the Province of Balochistan

[Gazette of Balochistan, Extraordinary, 3rd November, 2001]

No.Legis.2-92/Law/98, dated 3-11-2001.--The following Ordinance made by the Governor of Balochistan on 27th October, 2001, is hereby published for general information:---

Preamble.---Whereas, it is expedient to provide for the establishment of Clinical Laboratories, and matters connected therewith or ancillary thereto, in the Province of Balochistan, in the manner hereinafter appearing;

And whereas, the Governor of Balochistan is satisfied that circumstances exist which render it necessary to take immediate action;

Now, therefore, in pursuance of Article 4 of the Provisional Constitution (Amendment) Order, 1999 (Chief Executive's Order No.9 of 1999) and in exercise of all powers enabling him in that behalf, the Governor of Balochistan is pleased to make and promulgate the following Ordinance:---

1. Short title, extent and commencement ---(I) This Ordinance may be called The Balochistan Clinical Laboratories Regulatory Authority Ordinance, 2001.

(2) It extends to the whole of the province of Balochistan.

(3) It shall come in to force at once.

2. Definitions. In this Ordinance, unless the context otherwise requires, the following terms shall have the meaning hereby respectively assigned to them that is to say:---

(a) "Accreditation" means the process of officially recognizing registering, categorizing, and licensing a Clinical Laboratory;

(b) "Accredited Clinical Laboratory" means a Clinical Laboratory officially recognized and licensed to provide clinical laboratory services in the provinces, guaranteed to provide a certain level of professional quality according to its recognized category;

(e) "Authority" means the Balochistan Clinical Laboratory Regulatory Authority;

(d) "Clinical Laboratory" means any premises or unit independent or in a clinical or hospital building where practice of pathology or one or more of its recognized disciplines is carried out. But it does not include a unit or premises independent or in a clinic or hospital building where practice of other diagnostic disciplines of medicine like radiology etc, is carried out;

(e) "Department" means a specialized unit in an institution clinic, or hospital, which is specifically undertaking the practice of the discipline of pathology or one of its sub disciplines;

(f) "Licensee" means a Clinical Laboratory duly issued a Licence to operate by the Authority in the Province;

(g) "Medical Practitioner" means a Physician or such other person who is trained and holds qualifications and is recognized for the purpose of providing medical care to a patient and practice of medical science in Pakistan, by an official body such the Pakistan Medical and Dental Council, or equivalent Provincial body.

(h) "Pathologist" means a qualified physician with necessary postgraduate qualification recognized by the Pakistan Medical and Dental Council to practice the discipline of Pathology;

(i) "Pathology practice" means the practice of the discipline of medical science, which reveals with the analysis, and testing of human tissues excrements, body fluids, etc., for the purpose of diagnosis of disease or medial assessment of a human being. The main sub disciplines of the subject of Pathology include Histopathology, Chemical Pathology, Hematology, Clinical Hematology and Transfusion Medicine, Microbiology, and Immunology;

(j) "Physician" means a medical graduate holding M.B.B.S. or equivalent qualification recognized by the Pakistan Medical and Dental Council. But it also includes a qualified Dental Graduate holding B.D.S. or equivalent qualification recognized by the Pakistan Medical and Dental Council. It also includes postgraduate doctors in any discipline recognized for practice of medical science by the Pakistan Medical and Dental Council.

(k) "Province" means the Province of Balochistan;

(l) "Government" means the Government of Balochistan;

(m) "Regulations" means regulations made under this Ordinance;

(n) "Rules" mean rules made under this Ordinance.

3. General Provision. ---(1) The aim and objective of the Authority is to undertake all

measures insofar as possible, to ensure safety, protection, and promotion of human life through:---

- (a) a comprehensive, and quality Clinical Laboratory services in the Province;
- (b) ensuring a perpetual and sustained development of such services in the province to an internationally acceptable standards for such services;
- (c) and by regulating the costs of these services in such a manner which is mutually beneficial and affordable for the public and the provider of such services.

(2) Every Physician, Medical Practitioners, or any other person qualified to do so, will ensure that the clinical tests required for medical reasons, are undertaken by a Clinical Laboratory which has been duly licensed, and is accredited under this Ordinance:---

Provided that in case of emergency or a special situation, where question of saving injury to a human life occurs, and an accredited Laboratory is not available Clinical Test may be performed by a laboratory not accredited to undertake such test in a manner prescribed under the rules.

4. Establishment of Authority. ---(1) As soon as may be, but not later than thirty days after commencement of this Ordinance, the Government shall by Notification in the official gazette, establish an authority to be known as the Balochistan Clinical Laboratories Regulatory Authority, comprising of a Chairman, and other members, as prescribed hereunder:---

- (a) The- Secretary Health to the Government of Balochistan, shall be ex-officio Chairman of the Authority;
- (b) The Director General,- Health Service Balochistan, will be an ex-officio member;
- (c) A duly qualified member of the teaching faculty of Provincial Medical Education Institution, in the Province/sub-specialties of Pathology, not below the rank of Assistant Professor, shall be member, and function as Secretary or Authority;
- (d) A duly qualified member of the teaching, faculty of the Provincial Medical Education Institutions, in the subject of Pathology, from sub-specialties other than the member appointed under clause '(b)' not below the rank of Assistant Professor, shall be a member;
- (e) Two formally qualified Pathology, with at least 10 years professional experience, from the Specialist cadre in the Provincial health services, to be nominated by the Director General, Health Services shall be members to the Authority;
- (f) A representative of Clinical Laboratories in the private sector, who is a qualified Pathologist, to be nominated by the Government, shall be member,---

(g) Two representatives of Clinical Laboratories in the private sector, who is Medical Laboratory Technologist and at least holding recognized Medical Laboratory Technologist level qualification such as M.Sc. or B.Sc. in Medical Laboratory Technology or recognized equivalent qualification, to be nominated by the authority, shall be a member;

(2) Notwithstanding anything contained in this Ordinance every member shall have at least 10 years of relevant professional experience to his/her credit.

(3) Notwithstanding anything repugnant to the provisions laid down in subsection (3), every pathologist member of the Authority shall have at least 10 years of professional experience to his/her credit, after acquiring postgraduate qualification.

(4) A member shall, excluding the Chairman, unless he resigns or is removed from office earlier as hereinafter provided, hold office for a term of four years and shall be eligible for reappointment for a similar term.

(5) No act or proceedings of the authority shall be invalid by reason only of the existence of a vacancy in, or defect in, the constitution of the Authority.

(6) The Principal office of the authority shall be at Quetta and it may at such place or places, as the Authority may deem.

(7) There shall be a Vice Chairman of the authority, to be designated by the Authority from among its regular members, on rotation. The tenure of the Vice-Chairman shall be for a period of one year.

(8) In case of a vacancy, or vacancies occurring due to any reasons, the Government shall appoint a member on recommendation of the Authority.

(9) In line with the provisions of clause (c,) of subsection (1) of section 4 of the Ordinance to facilitate the working and initiation of the Authority, the first member/secretary to the Authority will be the member of the teaching faculty in Haemathology.

5. Resignation of members.---A member may resign from his office by removal submitting his resignation to the Government, or he may be removed from being a member to the Authority by the Government, if he is found unable to perform the functions of his office because of mental or physical incapability or misconduct.

6: Chairman etc., to be Public Servants.---The Chairman, members, staff, experts, consultant, advisors, and other employees of the Authority, when acting or purporting to act in pursuance of any of the provisions of this Ordinance or rules and regulations made hereunder, shall be deemed to be public servants within the meaning of section 21 of Pakistan Penal Code, 1860 (Act XLV of 1860).

7. Staff and advisors, etc.---(1) To carry out the purposes of this' Ordinance the Authority, in consultation with the Government, may from time to time, employ officers, members of its staff, experts, consultants, advisors, and other employees on such terms and conditions as may be prescribed in the rules.

(2) The Authority may seek assistance of qualified Pathologists, or a person deemed fit for the assignment by the Authority, as Evaluators, as prescribed in the rules, to investigate, verify, or to undertake any other task assigned by the Authority. The Evaluators will be eligible to receive remuneration for his/her professional services, to be determined by the Authority:---

Provided that in case of prejudice, or valid apprehension of any, other discrimination by any Evaluator, an incumbent being inspected may register complaint - with the Authority, which will dispose the matter as prescribed in the rules.

8. Meetings of the Authority. ---(1) The Secretary to the Authority on the directions of the Chairman shall call the meetings of the Authority the Authority shall, however, meet at least once in each quarter.

(2) The quorum for meetings in which a decision is to be taken shall be 3/4th of total of working members of the Authority.

(3) In the absence of Chairman the meetings shall be presided by the Vice-Chairman.

(4) All decisions of the Authority shall be taken by majority of members present, and in case of a tie, the Presiding Officer shall exercise a casting vote.

(5) All orders, determinations, and decisions of the Authority shall be taken in writing and shall identify the determination of the Chairman and each member.

9. Funds.---The Authority shall be funded from:---

(a) Grants from the Provincial Government, including initiating grants; and

(b) Fees and fines collected by it prescribed under the rules.

10. Accounts.---(1) The Authority shall maintain complete and accurate books of accounts of its actual expenses and receipts.

(2) The Accounts of the Authority shall be audited annually by the Directors Audit Balochistan.

11. Power to prescribe fee issue licences and grants.---(1) Notwithstanding anything repugnant to the provisions of this Ordinance, the Authority shall have powers, to be exercised in the manner prescribed in the rules, to register, and grant, extend, modify,

amend, suspend, or revoke a license in respect of creation, operation, and any other related matter, of a Clinical Laboratory in the Province:---

Provided that, in case of Clinical Laboratories in the public sector, the Authority shall determine special manner, standards, and conditions for issue and operation of licences to the public sector facilities, to be prescribed under the rules and to ensure that all receipts of fees are properly documented.

(2) All applications for the grant of any licence shall contain such information and be in such format as may be prescribed by the rules.

(3) A licence issued by the Authority shall be subject to such terms, conditions, restriction, or category, as may be prescribed by the Authority. The Authority shall have exclusive powers to grant Accreditation Status to all clinical laboratories in the Province:---

Provided that the Authority shall grant Accreditation status to any clinical laboratory on recommendations of its accreditation committee constituted under section 12:---

Provided further that, grant of accreditation status to a clinical laboratory does not allow any practice by such a clinical laboratory, which would be a contravention to the provisions of section 13.

(4) After commencement of this Ordinance a grace period of six calendar months, or as may be determined by the Authority, will be allowed for all Clinical Laboratories to be registered with and obtain a valid license from the Authority, after which no clinical laboratory shall work without such licence.

12. Accreditation Committee. ---(1) As soon as may be, but not later than thirty days, after its being established the Authority shall notify an Accreditation Committee comprising of a Chairman, and three members, to be nominated by the Authority.

(2) The Accreditation Committee will dispose its business in a manner as may be prescribed in the rules.

13. Power and functions of the Authority. ---(1) The Authority shall have the following powers and functions, to be exercised under this Ordinance:---

(a) Prescribe, review, approve, and regulate fees and charges pertaining to Clinical Laboratory services;

(b) Monitor and enforce compliance by licensees with conditions of their accreditation and licence;

(c) Protect interests of the patients and public, in accordance with the provisions of this Ordinance and the rules;

(d) Resolve complaints and other claims against licensees for contravention of the provisions of this Ordinance or the rules;

(e) Resolve problems and other issues to ensure smooth implementation of this Ordinance, and achievement Wits objectives for protection of human health;

(f) Formulate sub-committees and assign appropriate persons as their members to undertake any tasks consequential to the realization of the health protection and promotion objectives- of this Ordinance;

(g) Prescribe a uniform reporting system for professional services performed, and accounting by the Clinical Laboratories in the Province;

(h) Impose fines for contravention of the provisions of this Ordinance, as under the rules;

(i) Prescribe and collect licence fees and other charges in respect of any of its functions at such rates as may be determined from time to time, as prescribed in the rules;

(j) Safeguard the health interests of the patient and the public;

(k) Develop and implement training programmes to improve Clinical Laboratory Services in the Province.

(l) Undertake mass awareness and public education Clinical Laboratory Services by the public and the medical Professions:---

(m) Tender technical advice to the Government and authorities concerned to improve Clinical Laboratory Services in the Province, and on all such matters as may be required of it;

(n) Exercise all such powers as may be incidental of consequential to the performance of any of its functions or the exercise of any of its powers; and

(o) Undertake any assignment directed by the Government.

(2) In performing its functions under this Ordinance, rules and regulations, the Authority shall, as far as practicable, protect the interest of the patients and the public, and the providers of Clinical Laboratory services, in accordance with the Health Policy and guidelines for the time being in force, not inconsistent with the provisions of this Ordinance.

14. Relation with; Balochistan Hospital Regulatory Authority.-- Notwithstanding any, powers under this Ordinance, rules, and regulations, the Authority shall work in

close collaboration, and shall abide by the provisions of operational policy guidelines issued by the Balochistan Hospital Regulatory Authority:---

Provided that in case of conflict with the Balochistan Hospital Regulatory Authority the Chairman of the Balochistan Hospital Regulatory Authority shall constitute a Special Committee to resolve such a conflict. The Special Committee shall decide such a case within thirty days, and the decision of such a Special Committee shall be final and binding.

15. Offences, Penalty and Procedures. --- (1) Whoever, himself or by any other person on his behalf, or by any person under his supervision contravenes any of the Provisions of this Ordinance or any Rules or any Regulations framed under this Ordinance, shall be punished with suspension or cancellation of the licence in respect of such a Clinical Laboratory in respect of which the contravention occurred, and with fine which may extend to rupees five hundred thousand or an imprisonment with a term which may extend up to three years or both.

(2) Whoever himself or by any other person on his' behalf, or by any person under his supervision, willfully or recklessly undertakes any act which contravenes any of the provisions of this Ordinance or any rules or any regulation promulgated under this Ordinance, and thereby causes physical injury to the person of another, he shall be guilty of an offence punishable with imprisonment for a term which may extend to five years, or with fine up to Rupees ten hundred thousand or both.

(3) If any person himself or by any other person on his behalf, without lawful excuse, does any act with the intention of, interfering, without authorization, with the operations carried out for the purposes of this Ordinance, or by any licensee, and thereby causes damage to any facility equipment, material, patient or person, such a person shall be guilty of an offence punishable with imprisonment for a term which may extend to three years, or with fine up to rupees five hundred thousand, or with both.

(4) If any person himself or by other person on his behalf, or by any person under his supervision, conceals or connives to conceal, or falsely presents, or connives to falsely present any records, material, procedure, or situation, without lawful excuse, or obstruct an Evaluator, from accessing records, material, or other relevant evidence, in case of an investigation of contravention of the provisions of this Ordinance, rules, or regulations, he will be guilty of an offence punishable with imprisonment for a term which may extend to two years, or with fine up to rupees three hundred thousand, or with both.

(5) Whoever, having been committed an offence under this Ordinance, rules, or regulations, is again commits the same offence under this Ordinance, rules, or regulations, shall be punishable with imprisonment which may extend to five years, or with fine up to, rupee's ten hundred thousand, or with both.

(6) Where a person is found guilty of an offence under this Ordinance, rules, or regulations, is a company, group practice, hospital, department, corporation, firm or institution, every director, partner, and employee, of company, group practice, hospital, department, corporation, firm, or institution, unless he proves that the offence was committed without his knowledge or consent, be guilty of the like offence.

(7) If any person is convicted of an offence under this Ordinance, rules, or regulations, it shall be lawful for the Authority to cause the offender's name, place of residence, place of business, the offence which has been convicted, and the penalty inflicted upon him, to be published at the expense of such person in such newspaper or in such other manner as the Authority may direct:---

Provided that, the expenses of such publication shall be recoverable in the same manner as a fine is recoverable.

(8) Where any person has been convicted of an offence under this Ordinance, rules of regulations, it will be lawful for the equipment used, and any other related materials, in respect of which contravention has been made, to be confiscated to the Provincial Government. To be disposed of in a manner, decided by the provincial Government.

16. Cognizance of offence.---(1) No Court shall take cognizance of any offence punishable under this Ordinance; rules, or regulations, except on a complaint in writing by the Authority or by a person authorized by the Authority in this respect, and notified in the official Gazette.

(2) The provisions of Chapter XX of the Code of Criminal Procedure, 1898 (Act V, of 1898), shall apply to the trial of offences punishable under this Ordinance.

17. Power to make rules.---The Authority may, with the approval of the Government and by publication in the official Gazette, make rules to carry out the purposes of this Ordinance.

18. Power to make regulations. ---(1) The Authority may by notification in the official Gazette, make regulations not inconsistent with the provisions of this Ordinance or the rules made thereunder for carrying out its functions.

19. Immunity.---Except as expressly provided in this Ordinance, no criminal or other legal proceedings shall lie against the Authority, the Chairman, or any Member, or a member of any of its Committees, or Evaluators, or employee of the Authority, for anything which is, in good faith done or intended to be done in pursuance of this Ordinance or of any rule or order, made thereunder:---

Provided that the unscrupulous actions of the Authority the Chairman, or any Member, or a member of any of its Committees, or Evaluators, or employee of the

Authority, taken under this Ordinance, which may cause injury or damage to any person shall not be indemnified.

20. Relationship to other Laws.---The provisions of this Ordinance shall be in addition to. and not in derogation of any other law for the time being in force.

21. Sum payable to the Authority to be recoverable as land revenue arrears.---All sums payable to the Authority in accordance with provisions of this Ordinance, rules, and regulations, shall be recoverable as arrears of land revenue.

22. Removal of difficulty. ---If any difficulty arises in giving effect to any of the provisions of this Ordinance, the provincial Government may make such order, not inconsistent with the provisions of this Ordinance, as may appear to be necessary for the purpose of removing the difficulty.

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