

THE BALOCHISTAN CLINICAL LABORATORIES
REGULATORY AUTHORITY
ORDINANCE, 2001

(Baln. Ordinance XLV of 2001)

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'THE BALOCHISTAN CLINICAL LABORATORIES
REGULATORY AUTHORITY
ORDINANCE, 2001

(Baln. Ordinance XLV of 2001)

[3 November, 2001]

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

Preamble. WHEREAS, it is expedient to provide for the
establishment of Clinical Laboratory, 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 exercise of all powers
enabling him in that behalf, the Governor Balochistan is pleased
to make and promulgate the following Ordinance:—

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

commencemen

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

Balochistan.

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

Definitions. 2. 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

1 This Ord. was promulgated by the Governor of Balochistan on 27" October, 2001; published in the Balochistan Gazette

(Extraordinary) No. 179, dated 31 November, 2001. Declared continue to be in force by Article 270 A of the Constitution of the
Islamic Republic of Pakistan (1974).

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licensed to provide clinical laboratory services in the province, guaranteed to provide a certain level of professional quality according to its recognized category;

"Authority" means the Balochistan Clinical Laboratory Regulatory Authority;

"Clinical Laboratory" means any premises or unit independent or in a clinic 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;

"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;

"Licensee" means a Clinical Laboratory duly issued a License to operate by the Authority in the Province;

"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 as the Pakistan Medical and Dental Council, or equivalent Provincial body.

"Pathologist" means a qualified physician with necessary postgraduate qualification recognized by the Pakistan Medical and Dental Council to

practice the discipline of Pathology;

"Pathology practice" means the practice of the discipline of medical science, which deals 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, Haematology, Clinical

Haematology and _ Transfusion Medicine,
Microbiology, and Immunology;

(j) "Physician" means a medical graduate holding MBBS or equivalent qualification recognized by the Pakistan Medical and Dental Council. But it also includes a qualified Dental Graduate holding BDS 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" mean regulations made under this Ordinance;

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

General Provision. 3. (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 Practitioner, 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

Establishment of
Authority.

Tests may be performed by a laboratory not accredited to undertake such test in a manner prescribed under the rules.

4. (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:—

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The Secretary Health to the Government of Baluchistan, shall be the ex-officio Chairman of the Authority;

The Director General, Health Services Balochistan will be an_ ex-officio member;

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 of Authority;

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;

Two formally qualified Pathologist, 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;

A representative of Clinical Laboratories in the private sector, who is a qualified Pathologist, to be nominated by the Government, shall be member;

Two representatives of — Clinical

Resignation and of
members.

Laboratories in the private sector, | who is a Medical Lab Technologist, and at least holding recognized Medical Lab, Technologist level qualification such as M.Sc. or B.Sc. in Medical Lab, 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 sub-section (2), 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 proceeding 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 set-up sub-offices at such place or place, as the Authority may deem appropriate.

(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 reason, the Government shall appoint a member on recommendation of the Authority.

(9) In line with the provisions of clause (c) of sub-section (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 Haematology.

5. A member may resign from his office by removal

submitting his resignation to the Government, or he may be

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Chairman etc., to be
public.

Staff and advisors,
etc.

Meetings of the
Authority.

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. The Chairman, members, staff, experts, consultants, 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. (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. (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 3/4" 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

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Funds.

Accounts.

Power to prescribe
fee issue
licenses and
grants.

Authority shall be taken in writing and shall identify the determination of the Chairman and each member.

9. The Authority shall be funded from:

- (a) Grants from the Provincial Government, including initiating grant; and
- (b) Fees and fines collected by it as prescribed under the rules.

10. (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 Director Audit Balochistan.

11. (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 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 licenses 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 license shall contain such information and be in such format as may be prescribed by the rules.

(3) A license 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 be
such a clinical laboratory, which would be a contravention to

Accreditation
Committee.

Power and
functions of the
Authority.

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 a license.

12. (1) As soon as may be, but not later than thirty days, after it 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. (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 license;

(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 of its 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

Relation with
Balochistan
Hospital
Regulatory
Authority.

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accounting by the Clinical Laboratories
in the Province;

Impose fines for contravention of the
provisions of this ordinance, as under the
rules;

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

Safeguard the health interests of the
patients and the public;

Develop and implement training,
programmes to improve Clinical Lab,
Services in the Province;

Undertake mass awareness and public
education Clinical Laboratory services by
the public and the Medical Professions;

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;

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

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 interests 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. Notwithstanding any powers under this Ordinance, rules, and regulations, the Authority shall work in close collaboration, and shall abide by the provisions and operational policy guidelines issued by the Balochistan Hospital Regulatory

Offences, Penalty
and
Procedures.

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. (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 license 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 rule 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 any 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

Cognizance of
Offence.

Power to make
rules.

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 committed an offence under this Ordinance, rules, or regulations, 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 rupees Ten Hundred Thousand, or with both.

(6) | Where a person is found guilty of an offence under this Ordinance, rules or regulations, is a 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.

(7) Where any person has been convicted of an offence under this Ordinance, rules or 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 off in a manner decided by the Provincial Government.

16. (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. 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.

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

Immunity. 19. Except as expressly provided in this Ordinance, no

Criminal or other legal proceedings shall lie against the Authority, the Chairman, or an member, or 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 there under:

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.

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

Sum payable to the 21. All sums payable to the Authority in accordance with Authority to be provisions of this Ordinance, rules, and regulations, shall be

recoverable as recoverable as arrears of land revenue.
land revenue

arrears.

Removal of 22. If any difficulty arises in giving effect to any of the difficulty. 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.