AZAD GOVERNMENT OF THE STATE OF JAMMU AND KASHMIR
LAW AND PARLIAMENTARY AFFAIRS SECRETARIAT,
MUZAFFARABAD

Dated: 8th November, 2019

No. LD/Legis-Act/259-270/2019.The following Act of Assembly received the assent of the President on the 4th day of November 2019, is hereby published for general information.

(ACT XIX OF 2019)

An
Act

to provide for the establishment of Clinical Laboratories Authority in the Azad Jammu and Kashmir

WHEREAS laboratories are an essential and fundamental part of all health care system and laboratory testing results greatly affect critical decisions concerning well-being of individuals and health security.

AND WHEREAS, at present there is no mechanism for the registration and licensing of laboratories both in public and private sector. Most of the laboratories in private sector are being run by the unqualified persons and un-validated lab results posing great threat to the well-being and life of patients. Therefore, urgent need of registration and licensing of laboratories in AJ&K is required, so that the authorized, well-equipped and qualified staff could only run clinical laboratories;

AND WHEREAS, it is expedient to provide for the establishment of Clinical Laboratories, and matters connected therewith or ancillary thereto, in the manner hereinafter appearing;

It is hereby enacted as follows:-

1. **Short title, extent and commencement**.- (1) This Act may be called the Azad Jammu and Kashmir Clinical Laboratories Regulatory Authority Act, 2019.

(2) It extends to the whole of Azad Jammu and Kashmir.

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

2. **Definitions.** In this Act, unless the subject or 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 as per minimum standards laid down in Section 14 of this Act;

(b) **"Accredited Clinical Laboratory"** means a registered Clinical Laboratory to provide clinical laboratory services in the Azad Jammu and Kashmir, to a certain level of professional quality according to its recognized category;

(c) **"Authority"** means the Azad Jammu and Kashmir Clinical Laboratory Regulatory Authority, established under this Act;

(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 whether in public or private sector, 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 of Pathology"** 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) **"Government"** means the Azad Government of the State of Jammu and Kashmir;

(g) **"License"** means a license duly issued by the authority to a Clinical Laboratory established in pursuant to the provision of this Act, to operate in the Azad Jammu and Kashmir;

(h) **"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 by an official body such as the Pakistan Medical and Dental Council.

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

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

(k) **"Physician"** means a medical graduate holding Bachelor of Medicine and Bachelor of Surgery or equivalent qualification recognized by the Pakistan Medical and Dental Council and it also includes a qualified Dental Graduate holding Bachelor of Dental Surgery (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;

(l) **"Prescribe"** means prescribed by rules or regulations made under this Act;

(m) **"Regulations"** means regulations made under this Act;

(n) **"Rules"** mean rules made under this Act;

(o) **"Secretary"** means the Secretary of the Clinical Lab Authority; and

(p) **"Standards"** means the minimum service delivery standards provided in this Act or as prescribed under this Act.

3. **General Provision.-** (1) The aim and objective of the Authority is to undertake all measures in so far as possible, to ensure safety, protection, and promotion of human life through,-

(a) a comprehensive, and quality Clinical Laboratory services in the Azad Jammu and Kashmir both in public and private sector;

(b) ensuring a perpetual and sustainable development in the Azad Jammu and Kashmir to attain an internationally recognized standards for such services; and

(c) regulating the cost fee of these services in such a manner which is just and equitable as well as affordable for the public and within the cost justified of the services provider.

(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 Act:

Provided that if a Medical Practitioner found that a Clinical Laboratory is providing its services without being registered with the Authority, he shall be responsible to report the Authority forthwith.

4. **Establishment of Authority.-** (1) As soon as may be, but not later than thirty days after commencement of this Act, the Government shall by Notification in the

official gazette, establish an Authority to be known as the Azad Jammu and Kashmir Clinical Laboratories Regulatory Authority, comprising of a Chairman, and other members, as prescribed hereunder:-

(a) the Secretary Health shall be ex-officio Chairman of the Authority;

(b) the Director Health Services shall be ex-officio Member of the Authority;

(c) a senior Pathologist shall be Member-cum-Secretary of the Authority;

(d) two Pathologist from the Specialist cadre in the health services, shall be members of the Authority.

(e) one member from Teaching Faculty of AJ&K Government Medical Colleges;

(f) one representative of Clinical Laboratories in private sector who is qualified Pathologist on honorary basis.

(2) Notwithstanding anything repugnant to the provisions laid down in sub-section (1), every Pathologist Member of the Authority shall have at least 10 years of professional experience to his relevant field.

(3) Every Member of the Authority (except Chairman) shall be appointed for a renewable period of three years, unless he resigns or removes from office in the manner provided hereinafter.

(4) Any proceeding of the Authority shall not be called in question or declared invalid by reason that any Member is not present or any person who was not Member took part in the proceedings only of the existence of a vacancy in, or any defect in the constitution of the Authority.

(5) The Principal office of the authority shall be at Health Department Muzaffarabad, and it may establish

divisional offices at such other place or places, as the Authority may deem fit or appropriate.

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

5. **Resignation, Removal of Members.-** A Member of the Authority may by writing under his hand addressed to the Government, resign from his office, or may be removed from his office by the Government on the ground of physical or mental incapacity or on the basis of misconduct under the Removal from Service (Special Powers) Act, 2001 or any other disciplinary law for the time being in force.

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 Act or rules and regulations made hereunder, shall be deemed to be public servants within the meaning of Section 21 of Azad Penal Code, 1860 (Act XLV of 1860).

7. **Staff and Advisors, etc.-** To carry out the purposes of this Act, the Authority, in consultation with the Government, may from time to time, assign additional duties to the officers, staff, experts, consultants, advisors, and other employees of Health Department.

8. **Meetings of the Authority.-** (1) The Secretary of the Authority shall summon the meeting of the Authority on the direction of Chairman on such place which he deems fit. There shall be at least four meetings of the Authority in every year and three months shall not intervene between the meetings of the Authority.

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

(3) In the absence of Chairman the meetings shall be presided by the person nominated by the 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 and decisions of the Authority shall be taken in writing.

9. **Fund.-** There shall be established a separate Fund of the Authority and all fees and fines shall be credited in the Fund, which shall be regulated in the prescribed manner.

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 Directorate Audit, Azad Jammu and Kashmir.

11. **Power to issue license and grants.-** (1) Notwithstanding anything repugnant to the provisions of this Act, the Authority shall have powers, to be exercised in the manner prescribed in the rules, to register, 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 Azad Jammu and Kashmir:-

Provided that, in case of Clinical Laboratories in the public as well as private sector, the Authority shall determine special manner, standards, and conditions for issuance and operation of license to the public and private sector facilities, to be prescribed by rules made under this Act, and to ensure that all receipts of fees are properly documented and audited.

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

(3) A licence issued by the' Authority shall be subject to such terms, conditions, restriction, or category, as may be prescribed. The Authority shall have exclusive

powers to grant Accreditation Status to all clinical laboratories in the Azad Jammu and Kashmir:

Provided that the Authority shall grant Accreditation Status to any clinical laboratory on recommendations of 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 in contravention to the provisions of Section 13 and 14.

(4) After commencement of this Act, a grace period of six calendar months, 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 in private sector.

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, who shall be a technical member of the Authority and three members, to be nominated by the Authority.

(2) The Accreditation Committee shall perform such business as may be prescribed.

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

(a) act as licensing and registering body for licensing clinical laboratories at both public and private sector in the Prescribed manner;

(b) monitor and regulate, fees and charges pertaining to Clinical Laboratory services both in public and private sector;

(c) issue a monitor and enforce compliance by licensees with conditions of their accreditation and license;

(d) Develop, implement and update the lab standards, scope and guidelines to improve clinical laboratory services;

(e) resolve complaints and other claims against licensees for contravention of the provisions of this Act or the rules;

(f) resolve problems and other issues to ensure smooth implementation of this Act, and achievement with objective for protection of human health;

(g) formulate sub-committees and nominate appropriate persons as their members to undertake any tasks consequential to the realization of the health protection and promotion objectives of this Act;

(h) prescribe a uniform reporting system for professional services performed by the Clinical Laboratories;

(i) impose fines for contravention of the provisions of this Act, as Prescribed under the rules;

(j) prescribe and collect license fees and other charges in respect of any of its functions at such rates, as may be Prescribed;

(k) safeguard the health interests of the patient and the public;

(l) develop and implement training programmes to improve Clinical Laboratory Services;

(m) undertake mass awareness and public education Clinical Laboratory Services programmes for the public and the medical Professionals;

(n) tender technical advice to the Government and authorities concerned to improve Clinical Laboratory Services in the Azad Jammu and Kashmir, and on all such matters as may be required of it;

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

(p) undertake any assignment directed by the Government; and

(q) inspection and monitoring of clinical laboratories either by the Authority or through the District Health Officer and a Pathologist in each District and in case of non-availability of the Pathologist then the person nominated by the Authority;

(r) cancel any license which has been obtained by fraud or misrepresentation;

(s) suspend any license if repeated cases of negligence have been reported or provisions of this Act or rules made under it have been violated.

(2) In performing its functions under this Act, rules and regulations, the Authority shall, as far as practicable, protect the interest of the patients, public, and the providers of Clinical Laboratory services.

14. **Minimum Clinical Laboratory Standards.-** The minimum standard and specification for registration and licensing of clinical labs shall be,-

(1) **Infrastructure**: The minimum standard of infrastructure of Lab shall be as under,-

(a) minimum 300 Sq feet with at least 3 partition i.e. waiting area, office and working area;

(b) adequate water taps, sinks, bath room, and drains;

(c) adequate emergency power;

(d) adequate electrical outlets;

(e) adequate ventilation;

(f) adequate lighting; and

(g) adequate temperature control.

(2) **Staff:**

(a) The director in-charge of the clinical laboratory shall be a qualified Pathologist.

(b) All technical staff of a clinical laboratory shall be competent and qualified from a recognized professional institution.

(3) **Equipment.-** Major lab equipment shall be FDA/CE(IVD) Certified,-

(a) the principal of equipment is matching with the tests performs; and

(b) regular maintenance and calibrations.

(4) **Lab Waste Management:**

(a) Effective waste management system shall be in place in accordance with National Lab Policy; and

(b) Lab biorisk management system shall in place.

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 Act or any rules or any regulations framed under this Act, 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 two hundred thousand or an imprisonment with a term which may extend up to six months or both.

(2) If any person himself or by any other person on his behalf, without lawful excuse, does any act with the intention of, interfering, obstructing or creating hurdle, while the operations carried out for the purposes of this Act or rules or regulations made thereunder, or by any licensee, inspection team 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.

(3) 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 Act, rules, or regulations, he shall 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.

(4) Whoever, having been committed an offence under this Act, rules, or regulations, again commits the same offence under this Act, 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.

(5) Where a person is found guilty of an offence under this Act, 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.

(6) If any person is convicted of an offence under this Act, 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 Act, rules or regulations, it shall be lawful for the equipment used, and any other related materials, in respect of which contravention has been made, to be confiscated in favour of the Authority which shall be disposed of by the Authority in the prescribed manners.

16. **Cognizance of offence.-** (1) No Court shall take cognizance of any offence punishable under this Act, 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 Act.

17. **Power to make regulations.-** The Authority after Government approval, may by notification in the official Gazette, make regulations not inconsistent with the provisions of this Act and the rules made thereunder, for carrying out its functions.

18. **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 Act.

19. **Immunity.-** Except as expressly provided in this Act, 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 Act 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 Act, which may cause injury or damage to any person shall not be indemnified.

20. **Appeal**.- (1) A person who is aggrieved by any of the following order of the Authority may file an appeal before the High Court,-

(i) refusal of the Authority to issue or renew a license;

(ii) decision of the Authority to suspend or revoke a license;

(iii) order of closing down of a Laboratory or making improvements in the Laboratory;

(iv) order relating to equipments, apparatus, appliances, or other things at a Lab; or

(v) imposition of fine by the Authority.

(2) The Clinical Laboratory as the case may be, within thirty days from the date of communication of the order of the Authority, shall have the right to prefer an appeal to the High Court.

21. **Act to override other laws, etc.-** The provisions of this Act shall have effect notwithstanding anything contained in any other law for the time being in force or in any instrument having effect by virtue of any such law.

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

23. **Removal of difficulties**.- If any difficulty arises in giving effect to any provision of this Act, the Government may make an order not inconsistent with the provisions of this Act to remove the said difficulty.

Sd/-
(Rashid Kaleem)
Deputy Secretary (Legislation)