

Tanzania

Private Health Laboratories (Regulation) Act Chapter 136

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Private Health Laboratories (Regulation) Act

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Private Health Laboratories (Regulation) Act

Chapter 136

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[Note: This legislation has been thoroughly revised and consolidated under the supervision of the Attorney General's Office, in compliance with the Laws Revision Act No. 7 of 1994, the Revised Laws and Annual Revision Act (Chapter 356 (R.L.)), and the Interpretation of Laws and General Clauses Act No. 30 of 1972. This version is up-to-date as at 31st July 2002.]

[G.N. No. 766 of 1997; Act No. 10 of 1997]

An Act to regulate the registration and management of private health laboratories managed by approved persons and in respect of private health laboratory services to be rendered by private health laboratories and for related matters.

Part I – Preliminary provisions (ss. 1-3)

1. Short title

This Act may be cited as the Private Health Laboratories (Regulation) Act.

2. Application

This Act shall apply to all private health laboratories, approved persons and to any other person engaged in the management of a private health laboratory, whether as an owner or as an employee of that private health laboratory.

3. Interpretation

In this Act, unless the context requires otherwise–

"**approved person**" means a registered health laboratory technologist or a pathologist approved by the Board to manage a private health laboratory in accordance with the provisions of this Act;

"**Assistant Registrar**" means Assistant Registrar appointed under section 8 of this Act;

"**Board**" means the Private Health Laboratories Board established under section 4 of this Act;

"**Minister**" means the Minister responsible for matters relating to medical and health services;

"**pathologist**" means a medical practitioner who holds/possesses a post graduate qualification in either clinical chemistry, haematology, histopathology, microbiology with parasitology and registered with the Medical Practitioners and Dentists Ordinance;

"**private health laboratory**" means any health laboratory registered by the Board to provide private health laboratory services in accordance with this Act;

"**private health laboratory services**" means services provided by a health laboratory to an individual and the community and includes chemistry; haematology and blood transfusions; histopathology and cytology; microbiology and immunology; parasitology and medical entomology and research, health education and the provision of laboratory investigations supplies;

"**registered health laboratory technologist**" means any duly qualified person who is for the time being authorised to practise the health laboratory profession by virtue of that person being registered or licensed under the provisions of the Health Laboratory Technologists Registration Act ¹;

"**Registrar**" means the Registrar of Private Health Laboratories appointed under section 8 of this Act.

Part II – Establishment and functions of the Board (ss. 4-8)

4. Establishment of Board

- (1) There is hereby established a board to be known as the Private Health Laboratories Board which shall, subject to the provisions of this Act, be responsible for the registration, control and regulation of private health laboratories.
- (2) The composition, appointment, tenure, quorum proceedings and meetings of the members of the Board, shall be as provided in the Schedule to this Act.
- (3) The Minister may by order in the *Gazette* amend any or replace the Schedule to this Act.
- (4) In appointing members of the Board, the Minister shall have regard to the need to appoint persons with such qualifications and experience in health laboratory technology and the conduct or management of public affairs as would enable members to effectively and fully contribute to the discharge of the functions of the Board.

5. Functions of Board

The functions of the Board shall be—

- (a) to receive, scrutinize—
 - (i) approve and register or
 - (ii) disapprove and not register,all applications for establishing private health laboratories within Tanzania;
- (b) to monitor or regulate all private health laboratories within Tanzania;
- (c) to receive, scrutinize—
 - (i) approve and register; or
 - (ii) disapprove and not register,all applications of approved persons to run or manage private health laboratories;
- (d) to keep and maintain a register for—
 - (i) private health laboratories; and
 - (ii) approved persons;
- (e) to carry out any other functions as may be deemed necessary under the provisions of this Act;
- (f) to hold regular meetings to deliberate on matters relating to private health laboratories; and

¹

6. Power of Board to approve persons and set fees

- (1) The Board shall have powers to approve or disapprove, any application by a person to establish or manage a private health laboratory under the provisions of this Act.
- (2) The Board shall by Order published in the *Gazette*, prescribe requirements which persons must fulfil in order to qualify for approval under this section.
- (3) The Board shall set fees payable by owners of private health laboratories which fees shall include—
 - (a) application fees;
 - (b) registration fees; and
 - (c) any other fees, as may be prescribed by the Board.
- (4) The funds collected under subsection (3) of this section shall be retained by the Board for the purpose of facilitating the activities and functions of the Board as are provided for by this Act.
- (5) The Board shall authorise a person appointed by the Board to inspect or search any private health laboratory registered in accordance with the provisions of this Act.
- (6) Where a person contravenes provisions of this Act, the Board shall warn, suspend or cancel a certificate of registration issued pursuant to the provisions of this Act.
- (7) Where the Board approves the registration of a private health laboratory or an approved person under this section, the Board shall issue a certificate of registration which shall,—
 - (a) be in writing and under the hand of the Registrar.
 - (b) subject to section 11 be valid for such period as may be specified by the Board in that certificate of registration and may be renewed; and
 - (c) not be transferable.

7. Revocation of certificate of registration

The Board may at any time and after assigning reasons, revoke any certificate of registration issued to a private health laboratory or to an approved person in accordance with section 7 if the Board is satisfied that the approved person—

- (a) has ceased to be eligible for approval under this Act; or
- (b) is no longer able to effectively and fully manage a private health laboratory.

8. Sources of funds of Board

- (1) The sources of funds of the Board shall be from—
 - (a) fees to be collected by the Board under this Act and to be kept by the Registrar;
 - (b) other moneys and assets as may vest in or accrue to the Board whether in the course of the exercise of functions of the Board or otherwise.
- (2) The accounts of the Board shall be audited in accordance with the provisions of the Exchequer and Audit Ordinance.

Part III – Appointment of Registrar and management of private health laboratories (ss. 9-12)

9. Appointment of Registrar and Assistant Registrar

- (1) The Minister shall appoint a public officer to be the Registrar of Private Health Laboratories and may appoint any other public officer to be an Assistant Registrar of Private Health Laboratories, as the Minister may deem fit.
- (2) The Registrar shall be the Secretary to the Board.
- (3) The Registrar shall perform all duties prescribed in relation to his office by or under this Act and shall discharge other functions and duties as the Board may direct or prescribed by regulations made under this Act.
- (4) The Assistant Registrar shall assist the Registrar in the performance of duties under this Act and may, under the direction of the Registrar, exercise any of the functions of the Registrar.

10. Duties of Registrar in relation to registered private health laboratories

- (1) The Registrar shall keep a register in the prescribed form in which the Registrar shall enter the name of every private health laboratory registered by the Board and such other particulars relating to a registered private health laboratory as the Registrar may consider relevant.
- (2) The Registrar shall delete or amend any of the particulars under subsection (1) as circumstances may require.
- (3) At least once every year the Registrar shall publish in the *Gazette*, or in any newspaper which circulates throughout Tanzania, a list of all private health laboratories the registration of which is still in force.

11. Registration and publication of particulars of approved persons

- (1) The Registrar shall keep a register in the prescribed form in which the Registrar shall enter the name of every approved person and such other particulars relating to the persons as the Registrar may consider relevant.
- (2) The Registrar shall delete from the Register or amend any of the particulars as circumstances may require.
- (3) The Minister shall, by order in the *Gazette* prescribe the form of register.
- (4) At least once every year the Registrar shall publish in the *Gazette* or in any newspaper which circulates throughout Tanzania, a list of all approved persons whose approval is still in force.

12. Restriction on management by private health laboratories

- (1) No person shall manage or cause to be managed a private health laboratory unless that person is an approved person.
- (2) No person shall manage a private health laboratory unless that person is an approved person who is registered under this Act and possesses a certificate of registration in respect of that private health laboratory.
- (3) Any person who contravenes the provisions of this Act commits an offence and is liable upon conviction to a fine of not less than fifty thousand shillings or to a term of imprisonment not exceeding two years or to both that fine and imprisonment.

Part IV – Registration of private health laboratories (ss. 13-15)

13. Identification of private health laboratory

- (1) For the purposes of enabling members of the public to identify a private health laboratory, the Board may give directions in writing requiring all private health laboratories to be identified by such means as it may prescribe in the directions.
- (2) Every approved person shall comply with the directions given by the Board under subsection (1).
- (3) A person shall be deemed to manage a private health laboratory under this Act if, for himself on behalf of any other person, that person actually renders or holds himself out as ready and willing to render health laboratory services.

14. Registration of private health laboratories

- (1) No person or approved person shall manage any private health laboratory unless that private health laboratory is registered under this section.
- (2) An application for the registration of a private health laboratory shall be made by the approved person or the owner to the Board.
- (3) An application made under subsection (2) shall be in writing, specifying the private health laboratory in respect of which the application is made setting out such other particulars relating to the approved person or to the private health laboratory as the Minister may by order in the *Gazette*, prescribe.
- (4) There shall be a separate application and if registered, a separate certificate of registration, in respect of each private health laboratory managed by the approved person.
- (5) The registration of a private health laboratory under this section shall become void upon the expiration of thirty days from the date of any change in the ownership or management of the private health laboratory.
- (6) Upon receipt of an application together with the prescribed fees for the registration of a private health laboratory under this section, the Board may or may not accept the application.
- (7) Where the Board approves the application, the Board shall direct the Registrar to register the private health laboratory specified in the application and issue a certificate of registration in the prescribed form to be prescribed by the Minister, by regulations published in the *Gazette*.
- (8) Where the Board issues a certificate of registration under subsection (7), the Board may or may not set conditions as the Board may prescribe under that certificate of registration.
- (9) Every original certificate of registration issued under this section in respect of a private health laboratory shall be displayed in a conspicuous position within the premises of the laboratory.
- (10) Without prejudice to the general power conferred upon the Board to accept or not to accept an application under this section, the Board may refuse to register a private health laboratory if the Board is satisfied that—
 - (a) the applicant is not an approved person or is not eligible for approval under this Act;
 - (b) the private health laboratory specified in the application is not under the charge of a private health laboratory technologist or an approved person who is able to effectively manage a private health laboratory of the description given in the application;
 - (c) for reasons connected with the location, construction, accommodation, staffing or equipment of the private health laboratory or of any premises used in connection with the private health laboratory, it is not up to the required performance standard to register the private health laboratory.

- (11) Any person who manages any private health laboratory which is not registered under this Act or any private health laboratory the registration of which has been cancelled or has ceased to have effect for any other reason, commits an offence and is upon conviction liable to a fine not less than twenty thousand shillings and not exceeding one hundred thousand shillings or to imprisonment for a term not exceeding two years or to both that fine and imprisonment.
- (12) An application for approval or renewal of approval under this section shall be made to the Board in writing specifying the name and address of the approved person the private health laboratory in respect of which the application is made, and setting out such other information as may be prescribed by any regulation made under this Act.

15. Cancellation of registration of private health laboratories

- (1) Where, in respect of any registered private health laboratory, the Board is satisfied—
 - (a) that the premises of the private health laboratory are no longer fit to be used as a laboratory by reason of their being kept in an unclean or insanitary condition; or
 - (b) that the performance standards made for the laboratory service of persons attending the laboratory is inadequate; or
 - (c) that the approved person responsible for the management of the laboratory has failed to comply with any regulations made under this Act relating to the staff accommodation or equipment to be provided at a private health laboratory or prescribing minimum standards of services to the persons attending the laboratory the Board may by notice in writing require the approved person to remedy to the satisfaction of the Board defects specified in the notice within such period as it may specify in the notice.
- (2) If the approved person fails to comply with the requirements of a notice under subsection (1) within the specified period the Board may, after calling upon the approved person to show cause why the registration of the health laboratory should not be cancelled, cancel the registration.

Part V – General provisions (ss. 16-21)

16. Inspection and search

- (1) The Registrar of Private Health Laboratories and Assistant Registrar of Private Health Laboratories or any other public officer authorised by the Board in writing for that purpose may if it has reasonable cause to believe that laboratory services being given on any premises used as a private health laboratory, demand that the person in charge of those premises shall allow him free entry to premises and afford him all reasonable facilities to ascertain whether the private health laboratory service is being rendered in accordance with the provision of this Act or of the regulations made under it.
- (2) If the officer after producing proof of his authority to any person who may reasonably require that proof, is unable to gain entry to the premises without unreasonable delay or inconvenience, he may enter the premises without warrant and inspect them to ascertain the matters specified under subsection (1).

17. Offences by approved persons

Where any offence under this Act or any regulations made under it is committed by approved persons every persons charged with or concerned or acting in, the management of the affairs or activities of the private health laboratory shall also be guilty of the offence and shall be liable to be proceeded against and punished accordingly, unless that person proves to the satisfaction of the court that, through no act or omission on his part, he was not aware that the offence was being or was intended or about to be committed, or that he took all reasonable steps to prevent its commission.

18. Regulations

The Board may, after consultation with the Board, make regulations for the better carrying out of the purposes and provisions of this Act, and, without prejudice to the other provisions of this Act may make regulations—

- (a) prescribing forms to be used for the purposes of this Act;
- (b) prescribing fees which shall be payable in respect of any matters specified in any regulations made under this section;
- (c) requiring approved persons to provide facilities for the welfare of patients attending the private health laboratory;
- (d) regulating the staff, premises, profile of laboratory investigations and equipment to be provided at private health laboratory;
- (e) relating to any matter which is required or permitted to be prescribed under this Act.

19. Entitlement to practise for fees

Every approved person and every private health laboratory shall, subject to this Act, be entitled to demand, sue for, and recover in any court of competent jurisdiction with full costs of suit, reasonable charges for professional aid, advice and visits, and the value of any private health laboratory professional service or appliances supplied.

20. No fees recoverable unless approved person or private health laboratory is registered under this Act

No person shall be entitled to recover any charge in any court by way of claim, counter claim, set off or otherwise for any professional advice, attention or for the performance of any private health laboratory service as or by a private health laboratory service as prescribed or supplied within Tanzania unless that person or the private health laboratory, is at the time, approved and registered as such under this Act.

21. Appeal

Any person who is aggrieved by the decision of the Board in the performance of its functions under this Act may appeal to the High Court.

Schedule (Section 5(2))

The Board

1. Appointment, composition and tenure of office of the Board

- (1) The Board shall consist of—
 - (a) the Director of Hospital Services who shall be Chairman of the Board;
 - (b) a pathologist who shall be a member; and
 - (c) the Principal Health Laboratory Technologist;
 - (d) the Registrar who shall be the Secretary to the Board, and who shall be appointed by the Minister;
 - (e) a senior health laboratory technologist from any private health laboratory appointed by the Minister;

- (f) a senior health laboratory technologist representing voluntary agency organisations who shall be appointed by the Minister;
 - (g) a legally qualified person representing and nominated by the Attorney General from persons employed in the Attorney General's Chambers;
 - (h) not more than two other members appointed by the Minister.
- (2) A member appointed under this paragraph—
- (a) shall, unless his appointment is sooner terminated by the appointing authority or he ceases in any other way to be a member, hold office for a period of three years but shall be eligible for re-appointment;
 - (b) may at any time resign from his office by giving notice in writing addressed to the Minister, and from the date specified in the notice or, if no date is so specified from the date of the receipt of the notice by the Minister, he shall cease to be a member.

2. Vice-Chairman

The members of the Board shall elect from their number a Vice-Chairman of the Board and who shall, subject to his continuing to be a member, hold office for a term of one year from the date of his election, but shall be eligible for re-election.

3. Meetings of Board

- (1) The Board shall ordinarily meet at times and places as it deems necessary for the transaction of its business as required under this Act but shall meet at least once in every three months.
- (2) The Chairman, or in his absence, the Vice-Chairman, may at any time call a special meeting of the Board, and shall call a special meeting upon a written request by a majority of the members in office.
- (3) The Chairman or in his absence the Vice-Chairman shall preside at every meeting of the Board.
- (4) In the absence of both the Chairman and the Vice-Chairman, members present shall elect a member from amongst themselves to preside over the meeting.

4. Quorum

The quorum at any meeting of the Board shall be one third of the members amongst whom there must be members appointed under items (c), (d), either (e) or (f), (g) and at least one member appointed under item (h) of subparagraph (1) of this Schedule.

5. Decision of Board

- (1) Subject to subparagraph (2), questions proposed at a meeting of the Board shall be decided by a majority of votes of members present and voting, and in the event of an equality of votes, then the person presiding shall have a casting vote in addition to his deliberative vote.
- (2) A decision may be made by the Board without a meeting, by circulation of the relevant papers among the members and the expression of the views of the members in writing, but any member may require that the decision be deferred and the subject matter be considered at a meeting of the Board.

6. Minutes of meetings

- (1) The Board shall cause to be recorded and kept details all business conducted or transacted at its meetings, and the minutes of each meeting of the Board shall be read and confirmed, or amended and confirmed, at the next meeting of the Board signed by the person presiding at that meeting.
- (2) Any minutes purporting to be signed by the person presiding at a meeting of the Board shall, in the absence of proof of error, be deemed to be a correct record of the meeting.

7. **Vacancies, etc., not to invalidate proceedings**

The validity of any act or proceeding of the Board shall not be affected by any vacancy among its members or by any defect in the appointment of any of them.

8. **Board to regulate its own proceedings**

Subject to the provisions of this Schedule, the Board may regulate its own proceedings.