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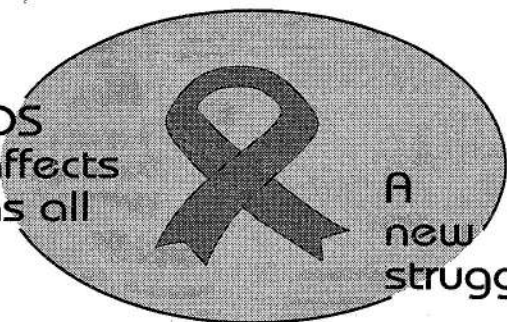
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PRETORIA, 3 SEPTEMBER 1999

No. 20430

We all have the power to prevent AIDS

AIDS
affects
us all



A
new
struggle

Prevention is the cure

**AIDS
HELPLINE**

0800 012 322

DEPARTMENT OF HEALTH

GENERAL NOTICE

NOTICE 1999 OF 1999

DEPARTMENT OF HEALTH

The Department of Health intends to introduce the National Health Laboratory Services Bill (hereinafter referred to as "the Bill") in Parliament late this year.

The Bill is hereby published for comment and the Department of Health will consider comments sent within one month from the date of publication.

Comments can be sent to:

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DRAFT BILL

To provide for the establishment of the National Health Laboratory Service, the abolition of the South African Institute for Medical Research; the Institute for Pathology and the National Centre for Occupational Health, and for matters connected therewith.

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Preamble.

RECOGNISING that the Constitution of the Republic of South Africa guarantees the right to health care services and requires the state to take legislative and other measures to achieve the realisation of the right;

BEING AWARE that the realisation of the right to health care can be achieved by, amongst others-

the establishment of a single national public entity to provide public health pathology services in the country;

the restructuring and transformation of the public health sector clinical laboratory services in order to make them part of a single national public entity;

the development of policies that will enable the single national public entity to provide pathology services as the preferred provider for all government departments rendering health services;

Be it enacted by the Parliament of the Republic of South Africa, as follows:

Definitions.

1. In this Act, unless the context otherwise indicates –

- (i) “**basic research**” means the creation, preservation, accumulation of knowledge by means of scientific investigations and methods in the field of the medical and related sciences as well as those sciences the application of which is important for the promotion of health or the combating of disease, and includes the acquisition, development and transfer of expertise and technology;

- (ii) **"Board"** means the National Health Laboratory Service Board referred to in section 6 (1) of the Act;
- (iii) **"Chief Executive Officer"** means the Chief Executive Officer of the Executive Management Committee referred to in section 10;
- (iv) **"Council on Higher Education"** means the body referred to in section 4 of the Higher Education Act, 1997 (Act No. 101 of 1997);
- (v) **"Executive Management Committee"** means the Executive Management Committee established under section 11 of the Act;
- (vi) **"laboratory service"** means a service for the testing of specimens in order to obtain diagnostic results;
- (vii) **"Minister"** means the Minister of Health in the national sphere of government;
- (viii) **"operational research"** means research that is conducted as a part of the process of improving quality, efficiency and effectiveness of the services;
- (ix) **"pathology service"** means a comprehensive service that involves the obtaining and testing of biological specimens, the interpretation of the results thereof and the extension of the laboratory service into clinical patient care;
- (x) **"public health sector"** means the departments and organs of all three spheres of government charged with the function of providing health services;¹
- (xi) **"rule"** means a rule made under section 28 of the Act;
- (xii) **"security"** means any bill of exchange, promissory note or instrument issued by the National Health Laboratory Service as security for any loan negotiated by it;
- (xiii) **"Service"** means the National Health Laboratory Service established by section 2 of this Act;
- (xiv) **"teaching platform"** means the environment established in the laboratories and other parts of the services that is suited for the teaching of students;
- (xv) **"tertiary education institution"** means a "higher education institution" as defined in the Higher Education Act, 1997 (Act No. 101 of 1997);
- (xvi) **"this Act"** includes the rules made in terms of this Act;
- (xvii) **"Treasury"** means the national treasury referred to in section 5 of the Public Finance Management Act, 1999 (Act No. 1 of 1999).

Establishment of the National Health Laboratory Service.

2. The National Health Laboratory Service is hereby established as a juristic person.

Objects of the Service.

3 The objects of the Service are:

- (a) to provide a cost-effective laboratory and pathology services to the public health sector,;
- (b) to support pathology research; and
- (c) to provide a training platform for health science education.

Functions of the Service.

4. The Service shall have the following functions:

- (a) to investigate, establish, operate, acquire, maintain, co-ordinate, amalgamate and carry on laboratories and other undertakings to provide efficient and cost-effective laboratory services to all public sector health care providers, any other government institution inside and outside of the Republic that may require such services and any private health care provider that requests such services;
- (b) to promote the training of laboratory and associated personnel and within the available resources, grant study bursaries and loans; and
- (c) to promote co-operation between the Republic and other countries with regard to the epidemiological surveillance and management of diseases through the monitoring of laboratory test results and the provision of expert pathology services;

¹(Still needs clarity regarding the SAMHS and local governments.)

Powers and duties of the Service

5. The Service shall have the following powers and duties:

- (a) undertake, on its own or in association or partnership with a tertiary education institution, operational research;
- (b) co-operate with persons and institutions undertaking basic research in the Republic and in other countries by the exchange of scientific knowledge and the provision of access to the resources and specimens available to the National Health Laboratory Service;
- (c) participate in joint research operations with departments of State, universities, technikons, colleges, museums, scientific institutions and other persons;
- (d) co-operate with educational authorities and scientific or technical societies or industrial institutions representing employers and employees, respectively, for the promotion of the instruction and training of pathologists, technologists, technicians, scientists, researchers, technical experts and other supporting personnel in universities, technikons, and colleges;
- (e) enter into agreements, with any person, any government, or institution, upon such conditions as the Service and that person, government, or institution may agree;
- (f) purchase or acquire any equipment, information technology hardware and software, furniture, stock-in-trade, plant, machinery, land, buildings, agencies, shares, debentures and any movable or immovable property;
- (g) manage, insure, lease, sell, mortgage, dispose of, give in exchange, work, develop, maintain, build on, improve, turn to account or in any other way deal with any of its property or assets;
- (h) apply for, purchase or by any other means acquire, protect, prolong or renew any patents, patent rights, licenses, trade marks, concessions or other rights and deal with or alienate them;
- (i) borrow money within or outside the Republic;
- (j) invest money in any manner;
- (k) open and operate on banking accounts;
- (l) make, draw, issue, execute, accept, endorse or discount promissory notes, bills of exchange and any other kind of negotiable or transferable instruments;
- (m) enter into indemnities, guarantees and suretyships and secure payment thereunder in any way;
- (n) enter into agreements to facilitate or secure the payment of commitments and to this end indemnify any person or cede, exchange or cancel agreements;
- (o) undertake and execute any trust, form and have an interest in any company or companies for the purpose of acquiring the business or all or any assets or liabilities of any company or for any other purpose which directly or indirectly, benefit the Service and take part in the management, supervision and control of the business or operations of any company or business and enter into partnerships;
- (p) make donations to further the interests of the Service;
- (q) act as principals, agents, contractors or trustees;
- (r) enter into contracts within or outside the Republic with persons, financial institutions, banks or governments of foreign countries, and execute any contract, deed or document in the Republic or any foreign country;
- (s) make and recover charges for the rendering of pathology tests, laboratory services and other services;
- (t) remunerate any person or persons, either in cash or by any other means, for services rendered in the operation and development of the Service's business;
- (u) appoint officers and employees at such remuneration and on such conditions as it may deem fit and on valid reasons, dismiss them;
- (v) pay gratuities and pensions and establish and manage pension schemes, medical aid schemes and other incentive schemes in respect of its officers and employees and appoint trustees and other officials;
- (w) produce and sell by-products; and

- (x) generally, enter into any contract or perform any act, whether within the Republic or outside, as will in the opinion of the Board contribute towards the attainment of the Service's objectives.

Management of the affairs of the Service.

- 6. (1) The affairs of the Service shall be managed by a Board which shall:
 - (a) determine policy and objectives and do the necessary planning in connection with the functions, powers and duties of the Service; and
 - (b) exercise control, generally, over the performance of its functions, the exercise of its powers and the fulfilment of its duties by the Service.
- (2) The Board shall perform, in addition to the function assigned to it by subsection (1), such other functions as may be assigned to it by this Act.

Constitution of the Board.

- 7. (1) The Board shall consist of the following members, appointed by the Minister, namely-
 - (a) a chairperson;
 - (b) the Chief Executive Officer of the Executive Committee *ex officio*;
 - (c) nine members, one to represent each provincial sphere of government *ex officio*;
 - (d) two members who represent the national Department of Health *ex officio*;
 - (e) three members who have special knowledge with regard to economic, financial, accounting or legal matters, pathology services, health research or epidemiology;
 - (f) two members nominated by the Council on Higher Education who represent university health science faculties and technikon;
 - (g) one member nominated by the Minister responsible for science and technology in the national sphere of government.
- (2) In addition to the members contemplated in subsection (1) the Minister may appoint a vice-chairperson of the Board.
- (3) The Minister shall appoint the members contemplated in subsections (1) (c), (d), (f) and (g) after consultation with the relevant bodies and institutions and shall ensure that appropriate laboratory and pathology professionals are appointed.
- (4) The Minister shall, before appointing members contemplated in subsection (1) (e), by notice in the Gazette invite all interested persons to submit, within the period mentioned in the notice, the names of persons who in the opinion of such interested persons are fit to be so appointed, stating the grounds upon which such opinion is based.
- (5) If a suitable person or the required number of persons is not nominated as contemplated in subsection (4), the Minister shall appoint the necessary person or persons.
- (6) The members of the Board, other than those who serve *ex officio*, shall each hold office for such a period, but not exceeding five years, as the Minister may determine at the time of appointment but shall be eligible for reappointment.
- (7) A member of the Board, excluding a member who is in the full-time employment of the State or the Service, shall be appointed on such conditions, as the Minister may, with the concurrence of the Minister of Finance, determine.

Disqualification as member of the Board and vacation of office.

- 8. (1) Any person shall be disqualified from being appointed as a member of the Board if -
 - (a) he or she is subject to an order of court declaring such person to be mentally ill; or
 - (b) he or she has at any time been convicted of any offence involving dishonesty and has been sentenced therefor to a period of imprisonment without the option of a fine.
- (2) Any appointed member of the Board shall vacate his or her office if-
 - (a) he or she submits his or her resignation to the Minister in writing;
 - (b) he or she becomes disqualified from being appointed as a member of the Board;
 - (c) he or she has been absent, without the leave of the Board, from more than two consecutive meetings of the Board. or
 - (d) the Minister withdraws his or her appointment if in the opinion of the Minister, and after consultation with the Board, he or she is incompetent or unfit to fulfil his or her duties.

(3) Whenever, the number of members of the Board becomes reduced to less than 12 for a continuous period of 3 months, the Minister may appoint any person to the Board including the chairperson or the vice chairperson.

(4) Whenever the chairperson of the Board is temporarily absent or for any other reason unable to perform his or her functions as chairperson, the vice-chairperson shall act as chairperson and, if the vice-chairperson is also absent or for any other reason unable to act as chairperson, the Minister may designate another member of the said Board to act as chairperson until the said chairperson or vice-chairperson is available.

(5) Any person acting as chairperson of the Board by virtue of the provisions of subsection (3) or (4), shall, while so acting, have all the powers, and perform, while so acting, all the functions, of the chairperson.

(6) Every vacancy on the Board arising from a circumstance referred to in subsection (2), and every vacancy caused by the death of a member, shall be filled by the appointment by the Minister, subject to the provisions of section 7, of another person as a member of the Board, and every member so appointed shall hold office for the unexpired portion of the period for which the vacating member was appointed.

(7) No decision of the Board or act performed under its authority shall be invalid by reason only of an interim vacancy on the Board or of the fact that a person who is disqualified from being a member of that Board, or with respect to those whose appointment the provisions of this Act have not been observed, sat or acted as a member at the time when the decision was taken or the act was performed or authorized, if the decision was taken or the act was performed or authorized by the requisite majority of the members of the Board present at the time and who were entitled to sit and act as members.

Meetings of the Board.

9. (1) The meetings of the Board and the conduct of the business at the meetings shall be prescribed by the rules made under section 28.

(2) A quorum for a meeting of the Board shall be the majority of its members.

(3) A decision of the majority of the members of the Board present at any meeting shall constitute a decision of the Board and, in the event of the equality of votes, the member presiding at the meeting shall have a casting vote in addition to his or her deliberative vote.

(4) Minutes of the proceedings of every meeting of the Board shall be drawn up and entered in a book kept for that purpose.

(5) Minutes of the proceedings of each meeting shall be submitted at the next ensuing meeting and, if then passed as correct, shall be confirmed by the signature of the chairperson or other member presiding thereat and shall, when so confirmed, be evidence in all courts of the proceedings of the first-mentioned meeting.

(6) In the absence from a particular meeting of the Board of the chairperson or the person acting as the chairperson, the members present at that meeting may elect one of their number to preside at that meeting.

Committees of the Board.

10. (1) The Board may appoint one or more committees from among its members to assist it with the performance of its functions and exercise of its powers.

(2) The Board may appoint one or more specialist advisory committees consisting of members other than members of the Board to assist it with the performance of its functions and exercise of its powers.

Constitution of the Executive Management Committee.

11. (1) The Board shall designate an Executive Management Committee, which shall consist of:

- (a) the Chief Executive Officer, who shall act as chairperson, of the Executive Management Committee; and
- (b) so many other members, who shall be employees of the Service, as the Board may deem necessary.

(2) The Executive Management Committee shall be responsible for the management of the affairs of the Service in accordance with the objective and policy of the Service.

Staff of the Service.

12. (1) The Service may from time to time and on such conditions, as it may determine, appoint such officers and employees as it may deem necessary to assist it in the performance of its functions.

(2) The Service may in the performance of its functions, in addition to or instead of the officers and employees referred to in subsection (1) make use of—

(a) officers and employees placed at its disposal in terms of the provisions of the Public Service Act, 1994 (Proclamation No.103 of 1994);

(b) persons in the employment of any other body or person, placed at its disposal in terms of an agreement between the itself and such body or person.

(3) The Service shall in respect of every officer or employee placed at its disposal in terms of subsection (2) (a) or person placed at its disposal in terms of subsection (2) (b) reimburse the State or the employer for every amount paid by the State or employer in respect of such officer, employee or person for as long as such officer, employee or person is placed at the disposal of the Service.

(4) The Service may for the purpose of the performance of any of its functions enter into an agreement for the execution of a particular task or the furnishing of particular services with any person who, on account of his or her qualifications or special knowledge, is, in the opinion of the Service, suitable to execute such a task or to furnish such services.

Provision of services by the Service.

13. (1) Public health sector service providers shall purchase laboratory and pathology services from the Service.

(2) Private health sector service providers may purchase laboratory and pathology services from the Service.

(3) The Service may in the performance of its functions enter into agreements with any university, technikon or technical college or any other tertiary education institution inside or outside the Republic for the purpose of establishing basic research projects and teaching platforms which in the opinion of the Service, will be beneficial to it in the pursuance of its objectives.

Rendering of laboratory services in foreign countries.

14. (1) The Service may, in addition to the powers conferred to it by section 5, and subject to prior approval by the Minister—

(a) render pathology and laboratory services in the Republic on behalf of any country which has requested a pathology or laboratory service;

(b) render pathology and laboratory services in any country outside the Republic, or to collect specimens for the purposes of testing them in the Republic, in any such territory which has requested a pathology or laboratory service, as the case may be; and

(c) import any human tissue or any blood, blood product or gamete in terms of section 25 of the Human Tissue Act, 1983 (Act No. 65 of 1983) for the purposes contemplated in sub-section (a) or (b).

(2) The provisions of this Act shall, in so far as they can be applied, apply in connection with the rendering of services in terms of subsection (1) (b) as if such services were rendered within the Republic for the public health sector.

(3) The Minister may with the concurrence of the Minister of Finance indemnify the Service against any losses the Service may incur as a result of services rendered in terms of this section.

Discoveries, inventions and improvements by employees of the Service and other persons

15. (1) The intellectual property rights in all discoveries and inventions and in all improvements in respect of processes, apparatus, machines and medicines made by—

(a) employees of the Service in the course of such employment;

(b) persons assisting the Service with any investigation or research in the course of such investigation or research; or

(c) persons to whom bursaries or grants-in-aid have been granted by the Service in the course of any research in respect of which such a bursary or grant-in-aid is received,

shall be determined on a case-by-case basis, taking into account:

- (i) the general principles of intellectual property law and intellectual property legislation;
- (ii) the nature of the intellectual property concerned;
- (iii) the parties involved in the creation of such intellectual property;
- (iv) contractual rights and obligations of the parties, both between the parties and in respect of outside parties;
- (v) the financial contribution of all parties to the creation of the intellectual property;
- (vi) the intellectual contribution of all parties to the creation of the intellectual property; and
- (vii) any other relevant factors; and

shall form part of an agreement to be concluded between the parties concerned in respect of such discoveries, inventions or improvements.

- (2) The Service may make the discoveries, inventions and improvements referred to in subsection (1) and the rights arising therefrom, available for use in the public interest subject to such conditions and the payment of such fees or royalties as the Service may determine.
- (3) Where the rights referred to in subsection (2) are vested jointly in the Service and one or more other parties, the Service and such other party or parties shall reach agreement on how to make the discoveries, inventions and improvements referred to in subsection (1) available for use in the public interest and on the conditions and the payment of fees or royalties associated therewith.
- (4) In respect of rights which are vested in the Service in terms of subsection (1), the Service may award to the person responsible for the discovery, invention or improvement such bonus as it deems fit, or make provision for financial participation by such person in the profits derived from the discovery, invention or improvement to such extent as the Minister may determine with the concurrence of the Minister of Finance.
- (5) Where rights are vested solely in the Service, the Service may apply for a patent in respect of any discovery, invention or improvement referred to in subsection (1), and shall for the purposes of the Patents Act, 1978 (Act No. 57 of 1978), be regarded as the assignee of the discoverer or inventor in question.

Financing of the Service.

16. (1) The funds of the National Health Laboratory Service shall consist of-

- (a) income earned from fees for services in terms of section 18;
- (b) income earned on surplus moneys deposited or invested;
- (c) money appropriated by Parliament on such terms conditions as the Minister with the concurrence of the Minister of Finance may determine;
- (d) grants, donations and bequests made to it;
- (e) any royalties referred to in section 15(2); and
- (f) money received from any other source.

Defrayment of expenditure.

17. (1) All expenditure incurred by the Service under this Act, including expenditure incidental to the performance of its functions by the Board, expenditure incidental to the payment of remuneration and allowances to members of the Board and the Executive Management Committee, shall be defrayed from the revenues of the Service under this Act.

(2) Any balance remaining at the end of the financial year of the Service may be utilized for any expenses in connection with the exercise of its powers or the performance of its functions.

Charges for services by the Service.

18. (1) The charges by the Service for laboratory tests and pathology services rendered by it shall -

(a) to purchasers in the public health sector and to foreign governments, be as determined after consultation with the Minister, and

(b) to purchasers in the private health sector, be as determined by the Service:

Provided that the Service may deviate from such charges if in its opinion, special circumstances exist justifying such departure; and

(c) be revised and amended from time to time by the Service in order to ensure a sound financial structure.

(2) Subject to the provisions of subsection (3) the Service may decrease or increase its charges in respect of services rendered in terms of subsection (1) (a), in a manner that will ensure global cost recovery with the minimal practical cross-subsidization between tests.

(3) The Service shall determine charges based on business plans that provide for full cost recovery and the operational research and development requirements that are essential to the effective and efficient performance of the objectives of this Act.

(4) The decrease or increase of charges shall be agreed to by the majority of the heads of provincial departments responsible for health and the treasury in respect of charges for the public sector.

Borrowing powers of the Service.

19. (1) The Service may from time to time borrow money for the purposes for which the Minister of Finance shall in respect of each year approve on the conditions which he or she may determine.

(2) Subject to the provisions of section 70 of the Public Finance Management Act, 1999 (Act No. 1 of 1999), the Minister may, with the concurrence of the Minister of Finance, for the period and on the conditions which he or she may determine, guarantee due performance by the Service of any contractual obligation incurred or to be incurred by the Service towards any party whether within or outside the Republic.

Accounting records.

20. The Service shall keep accounting records as are necessary to fairly present the state of its affairs and in accordance with the provisions of the Public Finance Management Act, 1999 (Act No. 1 of 1999).

Audit.

21. (1) The Service shall, after consultation with the Auditor General, appoint auditors in terms of section 58 of the Public Finance Management Act, 1999 (Act No. 1 of 1999) to examine the financial statements of the Service.

(2) The Service shall produce and submit to the auditors all of its accounting records with all vouchers in support thereof, and all books and documents in its possession or control.

(3) For the purposes of the audit, an auditor may hear and receive evidence upon oath or affirmation, which oath or affirmation he or she is hereby empowered to administer, and may by summons under his or her hand require such persons as he or she may think fit, to appear personally before him or her at a time and place to be stated in the summons and produce all such books and papers as may be necessary for such audit.

(4) Any person required to appear in terms of subsection (3) who, without lawful excuse, fails to attend or who, having appeared, refuses to be examined on oath or affirmation or to take such oath or affirmation or, having taken such oath or affirmation, to answer such questions as may be put to him or her, shall be guilty of an offence and liable on conviction to a fine not exceeding R5 000 or to imprisonment or to both such fine and imprisonment.

(5) The auditors shall—

(a) disallow every unauthorized payment made and surcharge it against the person who made or authorized such payment;

(b) surcharge against any person responsible therefor the amount of any deficiency or loss incurred by the negligence or misconduct of that person, or of any sum which ought to have been brought into account by that person; and

(c) in every case certify the amount due by such person.

(6) Every amount so certified by the auditors shall be paid by such person within 14 days after the said amount has been so certified to the officer appointed by the Service and may, if not so paid, be recovered from such person as a debt by the auditors, who shall be paid by the Service their reasonable costs and expenses incurred in such proceedings.

- (7) The auditors shall certify at least once a year whether or not—
- they have examined the financial statements of the Service;
 - the financial statements fairly present the financial position of the Service and the results of its functions in the manner required by this Act and the Public Finance Management Act, 1999 (Act No. 1 of 1999);
 - the value of the assets and liabilities of the Service has been correctly stated;
 - all of their requirements and recommendations as auditors have been complied with and carried out.

(8) The auditors shall once a year audit all books and accounts of the Service relating to transactions which in terms of any law may not be disclosed and shall report separately in respect of such transactions to the Board and the Minister without qualifying the Service's financial statements in respect thereof.

- (9) The expenses of and incidental to any audit shall be borne by the Service.

Annual Reports.

22. The Board shall, on or before the thirty-first day of August of each year, submit to the Minister a report on the affairs and functions of the Service during the previous year ending on the thirty-first day of March.

Exemptions from provisions of Companies Act.

23. The provisions of the Companies Act, 1973 (Act No. 61 of 1973), or of any other law on companies shall not apply to the Service.

Exemptions from income tax, stamp duty, levies or fees.

24. The Service is hereby exempted from the payment of any income tax, stamp duty, levies or fees which would otherwise have been payable by the Service to the State in terms of any law excluding a law regarding customs and excise or sales tax.

The Service not responsible for fulfilment of trusts attaching to securities.

25. Neither the Service nor any agent appointed by it shall be under any obligation in relation to the due fulfilment of any trust, whether expressed, implied or constructive, to which securities issued in the Republic may be subject, notwithstanding the fact that the Service or such agent has had notice that the securities are held subject to a trust.

Proceedings by Minister in case of non-compliance with Act by the Service.

26. (1) If at any time it appears to the Minister that the Service has failed to comply with any of the requirements of this Act, he or she may by notice in writing require the Service to remedy the default within a specified time.

(2) If the Service fails to comply with the terms of such notice, the Minister may apply to a High Court having jurisdiction for an order compelling the National Health Laboratory Service to remedy the default.

Delegation of functions by the Board.

27. (1) The Board may by resolution and on conditions as it may determine—

- delegate to any committee appointed under section 10, the Executive Management Committee or any member thereof or any officer or employee of the Service, any power conferred upon the Service or the Board by this Act, except the powers referred to in sections 5 and 28, on such conditions as the Board may determine; or
- authorize such committee, the Executive Management Committee or such member, officer or employee to perform any duty assigned to the Service or the Board by this Act.

(2) The Board may, on such conditions as it may determine, by resolution authorize any committee appointed under section 10, the Executive Management Committee or any member thereof or any officer or employee of the Service—

- to which or to whom any power has been delegated under subsection (1) (a), to further delegate such power to any officer or employee of the Service; or

- (b) which or who has been authorized to perform any duty under subsection (1) (b), to further authorize any officer or employee of the Service to perform such duty.
- (3) The Board may at any time by resolution withdraw—
 - (a) a delegation under subsection (1) (a); or
 - (b) an authorization under subsection (1) (b), (2) (a) or (2) (b),
 and any delegation or authorization shall not prevent the exercise of the relevant power or the performance of the relevant duty by the Board itself.
- (4) Any committee appointed under section 10, the Executive Management Committee or any member thereof or any officer or employee of the Service—
 - (a) to which or to whom any power has been delegated under subsection (1) (a) and which or who has further delegated such power to any officer or employee of the Service by virtue of an authorization under subsection (2) (a); or
 - (b) which or who has been authorized to perform any duty under subsection (1) (b) and which or who has further authorized any officer or employee of the Service to perform such duty by virtue of an authorization under subsection (2) (b),
 as the case may be, may—
 - (i) at any time withdraw such delegation or authorization and such delegation or authorization shall not prevent the exercise of the relevant powers or the performance of the relevant duty by such committee, the Executive Management Committee or such member, officer or employee; and
 - (ii) subject to the provisions of subsection (6), set aside or vary any decision by such officer or employee of the National Health Laboratory Service made in the exercise of such power delegated to him or her.
- (5) Subject to the provisions of subsection (6) the Board may set aside or vary any decision made in the exercise of any power delegated by it under subsection (1) (a) or delegated by virtue of an authorization under subsection (2) (a), including a decision setting aside or varying a decision under subsection (4) (b) (ii).
- (6) A decision made in the exercise of any power delegated under subsection (1) (a) or delegated by virtue of an authorization under subsection (2) (a) by which a right has been conferred upon any person shall not be set aside or varied.
- (7) Where a power is delegated under subsection (1) (a) or by virtue of an authorization under subsection (2) (a) to the holder of an office, that power may be exercised by the person who for the time being performs the functions attached to such office.

Rules.

- 28. (1) The Board may make rules not inconsistent with this Act relating to—
 - (a) the proceedings at meetings of, and the business of, the Board, committees appointed under section 10, and the Executive Management Committee;
 - (b) the period for which members appointed to the Executive Management Committee in terms of section 11 shall hold office;
 - (c) the duties of officers, employees and other persons in the employ of the Service, including the delegation of powers of appointment and dismissal to any particular officer;
 - (d) the salary, wages and other remuneration of persons in the employ of the Service, and the contributions to be paid by the Service to any such persons towards any pension, medical aid or other incentive scheme established by the Service;
 - (e) the mechanisms and mandates for wage negotiations;
 - (f) the construction, alteration, operation, protection and inspection of works, plant, machinery, apparatus, appliances and equipment required for the testing of laboratory specimens and the running of laboratories by the Services;
 - (g) the fees to be charged by the Service under this Act;
 - (h) the payment and collection of moneys due for the rendering of laboratory and pathology services and fines and penalties for overdue payments;
 - (i) the granting of discounts and other incentives for prompt payment by purchasers or the making of additional charges or the payment of interest in respect of delayed payments;

- (j) the suspension or termination of any laboratory tests or pathology services for non-payment of charges;
- (k) the receipt and utilization of grants, bequests and donations of any kind;
- (l) the constitution, quorum, functions, powers and duties of committees appointed by the Board under section 10;
- (m) the determination and setting of internal quality assurance standards, the process for the preparation for, and authority for application for accreditation of the laboratories in the Service;
- (n) the determination of an Essential Laboratory Tests List and management protocols, or equivalent range of tests that will be made available to the purchasers;
- (o) the conditions for the participation of the Service in the conducting of clinical trials, either on its own or in partnership with a tertiary education institution or private company.

(2) Any rule made under subsection (1) is of no force until approved by the Minister.

(3) The Board shall, not less than three months before any rule is made under subsection (1), cause a copy of the proposed rule to be published in the *Gazette* together with a notice declaring its intention to make that rule and inviting interested persons to furnish the Board with their comments thereon or any representations they may wish to make in regard thereto.

Transitional provisions.

29. The transitional provisions in the Schedule must be read and applied as substantive provisions of this Act..

Short title and commencement.

30. This Act shall be called the National Health Laboratory Service Act, 1999, and shall come into operation on a date to be determined by the President by proclamation in the *Gazette*.

Schedule

TRANSITIONAL PROVISIONS

1. Definitions.

In this Part—

- (i) “**Department**” means the Department of Health;
- (ii) “**commencement date**” means the date on which this Act commences;
- (iii) “**Institute for Pathology**” means the Institute for Pathology in the Department of Pathology in the Faculty of Medicine at the University of Pretoria;
- (iv) “**South African Institute for Medical Research**” means the South African Institute for Medical Research, and its laboratories, that were created by the government and the mining industry in the Founding Statement of 1917.

2. Abolition of the Institutes.

(1) The South African Institute for Medical Research, the National Institute for Virology, the National Centre for Occupational Health, forensic pathology and forensic chemistry laboratories all provincial health laboratory services and all other provincial and national pathology services, unless expressly excluded, shall cease to exist from the commencement date and incorporated into the Service.

(2) The pathology services of the South African Military Health Services and any research laboratories belonging to the health science faculties of universities shall not automatically be incorporated into the Service but may be incorporated by agreement.

(3) At the commencement of this Act anything done in terms of the provisions of the Health Act, 1977 (Act No. 63 of 1977), by virtue of the Founding Statement of 1917 that created the South African Institute for Medical Research, or any subsequent document that constituted the South African Institute for Medical Research, prior to such commencement and which could have been done in terms of the provisions of the terms of this Act, shall be deemed to have been done in terms of this Act.

3. Persons in service of the Departments.²

4. Persons in service of the South African Institute for Medical Research.

5. Persons becoming employees of the National Health Laboratory Service.

6. Rules and regulations.

(1) Any rules or regulations in force made by the South African Institute for Medical Research, the National Institute for Virology, the National Centre for Occupational Health, forensic pathology and forensic chemistry laboratories, provincial health laboratory services and other provincial and national pathology services shall, on the commencement date of this Act remain in force after the commencement of this Act in so far as they deal with any matter in respect of which the Board may make rules under section 28, until they are replaced by a rule made under section 28.

7. Assets and liabilities.

(1) On production of a certificate by a competent authority that immovable property that constitutes part of the resources of the public health laboratory service is owned by the South African Institute for Medical Research or the State, a registrar of deeds must make such entries or endorsements in or on any relevant register, title deed or other document to register that immovable property in the name of the National Health Laboratory Service.

²Transitional provisions regarding the protection of personnel, uniform conditions of service and setting out the process for the transfer of personnel are still to be negotiated in the Interim Negotiating Forum and will therefore only be finalized once there is agreement between the parties.

(2) No duty fee or other charge is payable in respect of a registration in terms of subsection (1).

(3) On production of a certified register by a competent authority that movable property that constitutes part of the resources of the public health laboratory service is owned by the South African Institute for Medical Research or the State, the Service must make such entries or endorsements in or on any relevant register or other document to register that movable property in its name, and in the case of a government department, such department must remove the asset from its asset register.

(4) No transfer cost, duty fee or other charge is payable in respect of the transfer of ownership and registration in terms of subsection (3).

(5) From the commencement date all contractual rights, obligations and liabilities of the South African Institute for Medical Research, the National Institute for Virology, the National Centre for Occupational Health, forensic pathology and forensic chemistry laboratories, all provincial health laboratory services and all other provincial and national pathology services, must be transferred to the Service.

8. Financial and administrative records.

(1) All financial, administrative and other records of the South African Institute for Medical Research, the National Institute for Virology, the National Centre for Occupational Health, forensic pathology and forensic chemistry laboratories, all provincial health laboratory services and all other provincial and national pathology services, unless expressly excluded, in the possession of the relevant parties before the commencement date, must be transferred to the Service.

9. Prices to be charged for laboratory services rendered by the National Health Laboratory Service.

(1) The prices to be charged by the National Health Laboratory Service for laboratory tests and pathology services rendered by it shall, from the date of commencement of this Act—

- (a) to purchasers in the public health sector, except in respect of Pretoria Academic Hospital, be as contained in the schedule of standard prices in force by the South African Institute for Medical Research immediately before the date of commencement of this Act;
- (b) in respect of Pretoria Academic Hospital, be as contained in the schedule of standard prices in force by the Institute for Pathology immediately before the date of commencement of this Act; and

10. Debt Owning to SAIMR.

(1) All debt owing to the South African Institute for Medical Research immediately before the date of commencement of this Act shall be payable to the Service and shall be managed under the same conditions that applied immediately prior to the commencement of this Act;

(2) The Board may alter the conditions under which the debt is managed after giving the debtors three months notice of the proposed changes.

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