

REPUBLIC OF SOUTH AFRICA

NATIONAL HEALTH LABORATORY SERVICE BILL

*(As amended by the Select Committee on Social Services (National Council of Provinces))
(The English text is the official text of the Bill)*

(SELECT COMMITTEE ON SOCIAL SERVICES)

[B 52B—2000]

ISBN 0 621 29636 8

No. of copies printed 1 800

BILL

To provide for the establishment of a juristic person to be known as the National Health Laboratory Service; to provide for the abolition of the South African Institute for Medical Research, the National Institute for Virology, the National Centre for Occupational Health, certain forensic chemistry laboratories and all provincial health laboratory services; and to provide for matters connected therewith.

PREAMBLE

RECOGNISING that the Constitution guarantees the right to health care services and requires the State to take legislative and other measures to achieve the progressive realisation of that 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 laboratory services in the country;
restructuring and transformation of the public health sector laboratory services in order to make them part of a single national public entity; and
development of policies that will enable the single national public entity to provide health laboratory services as the preferred provider for the public health sector.

BE IT THEREFORE 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 and accumulation of knowledge by means of scientific investigations and methods in—
 - (a) the field of medical and related sciences; and
 - (b) 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 Services Board referred to in section 7;
 - (iii) “chief executive officer” means the chief executive officer of the executive management committee referred to in section 13;
 - (iv) “executive management committee” means the executive management committee established under section 13;
 - (v) “forensic science service” means the obtaining of specimens from the scene of a crime and the testing thereof for the purposes of criminal investigation, the interpretation thereof and the giving of results as evidence for the criminal justice system;

- (vi) "health laboratory service" means a comprehensive service that includes the interpretation of the results thereof, the giving of results and the associated participation in patient care;
- (vii) "Minister" means the Minister of Health;
- (viii) "operational research" means research conducted as a part of the process of improving quality, efficiency and effectiveness of the health laboratory services; 5
- (ix) "public health sector" means, subject to section 2, the State departments and organs of all spheres of government charged with the function of providing health services; 10
- (x) "rule" means a rule made under section 27;
- (xi) "security" means any bill of exchange, promissory note or instrument issued by the Service as security for any loan negotiated by it;
- (xii) "Service" means the National Health Laboratory Service established by section 3; 15
- (xiii) "teaching environment" means the environment established in the laboratories regulated by this Act which is suitable for the teaching of students in the field of health laboratory services;
- (xiv) "tertiary education institution" means a higher education institution as defined in the Higher Education Act, 1997 (Act No. 101 of 1997); and 20
- (xv) "this Act" includes the rules made in terms of this Act.

Exclusion from application of this Act

- 2. (1) This Act does not apply to—
 - (a) the forensic science services provided by the South African Police Service; and 25
 - (b) the South African Military Health Services at—
 - (i) 1 Military Hospital situated in Pretoria; and
 - (ii) 2 Military Hospital situated in Cape Town.
- (2) Any research laboratories belonging to the health science faculties of universities are excluded from the Service, but may be incorporated by agreement. 30

Establishment of National Health Laboratory Service

- 3. (1) There is hereby established a juristic person to be known as the National Health Laboratory Service.
- (2) The Public Finance Management Act, 1999 (Act No. 1 of 1999), applies, with the necessary changes, to the Service. 35

Objects of Service

- 4. The objects of the Service are to—
 - (a) provide cost-effective and efficient health laboratory services to—
 - (i) all public sector health care providers;
 - (ii) any other government institution inside and outside of the Republic that may require such services; and 40
 - (iii) any private health care provider that requests such services;
 - (b) support health research; and
 - (c) provide training for health science education.

Functions, powers and duties of Service 45

- 5. (1) The Service must—
 - (a) investigate the need to establish, operate, acquire, maintain, co-ordinate and amalgamate laboratories and related undertakings to provide efficient and cost-effective laboratory services;
 - (b) promote the training of laboratory and associated personnel; 50
 - (c) within the available resources, grant study bursaries and loans for studies in the field of laboratory services; and

- (d) 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.
- (2) The Service may—
 - (a) undertake operational research, on its own or in association or partnership with a tertiary education institution; 5
 - (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 Service; 10
 - (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; 15
 - (e) enter into contracts within or outside the Republic, with any person, government, or institution, and execute any contract, deed or any other document in the Republic or any foreign country; 20
 - (f) purchase or acquire any movable or immovable property;
 - (g) manage, insure, lease, sell, mortgage, dispose of, develop, maintain, improve, or in any other way deal with any of its property or assets;
 - (h) apply for, purchase or by any other means acquire, protect, extend, renew, deal with or alienate any patents, patent rights, licences, trade marks, concessions or other rights; 25
 - (i) borrow money within or outside the Republic in terms of the provisions of the Public Finance Management Act, 1999;
 - (j) invest money in accordance with the framework prescribed in section 7 of the Public Finance Management Act, 1999; 30
 - (k) open and operate banking accounts in terms of section 7 of the Public Finance Management Act, 1999;
 - (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; 35
 - (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;
 - (p) form and have an interest in any company or companies for— 40
 - (i) the purpose of acquiring the business or all or any assets or liabilities, or both, of any company; or
 - (ii) any other purpose which directly or indirectly benefits the Service;
 - (q) take part in the management, supervision and control of the business or operations of any company or business; 45
 - (r) enter into partnerships;
 - (s) make donations to further the interests of the Service;
 - (t) act as principal, agent, contractor or trustee;
 - (u) charge for the rendering of laboratory services and other services;
 - (v) remunerate any person or persons, for services rendered in the operation and development of the Service's business; 50
 - (w) appoint officers and employees at such remuneration and on such conditions subject to the relevant labour legislation;
 - (x) pay gratuities and pensions to its officers and employees;
 - (y) establish and manage pension schemes in consultation with the Minister of Finance, medical aid schemes and other incentive schemes for its officers and employees, and appoint trustees and other officials for such schemes; 55

- (z) produce and sell by-products; and
- (zA) 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.

(3) The Service must exercise its functions, powers and duties in the interest of the Service and in accordance with the national health policy. 5

Control of Service

6. (1) The Service must be controlled by the Board.

(2) The Board must—

- (a) determine the policy of the Service; 10
- (b) do the necessary planning in connection with the functions, powers and duties of the Service; and
- (c) perform such other functions as may be assigned to it by this Act.

Composition of Board

7. The Board consists of the following members, appointed by the Minister, taking into account, among other things, the appropriate representation of race, gender and disability— 15

- (a) the chief executive officer;
- (b) one member from each province;
- (c) two members representing the national Department of Health; 20
- (d) three members who have special knowledge in—
 - (i) economics, financial matters or accounting;
 - (ii) legal matters;
 - (iii) health research; or
 - (iv) epidemiology; 25
- (e) two members nominated by the Council on Higher Education referred to in section 4 of the Higher Education Act, 1997 (Act No. 101 of 1997), who represent university health science faculties and technikons;
- (f) one member nominated by the national Minister responsible for science and technology; 30
- (g) one representative from the South African Local Government Association; and
- (h) one representative from organized labour.

Appointment of members of Board

8. (1) The Minister must appoint the members contemplated in section 7 (b), (c), (e), (f) and (g) after consultation with the relevant bodies and institutions and must ensure that appropriate laboratory professionals are appointed. 35

(2) The Minister must, before appointing the members contemplated in section 7(d), by notice in the *Gazette* and in a national newspaper circulating in every province of the Republic invite all interested persons to nominate, within the period specified in the notice, persons who in the opinion of such interested persons are fit to be so appointed, stating the grounds upon which such opinion is based. 40

(3) If a suitable person or the required number of persons is not nominated as contemplated in subsection (2), the Minister must appoint an appropriate person or persons who qualify to be appointed in terms of this Act. 45

(4) The members of the Board may hold office for a period of at least three years, as the Minister may determine at the time of appointment, but must be eligible for reappointment.

(5) A member of the Board, excluding a member who is in the full-time employment of the State or the Service, must be appointed on such conditions, as the Minister may, with the concurrence of the Minister of Finance, determine. 50

(6) If the number of members of the Board is reduced to such an extent that a quorum cannot be obtained, the Minister may appoint any suitably qualified persons on a temporary basis to serve on the Board until new members are appointed in terms of this section. 55

Chairperson and vice-chairperson of Board

9. (1) In addition to the members contemplated in section 7, the Minister must appoint a chairperson and vice-chairperson of the Board.

(2) Whenever the chairperson of the Board is absent or unable to perform his or her functions as chairperson, the vice-chairperson must act as chairperson and, if the vice-chairperson is absent or unable to act as chairperson the Minister must designate another member of the Board to act as chairperson until the chairperson or vice-chairperson is available. 5

(3) Any person acting as chairperson of the Board in terms of subsection (2), must exercise all the powers and perform all the functions and duties of the chairperson. 10

Disqualification from membership of Board and vacation of office

10. (1) A person may not be appointed as a member of the Board if that person—

- (a) is not a South African citizen and ordinarily resident in the Republic;
- (b) is an unrehabilitated insolvent;
- (c) has at any time been convicted of an offence involving dishonesty, whether in the Republic or elsewhere, and sentenced to imprisonment without the option of a fine; or 15
- (d) has been removed from an office of trust.

(2) A member of the Board must vacate his or her office if—

- (a) he or she becomes disqualified in terms of subsection (1), from being appointed as a member of the Board; 20
- (b) he or she submits his or her resignation to the Minister in writing;
- (c) he or she is declared by the High Court to be of unsound mind or mentally disordered or is detained under the Mental Health Act, 1973 (Act No.18 of 1973); 25
- (d) he or she has, without the leave of the Board, been absent from more than two consecutive meetings of the Board;
- (e) the Minister withdraws the appointment because in the opinion of the Minister, and after consultation with the Board, the member is incompetent or unfit to fulfil his or her duties; or 30
- (f) he or she ceases to be ordinarily resident in the Republic.

(3) If a member of the Board dies or vacates his or her office in terms of subsection (2), the Minister may, subject to section 8, appoint a person to fill the vacancy for the unexpired portion of the period for which that member was appointed.

Meetings of Board

11. (1) The meetings of the Board and the conduct of business at meetings must be prescribed by the rules.

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

(3) A decision of the majority of the members of the Board present at any meeting constitutes a decision of the Board and, in the event of an equality of votes, the member presiding at the meeting must have a casting vote in addition to his or her deliberative vote. 40

(4) A decision taken by the Board or an act performed under the authority of the Board is not invalid by reason only of a vacancy on the Board, or that a person who is not entitled to sit as a member of the Board sat as a member at the time when the decision was taken or the act was authorised, if the decision was taken or the act was authorised by the requisite majority of the members of the Board who were present at the time and entitled to sit as members. 45

(5) Minutes of the proceedings of every meeting of the Board must be prepared and entered in a book kept for that purpose. 50

(6) Minutes of the proceedings of each meeting must be submitted at the next meeting of the Board and, if passed as correct, must be confirmed by the signature of the

chairperson or other member presiding thereat and may, when so confirmed, be evidence in a court of law of the proceedings of the first-mentioned meeting.

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

5

Committees of Board

12. (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.

10

Executive management committee

13. (1) The Board must appoint an executive management committee, which consists of—

- (a) the chief executive officer, who must act as chairperson; and
- (b) as many other employees of the Service as the Board may deem necessary.

15

(2) The executive management committee is responsible for the management of the Service in accordance with the policy of the Service.

Staff of Service

14. (1) The Service may, subject to relevant labour legislation, 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.

20

(2) The Service may in the performance of its functions, in addition to or in the place 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 Public Service Act, 1994 (Proclamation No. 103 of 1994); or
- (b) persons in the employment of any other body or person, placed at its disposal in terms of an agreement between the Service and such body or person.

25

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

30

(b) The provisions of paragraph (a) apply 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 and duties enter into an agreement for the—

35

- (a) execution of a particular task; or
- (b) 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.

40

Purchasing of services

15. (1) Public health sector service providers must purchase laboratory services from the Service.

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

45

Rendering of laboratory services to foreign countries

16. (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 laboratory services in the Republic on behalf of any country which has requested a laboratory service;
- (b) render laboratory services in any country outside the Republic which has requested a laboratory service;

50

- (c) collect specimens for the purposes of testing them in the Republic, in any country which has requested a laboratory service;
- (d) 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 paragraph (a), (b) or (c); and 5
- (e) import any human waste products and any live or preserved agent responsible for or involved in disease transmission for the purposes contemplated in paragraph (a), (b), (c) or (d) and section 5(2)(a), (b) or (c).

(2) This Act must apply in connection with the rendering of services in terms of subsection (1)(b) or (c) as if such services were rendered within the Republic for the public health sector. 10

(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 Service and other persons 15

17. (1) The ownership of intellectual property rights in all discoveries, inventions and 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; or 20
- (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 was received,

must be determined on a case-by-case basis, taking into account—

- (i) the general principles of intellectual property law; 25
- (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 all the parties referred to in paragraph (iii);
- (v) the financial contribution of all parties to the creation of the intellectual property; 30
- (vi) the intellectual contribution of all parties to the creation of the intellectual property; and
- (vii) any other relevant factors.

(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, but must ensure that such availability will also be in the interest of persons who made such discoveries, inventions and improvements. 35

(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 must reach agreement on how to make the discoveries, inventions and improvements referred to in subsection (1) available for use on the conditions and on payment of fees or royalties associated therewith. 40

(4) In respect of rights which are vested in the Service in terms of subsection (1), the Service may reward the person responsible for the discovery, invention or improvement to the extent that 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, with the concurrence of the Minister of Finance, may determine. 45

(5) (a) Where patent rights are vested solely in the Service, the Service may apply to register for a patent right in respect of any discovery, invention or improvement referred to in subsection (1). 50

(b) For the purposes of the Patents Act, 1978 (Act No. 57 of 1978), the Service must be regarded as the assignee of the discoverer or inventor in question.

Finances of Service

18. The funds of the Service may consist of—

- (a) income earned from fees for services rendered in terms of section 20;
- (b) income earned on surplus moneys deposited or invested;
- (c) money appropriated by Parliament on such terms and conditions as the Minister, with the concurrence of the Minister of Finance, may determine; 5
- (d) grants, donations and bequests made to it;
- (e) royalties; or
- (f) money received from any other source.

Defrayment of expenditure 10

19. (1) All expenditure incurred by the Service under this Act must be defrayed from the funds of the Service, including expenditure—

- (a) in connection with the performance of its functions by the Board;
- (b) incidental to the payment of remuneration and allowances to members of the Board and the executive management committee. 15

(2) Any surplus remaining at the end of the financial year of the Service may be utilised for any expenses in connection with the exercise of its powers or the performance of its functions, provided that the provisions of the Public Finance Management Act, 1999, are complied with.

Charges for services 20

20. (1) (a) The public health sector and foreign governments that purchase laboratory tests from the Service must pay such prescribed fees as determined from time to time by the Service after consultation with the Minister.

(b) The Minister must consult with the Members of the Executive Council responsible for health, the Treasury and the provincial treasuries in respect of fees for the public health sector. 25

(2) The private health sector that purchases laboratory tests from the Service must pay such prescribed fees as determined from time to time by the Service after consultation with the Minister.

(3) The Service may decrease or increase its charges in respect of services rendered in terms of subsection (1). 30

Borrowing powers of Service

21. (1) The Service may from time to time borrow money as authorised by the Minister of Finance in terms of section 66 of the Public Finance Management Act, 1999.

(2) The Minister may issue a guarantee, indemnity or security which binds the Service in accordance with the provisions of section 70 of the Public Finance Management Act, 1999. 35

Accounting records

22. The Public Finance Management Act, 1999, must, with the necessary changes, be applied in respect of the keeping of financial records by the Service. 40

Audit

23. (1) The Service must consult the Auditor-General on the appointment of auditors to examine the financial statements of the Service.

(2) The annual financial statements of the Service must be audited by a person registered in terms of section 15 of the Public Accountants' and Auditors' Act, 1991 (Act No. 80 of 1991), as an accountant and auditor, and engaged in public practice as such. 45

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

(4) For the purposes of the audit an auditor —

- (a) is empowered to administer an oath and take an affirmation; 5
- (b) may hear and receive evidence upon oath or affirmation; and
- (c) may issue summons under his or her hand requiring such persons as he or she may think fit, to appear personally before him or her at a time and place stated in the summons and produce all such books, papers, documents and objects as may be necessary for such audit. 10

(5) The auditors must certify at least once a year to the executive management committee whether or not—

- (a) they have examined the financial statements of the Service;
- (b) the financial statements fairly present the financial position of the Service and the results of its functions in the manner required by this Act. The Public Finance Management Act, 1999, must also apply in respect of financial statements of the Service; 15
- (c) the value of the assets and liabilities of the Service have been correctly stated; and
- (d) all of their requirements and recommendations as auditors have been complied with and carried out. 20

(6) The expenses of any audit must be borne by the Service.

Annual reports

24. The Board must, on or before 31 August of each year, submit to the Minister a report on the affairs and functions of the Service during the previous year ending on 31 March. 25

Proceedings by Minister for non-compliance with Act by Service

25. (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 written notice require the Service to remedy the default within a specified time. 30

(2) The Minister may apply to a High Court having jurisdiction for an order compelling the Service to remedy the default if the Service fails to comply with the terms of a notice referred to in subsection (1).

Delegation of functions by Board

26. (1) (a) The Board may, by resolution, delegate any of its powers, with the exception of powers referred to in sections 6 and 27, to— 35

- (i) a committee appointed under section 12;
- (ii) the executive management committee or any member thereof; or
- (iii) any officer or employee of the Service.

(b) The Board may delegate its powers subject to any conditions it may determine. 40

(2) When a power has been delegated under subsection (1) the Board may, by resolution and on conditions as it may determine, authorise the further delegation of the power concerned by a committee appointed under section 12, the executive management committee or any member thereof or any officer or employee of the Service.

(3) When a power has been further delegated under subsection (2), the committee appointed under section 12, the executive management committee or any member thereof, or the officer or employee of the Service concerned may— 45

- (a) at any time withdraw such delegation and such delegation does not prevent the exercise of the relevant powers by such committee, the executive management committee or such member, officer or employee; and 50
- (b) set aside or vary any decision by an officer or employee of the Service made in the exercise of the power delegated to him or her.

(4) The Board may, by resolution and on conditions as it may determine, authorise any committee appointed under section 12, the executive management committee or any member thereof, officer or employee of the Service to perform any duty assigned to the Service or the Board by this Act. 55

(5) When an authorisation has been given in terms of subsection (4) the Board may, by resolution and on conditions as it may determine, authorise the committee, the executive management committee or any member thereof, or officer or employee of the Service concerned to further authorise any officer or employee of the Service to perform such duty. 5

(6) When an authorisation to perform a duty has been further authorised under subsection (5), the committee, the executive management committee or any member thereof, or the officer or employee of the Service may—

- (a) at any time withdraw such authorisation and such authorisation shall not prevent the performance of the relevant duty by such committee, the executive management committee or such member, officer or employee; and 10
- (b) set aside or vary any decision by an officer or employee of the Service made in the exercise of the power delegated to him or her.

(7) The Board may at any time by resolution withdraw—

- (a) a delegation under subsection (1); or 15
- (b) an authorization under subsection (2),(4) or (5).

(8) The Board may set aside or vary any decision made in the exercise of any power delegated by it under subsection (1) or by virtue of an authorisation under subsection (2), including a decision setting aside or varying a decision under subsection (3)(b) or (6)(b).

Rules 20

27. (1) The Board may make rules not inconsistent with this Act relating to the—

- (a) proceedings at meetings of, and the business of, the Board, committees appointed under section 12, and the executive management committee;
- (b) period for which members appointed to the executive management committee in terms of section 13 must hold office; 25
- (c) duties of officers, employees and other persons in the employ of the Service;
- (d) delegation to any particular officer of powers of appointment and dismissal and such rules must comply with the relevant labour legislation.
- (e) disciplinary rules that establish the standard of conduct required of their employees within the parameters of the relevant labour legislation; 30
- (f) 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 in accordance with relevant labour legislation;
- (g) 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 Service; 35
- (h) fees to be charged by the Service under this Act;
- (i) payment and collection of moneys due for the rendering of laboratory services and fines and penalties for overdue payments; 40
- (j) 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;
- (k) suspension or termination of any laboratory tests for non-payment of charges;
- (l) receipt and utilisation of grants, bequests and donations of any kind; 45
- (m) composition, quorum, functions, powers and duties of committees appointed by the Board under section 12;
- (n) determination and setting of internal quality assurance standards;
- (o) process for the preparation for, and authority for application for accreditation of the laboratories in the Service; or 50
- (p) 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 must, 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. 5

Transitional provisions

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

Short title and commencement 10

29. (1) This Act is called the National Health Laboratory Service Act, 2000, and comes into operation on a date fixed by the President by proclamation in the *Gazette*.

(2) Different dates may be determined in terms of subsection (1) for the commencement of different provisions of this Act and dates so fixed may differ in respect of different provinces and bodies affected by this Act. 15

Schedule

(Section 28)

TRANSITIONAL PROVISIONS

Definitions

1. In this Schedule—

- (i) “Department” means the Department of Health;
- (ii) “commencement date” means the date determined in terms of section 29(2) on which this Act comes into operation;
- (iii) “designated employees” means—
 - (a) the employees in the employ of the department at the commencement date as designated by the Minister in terms of item 3(1); or
 - (b) the employees in the employ of the provincial health department at the commencement date as designated by the Member of the Executive Council responsible for health in the provinces in terms of item 3(2); and
- (iv) “South African Institute for Medical Research” means the South African Institute for Medical Research, and its laboratories, that were established by the State and the mining industry in the Founding Statement of 1917.

Abolition of the bodies and laboratories

2. The following bodies and laboratories must cease to exist, and together with their employees be incorporated into the Service from the commencement date:

- (a) South African Institute for Medical Research;
- (b) National Institute for Virology;
- (c) National Centre for Occupational Health;
- (d) forensic chemistry laboratories owned by the State; and
- (e) all provincial health laboratory services.

Persons in service of State

3. (1) The Minister of Health must, at least 30 days before the commencement date, designate every employee of the Department who is engaged in the provision of laboratory services as employees to be transferred to the Service.

(2) The Member of the Executive Council responsible for health, must, at least 30 days before the commencement date, designate every employee of the provincial department of health who is engaged in the provision of laboratory services as employees to be transferred to the Service.

(3) An employee contemplated in subitems (1) or (2) must, as soon as possible after designation, be informed in writing of such designation.

(4) The transfer of designated employees must be done in terms of—

- (a) relevant labour legislation;
- (b) the Public Service Act, 1994; and
- (c) any collective agreement reached between employers and employees.

(5) Any designated employee who disputes a transfer to the Service may refer such a dispute to the Commission for Conciliation, Mediation and Arbitration in terms of Chapter VII of the Labour Relations Act, 1995.

Rules and regulations

4. Rules or regulations made by the bodies referred to in item 2 which are in force on the commencement date 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 27, until they are replaced by a rule made under section 27.

Assets and liabilities

5. (1) Immovable property owned by—
- (a) the South African Institute for Medical Research; or
 - (b) the State, but which was used for purposes of a public health laboratory, is transferred to the Service.
- (2) The registrar of deeds must register the property referred to in sub-item (1) and make such entries or endorsements in any relevant register, title deed or other document.
- (3) No duty fee is payable in respect of a registration in terms of sub-item (2).
- (4) 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.
- (5) From the commencement date all contractual rights, obligations, assets and liabilities of the bodies referred to in item 2, are transferred to the Service.

Fees to be charged for laboratory services rendered by Service

6. The fees to be charged by the Service for laboratory tests rendered to purchasers in the public health sector must, from the commencement date, be as contained in the schedule of standard prices in force and used by the South African Institute for Medical Research immediately before the commencement date until they can be determined in terms of section 20.

Debt owing to SAIMR and other bodies and laboratories to be abolished

7. (1) All debt owing to the South African Institute for Medical Research and all bodies and laboratories to be abolished by this Act, immediately before the date of commencement, is payable to the Service and must be managed under the same conditions that applied immediately prior to the commencement date.
- (2) The Board may alter the conditions under which the debt is managed after giving the debtors three months notice of the proposed changes.

MEMORANDUM ON THE OBJECTS OF THE NATIONAL HEALTH LABORATORY SERVICE BILL, 2000

1. BACKGROUND

1.1. The Bill seeks to provide for the establishment of a public entity, the National Health Laboratory Service ("the Service"), that will amalgamate all existing laboratories in the public health sector except those managed by the South African Military Health Service and the South African Police Service. Research laboratories of the health science faculties of universities are excluded from the Service, but may be incorporated by agreement.

1.2. Provincial health departments, other State departments or the private sector requiring health laboratory services will purchase the services from the Service. The Service may in turn purchase services from tertiary educational institutions or any other source.

2. OBJECTS OF BILL

2.1. Clause 1 provides for the definitions.

2.2. Clause 2 aims to provide for the exclusion of certain laboratories from the operation of the Act once the Bill becomes an Act. It aims to exclude, among others, laboratories managed by the South African Military Health Service and the South African Police Service.

2.3 Clauses 3, 4 and 5 provide for the establishment of the Service, its objects and functions, powers and duties.

2.4 Clause 6 provides for the control of the Service. It provides, among other things, that the Service will be controlled by a Board appointed by the Minister of Health (the Minister).

2.5 Clauses 7, 8, 9, 10, 11, 12 and 13 provide for the composition of the Board, appointment of members of the Board, chairperson and vice-chairperson of the Board, disqualification from membership of the Board and vacation of office, meetings of the Board and Committees of the Board and the Executive Management Committee, respectively.

2.6 Clause 14 seeks to provide for the staff of the Service.

2.7 Clauses 15 and 16 aim to provide for the purchasing of services from the Service and the rendering of services to foreign countries by the Service.

2.8 Clause 17 provides for discoveries, inventions and improvements by employees of the Service.

2.9 Clause 18 provides for the finances of the Service. It provides, among other things that the funds of the Service may consist of income earned from fees for services rendered, income earned on surplus moneys deposited or invested, money by appropriated by Parliament, grants, donations and bequests made to it.

2.10 Clauses 19 and 20 deal with defrayment of expenditure and charges for services.

2.11 Clauses 21, 22, 23 and 24 deal with borrowing powers of the Service, accounting records, audits, and annual reports.

2.12 Clause 25 deals with proceedings by the Minister in instances where the Service fails to comply with the provisions of the Act.

2.13 Clause 26 deals with the delegation of functions by the Board.

2.14 Clause 27 provides for the making of rules by the Board relating to the day to day functioning of the Board and the Service.

2.15 Clauses 28 and 29 provide for transitional provisions and short title of the Act.

2.16 There is also a Schedule that provides for transitional provisions mainly relating to the abolition of existing laboratories, and matters connected therewith.

3. FINANCIAL IMPLICATIONS

The Service will be funded from the current sources and it is not envisaged that the cost will be more than the current level of expenditure. There will be significant restructuring of the manner in which the budget and expenditure will be designed.

4. IMPLICATIONS FOR THE PROVINCES

The Bill provides for a medical service which falls under the functional area of concurrent national and provincial legislative competence. All provinces have been consulted and they support the Bill.

5. PERSONS/ORGANISATIONS/BODIES CONSULTED

The following were consulted:

- All national departments.
- All provincial health departments.
- Deans, Departmental Heads of Pathology and Principals of all Medical Schools.
- Principals of all technikons.
- All relevant professional associations.
- All relevant trade unions.
- Members of the public in general.

6. PARLIAMENTARY PROCEDURE

The State Law Advisers and the Department of Health are of the opinion that the Bill must be dealt with in accordance with section 76 of the Constitution because the Bill falls within a functional area listed in Schedule 4 of the Constitution, namely “Health services”.