

REPUBLIC OF SOUTH AFRICA

**NATIONAL HEALTH
LABORATORY SERVICE
AMENDMENT BILL**

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

(MINISTER OF HEALTH)

[B 15D—2017]

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GENERAL EXPLANATORY NOTE:

[] Words in bold type in square brackets indicate omissions from existing enactments.

 Words underlined with a solid line indicate insertions in existing enactments.

BILL

To amend the National Health Laboratory Service Act, 2000, so as to define certain expressions and to amend or delete certain definitions; to make the Preferential Procurement Policy Framework Act, 2000, applicable to the National Health Laboratory Service; to adjust the objects and duties of the National Health Laboratory Service; and to strengthen the governance and funding mechanism of the National Health Laboratory Service; and to provide for matters connected therewith.

BE IT ENACTED by the Parliament of the Republic of South Africa, as follows:—

Amendment of section 1 of Act 37 of 2000

- 1.** Section 1 of the National Health Laboratory Service Act, 2000 (hereinafter referred to as “the principal Act”), is hereby amended—
- (a) by the substitution for the definition of “chief executive officer” of the following definition:

“**‘chief executive officer’** means the chief executive officer **[of the executive management committee referred to in section 13] of the Service appointed in terms of section 13A;**”;
 - (b) by the insertion after the definition of “chief executive officer” of the following definition:

“**‘diagnostic health laboratory services’** means a comprehensive service that includes conducting of tests, the interpretation of the results, the communication of the results and the associated participation in patient care with information about the presence, severity and cause of **diseases in patients;**”;
 - (c) by the insertion after the definition of “Minister” of the following definition:

“**‘National Health Council’** means the National Health Council established by section 22(1) of the National Health Act, 2003 (Act No. 61 of 2003);”;
 - (d) by the insertion after the definition of “operational research” of the following definitions:

“**‘prescribed’** means prescribed by regulation made in terms of this Act;

- ‘private health sector’ means that part of the health sector that is not owned or controlled by an organ of state as defined in section 239 of the Constitution of the Republic of South Africa, 1996;” and
 (e) by the deletion of the definition of “teaching environment”.

Amendment of section 3 of Act 37 of 2000 5

2. Section 3 of the principal Act is hereby amended—
 (a) by the substitution for subsection (2) of the following subsection:
 “(2) The Public Finance Management Act, 1999 (Act No. 1 of 1999), [applies] and the Preferential Procurement Policy Framework Act, 2000 (Act No. 5 of 2000), apply, with the necessary changes, to the Service.”; 10
 and
 (b) by the addition of the following subsection:
 “(3) The Board is the accounting authority of the Service.”.

Amendment of section 4 of Act 37 of 2000

3. Section 4 of the principal Act is hereby amended— 15
 (a) by the substitution in paragraph (a) for the words preceding subparagraph (i) of the following words:
 “provide cost-effective and efficient diagnostic health laboratory services to—”; and
 (b) by the substitution for paragraph (c) of the following paragraph: 20
 “(c) provide and support training for health science education.”.

Amendment of section 5 of Act 37 of 2000

4. Section 5 of the principal Act is hereby amended—
 (a) by the substitution in subsection (1) for paragraph (b) of the following paragraph: 25
 “(b) promote the training of its laboratory and associated personnel;”;
 and
 (b) by the substitution in subsection (2) for paragraphs (c) and (d) of the following paragraphs, respectively:
 “(c) participate in joint research operations with departments of State, 30
 universities, [technikons] universities of technology, colleges, museums, scientific institutions and other persons;
 (d) co-operate with educational authorities and scientific or technical societies or industrial institutions representing employers and 35
 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,] universities of technology and colleges;”.

Substitution of section 7 of Act 37 of 2000 40

5. The following section is hereby substituted for section 7 of the principal Act:

“Composition of Board

7. (1) The Board consists of the following members, appointed by the Minister: 45
 (a) The chief executive officer by virtue of his or her office;
 (b) the chief financial officer of the Service by virtue of his or her office;
 (c) three members representing—
 (i) the national Department of Health;
 (ii) the Department of Science and Technology, nominated by the Director-General of that Department; 50
 (iii) the higher education sector, nominated by the Council on Higher Education;

- (d) six members who must have extensive experience in one or more of the following fields:
- (i) Commerce, finance, auditing and economic matters;
 - (ii) corporate management;
 - (iii) public health;
 - (iv) diagnostic laboratory services;
 - (v) legal matters;
 - (vi) epidemiology;
- (e) one representative from organised labour; and
- (f) three members, each representing a cluster of three provinces that must be prescribed based on demographics, access to laboratory services and laboratory services distribution, and who must be nominated on a rotational basis by the respective provinces in the prescribed manner.
- (2) The Board is accountable to the Minister.”.

Amendment of section 8 of Act 37 of 2000

6. Section 8 of the principal Act is hereby amended—

- (a) by the substitution for subsections (1) and (2) of the following subsections, respectively:

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

(2) The Minister must, before appointing the members contemplated in [section 7(d)] section 7(1)(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.”; and

- (b) by the substitution for subsection (4) for the following subsection:

“(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, which reappointment must not be more than once.”.

Substitution of section 9 of Act 37 of 2000

7. The following section is hereby substituted for section 9 of the principal Act:

“Chairperson and vice-chairperson of Board

9. (1) The Minister must appoint a chairperson and a vice-chairperson for the Board from amongst the members appointed in terms of section 7(1)(c), (d) or (e).

(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 members must designate another member of the Board to act as chairperson until the chairperson or vice-chairperson is available.

(3) In the event that the chairperson or the vice-chairperson is absent or unavailable for two consecutive meetings, the Board in consultation with the Minister must designate a member to act as chairperson or vice-chairperson until such time that the chairperson or vice-chairperson is able to resume his or her functions as chairperson or vice-chairperson.

(4) Any person acting as chairperson of the Board in terms of subsection (2) or (3), must perform all the functions of the chairperson.”.

Amendment of section 10 of Act 37 of 2000

8. Section 10 of the principal Act is hereby amended by the substitution in subsection (2) for paragraph (d) of the following paragraph:

“(d) he or she has, without the leave of the Board, been absent **[from more than]** for two consecutive meetings of the Board;”.

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Insertion of section 10A in Act 37 of 2000

9. The following section is hereby inserted in the principal Act after section 10:

“Dissolution of Board

10A. (1) The Minister may dissolve the Board—

- (a) if the Board is unable to perform its duties in terms of this Act or on the grounds of mismanagement; 10
 (b) if there is a total breakdown in the relationship between the Minister and the Board; or
 (c) if there is a breakdown in the relationship amongst the members of the Board, which renders the continued effective functioning of the Board impossible. 15

(2) In exercising his or her powers in terms of this section, the Minister must comply with the Promotion of Administrative Justice Act, 2000 (Act No. 3 of 2000).

(3) Within 21 days of the dissolution of the Board, the Minister must appoint an Interim Board, consisting of a minimum of three persons, to assume the responsibilities of the Board until a new Board is constituted in accordance with the procedure set out in section 8. 20

(4) A new Board must be constituted within 180 days of the dissolution of the previous Board. 25

(5) The Minister may appoint to the new Board a person who was a member of the Board that was dissolved in terms of this section.

(6) The subparagraph (5) appointment is subject to persons who were members of the dissolved Board not constituting more than six members of the Board.”. 30

Amendment of section 11 of Act 37 of 2000

10. Section 11 of the principal Act is hereby amended—

- (a) by the substitution for subsection (1) of the following subsection:

“(1) The meetings of the Board and the conduct of the business at meetings must be **[prescribed]** determined by the rules;”;

- (b) by the substitution for subsection (3) of the following subsection:

“(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

Amendment of section 13 of Act 37 of 2000

11. Section 13 of the principal Act is hereby amended by the substitution in subsection (1) for paragraph (b) of the following paragraph:

“(b) the chief financial officer and as many other employees of the Service as the Board may deem necessary.”.

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Insertion of sections 13A and 13B in Act 37 of 2000

12. The following sections are hereby inserted in the principal Act after section 13:

“Appointment of chief executive officer

13A. (1) The Board must, in consultation with the Minister, appoint a fit

and proper and suitably qualified South African citizen as the chief executive officer of the Service and determine his or her remuneration.

(2) The chief executive officer holds office for a term of five years and may be reappointed for one additional term of five years.

(3) The appointment of a person as the chief executive officer is subject to the conclusion of a written performance agreement entered into between that person and the Board.

(4) The Board and the chief executive officer may, in writing and by agreement, amend the performance agreement.

(5) The Board may, in consultation with the Minister, remove the chief executive officer from office on account of serious misconduct, incapacity or incompetence, after affording him or her reasonable opportunity to be heard and subject to applicable legislation.

(6) The Board, in consultation with the Minister, may designate an employee of the Service to act as chief executive officer—

(a) if the chief executive officer is unable to perform his or her functions as chief executive officer; or

(b) during a vacancy in the office of chief executive officer.

(7) No person may be designated as an acting chief executive officer for a period longer than 180 days.

Functions of chief executive officer

13B. (1) The chief executive officer—

(a) is the administrative head of the Service;

(b) is responsible for the proper and diligent implementation of the Public Finance Management Act, 1999 (Act No. 1 of 1999); and

(c) subject to section 14, must appoint suitably qualified persons as employees of the Service in accordance with an organisational structure and terms and conditions approved by the Board.

(2) As administrative head of the Service, the chief executive officer is responsible for—

(a) delivering on the agreed mandate of the Service as determined by the Board in terms of this Act;

(b) the formation and development of internal rules and directives for an efficient administration;

(c) the organisation and control of staff;

(d) the maintenance of discipline;

(e) the effective deployment and utilisation of staff to achieve maximum operational results;

(f) the issuing of guidelines regarding the manner in which claims should be handled;

(g) the exercise of any such powers and performance of any such duties as may be delegated or assigned to him or her by the Board; and

(h) making the annual report, financial statements and audit report on those statements in respect of the Service accessible to the public once the annual report, financial statements and the audit report have been tabled in Parliament by the Minister.

(3) The chief executive officer must, upon request by the Minister—

(a) furnish the Minister with information or a report in respect of any case, matter or subject dealt with by the Service; and

(b) provide the Minister with reasons for any decision taken by the Service, the Board, the chief executive officer or any other employee of the Service.”

Substitution of section 18 of Act 37 of 2000

13. The following section is hereby substituted for section 18 of the principal Act:

“Finances of Service

18. (1) The Minister, in consultation with the Minister of Finance, must prescribe a financing mechanism for the Service in order to ensure that the

Service is adequately and sustainably funded and thereby enabling the Service to achieve the objects of this Act.

- (2) The Service is funded through—
- (a) money appropriated by Parliament on such terms and conditions as the Minister, with the concurrence of the Minister of Finance, may determine;
 - (b) fees collected for services rendered;
 - (c) income earned on surplus moneys deposited or invested;
 - (d) grants, donations and bequests made to it;
 - (e) royalties; or
 - (f) money received from any other source.
- (3) The Service must charge such fees for services rendered that are not covered by the financing mechanism contemplated in subsection (1) as prescribed by the Minister, after consultation with the Minister of Finance.”.

Repeal of section 20 of Act 37 of 2000

14. Section 20 of the principal Act is hereby repealed.

Amendment of section 27 of Act 37 of 2000

15. Section 27 of the principal Act is hereby amended—
- (a) by the substitution for the heading of the following heading: **“Rules and Regulations”**; and
 - (b) by the addition of the following subsections:
 - “(4) The Minister, after consultation with the National Health Council, may make regulations regarding—
 - (a) anything which may or must be prescribed in terms of this Act; and
 - (b) any ancillary or incidental administrative or procedural matter that it is necessary to prescribe for the proper implementation or administration of this Act.
 - (5) Before the Minister makes any regulation under this section, he or she must publish a draft of the proposed regulation in the *Gazette* together with a notice calling on interested persons to comment, in writing, within a period stated in the notice of not less than 30 days from the date of publication of the notice.
 - (6) If the Minister alters the draft regulations as a result of any comment, he or she need not publish those alterations before making the regulations.”.

Transitional provisions

16. (1) The Board of the Service as it existed immediately before the commencement of section 5 of this Act ceases to exist on the day immediately preceding the date of the first meeting of the Board appointed in terms of section 7 of the principal Act as amended by this Act.

(2) The chief executive officer of the Board who was in office immediately before the commencement of section 5 of this Act remains in office for the duration of his or her contract notwithstanding the amendment of the principal Act by this Act.

Short title and commencement

17. This Act is called the National Health Laboratory Service Amendment Act, 2018, and comes into operation on a date fixed by the President by proclamation in the *Gazette*.

MEMORANDUM ON THE OBJECTS OF THE NATIONAL HEALTH LABORATORY SERVICE AMENDMENT BILL

1. BACKGROUND

The Bill seeks to amend the National Health Laboratory Services Act, 2000 (Act No. 37 of 2000) (“the Act”), in order to improve the governance, accountability and financial sustainability of the National Health Laboratory Service (“the Service”). The said improvement will enable the Service to provide diagnostic health laboratory services in a more cost-effective manner and with greater efficiency, thereby increasing the quality of clinical care provided to patients through timely and judicious clinical management.

2. ANALYSIS OF BILL

The Bill seeks to amend the following sections of the Act:

- 2.1 Clause 1 proposes amendments to section 1 of the Act by, firstly, the deletion of the definition of “teaching environment” as the expression is never used in the Act. The clause also seeks to define words and expressions inserted in the Act by the Bill, namely “National Health Council”, “prescribed”, “private health sector” and “diagnostic health laboratory services” and to amend the expression of “chief executive officer”.
- 2.2 Clause 2 seeks to amend section 3 of the Act by including the Preferential Procurement Policy Framework Act, 2000 (Act No.5 of 2000), thereby making the provisions of that Act applicable to the Service. The clause also seeks to provide that the Board of the Service is the accounting authority of the Service.
- 2.3 Clause 3 proposes amendments to section 4 of the Act. The clause seeks to insert the word “diagnostic” in paragraph (a) to ensure that the core mandate of the Service is to provide “diagnostic health laboratory services” to the public. Furthermore, in paragraph (b) of the section it is proposed that the word “provide” be replaced with the word “support” in order to reduce the burden on the Service by giving the Service a supporting role instead of the Service being the provider of training for health science education.
- 2.4 Clause 4 seeks to amend section 5 of the Act in order to make it clear that it is the duty of the Service to promote the training of its staff members only.
- 2.5 Clause 5 seeks to replace section 7 of the Act and to provide for the composition of the Board of the Service anew. In terms of the new section 7, the Board will consist of—
 - the chief executive officer by virtue of his or her office;
 - the chief financial officer of the Service by virtue of his or her office;
 - three members representing—
 - o the national Department of Health;
 - o the Department of Science and Technology;
 - o the higher education sector;
 - six members who must have extensive experience in the fields of commerce, finance, auditing and economic matters, corporate management, public health, diagnostic laboratory services, legal matters and epidemiology; and
 - one representative from organised labour.

It is further proposed that the Board is accountable to the Minister of Health.

- 2.6 Clause 6 proposes amendments to section 8 of the Act in order to align that section with the amendments proposed to section 7. It is also proposed that the words “and must ensure that appropriate laboratory professionals are appointed” be omitted in section 8(1) of the Act as the members from the bodies and institutes referred in the new section 7 are not necessarily laboratory professionals.
- 2.7 Clause 7 seeks to replace section 9 of the Act and to provide for the appointment of the chairperson and vice-chairperson of the Board of the Service in more detail. The Minister appoints a chairperson and a vice-chairperson for the Board from amongst the non-executive members of the Board. 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 members must designate another member of the Board to act as chairperson until the chairperson or vice-chairperson is available. The clause also proposes that in the event that the chairperson or the vice-chairperson being absent or unavailable for two consecutive meetings, the Board in consultation with the Minister designate a member to act as chairperson or vice-chairperson until such time that the chairperson or vice-chairperson is able to resume his or her functions as chairperson or vice-chairperson.
- 2.8 Clause 8 seeks to amend section 10 of the Act in order to provide that a member must vacate his or her office if he or she has been absent for two consecutive meetings of the Board without the leave of the Board. The current position is that the member must be absent “from more than” two meetings without such leave.
- 2.9 Clause 9 proposes the insertion of section 10A in the Act and seeks to provide for the dissolution of the Board by the Minister under certain circumstances and the appointment of an Interim Board. It is further proposed that a new Board must be constituted within 180 days of the dissolution of the old Board.
- 2.10 Clause 10 seeks to amend section 11 of the Act by providing that the meetings of the Board and the conduct of business at meetings must be “determined” by the rules. The replacement of the word “prescribed” with “determined” is necessary as a result of amendments proposed to section 27 of the Act. In terms of those proposals the Minister will be empowered to “prescribe” certain matters by the making of regulations (see paragraph 2.16 below).
- 2.11 Clause 11 seeks to amend section 13 of the Act by providing that the Chief Financial Officer must be appointed to the executive management committee of the Board.
- 2.12 Clause 12 proposes the insertion of sections 13A and 13B in the Act. Sections 13A provides for the appointment of the chief executive officer of the Board and section 13B for the functions of the chief executive officer.
- 2.13 Clause 13 seeks to replace section 18 of the Act by providing that the Minister in consultation with the Minister of Finance may prescribe a financing mechanism for the service. It also provides for the funds of the Service.
- 2.14 Clause 14 seeks to repeal section 20 of the Act. The provisions of that section have become redundant as a result of the new proposed section 18.
- 2.15 Clause 15 seeks to repeal section 25 of the Act. The provisions of that section have become redundant as a result of the proposed insertion of section 10A in the Act (see paragraph 2.9 above).
- 2.16 Clause 16 seeks to amend section 27 of the Act. The section is to be amended to empower the Minister to make regulations regarding amongst others anything that must or may be prescribed in terms of the Act. The Minister

makes the regulations after consultation with the National Health Council. Before the Minister makes any regulation, the regulation must be published in the *Gazette* for at least one month calling for interested persons to submit their comment.

2.17 Clause 17 proposes transitional provisions in respect of the current Board and chief executive officer of the Board.

2.18 Clause 18 provides for the short title and commencement date.

3. DEPARTMENTS/BODIES CONSULTED

The draft Bill was published for public comment on 11 November 2015 and the comment period extended on 26 January 2016. Comments were received from the following departments, bodies and persons:

- National Institute for Occupational Health;
- Section 27;
- National Treasury;
- University of Free State;
- Western Cape Government; and
- the Service.

Consultation in respect of the draft Bill has also taken place within the Social Cluster Departments, namely the Department of Social Development, Department of Basic Education and Department of Women, Children and People with Disabilities.

4. FINANCIAL IMPLICATIONS FOR STATE

The Bill has no direct financial implications in respect of its implementation. The new funding model moves away from an inefficient fee-for-service reimbursement system and offers significant benefit for Provincial Health Departments. With regard to the core mandate of providing pathology services to the public health sector, tests will be based on current cost structures through a capitated model of reimbursement. The combined savings across all Provincial Health Departments for the 2016/17 financial year would be just under R900 million.

5. PARLIAMENTARY PROCEDURE

5.1 The legislative authority of Parliament is provided for in Chapter 4 of the Constitution of the Republic of South Africa, 1996 (“the Constitution”). Section 44(1)¹ of the Constitution confers on the National Assembly the power to amend the Constitution, to pass legislation with regard to any matter, including a matter within a functional area listed in Schedule 4 to the Constitution but excluding, subject to subsection (2), a matter within a functional area listed in Schedule 5 to the Constitution. The section also confers on the National Council of Provinces the power to participate in the amendment of the Constitution, to pass in accordance with section 76 of the Constitution legislation with regard to any matter within the functional area listed in Schedule 4, and to consider, in accordance with section 75 of the Constitution, any other legislation passed by the National Assembly.

¹ “(1) The national legislative authority as vested in Parliament—

- (a) confers on the National Assembly the power—
- (i) to amend the Constitution;
 - (ii) to pass legislation with regard to any matter, including a matter within a functional area listed in Schedule 4, but excluding, subject to subsection (2), a matter within a functional area listed in Schedule 5; and

- 5.2 Part A of Schedule 4 to the Constitution lists the functional areas of concurrent national and provincial legislative competence, whilst Part B of that Schedule lists local government matters that may be legislated upon within the framework provided for in section 155(6)(a) and (7) of the Constitution. Part A of Schedule 5 to the Constitution on the other hand lists the functional areas of exclusive provincial competence, with Part B of that Schedule listing local government matters that may be legislated upon within the framework mentioned above.
- 5.3 Sections 74 to 77 of the Constitution outline the process to be followed when processing Bills in Parliament. Section 75 outlines the process to be followed when the National Assembly passes a Bill other than a Bill to which the procedure set out in section 74 or 76 applies. Section 76 on the other hand outlines the process when the National Assembly passes a Bill referred to in subsection (3), (4) or (5) of that section. Section 76(3) of the Constitution reads as follows:

“(3) A Bill must be dealt with in accordance with the procedure established by either subsection (1) or subsection (2) if it falls within a functional area listed in Schedule 4 or provides for legislation envisaged in any of the following sections:

- (a) Section 65(2);
- (b) section 163;
- (c) section 182;
- (d) section 195(3) and (4);
- (e) section 196; and
- (f) section 197.” (emphasis added).

- 5.4 In terms of section 76(3) of the Constitution, a Bill falling within a functional area listed in Schedule 4 to the Constitution must be dealt with in accordance with the procedure set out in section 76(1) or (2) of the Constitution.
- 5.5 In order to determine if a provision of a Bill falls in an area listed in Schedule 4 to the Constitution, the courts have developed tagging guidelines. In *Tongoane and Others v National Minister for Agriculture and Land Affairs and Others*², the Constitutional Court indicated the following regarding the test for tagging and purpose of tagging:

“[59] . . . the tagging test is distinct from the question of legislative competence. It focuses on all the provisions of the Bill in order to determine the extent to which they substantially affect functional areas listed in Schedule 4, and not on whether any of its provisions are incidental to its substance.

[60] The test for tagging must be informed by its purpose. Tagging is not concerned with determining the sphere of government that has the competence to legislate on a matter. Nor is the process concerned with preventing interference in the legislative competence of another sphere of government. The process is concerned with the question of how the Bill should be considered by the provinces and in the . . . (National Council of Provinces), and how a Bill must be considered by the provincial legislatures depends on whether it affects the provinces.

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- (iii) to assign any of its legislative powers, except the power to amend the Constitution, to any legislative body in another sphere of government; and
 - (b) confers on the National Council of Provinces the power—
 - (i) to participate in amending the Constitution in accordance with section 74;
 - (ii) to pass, in accordance with section 76, legislation with regard to any matter within a functional area listed in Schedule 4 and any other matter required by the Constitution to be passed in accordance with section 76; and
 - (iii) to consider, in accordance with section 75, any other legislation passed by the National Assembly.”.

² 2010 (8) BCLR 741 (CC).

The more it affects the interests, concerns and capacities of the provinces, the more say the provinces should have on its content.

...

[64] The purpose of tagging is, therefore, to determine the nature and extent of the input of provinces on the content of legislation affecting them. Indeed, all the legislation mentioned in s 76(3) is legislation that substantially affects the interests of provinces.

...

[71] ... the ‘substantial measure’ test permits a consideration of the provisions of the Bill and their impact on matters that substantially affect the provinces. This test ensures that legislation that affects the provinces will be enacted in accordance with a procedure that allows the provinces to fully and effectively play their role in the law-making process. This test must therefore be endorsed.

[72] To summarise: any Bill whose provisions substantially affect the interests of the provinces must be enacted in accordance with the procedure stipulated in ... (section) 76. This naturally includes proposed legislation over which the provinces themselves have concurrent legislative power, but it goes further. It includes Bills providing for legislation envisaged in the further provisions set out in ... (section) 76(3)(a)—(f), over which the provinces have no legislative competence, as well as Bills, the main substance of which falls within the exclusive national competence, but the provisions of which nevertheless substantially affect the provinces. What must be stressed, however, is that the procedure envisaged in ... (section) 75 remains relevant to all Bills that do not, in substantial measure, affect the provinces. Whether a Bill is a ... (section) 76 Bill is determined in two ways. First, by the explicit list of legislative matters in ... (section) 76(3)(a)—(f); and second by whether the provisions of a Bill in substantial measure fall within a concurrent provincial legislative competence.” (footnotes omitted and emphasis added).

5.5 The *Tongoane* judgement therefore laid down the substantial measure test for the tagging of a Bill which requires the determination whether the legislation under consideration to a substantial extent regulates matters falling within Schedule 4 to the Constitution.

5.6. “Health services” is a functional area of concurrent national and provincial legislative competence listed in Schedule 4 to the Constitution.

5.7. The Collins English Dictionary defines “health” as follows:

“ **‘health’** means—

1. the state of being bodily and mentally vigorous and free from disease
2. the general condition of body and mind: *on poor health*

...

6. (*modifier*) of or relating to health, esp to the administration of health: *a health committee; health resort; health service*”.

5.8. Section 1 of the National Health Act, 2003 (Act No. 61 of 2003), defines “health services” as follows:

“ **‘health services’** means—

- (a) health care services, including reproductive health care and emergency medical treatment, contemplated in section 27 of the Constitution;

- (b) basic nutrition and basic health care services contemplated in section 28(1)(c) of the Constitution;
- (c) medical treatment contemplated in section 35(2)(e) of the Constitution; and
- (d) municipal health services;”.

5.9. The Bill seeks to amend the Act in order to emphasise that the “health services” that the Service provide, must be “cost-effective and efficient diagnostic health laboratory services”. In terms of the definition of “diagnostic health laboratory services”, it is “a comprehensive service that includes conducting of tests, the interpretation of the results, the communication of results and the associated participation in patient care with information about the presence, severity, and cause of diseases in patients”. (emphasis added).

5.10. The provisions of the Bill therefore in substantial measure fall within a concurrent provincial legislative competence and must therefore be dealt with in accordance with the procedure established by section 76(1) or (2) of the Constitution.

6. The State Law Advisers are of the opinion that it may not be necessary to refer this Bill to the National House of Traditional Leaders in terms of section 18(1)(a) of the Traditional Leadership and Governance Framework Act, 2003 (Act No. 41 of 2003), since it does not contain provisions pertaining to customary law or customs of traditional communities.

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