

House of Representatives
Supplementary Order Paper

Tuesday, 17 February 2004

**Health (National Cervical Screening Programme)
Amendment Bill**

Proposed amendments

Hon Annette King, in Committee, to move the following amendments:

Clause 2

To omit this clause (lines 8 and 9 on page 2), and substitute the following clause:

2 Commencement

- (1) This section, **section 112D** of the principal Act (as inserted by **section 4** of this Act), and **section 6**, come into force on **1 July 2004**.
- (2) The rest of this Act comes into force 12 months after the date on which this Act receives the Royal Assent.

Clause 4: new section 112A

To omit *paragraph (a)* (lines 22 to 25 on page 2), and substitute the following paragraph:

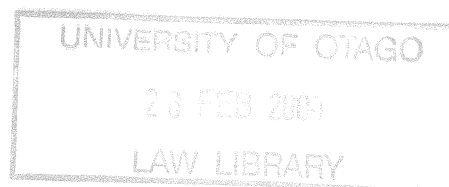
- “(a) to reduce the incidence and mortality rate of cervical cancer by providing for the continuation of the NCSP; and

Clause 4: new section 112B

To insert, after the definition of **health information** (after line 12 on page 4), the following definition:

“**health practitioner** has the meaning set out in section 5 of the Health Practitioners Competence Assurance Act 2003

To omit the definition of **NCSP** (lines 16 and 17 on page 4), and substitute the following definition:



“NCSP means the programme that, at the date of commencement of this section, is operated by the Ministry of Health and known as the National Cervical Screening Programme

To omit the definition of **registered health professional** (lines 32 and 33 on page 4).

To add, after the definition of **relevant woman** (after line 3 on page 5), the following definition:

“**review committee** means an NCSP review committee established under **section 1120A**

Clause 4: new section 112D

To omit *subsection (1)* (lines 9 to 12 on page 6), and substitute the following subsections:

“(1) All persons appointed to operate the NCSP, and to perform functions in relation to the operation of that programme, must be appointed under section 59 of the State Sector Act 1988, unless it is not reasonably practicable to do so.

“(1A) If the Director-General wishes to appoint a particular person to perform particular functions in relation to the operation of the NCSP, and it is not reasonably practicable to appoint that person under section 59 of the State Sector Act 1988, the Director-General may appoint that person to perform those functions under this subsection.

To insert, in *subsection (2)*, after the word “appoint” (line 13 on page 6), the words “, either under section 59 of the State Sector Act 1988 or under **subsection (1A)**,”.

To omit from *subsection (3)* the words “under **subsection (1)**” (lines 15 and 16 on page 6), and substitute the words “under section 59 of the State Sector Act 1988 or under **subsection (1A)**”.

Clause 4: new section 112EA

To omit this section (lines 14 to 18 on page 7).

Clause 4: new section 112I

To insert in *subsection (1)(aa)*, after the word “cancelled” (line 15 on page 9), the words “or, as the case requires, that she will not be enrolled”.

To omit from *subsection (3)(b)* the word “Act” (line 18 on page 10), and substitute the word “section”.

Clause 4: new section 112K(1)

To insert, after *paragraph (b)* (after line 2 on page 11), the following paragraph:

“(ba) to a review committee, in accordance with a request from that committee under **section 1120C(1)**; or

To omit from *paragraph (c)* the words “registered health professional” in both places where they appear (line 3 and line 6 on page 11), and substitute in each case the words “health practitioner”.

Clause 4: proposed new cross-heading and new sections 1120A to 1120E
To add, after *new section 1120*, the following cross-heading and sections (after line 12 on page 14):

“Review of NCSP and duty of Director-General to report

“1120A Establishment of NCSP review committee

“(1) The Minister may from time to time, and must at least once every 3 years, establish a review committee of up to 3 persons to review—

“(a) the operation of the NCSP; and

“(b) evaluation activities of the kind described in **section 112P** that have been carried out or are proposed to be carried out.

“(2) The focus of a review committee must be the continuous quality improvement of components of the NCSP, with a view to reducing the incidence and mortality rates of cervical cancer.

“(3) No person appointed to a review committee may be—

“(a) a member of Parliament; or

“(b) an officer or employee of the Ministry of Health; or

“(c) a person who is, or has been, designated under **section 112Q** as a screening programme evaluator; or

“(d) a person who would have a material conflict of interest if appointed.

“(4) In order to facilitate the review being carried out in a timely and efficient manner, the Minister must appoint persons who collectively have an appropriate balance of skills and knowledge, including knowledge of cervical screening.

“(5) The Minister may appoint persons to the review committee—

“(a) on terms and conditions as to remuneration and other benefits that are in accordance with the appropriate fees framework determined by the Government for statutory and other bodies; and

“(b) on any other terms and conditions that the Minister considers appropriate.

“1120B Work of review committee

“(1) Before beginning its review, the review committee must prepare a review plan.

“(2) In preparing its review plan, the review committee must—

“(a) ensure that the plan—

“(i) applies the focus referred to in **section 1120A(2)**; and

“(ii) takes into account the need for timeliness in the completion of the review; and

- “(b) consult with interested parties about any significant issues that may warrant review, in relation to the operation of the NCSP or evaluation activities that have been, or are proposed to be, carried out; and
 - “(c) following that consultation, determine—
 - “(i) which issues are to be reviewed; and
 - “(ii) the expected date of completion of the review; and
 - “(d) provide the review plan to the Minister for comment, and fully take into account any comments made by the Minister before finalising that plan.
- “(3) After finalising the review plan, the review committee must conduct the review in accordance with that plan.
- “(4) When making any recommendations resulting from its review, the review committee must take into account—
- “(a) the objectives of the NCSP; and
 - “(b) the need for fiscal responsibility.
- “(5) The review committee may, subject to any written direction by the Minister, regulate its own procedure.

“112OC **Review committee’s access to information**

- “(1) For the purposes of carrying out its review, the review committee may request any information held by the NCSP that is directly relevant to the subject matter of its review.
- “(2) The NCSP manager must provide to a review committee any information held by the NCSP that is requested by that review committee under **subsection (1)**.
- “(3) To avoid doubt, the confidentiality obligations set out in **section 112K** apply to members of a review committee.

“112OD **Report by review committee**

- “(1) The review committee must—
- “(a) set out in a report—
 - “(i) the details of its review; and
 - “(ii) the conclusions it has reached; and
 - “(iii) the recommendations (if any) it makes as a result of that review; and
 - “(b) submit that report to the Minister as soon as reasonably practicable after it is completed.
- “(2) The Minister must present the report to the House of Representatives not later than 10 sitting days after the date on which the Minister receives the report from the committee, and, following that presentation, must make the report publicly available.

“112OE Duty of Director-General to report

The Director-General must, from time to time, provide information to the public on the quality and effectiveness of the NCSP including, if it is appropriate, information based on the results of evaluations.

Clause 4: new section 112U

To omit *subparagraph (2)(e)(i)* (line 8 on page 17), and substitute the following subparagraph:

“(i) health practitioner; or

To insert, after subsection (2C), the following subsection (after line 20 on page 17):

(2D) When a screening programme evaluator accesses health information under **subsection (2)(e)(i)** that is held by, or otherwise in the power or control of, a health practitioner, that health practitioner may oversee that access.

Clause 4: new section 112X(2)

To omit *paragraph (b)* (lines 10 to 16 on page 19), and substitute the following paragraph:

“(b) use and disclose evaluation material for the purpose of referring a concern about the competence of a health practitioner to the authority responsible for the registration of practitioners of the profession that the person concerned practises, if the screening programme evaluator has first obtained the consent of the Director-General to use and disclose the material for that purpose; and

To omit from *paragraph (c)* the words “health professional” (line 20 on page 19), and substitute the words “health practitioner”.

Clause 4: new section 112ZAA

To omit from the heading to this section the words “**registered health professionals**” (line 3 on page 22), and substitute the words “**health practitioners**”.

To omit from *subsection (1)* the words “registered health professional” (line 4 on page 22), and substitute the words “health practitioner”.

To omit from *subsection (2)* the words “registered health professional” (line 11 on page 22), and substitute the words “health practitioner”.

Clause 4: new section 112ZD

To add to *subsection (2)* the following paragraphs (after line 9 on page 25):

“(h) prescribing offences for a breach of—

“(i) a regulation made under any of **paragraphs (a) to (f)**:

“(ii) a standard prescribed under **paragraph (g)**, or any part of that standard:

“(i) setting out defences to offences prescribed under **paragraph (h)**:

- “(j) setting the maximum penalty for each offence prescribed under **paragraph (h)**, which must not exceed the maximum penalty specified in section 136.

To add, after *subsection (3)* the following subsection (after line 18 on page 25):

- “(4) **Subsection (3)** does not apply to regulations made under **subsection (2)(g)** that—
- “(a) incorporate standards by reference; or
- “(b) state that an amendment to, or replacement of, standards incorporated by reference has legal effect as part of the regulations.

Clause 4: proposed new sections 112ZDA to 112ZDI

To add the following new sections (after line 18 on page 25):

“112ZDA **Incorporation of standards by reference in regulations**

- “(1) Regulations made under **section 112ZD(2)(g)** may incorporate by reference any standards prepared by or for the NCSP that apply to providers of screening, diagnostic, and treatment services (including, but not limited to, any New Zealand Standard).
- “(2) Standards may be incorporated by reference in regulations—
- “(a) in whole or in part; and
- “(b) with modifications, additions, or variations specified in the regulations.
- “(3) Standards incorporated by reference in regulations have legal effect as part of the regulations.

“112ZDB **Effect of amendments to, or replacement of, standards incorporated by reference in regulations**

An amendment to, or replacement of, standards incorporated by reference in regulations (**regulations A**) has legal effect as part of regulations A only if regulations made under **section 112ZD(2)(g)** after the making of regulations A state that the particular amendment or replacement has that effect.

“112ZDC **Proof of standards incorporated by reference**

- “(1) A copy of standards incorporated by reference in regulations, including any amendment to, or replacement of, the standards, (**standards**) must be—
- “(a) certified as a correct copy of the standards by the Director-General; and
- “(b) retained by the Director-General.
- “(2) The production in proceedings of a certified copy of the standards is, in the absence of evidence to the contrary, sufficient evidence of the incorporation in the regulations of the standards.

**“112ZDD Effect of expiry or revocation of standards
incorporated by reference**

Standards incorporated by reference in regulations that expire or that are revoked or that cease to have effect cease to have legal effect as part of the regulations only if regulations made under **section 112ZD(2)(g)** state that the standards cease to have legal effect.

“112ZDE Requirement to consult

“(1) This section applies to regulations made under **section 112ZD(2)(g) that—**

- “(a) incorporate standards by reference; or**
- “(b) state that an amendment to, or replacement of, standards incorporated by reference in regulations has legal effect as part of the regulations.**

“(2) Before regulations to which this section applies are made, the Director-General must—

- “(a) prepare the standards proposed to be incorporated by reference or the proposed amendment to, or replacement of, standards incorporated by reference (**proposed standards**) in consultation with persons or organisations whom the Director-General considers appropriate, including persons who are able to represent the views of health practitioners, or of classes of health practitioner, who will be directly affected by the proposed standards; and**
- “(b) make copies of the proposed standards available for inspection during working hours for a reasonable period, free of charge, at the head office of the Ministry of Health and at any other places that the Director-General determines are appropriate; and**
- “(c) make copies of the proposed standards available for purchase at a reasonable price; and**
- “(d) make copies of the proposed standards available on an Internet website maintained by or on behalf of the Ministry of Health; and**
- “(e) give notice in the *Gazette* stating that—**
 - “(i) the proposed standards are available for inspection during working hours free of charge, the place or places at which they can be inspected, and the period during which they can be inspected; and**
 - “(ii) copies of the proposed standards can be purchased and the place or places at which they can be purchased; and**
 - “(iii) the standards are available on the Internet free of charge, and the website address; and**

- “(f) allow a reasonable opportunity for persons to comment on the proposal to incorporate the proposed standards by reference; and
- “(g) consider any comments they make.
- “(3) A failure to comply with this section does not invalidate regulations that incorporate standards by reference.

“112ZDF **Access to standards incorporated by reference**

- “(1) The Director-General must—
 - “(a) make the standards referred to in **subsection (2) (standards)** available for inspection during working hours free of charge at the head office of the Ministry of Health and at any other places that the Director-General determines are appropriate; and
 - “(b) make copies of the standards available for purchase at a reasonable price; and
 - “(c) make copies of the standards available on an Internet website maintained by or on behalf of the Ministry of Health; and
 - “(d) give notice in the *Gazette* stating that—
 - “(i) the standards are incorporated in the regulations and the date on which the regulations were made; and
 - “(ii) the standards are available for inspection during working hours free of charge and the place or places at which they can be inspected; and
 - “(iii) copies of the standards can be purchased and the place or places at which they can be purchased; and
 - “(iv) the standards are available on the Internet, free of charge, and the website address.
- “(2) The standards are—
 - “(a) standards incorporated by reference in regulations made under **section 112ZD(2)(g)**;
 - “(b) any amendment to, or replacement of, those standards that is incorporated in the regulations or the standards referred to in **paragraph (a)** with amendments or replacement standards incorporated.
- “(3) A failure to comply with this section does not invalidate regulations that incorporate standards by reference.

“112ZDG **Acts and Regulations Publication Act 1989 not applicable to standards incorporated by reference**

The Acts and Regulations Publication Act 1989 does not apply to standards incorporated by reference in regulations or to an amendment to, or replacement of, those standards.

**“112ZDH Application of Regulations (Disallowance) Act 1989
to standards incorporated by reference**

- “(1) Nothing in section 4 of the Regulations (Disallowance) Act 1989 requires standards that are incorporated by reference in regulations to be laid before the House of Representatives.
- “(2) The Regulations (Disallowance) Act 1989, apart from the modification to the application of section 4 of that Act made by **subsection (1)** of this section, applies to regulations that incorporate standards by reference.

“112ZDI Application of Standards Act 1988 not affected

Sections 112ZDA to 112ZDH do not affect the application of sections 22 to 25 of the Standards Act 1988.

Clause 4: new section 112ZE

To omit *subclause (1)* (lines 20 to 24 on page 25), and substitute the following subclause:

- “(1) Every person commits an offence against this Act who, without reasonable excuse, fails to comply with the requirements of any of **section 112K(1), section 112X(1), (3)(d), or (4)(b), or section 112Y.**

Clause 6 and new clause 7

To omit *clause 6* (line 13 on page 27 to line 2 on page 28), and substitute the following clauses:

6 Transitional provision

- (1) To avoid doubt, and without limiting their rights and obligations under this Part, every person who, immediately before the commencement of this section, was employed by the Director-General under the State Sector Act 1988 to work in the NCSP continues to be employed under, and governed by, that Act.
- (2) The NCSP manager must take reasonable steps to ensure that information about the programme and the effect of this Act is made available to women who have results included on the NCSP register.
- (3) Despite section 74A(5) of the principal Act, information on the NCSP register that identifies a woman may be disclosed for the purpose of enabling information to be provided to women under **subsection (2)**.
- (4) For the purposes of this section,—
- NCSP means the programme that, at the date of commencement of this section, is operated by the Ministry of Health and known as the National Cervical Screening Programme
- NCSP manager means—
- (a) the person appointed under **section 112D(2)** as the NCSP manager; or,

- (b) if no person has been appointed as the NCSP manager, the Director-General

NCSP register means the register maintained under section 74A of the principal Act.

7 Further transitional provision relating to enrolment in NCSP

- (1) The NCSP register is the same register that was maintained under section 74A of the principal Act immediately before the commencement of this section.
- (2) Every woman who, immediately before the commencement of this section, had results included on the NCSP register is deemed to have been enrolled in the NCSP in accordance with **section 112F**.
- (3) To avoid doubt, **subsection (2)** applies to a woman who, before the commencement of this section, requested that 1 or more results that relate to her not be included on the NCSP register, but did not request that all results that relate to her be removed from that register.
- (4) If the NCSP manager knows that a woman, before the commencement of this section, requested that all results that relate to her be removed from the NCSP register, the NCSP manager must take reasonable steps to deal with all information held by the NCSP relating to that woman in accordance with **section 112I** as if that woman had cancelled her enrolment in the NCSP under **section 112H(1)**.

Explanatory note

This Supplementary Order Paper sets out proposed amendments to the Health (National Cervical Screening Programme) Amendment Bill.

Clause 2, which is the commencement clause, is proposed to be replaced with a new commencement clause. The new clause provides that the Act comes into force 12 months after the date on which it receives the Royal Assent, except for *section 2*, *new section 112D*, and *section 6* which come into force on 1 July 2004. The sections that come into force earlier are the commencement section itself, *new section 112D* (which provides for persons to be appointed to operate the NCSP), and a transitional provision. Bringing *new section 112D* into force on the earlier date will enable appropriate appointments to be made under the Act before the main part of the Act comes into force. Bringing the transitional provision into force at the earlier date will enable women enrolled in the programme to be informed about the effect of the Act before the main part of the Act comes into force.

A number of amendments are proposed to be made to *clause 4*, which inserts *new Part 4A* into the Health Act 1956.

New section 112A sets out the purposes of that new Part. An amendment is proposed to this section to make it more clear that the National Cervical Screening Programme (NCSP) referred to in the new Part is a continuation of the same programme that currently exists, and not a new programme. In *new section 112B*, the definition of NCSP is also amended for this purpose.

Also in *new section 112B*, the definition of **registered health professional** is omitted, and a definition of **health practitioner** is substituted that cross-references the Health Practitioners Competence Assurance Act 2003. Throughout the Bill, all references to a registered health professional, or health professional, are also replaced with references to a health practitioner.

Amendments are proposed to *new section 112D* to clarify that there are 2 methods by which persons may be appointed to operate the NCSP or to perform functions in relation to the operation of that programme. Those methods are by appointing a person under:

- (a) section 59 of the State Sector Act 1988; or
- (b) *new section 112D(1A)*.

The standard method of appointing persons to work in the NCSP will be under the State Sector Act 1988. However, where this is not reasonably practicable, appointments may instead be made under *new section 112D(1A)*. This will apply in cases where it is desirable to appoint an overseas expert, or a person who is already employed by another agency, to perform particular functions. It will also apply in cases where it is desirable to appoint an organisation, such as a District Health Board, to perform particular functions.

New section 112EA is omitted from its current location in the Bill, and reinserted in a new location as *new section 112OE*.

Some additional words are proposed to be inserted in *new section 112I(1)(aa)*. That section provides that the NCSP must notify women when their enrolment in the programme has been cancelled. The additional wording deals with the situation of a woman who is having her first smear test in New Zealand, and who advises that she does not wish to be enrolled in the NCSP. In this situation, the NCSP must notify her that she will not be enrolled.

In *new section 112I(3)(b)*, a reference to the commencement of “this Act” is replaced with a reference to the commencement of “this section”, because the Act is now proposed to commence in 2 separate stages.

A new cross-heading and *new sections 112OA to 112OE* are inserted. *New sections 112OA to 112OD* provide for a review committee to be established to review the operation of the NCSP and evaluation activities. Review committees must be established at least once every 3 years, and will report to the Minister. The focus of review committees will be on the continuous quality improvement of components of the NCSP, with a view to reducing the incidence and mortality rates of cervical cancer. They will have access to information held by the NCSP and will be subject to the same confidentiality requirements applicable to other persons who have access to that information. Review committee reports must be presented to the House of Representatives and made publicly available. A consequential amendment is made to *new section 112K(1)*, which lists exceptions to the general requirement to keep NCSP

information confidential. Supplying information to a review committee, in accordance with a request from that committee, is added to the list of permitted exceptions.

A new section 112U(2D) is added, which gives health practitioners the right to oversee a screening programme evaluator's access to health information that is held or controlled by that health practitioner.

New section 112X(2)(b) is reworded. That section, in its reported back form, allows a screening programme evaluator to disclose evaluation material to the Health and Disability Commissioner for the purpose of referring a concern about a health professional, but only if the Director-General consents to the disclosure for that purpose. The proposed new section permits a screening programme evaluator to refer concerns to the appropriate registering body, rather than to the Health and Disability Commissioner.

Some new provisions are proposed to be inserted that relate to the NCSP's ability to create standards to apply to providers of screening, diagnostic, and treatment services.

First, new paragraphs (h) to (j) are added to new section 112ZD(2) to make it clear that regulations may be made that prescribe offences for breaches of regulations or standards. The maximum penalty that may be specified for offences relating to breach of the regulations or standards is that set out in section 136 of the Health Act, which is currently a fine not exceeding \$500 and, if the offence is a continuing one, a further fine not exceeding \$50 for every day on which it continues. The power to create offences for breaching regulations and standards was already implicit in new section 112ZE(1), but it has now been made explicit in order to clarify that it will be possible to make regulations that prescribe offences for breaches of parts of standards. Because this power is now made explicit in new section 112ZD(2)(h) to (j), the wording relating to offences for breaching regulations has been removed from new section 112ZE(1).

Secondly, new sections 112ZDA to 112ZDI have been added. These sections enable the NCSP to prescribe standards by creating a document that sets out the standards, and by adopting that document into regulations by reference. Proposed new section 112ZDE sets out express consultation requirements when adopting standards by reference. The standards must be prepared in consultation with persons or organisations that the Director-General considers are able to represent the views of health practitioners, or classes of health practitioner, who will be directly affected by those standards. Once they have been prepared, and before they are adopted by regulation, the standards must be notified in the *Gazette* and copies made available. Any person may comment on the proposals and the Director-General must consider those comments. Because these specific consultation provisions have been incorporated in relation to standards proposed to be adopted by reference, a new subsection 112ZD(4) is added, which provides that the general consultation provision applicable to regulations made under new section 112ZD does not apply to regulations that incorporate standards by reference. This avoids a double requirement to consult in relation to regulations that incorporate standards by reference.

Clause 6 has been split into 2 separate transitional provisions. *Clause 6* will come into force on 1 July 2004, and *new clause 7* will come into force later (along with the bulk of the Act).

The substituted *clause 6(1)* is a revised version of *clause 6(2)*. It has been reworded because *clause 6(2)* refers to persons appointed to maintain the NCSP register. However, the persons who currently run the NCSP are Ministry of Health employees, rather than persons specifically appointed by the Director-General. The reworded subclause is for the avoidance of doubt, and confirms that the State Sector Act 1988 provisions that govern those employees will continue to apply.

The substituted *clause 6(2)* is effectively the same as *clause 6(5)*. It obliges the NCSP manager to provide information to women on the NCSP register about the programme and the effect of the Act. The substituted *clause 6(3)* has been added to enable the NCSP to use information currently held on the NCSP register to send letters to women who have results recorded on the NCSP register advising them about the effect of the Act, before the main part of the Act comes into force. The substituted *clause 6(4)* sets out definitions that apply to the section.

New clause 7 contains the remainder of *clause 6*. *New clause 7(1)* corresponds to *clause 6(1)*, *new clause 7(2)* corresponds to *clause 6(3)*, *new clause 7(3)* corresponds to *clause 6(4)*, and *new clause 7(4)* corresponds to *clause 6(6)*.