

Health (Screening Programmes) Amendment Bill

Government Bill

As reported from the Health Committee

Commentary

Recommendation

The Health Committee has examined the Health (Screening Programmes) Amendment Bill and recommends that it be passed with the amendments shown.

Introduction

This commentary focuses on the major issues we examined and discusses the amendments we recommend. We have also recommended some technical amendments, which are not covered by this commentary.

Background

The bill implements several key recommendations from the Ministerial Inquiry into the Under-Reporting of Cervical Smear Abnormalities in the Gisborne Region (April 2001). The bill amends the Health Act 1956 by inserting a new Part 4A. The bill is intended to enhance the operation and evaluation of the National Cervical Screening Programme.

The bill includes safeguards to ensure confidentiality and to protect health information—in particular, information used to evaluate the National Cervical Screening Programme.

The ministerial inquiry and the McGoogan report

The Minister of Health appointed a committee of inquiry to respond to public concern that cervical abnormalities may have been under-reported because of cervical smear tests being misread at Gisborne Laboratories. The ministerial inquiry made recommendations about cervical cancer screening in New Zealand. The inquiry recognised the importance of certain information being available to designated screening programme evaluators to evaluate the safety and effectiveness of the National Cervical Screening Programme.

Dr Euphemia McGoogan wrote two subsequent reports about the progress being made towards implementing these recommendations, the final of which was released in June 2003. This report concluded that there was still a lot of work to be done in order for the National Cervical Screening Programme to be 'the best cervical screening programme in the world'.

Operation of the National Cervical Screening Programme

The National Cervical Screening Programme was established in response to a recommendation in the Report of the Cervical Cancer Inquiry 1988 (the Cartwright Inquiry). The National Cervical Screening Programme encompasses a range of agencies and service providers. The National Cervical Screening Programme generates and requires a variety of information including that relating to the screening histories of individual women, information needed by the programme itself and information required to evaluate the programme. The bill further refines the National Cervical Screening Programme, and provides protections for this information.

Under the bill, a woman is automatically enrolled in the National Cervical Screening Programme when she has a screening test or if she undergoes a colposcopic examination. These results are reported to the National Cervical Screening Programme. The woman's enrolment is then confirmed by the National Cervical Screening Programme manager. Information provided to participants at this time will discuss the risks and benefits of programme participation and of evaluation of the National Cervical Screening Programme.

Evaluations are necessary for the continuous improvement and quality assessment of the National Cervical Screening Programme. They provide valuable information on the competence of health

professionals and act as a safeguard to ensure the accuracy of cervical screening reporting.

Such evaluations may require the use by screening programme evaluators of evaluation material relevant to the woman. This material is used only for purposes necessary for performing the function of the screening programme evaluator.

Women may leave programme

We considered carefully the provision in the bill that establishes the National Cervical Screening Programme as an 'opt-off' programme.¹ The programme moved to an opt-off system in 1993, after it became apparent that the initial 'opt-on' approach did not provide sufficient coverage for successful operation of the programme. The system established in 1993 allowed women to choose to remove particular smear test results from the register. This bill changes the 1993 system so that women can opt off the entire programme rather than removing individual results only.

A woman may, at any time, opt off the National Cervical Screening Programme by notifying the National Cervical Screening Programme manager. The National Cervical Screening Programme manager has a duty to send a notice to the woman confirming her cancellation. Any information relating to the woman's screening history must be deleted from the National Cervical Screening Programme register and any information held by the programme in hard copy must be either returned to the woman or destroyed.

Some of us believe the National Cervical Screening Programme should be an opt-on programme, with women signing a consent form at the time of their first smear test. However, the majority agree that an opt-off programme is essential to ensure high rates of enrolment and participation in the programme. Without automatic enrolment, the programme cannot achieve its aims of decreasing the incidence of cervical cancer in New Zealand.

The changes in the bill are intended to ensure women's case histories are both complete and accurate. Incomplete screening histories pose a clinical risk to both the individual woman concerned and the health professionals involved in her care, as incomplete data may

¹ An 'opt-off' system means women are automatically enrolled in the programme after their first smear test and must actively choose to be removed from the programme. An 'opt-on' programme requires women to explicitly enrol in the programme.

affect clinical management recommendations. Incomplete screening histories also impede the effective evaluation of the National Cervical Screening Programme and reduce the ability of the programme to meet its goal of reducing the incidence of, and mortality from, cervical cancer.

The retention of complete screening histories will enable the National Cervical Screening Programme to implement the recommendation of the ministerial inquiry that cervical smear test results and histology histories of enrolled women should be made available electronically.

Access to primary care records

We recommend that the consent process for access to primary care records be removed. This will give a screening programme evaluator automatic access to health information located in primary health records, if that information is necessary for the evaluation. This change meets the recommendations of the ministerial inquiry. The bill already provides for screening programme evaluators to have access to relevant information about individual women on the register held by hospitals or laboratories.

We met with the Minister of Health to discuss this issue. She advised us that during the policy development stage of the bill there was a high level of concern at the prospect of access to primary health care records. At that time, it was considered that an extra consent process was required, to prevent women from leaving the screening programme. She noted that this was less likely to happen if women were better informed about who could access the information and under what circumstances.

Most of us consider primary care records are essential for effective internal and external evaluations. Screening programme evaluators, as professionals, are not interested in other aspects of patients' personal information. Most of us believe there are adequate safeguards in place to ensure screening programme evaluators are permitted access only to necessary health information.

Availability of information to screening programme evaluators

We also recommend an amendment that requires every health professional to make relevant health information or specimens available

to a screening programme evaluator. The availability of such information and specimens must be free of charge. The information and specimens requested must be relevant, and necessary for the screening programme evaluator to complete his or her duties.

This amendment ensures that screening programme evaluators can readily access all necessary evaluation material.

Extension of bill to other screening programmes

We recommend limiting this bill to cervical screening programmes only. The bill as introduced allowed for the provisions of the bill to be extended to other screening programmes by Order in Council.

We asked the Regulations Review Committee to comment on the appropriateness of extending the legislation in this way. That committee noted that it is a constitutional principle that matters of policy are set out in an Act of Parliament and the details of those matters are left for regulation. Using regulations to extend the bill to other screening initiatives infringes this principle, as any future screening programme should be a matter that is sanctioned by Parliament and not by secondary legislation.

A further concern is the bill as introduced's provision that modification to the primary legislation, which would need to occur should the bill be extended to other screening programmes, would be by Order in Council. This offends against the principle that Acts should be amended only by other Acts.

We suggest that an alternative approach would be to enact generic legislation that allows for application to new screening initiatives, as the policies and principles would be contained in the parent legislation.

We recommend changing the name of the bill to the Health (National Cervical Screening Programme) Amendment Bill to reflect the limitation to the National Cervical Screening Programme.

Publication of evaluation results

We recommend requiring the Director-General of Health to provide information to the public on the effectiveness and quality of the National Cervical Screening Programme. If it is appropriate, the published information may be based on evaluation results. We also recommend making access to information one of the objectives of the programme.

Some submitters were concerned at the current lack of public disclosure and accountability. It was felt that both the public and women in the programme should be informed of evaluation requirements and quality improvement activities.

Publication of Māori women's data

Some of us were concerned about screening programme evaluator access to aggregate Māori women's data on the National Cervical Screening Programme register. Access to this information is subject to the Health (Cervical Screening (Kaitiaki)) Regulations 1995. However, we were advised that the regulations do not prevent screening programme evaluators from evaluating data about identifiable Māori women.

The regulations relate only to disclosure, use and publication of aggregate data about Māori women and require any such use of this data, including for evaluation purposes, to be approved by the National Kaitiaki Group. The National Kaitiaki Group provides guardianship for Māori women's summary data by permitting access to the data only if it is to be used for the benefit of Māori women.

We do not recommend any changes to these regulations. However, some of us consider this exception is not appropriate, as access to all information is essential for a robust screening programme.

Information held by other specialists

We recommend extending the powers of screening programme evaluators to access certain specimens and information held by private specialists. This will permit screening programme evaluators to access relevant health information held either in a hospital or in a specialist's private rooms. Previously the bill only provided for all records and specimens held by a hospital to be accessed by screening programme evaluators.

Definition of cancer and cervical cancer

We recommend definitions of both cancer and cervical cancer be included in the bill. Cancer can be defined by reference to the definition of cancer in the Cancer Registry Act 1993. This definition covers precursors to cervical cancer (CIN3).

We recommend that cervical cancer be defined as any cancer of the cervix.

Screening programme evaluator concerns about practitioner competence

We recommend an amendment to the procedure for screening programme evaluators to report concerns about practitioner competence. Screening programme evaluators will have to seek the agreement of the Director-General of Health before reporting any concerns about a practitioner's performance. This will act as a check against inaccurate reporting.

We also recommend requiring concerns to be reported to the Health and Disability Commissioner, rather than to the registering authority. This would provide greater consistency with the provisions of the Health Practitioners Competence Assurance Bill.

Care of specimens

We recommend stronger requirements for the adequate care of specimens by screening programme evaluators, and for their return when they are no longer required. We also recommend an amendment that obliges the screening programme evaluator to return unused specimens once the material is finished with.

Incorporation by reference

The Ministry of Health requested that the bill be amended to allow policy and quality standards to be incorporated by reference. However, we have not recommended such a change.

Incorporation by reference allows the creation or definition of rights, powers, and obligations by reference in an Act of Parliament or delegated legislation to another document whose provisions are not set out in the legislation.

We asked the Regulations Review Committee whether this proposed amendment was appropriate. That committee did not consider incorporation by reference appropriate in these circumstances. We agree that standards to be met by providers of screening programme services should be clearly set out as a matter of law and should be publicly accessible. We consider this can best be achieved by prescribing these matters directly in regulations.

Green Party minority view

The Green Party believes the National Cervical Screening Programme should be an 'opt on' programme, similar to the breast-screening programme, where women sign a consent form at the time of their first smear, rather than an 'opt off' programme proposed in the bill, in which women are automatically enrolled.

The Green Party strongly opposes the amendment to the bill which gives screening programme evaluators automatic access to women's primary healthcare records, without their consent.

The Green Party believes there is no guarantee that sensitive records on sexually transmitted infections, sexual abuse, terminations etc which are not necessary for the effective running of the National Cervical Screening Programme, would be kept separate from information relating to a person's cervical cancer history.

The Green Party notes that many consumer groups have expressed great concern at the prospect of evaluators accessing primary health care records without consent. This was one of the reasons why Cabinet opposed the approach now recommended by the select committee.

The Green Party does not believe that a convincing rationale has been given as to why the privacy of personal health information and the approach New Zealand has taken to privacy issues over recent years should be set aside in this way.

The Green Party believes that the vast majority of women will consent to be on the National Cervical Screening Programme, providing that the confidentiality and security of sensitive health information is assured. Around 90 percent of women have already given consent, under existing legislation, to having their register information, including clinical records and laboratory slides, accessed by evaluators.

Given the high percentage of women who have participated on the basis of informed consent, the Green Party is extremely sceptical of claims that insufficient numbers of women would agree to participate if their explicit consent was required.

The Green Party is not convinced that giving evaluators automatic access to women's primary health care records will strengthen the screening programme. On the contrary, the Green Party believes there is a real risk that it will result in a backlash against the National Cervical Screening Programme, and a reduction in its participation

rate, as significant numbers of women opt out of the programme because they do not want their primary health care records accessed by an unspecified number of evaluators.

The Green Party notes that the approximately one million women who are presently enrolled on the National Cervical Screening Programme have done so on the basis that only their screening records can be automatically accessed. These women will not necessarily agree that auditors should be able to access their personal health information, including sensitive primary health care records, held in other places outside the programme.

The Green Party believes the requirement that general practitioners give evaluators automatic access to sensitive patient records without obtaining women's consent will undermine the confidentiality of the general practitioner patient relationship and provide a precedent for further undermining the privacy of personal health information in New Zealand.

For all of these reasons the Green Party believes consent should always be sought before personal health care records are accessed. The main purpose for accessing primary health care records is to evaluate whether women who develop cancer or early signs of cancer were properly referred and treated by their general practitioners. Given that only about 160 women develop cervical cancer each year, it would be relatively easy to obtain consent from these women to carry out an evaluation of their primary health care records at the time they are diagnosed.

Appendix

Committee process

The Health (Screening Programmes) Amendment Bill was referred to the committee on 18 February 2003. The closing date for submissions was 11 April 2003. We received and considered 15 submissions from interested groups and individuals. We heard 10 submissions. Hearing of evidence took 4 hours and 9 minutes and consideration took 10 hours and 9 minutes.

We received advice from the Ministry of Health. The Regulations Review Committee reported to us on the powers contained in new sections 112ZD and 112ZF, and on the issue of incorporation by reference.

Committee membership

Steve Chadwick (Chairperson)

Judith Collins

Dave Hereora

Sue Kedgley

Moana Mackey

Nanaia Mahuta

Pita Paraone

Heather Roy

Dr Lynda Scott

Judy Turner

Dianne Yates

On 30 July 2003, Moana Mackey replaced Ann Hartley as a permanent member of the committee.

Barbara Stewart replaced Pita Paraone for this item of business.

**Health
(Screening Programmes) Amendment**

Key to symbols used in reprinted bill

As reported from a select committee

Struck out (unanimous)

Subject to this Act,

Text struck out unanimously

New (unanimous)

Subject to this Act,

Text inserted unanimously

(Subject to this Act,)

Words struck out unanimously

Subject to this Act,

Words inserted unanimously

Hon Annette King

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

Government Bill

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The Parliament of New Zealand enacts as follows:

1 Title

- (1) This Act is the Health (National Cervical Screening Programme(s)) Amendment Act **2002**.
- (2) In this Act, the Health Act 1956¹ is called “the principal Act”. 5
- ¹ 1956 No 65

**Part 1
Preliminary provision**

2 Commencement

This Act comes into force on **1 July (2003) 2004**.

**Part 2
Amendments to principal Act and transitional provision** 10

3 Section 74A repealed

The principal Act is amended by repealing section 74A.

4 New Part 4A inserted 15

The principal Act is amended by inserting, after Part IV, the following Part:

**“Part 4A
National Cervical Screening Programme(s)**

“112A Purpose 20

The purpose of this Part is—

- “(a) to reduce the incidence and mortality rate of cervical cancer by providing for persons to be appointed to operate a nationally organised screening programme for cervical cancer; and 25
- “(b) to facilitate the operation and evaluation of that national cervical screening programme by—
- “(i) enabling access to information and specimens by the persons operating the programme; and
- “(ii) enabling access to information and specimens by screening programme evaluators appointed to evaluate that programme. 30

Struck out (unanimous)

“(c) to provide a mechanism for extending the provisions in this Part to other screening programmes, after appropriate consultation.

112B Interpretation

In this Part, unless the context otherwise requires,—

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New (unanimous)

“**cancer** has the meaning set out in section 2 of the Cancer Registry Act 1993

“**cancer registry** means the cancer registry maintained under the Cancer Registry Act 1993

New (unanimous)

“**cervical cancer** means any cancer of the cervix

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Struck out (unanimous)

“**diagnostic test**,—

“(a) in relation to a screening programme, means a test taken as part of the assessment of a person who has a positive screening test result, or who has signs or symptoms that may indicate that that person has the condition to which the screening programme relates; and

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“(b) in relation to the NCSP, means a test taken to determine or confirm the presence of a precursor to cancer, or cancer, in a woman’s cervix; and may include—

“(i) a colposcopic examination of the woman’s cervix; and

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“(ii) an examination of a histological specimen taken from the woman

New (unanimous)

“**diagnostic test** means a test taken to determine or confirm the presence of cancer, or a precursor to cancer, in a woman’s cervix, and may include—

- “(a) a colposcopic procedure:
- “(b) an examination of a histological specimen taken from the woman

“**evaluate** has the meaning set out in **section 112P(1)**

“**evaluation material** means any information about, and any specimen taken from, an identifiable individual that was obtained by a screening programme evaluator under this Part

“**health information** has the meaning set out in paragraphs (a) and (c) of the definition of that term in section 22B

“**hospital** means a hospital care institution within the meaning of section 58(4) of the Health and Disability Services (Safety) Act 2001

“**NCSP** means the National Cervical Screening Programme operated by the persons appointed under **section 112D**

“**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 National Cervical Screening Programme register maintained by the persons appointed under **section 112D**

Struck out (unanimous)

“**NCSP screening test** means a screening test, such as a cervical smear test, designed to identify women who may have a precursor to cervical cancer or cervical cancer

“**personal representative**, in relation to a deceased person, means the executor, administrator, or trustee of the estate of that person

“**registered health professional** has the meaning set out in section 4 of the Health and Disability Commissioner Act 1994

“**relevant (person) woman**, for the purposes of **sections 112U, (112V,) 112ZAA, 112ZA, and 112ZB**, has the meaning set out in **section 112U(1)**

“**screening programme evaluator** means a person designated as a screening programme evaluator under **section 112Q(1)**

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Struck out (unanimous)

“**screening test** means a routine test designed to identify persons who may have the condition, or a precursor to the condition, to which a screening programme relates

New (unanimous)

“**screening test** means a routine test, such as a cervical smear test, designed to identify women who may have cervical cancer or a precursor to cervical cancer

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Struck out (unanimous)

“**specimen**,—

“(a) in relation to a screening programme, means a bodily sample or a tissue sample taken from a person for the purpose of a screening test or a diagnostic test; and

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“(b) in relation to the NCSP, includes cervical cytology and histology slides and blocks.

New (unanimous)

“**specimen** means a bodily sample or tissue sample taken from a woman for the purpose of a screening test or a diagnostic test, and includes cervical cytology and histology slides and blocks.

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Struck out (unanimous)

“112C Application of this Part

This Part applies to—

- “(a) the NCSP; and
- “(b) any other screening programme to the extent that an Order in Council under **section 112ZF** extends any of the provisions of this Part to that other programme. 5

“Operation of NCSP

“112D Appointment of persons to operate NCSP

- “(1) The Director-General may appoint persons to operate a programme to be known as the National Cervical Screening Programme, or to perform particular functions in relation to the operation of that programme. 10
- “(2) The Director-General may appoint 1 person to be the manager of the NCSP.
- “(3) The NCSP manager may direct a person appointed under **subsection (1)** in relation to the performance of that person’s functions, and that person must comply with the NCSP manager’s direction. 15
- “(4) The Director-General may direct the NCSP manager in relation to the performance of the NCSP manager’s functions, and the NCSP manager must comply with the Director-General’s direction. 20

“112E Objectives of NCSP

The objectives of the NCSP are to—

- “(a) promote high quality cervical screening, assessment, and treatment services, while recognising and managing the differences between the various types of cervical cancer, with a view to reducing the incidence and mortality rate of cervical cancer; and 25
- “(b) inform women and the community of the risks, benefits, and expected population health gains from participation in the NCSP; and 30
- “(c) promote the regular recall of women who are enrolled in the NCSP for (NCSP) screening tests; and

- “(d) facilitate continuous quality improvement by allowing and performing regular evaluations of the NCSP; and
- “(e) ensure that information that is collected for the purposes of the NCSP is—
 - “(i) available *(to authorised persons)*, in a reliable, accurate, and timely manner, to persons authorised under this Part, or any other enactment, to have access to it; and
 - “(ii) safely stored, including on the NCSP register; and

New (unanimous)

- “(f) provide information to women about the quality and effectiveness of the NCSP including, if it is appropriate, information based on the results of evaluations.

“112EA 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.

“112F Enrolment in NCSP

- “(1) The NCSP manager must enrol in the NCSP every woman who—
 - “(a) has *(an NCSP)* a screening test, the result of which is reported to the NCSP; or
 - “(b) undergoes a colposcopic *(examination)* procedure, the result of which is reported to the NCSP.
- “(2) The NCSP manager may, at his or her discretion, enrol in the NCSP a woman who undergoes a surgical procedure during which a histological specimen is taken that includes a cervical component if the results of an analysis of that specimen are reported to the NCSP.
- “(3) **Subsections (1) and (2)** do not apply if the woman to whom the results relate—
 - “(a) is already enrolled in the NCSP; or
 - “(b) has cancelled her enrolment in the NCSP; or

“(c) has notified the NCSP manager, under **section 112H(2)**, that she does not wish to be enrolled in the NCSP.

“112G Duties of NCSP manager that relate to enrolled women

- “(1) As soon as practicable after enrolling a woman in the NCSP, the NCSP manager must— 5
- “(a) notify the woman that she has been enrolled in the NCSP; and
- “(b) provide information to the woman about— 10
- “(i) the importance of having regular (*NCSP*) screening tests; and
- “(ii) the risks and benefits of participation in the NCSP; and
- “(iii) who has access to information on the NCSP register, and the uses to which that information may be put; and 15
- “(iv) the objectives of the NCSP, including that of continuous quality improvement through evaluation; and
- “(v) the possible use by screening programme evaluators of evaluation material relevant to the woman for the purpose of evaluations of the NCSP; and 20
- “(c) advise the woman that she may cancel her enrolment by advising the NCSP manager under **section 112H(1)**. 25
- “(2) The NCSP manager must record on the NCSP register every result that is reported to the NCSP manager from a (*NCSP*) screening test, or from a (*colposcopic examination, or from the analysis of a histological specimen*) diagnostic test, if that result relates to a woman who is enrolled in the NCSP. 30

“112H Procedure to prevent or cancel enrolment in NCSP

- “(1) A woman who is enrolled in the NCSP may, at any time, cancel that enrolment by advising the NCSP manager in the manner and form specified by the NCSP manager.
- “(2) A woman who is not enrolled in the NCSP, and who does not wish to be enrolled, may, at any time, notify the NCSP that she does not wish to be enrolled. 35

- “(3) A notification under **subsection (2)** must—
- “(a) be in the manner and form specified by the NCSP manager; and
 - “(b) include information that will enable the NCSP manager, in the future, to identify the woman as a woman who must not be enrolled in the NCSP (which information may be kept on the NCSP register and used by the NCSP manager for that purpose).

“112I **Duties of NCSP manager when women cancel enrolment in NCSP**

- “(1) If a woman cancels her enrolment in the NCSP under **section 112H(1)**, or notifies the NCSP manager that she does not wish to be enrolled under **section 112H(2)**, the NCSP manager must—

New (unanimous)

“(aa) send a notice to the woman confirming that her enrolment in the NCSP has been cancelled; and

“(a) delete any information that relates to that woman from the current NCSP register; and

Struck out (unanimous)

“(b) return or destroy any information that is held by the NCSP manager in hard copy format and that relates to that woman; and

New (unanimous)

“(b) dispose of any information that is held by the NCSP manager in hard copy format and that relates to that woman by either—

- “(i) returning it to her; or
- “(ii) destroying it (if she requests that it be destroyed);

and

“(c) while that woman is not enrolled in the NCSP,—

- “(i) ensure that no information that is provided to the NCSP and that relates to that woman is included on the NCSP register; and
- “(ii) return or destroy any information that is provided to the NCSP and that relates to that woman. 5
- “(2) **Subsection (1)** does not apply to information that the NCSP manager determines it is necessary to keep for the purpose of identifying the woman as a woman whose results must not be entered on the NCSP register, such as, for example, her name, address, date of birth, and national health index number, but the information that is retained must be no more than is required for that purpose. 10
- “(3) Despite **subsection (1)(b)**, the NCSP manager may retain information that relates to a woman who cancels her enrolment in the NCSP if that information— 15
- “(a) is in hard copy format; and
- “(b) was received before the date of commencement of this Act.
- “(4) To avoid any doubt, **subsection (1)** overrides the Health (Retention of Health Information) Regulations 1996 (SR 1996/343). 20
- “112J **Procedure to re-enrol in NCSP**
- “(1) A woman who has cancelled her enrolment in the NCSP may re-enrol, at any time, by advising the NCSP manager in the manner and form specified by the NCSP manager.
- “(2) A woman who has notified the NCSP manager, under **section 112H(2)**, that she does not wish to be enrolled in the NCSP may cancel that notification and enrol in the NCSP, at any time, by advising the NCSP manager in the manner and form specified by the NCSP manager. 25
- “112K **Certain information held by NCSP must not be disclosed** 30
- “(1) No person may disclose information from the NCSP register, or information that is held by the NCSP as a result of an evaluation, if that information identifies a woman unless that information is disclosed— 35
- “(a) with the consent of the woman or her personal representative; or

- “(b) to a screening programme evaluator under **section 112U(2)(a)**; or
 - “(c) to a registered health professional who has been engaged by, or on behalf of, the woman, and the information is disclosed for the purpose of assisting that registered health professional to provide health services to that woman; or 5
 - “(d) for the purpose of enabling results from a screening test or a diagnostic test to be followed up; or
 - “(e) for the purpose of enabling notices related to the NCSP to be sent to women who are enrolled in the NCSP, including reminder notices to women who are due for another (NCSP) screening test; or 10
 - “(f) for the purpose of giving access to the NCSP register, in accordance with regulations made under **section 112ZD(2)(a)**, to persons researching cancer; or 15
 - “(g) subject to any regulations made under **section 112ZD(2)(b)**, for the purpose of enabling the compilation and publication of statistics that do not enable the identification of the women to whom those statistics relate. 20
- “(2) Despite **subsection (1)**, a screening programme evaluator may disclose information in accordance with **section 112X(2)(a) to (d)**.

“112L **Delegation of functions and powers**

- “(1) The Director-General may, in writing, delegate to the NCSP manager any of his or her functions or powers under **sections 112N(2)(b) and (c), 112O(2)(b) and (c), 112ZAA(2), 112ZA(2), and 112ZB(2)**, on any conditions that the Director-General thinks fit. 25
- “(2) The NCSP manager may, in writing, delegate to any person any of his or her functions or powers under this Part, on any conditions that the NCSP manager thinks fit, except— 30
 - “(a) any power or function delegated to the NCSP manager by the Director-General; and
 - “(b) this power of delegation.
- “(3) Subject to any general or special directions given or conditions attached by the NCSP manager or the Director-General, the person to whom any powers are delegated under this section may exercise those powers in the same manner and with the same effect as if they had been conferred on him or her directly under this Part and not by delegation. 35

- “(4) Any delegation under **subsection (2)** may be made to a specified person or to the holder or holders for the time being of a specified office or specified class of offices.
- “(5) Every person who purports to act under a delegation under this section is presumed to be acting in accordance with its terms in the absence of evidence to the contrary. 5
- “(6) A delegation under this section—
- “(a) is revocable, in writing, at will; and
 - “(b) continues in force until it is revoked, even if the NCSP manager or Director-General by whom it was made ceases to hold office, and continues to have effect as if made by his or her successor in that office. 10
- “(7) A delegation under this section does not affect or prevent the performance or exercise of any function or power by the delegator, and does not affect the responsibility of the delegator for the actions of any person acting under that delegation. 15
- “(8) **Subsection (1)** does not limit the Director-General’s power to delegate any of his or her functions under this Part in accordance with section 41 of the State Sector Act 1988. 20

“Duties to provide information to women and to NCSP

“112M **Duties of persons taking specimens for (NCSP) screening tests**

- “(1) Every person who takes a specimen from a woman for the purpose of a (NCSP) screening test, and who believes that it is that woman’s first (NCSP) screening test in New Zealand, must— 25
- “(a) explain the procedure and provide information about the importance of having regular (NCSP) screening tests, the objectives of the NCSP, the risks and benefits of participation in the NCSP, who has access to information on the NCSP register, and the uses to which that information may be put; and 30
 - “(b) advise the woman that she will be enrolled in the NCSP, but that she may prevent or cancel that enrolment by advising the NCSP manager under **section 112H**. 35
- “(2) Every person who takes a specimen from a woman for the purpose of a (NCSP) screening test, and who believes that it is not that woman’s first (NCSP) screening test in New Zealand,

must provide that woman with information about the procedure and about the NCSP to the extent that is reasonable in the circumstances.

- “(3) **Subsections (1) and (2)** do not limit any other obligation to provide information that arises under any other enactment or rule of law. 5

“112N **Duty of persons performing (*colposcopy examinations*) colposcopic procedure**

- “(1) Every person who performs a (*colposcopy examination*) colposcopic procedure on a woman must— 10

- “(a) explain the procedure to the woman; and
“(b) provide information, to the extent that is reasonable in the circumstances, about the objectives of the NCSP and the NCSP register, the importance of having regular (*NCSP*) screening tests, who has access to information on the NCSP register, and the uses to which that information may be put; and 15

- “(c) if he or she believes that the woman is not enrolled in the NCSP, advise her that she will be enrolled but that she may prevent or cancel that enrolment by notifying the NCSP manager under **section 112H**; and 20

- “(d) cause a report in relation to that (*colposcopy*) colposcopic procedure to be forwarded to the NCSP manager.

- “(2) A report under **subsection (1)(d)** must— 25

- “(a) be provided free of charge; and
“(b) contain the information specified by the Director-General; and
“(c) be provided in the manner and form specified by the Director-General. 30

“112O **Duty of laboratories where specimens are analysed**

- “(1) The person in charge of a laboratory where a specimen is analysed must cause a report in relation to that specimen to be forwarded to the NCSP manager if—

- “(a) the specimen was obtained for the purpose of a (*NCSP*) screening test; or 35

- “(b) the specimen was obtained for the purpose of a diagnostic test *(to ascertain the presence of a precursor to cervical cancer or cervical cancer)*; or
- “(c) the specimen—
 - “(i) was obtained during a surgical procedure; and 5
 - “(ii) includes a cervical component.
- “(2) A report under **subsection (1)** must—
 - “(a) be provided free of charge; and
 - “(b) contain the information specified by the Director-General; and 10
 - “(c) be provided in the manner and form specified by the Director-General.

“*Screening programme evaluators*

“112P **Meaning of evaluate**

- “(1) For the purposes of this Part, **evaluate** means to monitor and assess the service delivery and outcomes of *(a screening programme) the NCSP* so as to promote the fulfilment of *(the) its objectives (of that screening programme)* by determining whether there are any systemic issues to address within *(that) the programme or quality improvements that may be made to (that programme) it.* 15 20
- “(2) An evaluation may, from time to time, include a review of, and an investigation into, the cases of—
 - “(a) any *(persons who are enrolled in the screening programme) woman who is enrolled in the NCSP (whether or not (they have developed the condition to which the programme relates) she has developed any cervical cancer)*; and 25
 - “(b) any *(persons who have developed the condition to which the screening programme relates) woman who has developed any cervical cancer (whether or not (those persons are enrolled in that programme) she is enrolled in the NCSP)*; and 30
 - “(c) any deceased persons to whom **paragraph (a) or paragraph (b)** applied at the time of death. 35

“112Q Director-General may designate screening programme evaluators

- “(1) The Director-General may, at any time and entirely at his or her discretion, designate 1 or more persons as screening programme evaluators on whatever terms and conditions the Director-General considers appropriate. 5
- “(2) The Director-General must specify the particular evaluation functions to be performed by each person whom he or she designates as a screening programme evaluator.
- “(3) The Director-General may limit the type of information that a person who is designated as a screening programme evaluator may have access to under this Part in accordance with the evaluation functions to be performed by that person. 10

“112R Criteria for designating employees of Ministry

Despite **section 112Q**, the Director-General must not designate a person who is an employee of the Ministry as a screening programme evaluator unless the Director-General is satisfied that— 15

- “(a) the person has the technical competence to undertake the functions of a screening programme evaluator; and 20
- “(b) the Ministry and the person will appropriately manage any conflicts of interest that arise.

“112S Criteria for designating persons who are not Ministry employees

Despite **section 112Q**, the Director-General must not designate a person who is not an employee of the Ministry as a screening programme evaluator unless the Director-General is satisfied that the person— 25

- “(a) has, or employs persons who have, the technical competence to undertake the functions of a screening programme evaluator; and 30
- “(b) has in place effective arrangements to avoid or manage any conflicts of interest that may arise; and
- “(c) will administer those arrangements properly and competently and in compliance with any conditions on which the designation is given; and 35
- “(d) will comply with the obligations on that person under this Part.

Struck out (unanimous)

“112T **Screening programme evaluator may only access information for purpose of performing functions**

“(1) A screening programme evaluator may only access information and specimens under sections 112U, 112V, and 112W for the purpose of performing, and to the extent necessary to perform, that person’s functions as a screening programme evaluator.

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“(2) **Subsection (1)** is subject to **section 112ZC**.

“112U **Power of screening programme evaluators to access (certain) specimens and health information**

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“(1) For the purposes of this section, (**section 112V**) **section 112ZAA**, **section 112ZA**, and **section 112ZB**, a relevant (*person*) woman is—

“(a) a (*person*) woman who is enrolled (*in a screening programme that is being evaluated by a screening programme evaluator*) in the NCSP; or

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“(b) a (*person*) woman who is not enrolled (*in that programme*) in the NCSP but who has developed (*the condition to which that programme relates*) any cervical cancer; or

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“(c) a deceased (*person*) woman to whom **paragraph (a) or paragraph (b)** applied at the time of (*his or*) her death.

“(2) Except to the extent that regulations have been made under **section 112ZD(2)(c) or (d)** limiting access to certain information, or that the Director-General has limited a screening programme evaluator’s access to certain information under **section 112Q(3)**, a screening programme evaluator has full access to(*, and may take copies of,*)—

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“(a) all information held by the persons operating the (*screening programme that the screening programme evaluator is evaluating*) NCSP; and

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Struck out (unanimous)

“(b) all records and specimens held by a laboratory that relate to a relevant person; and

Struck out (unanimous)

“(c) all records and specimens held by a hospital that relate to a relevant person; and

“(d) all information on the cancer registry that relates to a relevant *(person)* woman; and

New (unanimous)

“(e) all health information and all specimens that relate to a relevant woman and that are held by, or are otherwise under the power and control of, any—
“(i) registered health professional; or
“(ii) laboratory; or
“(iii) hospital.

“(2A) A screening programme evaluator may—

“(a) take copies of all information and records to which he or she has access; and

“(b) take any specimen to which he or she has access, or take a part of that specimen.

“(2B) A screening programme evaluator may only access or copy information and specimens under **subsection (2) or (2A)** for the purpose of performing, and to the extent necessary to perform, that person’s functions as a screening programme evaluator.

“(2C) **Subsection (2B)** is subject to **section 112ZC**.

“(3) To avoid doubt, **subsection (2)** does not affect the Health (Cervical Screening (Kaitiaki)) Regulations 1995 (SR 1995/29).

Struck out (unanimous)

“112V Power of screening programme evaluator to access other health information with consent

“(1) Any provider of health services who holds health information that relates to a relevant person, other than health information that is accessible to a screening programme evaluator under **section 112U(2)**, must make that health information available, free of charge, to a screening programme evaluator if—

Struck out (unanimous)

- “(a) the person to whom the information relates, or a person who is entitled to give consent on his or her behalf, has consented to the information being made available; or
- “(b) the person to whom the information relates has died and his or her personal representative has consented to the information being made available. 5
- “(2) The Director-General may specify, by notice in writing to the provider of health services, the manner and form in which information that is required to be provided under **subsection (1)** must be provided, and the provider of health services must provide the information in that manner and form. 10
- “112W Director-General may require health information to be made available to screening programme evaluator without consent**
- “(1) The Director-General may, if satisfied of the matters in **subsection (2)**, issue a notice to any person requiring that person to make available to a screening programme evaluator any health information that relates to a person who has been diagnosed as having the condition to which a screening programme relates. 15
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- “(2) Before requiring a person to make health information available to a screening programme evaluator under **subsection (1)**, the Director-General must be satisfied that—
- “(a) it has not been possible to obtain the consent of the person to whom the information relates because, despite reasonable efforts having been made, he or she has not been found; or 25
- “(b) the person has died and it has not been possible to obtain the consent of his or her personal representative because, despite reasonable efforts having been made, the person’s personal representative has not been found. 30
- “(3) Any person who is issued a notice under **subsection (1)** must make the health information specified in that notice available, free of charge, to the screening programme evaluator named in the notice in the manner and form, and on the terms, specified in that notice. 35

“112X **Duties of screening programme evaluators**

- “(1) No screening programme evaluator may use or disclose any evaluation material for a purpose other than performing that person’s functions as a screening programme evaluator.
- “(2) Despite **subsection (1)**, a screening programme evaluator may— 5
- “(a) disclose evaluation material to a person who is assisting the screening programme evaluator to perform the screening programme evaluator’s functions, and who requires the material for that purpose; and
- “(b) use and disclose evaluation material for the purpose of referring a concern about the competence of a health professional to the *(appropriate registering body for that health professional)* Health and Disability Commissioner, if the screening programme evaluator has first obtained the consent of the Director-General to use and disclose the material for that purpose; and 10 15
- “(c) disclose evaluation material to the Accident Compensation Corporation or the Health and Disability Commissioner for the purpose of assisting an investigation into concerns about the competence of a health professional; and 20
- “(d) use and disclose evaluation material for the purpose of advising the *(person in charge of the relevant screening programme)* NCSP manager that, in the screening programme evaluator’s opinion, a particular person who is enrolled in the *(screening programme)* NCSP may benefit from follow-up action; and 25
- “(e) use evaluation material to prepare academic papers or articles for publication in accordance with **section 112Z**.
- “(3) Every screening programme evaluator must— 30
- “(a) take appropriate measures to safeguard all evaluation material from use or disclosure for a purpose other than a purpose that is specified in **subsection (1) or subsection (2)**; and
- “(b) report to the Director-General any cases where evaluation material has been used or disclosed for an unauthorised purpose; and 35
- “(c) return all evaluation material that was provided in hard copy or electronic form to the supplier of that material as soon as it is no longer required for the purpose for 40

which it was obtained, and destroy all copies of that material; and

New (unanimous)

“(ca) take appropriate measures to keep all specimens in a secure environment that will preserve their physical integrity, and return them to the person who supplied them as soon as they are no longer required for the purpose for which they were obtained; and 5

“(d) advise each person to whom the screening programme evaluator discloses evaluation material under **subsection (2)(a)** of the duties of the screening programme evaluator in relation to that information, and of the duties of that person under **section 112Y**. 10

“(4) Every screening programme evaluator who is not an employee of the Ministry must—

“(a) provide to the Director-General, as soon as practicable after completing an evaluation of a screening programme, a written report containing the results of that evaluation; and 15

“(b) provide to the Director-General, as soon as practicable after being requested by the Director-General to do so, a statutory declaration as to whether or not the requirements of **subsection (3)(a) to (c)** have been complied with, and, if not, to what extent they have not been complied with. 20

“(5) **Subsections (1) and (3)(a) and (c)** are subject to **section 112ZC**. 25

“112Y Duties of persons to whom evaluation material is supplied by screening programme evaluator

“(1) Every person to whom evaluation material is supplied by a screening programme evaluator, under **section 112X(2)(a)**, must— 30

“(a) use that material only for the purpose for which it was supplied; and

“(b) take appropriate measures to safeguard that material from disclosure to any other person; and

“(c) return all evaluation material that was provided in hard copy or electronic form to the screening programme 35

evaluator as soon as it is no longer required for the purpose for which it was supplied, and destroy all copies of it; and

New (unanimous)

“(d) take appropriate measures to keep all specimens in a secure environment that will preserve their physical integrity, and return them to the screening programme evaluator as soon as they are no longer required for the purpose for which they were supplied. 5

“(2) **Subsection (1)** is subject to **section 112ZC**.

“112Z **Screening programme evaluator may publish non-identifiable information obtained during evaluation** 10

“(1) Despite **section 112X(1)**, a screening programme evaluator may publish academic papers or articles that are wholly or partly based on evaluation material obtained by the screening programme evaluator during an evaluation if— 15

“(a) the paper or article does not contain information that could identify any individual person, without that person’s consent; and

“(b) the *(person in charge of the screening programme) NCSP manager* consents to the publication of the paper or article and to the timing of that publication; and 20

“(c) the publication of the paper or article is in accordance with any regulations made under **section 112ZD(2)(f)**.

“(2) The *(person in charge of a screening programme) NCSP manager* may not withhold consent under **subsection (1)(b)** unless he or she believes, on reasonable grounds, that the publication of the paper or article, or the proposed timing of that publication, poses a serious risk to the effective operation of the *(screening programme) NCSP*. 25

“Duties to provide information to screening programme evaluators

New (unanimous)

“112ZAA Duty of registered health professionals

“(1) Every registered health professional must make available, free of charge, to a screening programme evaluator, for the purpose of enabling that screening programme evaluator to perform the screening programme evaluator’s functions, any health information and specimens that relate to a relevant woman. 5

“(2) The Director-General may specify, by notice in writing to the registered health professional, the manner and form in which health information or specimens that are required to be provided under **subsection (1)** must be provided, and that information or those specimens must be provided in that manner and form. 10 15

“112ZA Duty of persons who hold specimens

“(1) The person in charge of a laboratory or other premises where specimens are held must make available, free of charge, to a screening programme evaluator, for the purpose of enabling that screening programme evaluator to perform the screening programme evaluator’s functions, any *(records)* health information and specimens that relate to a relevant *(person)* woman. 20

“(2) The Director-General may specify, by notice in writing to the person in charge of the laboratory or other premises, the manner and form in which *(a record)* health information or a specimen that is required to be provided under **subsection (1)** must be provided, and that *(record)* information or that specimen must be provided in that manner and form. 25

“112ZB Duty of hospitals 30

“(1) The person in charge of a hospital must make available, free of charge, to a screening programme evaluator, for the purpose of enabling that screening programme evaluator to perform the screening programme evaluator’s functions, any

(records) health information and specimens that relate to a relevant (person) woman.

- “(2) The Director-General may specify, by notice in writing to the person in charge of the hospital, the manner and form in which (a record) health information or a specimen that is required to be provided under **subsection (1)** must be provided, and that (record) information or that specimen must be provided in that manner and form. 5

“*Miscellaneous*

“112ZC **Screening programme employees may retain, access, use, and disclose information to perform functions** 10

- “(1) Nothing in this Part prevents any employee of (a screening programme) the NCSP from retaining, accessing, using, and disclosing any information to the extent necessary to perform his or her functions as an employee of that programme, including— 15

“(a) information that is held by or accessible to the persons operating (that programme) the NCSP; and

“(b) information and evaluation material obtained by that employee for the purposes of performing an evaluation (including information obtained in his or her capacity as a screening programme evaluator or as a person assisting a screening programme evaluator); and 20

“(c) information and evaluation material provided to the (screening programme) NCSP by a screening programme evaluator during or following an evaluation. 25

- “(2) For the purposes of **subsection (1)**, a person is an employee of (a screening programme) the NCSP if the person—

“(a) is appointed to operate that programme, or to perform particular functions in relation to the operation of that programme, by the Director-General or the Ministry; or 30

“(b) is employed to work in that programme by the Ministry or by the persons appointed to operate the programme.

112ZD Regulations

Struck out (unanimous)

“(1) For the purposes of this section **screening programme** means the NCSP and any other screening programme to which the provisions of this Part are extended by Order in Council under **section 112ZF**.

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“(2) Regulations may be made under this Part for any 1 or more of the following purposes:

“(a) regulating access to information held by *(a screening programme)* the NCSP by persons researching cancer:

“(b) prohibiting the disclosure, under **section 112K(1)(g)**, of information that relates to any class or classes of person specified in the regulations, including prohibiting the disclosure of that information without the approval of any person or group of persons or body or organisation specified in the regulations:

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“(c) imposing restrictions, in addition to those imposed by this Part, on the use, disclosure, and publication of information held by *(a screening programme)* the NCSP:

“(d) prohibiting the use, disclosure, and publication of information from *(a screening programme)* the NCSP register, or derived from the operation of *(a screening programme)* the NCSP, if the information relates to any class or classes of person specified in the regulations, including prohibiting the use, disclosure, and publication of that information without the approval of any person or group of persons or body or organisation specified in the regulations:

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“(e) providing for the establishment, appointment, procedures, and powers of any person or group of persons or body or organisation established to perform specific functions or to make specific decisions that relate to *(a screening programme)* the NCSP or to the matters referred to in **paragraphs (b) and (d)**:

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- “(f) imposing restrictions on the publication by screening programme evaluators, under **section 112Z**, of academic papers or articles that are wholly or partly based on evaluation material obtained for the purposes of an evaluation: 5
- “(g) prescribing standards that must be met by providers of screening, diagnostic, and treatment services relevant to *(a screening programme)* the NCSP, and the means of implementing those standards.
- “(3) Before making regulations under **subsection (2)**, the Governor-General must be satisfied that appropriate consultation has been carried out, including (without limitation),— 10
- “(a) adequate and appropriate notice of the intention to make the regulations; and
- “(b) a reasonable opportunity for interested persons to make submissions; and 15
- “(c) adequate and appropriate consideration of any submissions received.

“112ZE **Offences**

- “(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)**, **section 112Y**, or any regulation made under **section 112ZD** that specifies that a breach of that regulation is an offence. 20
- “(2) Every person commits an offence against this Act who, without reasonable excuse, fails to make available any information or specimens that the person is required to make available under any of **sections (112V, 112W(4),) 112ZAA, 112ZA, and 112ZB**. 25
- “(3) Every person who commits an offence under **subsection (2)** is liable on summary conviction to a fine not exceeding \$10,000.” 30

Struck out (unanimous)

“112ZF **This Part may be extended to other screening programmes by Order in Council**

- “(1) The Governor-General may, by Order in Council, extend all or any of the provisions in this Part, other than the regulation- 35

Struck out (unanimous)

- making power in **section 112ZD**, to apply to any health screening programme.
- “(2) Before making an Order in Council under **subsection (1)**, the Governor-General must be satisfied that appropriate consultation has been carried out, including (without limitation),— 5
- “(a) adequate and appropriate notice of the intention to extend the sections to that other programme; and
- “(b) a reasonable opportunity for interested persons to make submissions; and
- “(c) adequate and appropriate consideration of any submissions received. 10
- “(3) For the purpose of giving effect to the extension of any provisions of this Part to a health screening programme, an Order in Council made under **subsection (1)** may—
- “(a) include any modifications (including any amendments) of those provisions that are required for that extension; 15
- and
- “(b) provide that the extension is to take effect subject to any exceptions or conditions specified in the Order in Council. 20
- “(4) Despite **subsection (3)**, no Order in Council may modify the provisions in this Part in a manner that reduces the level of protection of information that is provided by those provisions.
- “(5) As soon as possible after an Order in Council is made under **subsection (1)**, a notice must be published in the *Gazette* setting out the effect of that Order in Council and the date on which it comes into force. 25
- “(6) An Order in Council made under **subsection (1)** is a regulation for the purposes of the Regulations (Disallowance) Act 1989.”

- 5 Regulations as to retention of health information 30**
- (1) Section 121A(1)(a) of the principal Act is amended by omitting the words “health information” in both places where they occur, and substituting the words “health information or specimens”.
- (2) Section 121A(1)(b) of the principal Act is amended by omitting the words “health information” wherever they occur, and 35

substituting in each case the words “health information or specimens”.

- (3) Section 121A(1)(c) of the principal Act is amended by omitting the words “health information” in both places where they occur, and substituting the words “health information or specimens”. 5
- (4) Section 121A(1)(c) of the principal Act is amended by omitting the words “that information”, and substituting the words “that information or those specimens”.
- (5) Section 121A(2) of the principal Act is amended by adding the words “and **specimen** means a bodily sample or tissue sample taken from a person”. 10

6 Transitional provision

- (1) The NCSP register is the same register that was maintained under section 74A of the principal Act immediately before the commencement of this Act. 15
- (2) Every person who, immediately before the commencement of this Act, was appointed by the Director-General to maintain the NCSP register is deemed to have been appointed to operate the NCSP under **section 112D**. 20
- (3) Every woman who, immediately before the commencement of this Act, had results included on the NCSP register is deemed to have been enrolled in the NCSP in accordance with **section 112F**.
- (4) To avoid doubt, **subsection (3)** applies to a woman who, before the commencement of this Act, 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. 25
- (5) 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 are deemed to have been enrolled in the NCSP under **subsection (3)**. 30
- (6) If the NCSP manager knows that a woman, before the commencement of this Act, 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** 35

112I as if that woman had cancelled her enrolment in the NCSP under **section 112H(1)**.

Legislative history

16 May 2002

Introduction (Bill 214-1)

18 February 2003

First reading and referral to Health Committee
