Health (National Cervical Screening Programme) Amendment Act 2004

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The Parliament of New Zealand enacts as follows:

1 Title

(1) This Act is the Health (National Cervical Screening Programme) Amendment Act 2004.

(2) In this Act, the Health Act 1956 is called "the principal Act".

Part 1
Preliminary provision

2 Commencement

(1) This section, section 112C 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.

Part 2
Amendments to principal Act and transitional provisions

3 Section 74A repealed

The principal Act is amended by repealing section 74A.

4 New Part 4A inserted

The principal Act is amended by inserting, after Part 4, the following Part:

"Part4A
"National Cervical Screening Programme

"112A Purpose

The purpose of this Part is—

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

"(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.

"112B Interpretation

In this Part, unless the context otherwise requires,—

"**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

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

"**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 112T(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

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

"**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 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 112C(3) 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 112C

"**relevant woman**, for the purposes of sections 112X, 112ZB, 112ZC, and 112ZD, has the meaning set out in section 112X(1)

"**review committee** means an NCSP review committee established under section 112O

"**screening programme evaluator** means a person designated as a screening programme evaluator under section 112U(1)

"**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

"**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.

"*Operation of NCSP*

"**112C Appointment of persons to operate NCSP**

"(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.

"(2) 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.

"(3) The Director-General may appoint, either under section 59 of the State Sector Act 1988 or under subsection (2), 1 person to be the manager of the NCSP.

"(4) The NCSP manager may direct a person appointed under section 59 of the State Sector Act 1988 or under subsection (2) in relation to the performance of that person's functions, and that person must comply with the NCSP manager's direction.

"(5) 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.

"**112D 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

"(b) inform women and the community of the risks, benefits, and expected population health gains from participation in the NCSP; and

"(c) promote the regular recall of women who are enrolled in the NCSP for 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, 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

"(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.

"**112E Enrolment in NCSP**

"(1) The NCSP manager must enrol in the NCSP every woman who—

"(a) has a screening test, the result of which is reported to the NCSP; or

"(b) undergoes a colposcopic 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 112G(2), that she does not wish to be enrolled in the NCSP.

"**112F 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—

"(a) notify the woman that she has been enrolled in the NCSP; and

"(b) provide information to the woman about—

"(i) the importance of having regular 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

"(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

"(c) advise the woman that she may cancel her enrolment by advising the NCSP manager under section 112G(1).

"(2) The NCSP manager must record on the NCSP register every result that is reported to the NCSP manager from a screening test, or from a diagnostic test, if that result relates to a woman who is enrolled in the NCSP.

"**112G 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.

"(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).

"**112H Duties of NCSP manager when women cancel enrolment in NCSP**

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

"(a) send a notice to the woman confirming that her enrolment in the NCSP has been cancelled or, as the case requires, that she will not be enrolled; and

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

"(c) 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

"(d) 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.

"(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.

"(3) Despite subsection (1)(c), the NCSP manager may retain information that relates to a woman who cancels her enrolment in the NCSP if that information—

"(a) is in hard copy format; and

"(b) was received before the date of commencement of this section.

"(4) To avoid any doubt, subsection (1) overrides the Health (Retention of Health Information) Regulations 1996 (SR 1996/343).

"**112I 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 112G(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.

"**112J Certain information held by NCSP must not be disclosed**

"(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—

"(a) with the consent of the woman or her personal representative; or

"(b) to a screening programme evaluator under section 112X(2)(a); or

"(c) to a review committee, in accordance with a request from that committee under section 112Q(1); or

"(d) to a health practitioner who has been engaged by, or on behalf of, the woman, and the information is disclosed for the purpose of assisting that health practitioner to provide health services to that woman; or

"(e) for the purpose of enabling results from a screening test or a diagnostic test to be followed up; or

"(f) 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 screening test; or

"(g) for the purpose of giving access to the NCSP register, in accordance with regulations made under section 112ZF(1)(a), to persons researching cancer; or

"(h) subject to any regulations made under section 112ZF(1)(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.

"(2) Despite subsection (1), a screening programme evaluator may disclose information in accordance with section 112Y(2)(a) to (d).

"**112K 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 112M(2)(b) and (c), 112N(2)(b) and (c), 112ZB(2), 112ZC(2), and 112ZD(2), on any conditions that the Director-General thinks fit.

"(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—

"(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.

"(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.

"(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.

"(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.

"(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.

"*Duties to provide information to women and to NCSP*

"**112L Duties of persons taking specimens for screening tests**

"(1) Every person who takes a specimen from a woman for the purpose of a screening test, and who believes that it is that woman's first screening test in New Zealand, must—

"(a) explain the procedure and provide information about the importance of having regular 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

"(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 112G.

"(2) Every person who takes a specimen from a woman for the purpose of a screening test, and who believes that it is not that woman's first 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.

"**112M Duty of persons performing colposcopic procedure**

"(1) Every person who performs a colposcopic procedure on a woman must—

"(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 screening tests, who has access to information on the NCSP register, and the uses to which that information may be put; and

"(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 112G; and

"(d) cause a report in relation to that colposcopic procedure to be forwarded to the NCSP manager.

"(2) A report under subsection (1)(d) must—

"(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.

"**112N 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 screening test; or

"(b) the specimen was obtained for the purpose of a diagnostic test; or

"(c) the specimen—

"(i) was obtained during a surgical procedure; and

"(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

"(c) be provided in the manner and form specified by the Director-General.

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

"**112O 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 112T 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 112U 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.

"**112P 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 112O(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.

"**112Q Review committee's access to information**

"(1) For the purposes of carrying out its review, a 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 112J apply to members of a review committee.

"**112R 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.

"**112S 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.

"*Screening programme evaluators*

"**112T Meaning of evaluate**

"(1) For the purposes of this Part, evaluate means to monitor and assess the service delivery and outcomes of the NCSP so as to promote the fulfilment of its objectives by determining whether there are any systemic issues to address within the programme or quality improvements that may be made to it.

"(2) An evaluation may, from time to time, include a review of, and an investigation into, the cases of—

"(a) any woman who is enrolled in the NCSP (whether or not she has developed any cervical cancer); and

"(b) any woman who has developed any cervical cancer (whether or not she is enrolled in the NCSP); and

"(c) any deceased persons to whom paragraph (a) or paragraph (b) applied at the time of death.

"**112U 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.

"(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.

"**112V Criteria for designating employees of Ministry**

Despite section 112U, 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—

"(a) the person has the technical competence to undertake the functions of a screening programme evaluator; and

"(b) the Ministry and the person will appropriately manage any conflicts of interest that arise.

"**112W Criteria for designating persons who are not Ministry employees**

Despite section 112U, 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—

"(a) has, or employs persons who have, the technical competence to undertake the functions of a screening programme evaluator; and

"(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

"(d) will comply with the obligations on that person under this Part.

"**112X Power of screening programme evaluators to access specimens and health information**

"(1) For the purposes of this section, section 112ZB, section 112ZC, and section 112ZD, a **relevant woman** is—

"(a) a woman who is enrolled in the NCSP; or

"(b) a woman who is not enrolled in the NCSP but who has developed any cervical cancer; or

"(c) a deceased woman to whom paragraph (a) or paragraph (b) applied at the time of her death.

"(2) Except to the extent that regulations have been made under section 112ZF(1)(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 112U(3), a screening programme evaluator has full access to—

"(a) all information held by the persons operating the NCSP; and

"(b) all information on the cancer registry that relates to a relevant woman; and

"(c) 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) health practitioner; or

"(ii) laboratory; or

"(iii) hospital.

"(3) 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.

"(4) A screening programme evaluator may only access or copy information and specimens under subsection (2) or (3) for the purpose of performing, and to the extent necessary to perform, that person's functions as a screening programme evaluator.

"(5) Subsection (4) is subject to section 112ZE.

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

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

"**112Y 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—

"(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 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

"(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 practitioner; and

"(d) use and disclose evaluation material for the purpose of advising the NCSP manager that, in the screening programme evaluator's opinion, a particular person who is enrolled in the NCSP may benefit from follow-up action; and

"(e) use evaluation material to prepare academic papers or articles for publication in accordance with section 112ZA.

"(3) Every screening programme evaluator must—

"(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

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

"(d) 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

"(e) 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 112Z.

"(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

"(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.

"(5) Subsections (1) and (3)(a) and (c) are subject to section 112ZE.

"**112Z 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 112Y(2)(a), must—

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

"(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.

"(2) Subsection (1) is subject to section 112ZE.

"**112ZA Screening programme evaluator may publish non-identifiable information obtained during evaluation**

"(1) Despite section 112Y(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—

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

"(b) the NCSP manager consents to the publication of the paper or article and to the timing of that publication; and

"(c) the publication of the paper or article is in accordance with any regulations made under section 112ZF(1)(f).

"(2) The 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 NCSP.

"Duties to provide information to screening programme evaluators

"**112ZB Duty of health practitioners**

"(1) Every health practitioner 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.

"(2) The Director-General may specify, by notice in writing to the health practitioner, the manner and form in which health information or specimens that are required to be made available under subsection (1) must be made available, and that information or those specimens must be made available in that manner and form.

"**112ZC 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 health information and specimens that relate to a relevant woman.

"(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 health information or a specimen that is required to be provided under subsection (1) must be provided, and that information or that specimen must be provided in that manner and form.

"**112ZD Duty of hospitals**

"(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 health information and specimens that relate to a relevant 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 health information or a specimen that is required to be provided under subsection (1) must be provided, and that information or that specimen must be provided in that manner and form.

"Miscellaneous

"**112ZE Screening programme employees may retain, access, use, and disclose information to perform functions**

"(1) Nothing in this Part prevents any employee of 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—

"(a) information that is held by or accessible to the persons operating 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

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

"(2) For the purposes of subsection (1), a person is an employee of 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

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

"**112ZF Regulations**

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

"(a) regulating access to information held by the NCSP by persons researching cancer:

"(b) prohibiting the disclosure, under section 112J(1)(h), 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:

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

"(d) prohibiting the use, disclosure, and publication of information from the NCSP register, or derived from the operation of 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:

"(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 the NCSP or to the matters referred to in paragraphs (b) and (d):

"(f) imposing restrictions on the publication by screening programme evaluators, under section 112ZA, of academic papers or articles that are wholly or partly based on evaluation material obtained for the purposes of an evaluation:

"(g) prescribing standards that must be met by providers of screening, diagnostic, and treatment services relevant to the NCSP, and the means of implementing those standards:

"(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.

"(2) Before making regulations under subsection (1), the Governor-General must be satisfied that appropriate consultation has been carried out, including (without limitation),—

"(a) adequate and appropriate notice of the intention to make the regulations; and

"(b) a reasonable opportunity for interested persons to make submissions; and

"(c) adequate and appropriate consideration of any submissions received.

"(3) Subsection (2) does not apply to regulations made under subsection (1)(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.

"**112ZG Incorporation of standards by reference in regulations**

"(1) Regulations made under section 112ZF(1)(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.

"**112ZH 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 112ZF(1)(g) after the making of regulations A state that the particular amendment or replacement has that effect.

"**112ZI 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.

"**112ZJ 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 112ZF(1)(g) state that the standards cease to have legal effect.

"**112ZK Requirement to consult**

"(1) This section applies to regulations made under section 112ZF(1)(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.

"**112ZL 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 112ZF(l)(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 the amendments or replacement standards incorporated.

"(3) A failure to comply with this section does not invalidate regulations that incorporate standards by reference.

"**112ZM 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.

"**112ZN 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.

"**112ZO Application of Standards Act 1988 not affected**

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

"**112ZP Offences**

"(1) Every person commits an offence against this Act who, without reasonable excuse, fails to comply with the requirements of any of section 112J(1), section 112Y(1), (3)(e), or (4)(b), or section 112Z.

"(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 112ZB, 112ZC, and 112ZD.

"(3) Every person who commits an offence under subsection (2) is liable on summary conviction to a fine not exceeding $10,000."

5 Regulations as to retention of health information

(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 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".

(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".

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 112C(3) 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 112E.

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

Legislative history

16 May 2002	Introduction (Bill 214-1)
18 February 2003	First reading and referral to Health Committee
22 September 2003	Reported from Health Committee (Bill 214-2)
2 December 2003	Second reading
24, 25 February 2004	Committee of the whole House (Bill 214-3)
2 March 2004	Third reading