Health (Screening Programmes) Amendment Bill

Government Bill

Explanatory note

General policy statement

The Bill aims to assist the operation and evaluation of the National Cervical Screening Programme (**NCSP**) and any other screening programmes to which the provisions in the Bill are later extended. The NCSP's objectives as set out in the Bill include the promotion of high quality cervical screening, assessment, and treatment services; the provision of information to women; and the facilitation of continuous quality improvement of the NCSP.

Operation of the NCSP is facilitated by providing that the NCSP can collect the information that it requires to operate in a safe and effective manner. Issues of confidentiality are paramount and the bill includes a number of safeguards to protect health information and, in particular, information that is used to evaluate the NCSP. All women will be automatically enrolled in the NCSP when they have a cervical screening test or colposcopy, unless they advise the NCSP that they do not wish to be enrolled. Health professionals must forward to the NCSP information about the screening test results, colposcopy results, and cervical biopsy results of all women. If a woman does not want her results to be retained by the NCSP, she may cancel her enrolment by advising the NCSP at any time.

Evaluation of the NCSP is facilitated by ensuring that certain information required to evaluate the safety and effectiveness of the NCSP is made available to designated screening programme evaluators. NCSP evaluators may access and use specified information about a woman who is either enrolled in the screening programme or who has developed cervical cancer. The importance of this evaluation for

the ongoing review and enhancement of the NCSP was recognised in the *Ministerial Inquiry into the Under-Reporting of Cervical Cancer Smear Abnormalities in the Gisborne Region.*

The information that may be used and accessed comprises information from the NCSP Register, relevant information from the Cancer Registry, cervical specimens, and hospital records. The people or organisations who hold the information will be required to make it available to the evaluators. The Director-General of Health will be able to limit the information that the evaluators may access and use.

If further health information is required (ie, non-hospital records such as primary health care records), these will be made available to screening programme evaluators if the person to whom the information relates gives his or her consent. If the person has died, his or her personal representative will be able to consent to the use of that health information. If the person cannot be found, or if he or she has died and his or her personal representative cannot be found, the Director-General will be able, in the case of a woman who has been diagnosed as having cervical cancer, to require the release of that health information to screening programme evaluators.

The Bill initially applies only to the NCSP but some or all of the provisions in the Bill may be extended to any other screening programme by an Order in Council following consultation.

Clause by clause analysis

Clause 1 is the Title clause.

Part 1
Preliminary provision

Clause 2 is the commencement clause. This Bill will come into force on **1 July 2003**.

Part 2
Amendments to principal Act and transitional provision

Clause 3 repeals section 74A of the principal Act, which relates to the national cervical screening register.

Clause 4 inserts a *new Part 4A* into the principal Act. There are 3 main purposes of that new Part, which are set out in *new section 112A*. The first is to provide for the appointment of persons to operate the NCSP. The second is to facilitate the operation and

evaluation of that programme by enabling the persons who operate it, and screening programme evaluators appointed to evaluate it, to have access to information and specimens. The third is to provide a mechanism that will allow the provisions in *new Part 4A* to be extended to other screening programmes after appropriate consultation.

New section 112B is the interpretation section for *new Part 4A*. It contains definitions of the terms **cancer registry**, **diagnostic test**, **evaluate**, **evaluation material**, **health information**, **hospital**, **NCSP**, **NCSP manager**, **NCSP register**, **NCSP screening test**, **personal representative**, **registered health professional**, **relevant person**, **screening programme evaluator**, **screening test**, and **specimen**.

New section 112C is the application provision. Its effect is that the provisions of *new Part 4A* will only apply to the NCSP unless and until an Order in Council is made that extends the provisions to any other screening programme. (There is provision to make an Order in Council extending the provisions to other screening programmes under *new section 112ZF*.)

Operation of NCSP

New section 112D provides that the Director-General may appoint persons to operate the NCSP, and to perform particular functions in relation to the operation of the NCSP. The Director-General may also appoint 1 person to be the NCSP manager. *Clause 6(2)* deems the persons who are currently appointed to operate the NCSP to have been appointed under *new section 112D*.

Under *new section 112D(3)*, the NCSP manager may give directions to any person who is appointed to perform a particular function in relation to the NCSP programme. This will enable, for example, the Director-General to appoint District Health Boards to perform specific functions, such as enrolling women in the NCSP and providing information to women who are enrolled, and will give the NCSP manager some control in relation to the performance of those functions. Under *new section 112D(4)* the Director-General may give directions to the NCSP manager in relation to the performance of his or her functions.

New section 112E sets out the objectives of the NCSP, which include the following:

- promoting high quality cervical screening, assessment, and treatment services, with a view to reducing the incidence of, and mortality from, cervical cancer:
- informing women of the risks and benefits from participation in the programme:
- promoting the regular recall of women who are enrolled in the programme for NCSP screening tests:
- facilitating continuous quality improvement by allowing, and performing, regular evaluations of the programme:
- ensuring the information that is collected is safely stored and available to authorised persons in an accurate and timely manner.

New section 112F provides that, whenever the NCSP manager receives the result of an analysis of a specimen that was obtained from a woman during a NCSP screening test or colposcopy, that woman must be enrolled in the NCSP unless she is already enrolled, or has cancelled her enrolment, or has notified the NCSP manager that she does not wish to be enrolled. Because laboratories and colposcopists are obliged to send all results of NCSP screening tests and colposcopies to the NCSP, this has the effect that every woman who has a smear test or colposcopy will be enrolled in the NCSP unless she takes positive steps to prevent or cancel her enrolment. Laboratories must also report to the NCSP when they analyse specimens taken during surgical procedures that include a cervical component. In those cases, if the woman is neither enrolled in the NCSP nor listed as a person who does not wish to be enrolled, the NCSP manager has a discretion as to whether or not to enrol the woman in the programme.

New section 112G obliges the NCSP manager to provide certain advice to women on enrolment in the NCSP, and to record on the NCSP register every result that is received that relates to a woman who is enrolled.

New section 112H provides that a woman may cancel her enrolment in the NCSP by advising the NCSP manager in the manner and form specified by the NCSP manager. She may also prevent enrolment in the NCSP taking place in the future by notifying the NCSP manager that she does not wish to be enrolled.

New section 112I sets out the duties of the NCSP manager when a woman cancels her enrolment in the programme or advises that she

does not wish to be enrolled. When this happens, any information relating to that woman must be deleted from the current NCSP register and all hard copies returned or destroyed. Any information that is subsequently received about her must be returned or destroyed and may not be included on the register. The NCSP manager may, however, keep information that was received in hard copy form, if that information was received before the commencement of this Bill. Also, under *new sections 112H(3)(b) and 112I(2)*, the NCSP manager may keep sufficient information about a woman to identify her as a woman who does not wish to be enrolled, or who has cancelled her enrolment, in the programme.

New section 112J provides that a woman who has notified the NCSP that she does not wish to be enrolled, or who has cancelled her enrolment, in the NCSP may enrol, or re-enrol, at any time, by advising the NCSP manager.

New section 112K(1) provides that information on the NCSP register, or held by the NCSP as a result of an evaluation, that relates to an identifiable woman must not be disclosed except in certain limited circumstances. Those circumstances are if the disclosure is made—

- with the woman's consent (or with that of her personal representative):
- to a screening programme evaluator:
- to a registered health professional who is providing services to the woman:
- to allow a test result to be followed up or a reminder notice to be sent:
- in accordance with regulations that allow access to the register to persons researching cancer:
- to enable the compilation and publication of statistics that do not identify individual women.

This section substantially repeats current section 74A(5) of the principal Act, except that—

- it has been extended to protect information that is held by the NCSP as a result of an evaluation; and
- the ability to disclose certain identifying information to a screening programme evaluator is new; and

- *subsection (2)* is new, and creates an exception that allows a screening programme evaluator to disclose identifying information for the particular purposes set out in *new section 112X(2)(a) to (d).*

New section 112L deals with delegations. *Subsection (1)* allows the Director-General to delegate certain functions and powers to the NCSP manager. Although the State Sector Act 1988 will enable the Director-General to delegate any of his or her functions to the NCSP manager if the NCSP manager is an employee of the Ministry, specific power to delegate is needed to enable the Director-General to delegate functions or powers to the NCSP manager if the NCSP manager is not a Ministry employee. *Subsection (2)* allows the NCSP manager to delegate to any person his or her functions and powers under *new Part 4A*, other than functions or powers delegated to the NCSP manager by the Director-General.

Duties to provide information to women and to NCSP

New section 112M(1) obliges every person who takes a specimen from a woman for a NCSP screening test, believing it to be that woman's first NCSP screening test in New Zealand, to provide certain advice to her. First, the person must explain the procedure and provide information about the importance of having regular smear tests, the objectives of the NCSP, who has access to information on the NCSP register, and what that information may be used for. Second, the person must tell the woman that she will be enrolled in the NCSP and how she may prevent or cancel that enrolment.

New section 112M(2) obliges a person who takes a specimen for a subsequent NCSP screening test to provide information about the procedure and the NCSP to the extent that is reasonable in the circumstances. *Subsection (3)* clarifies that these obligations do not limit any other legal obligation to provide information.

New section 112N requires colposcopists to provide certain information to women who have colposcopies, including information about enrolment on the NCSP and the woman's ability to prevent or cancel that enrolment. It also requires colposcopists to forward a report to the NCSP in relation to each colposcopy that they perform. That report must be provided, free of charge, in the manner and form specified by the Director-General.

New section 112O requires laboratories that analyse specimens from NCSP screening tests and diagnostic tests for cervical cancer to

forward a report to the NCSP in relation to each specimen that they analyse. Laboratories must also forward to the NCSP a report in relation to any histological specimen that they analyse that was taken from a woman during a surgical procedure and that includes a cervical component. Laboratory reports must be provided, free of charge, in the manner and form specified by the Director-General.

Screening programme evaluators

New sections 112P to 112Z provide for the Director-General to appoint screening programme evaluators, and set out the powers and duties of screening programme evaluators.

The function of a screening programme evaluator is to evaluate a screening programme, and *new section 112P* defines the word **evaluate**. An evaluation is an assessment of the service delivery and outcomes of a screening programme, and whether any systemic issues exist for that programme. The definition makes it clear that an evaluation of a screening programme may include reviewing and investigating the cases of—

- persons who are enrolled in that screening programme (whether or not they have developed the condition to which the screening programme relates); and
- persons who have developed the condition to which that screening programme relates (whether or not they are enrolled in that programme); and
- deceased persons who, at the time of their death, were enrolled in that screening programme or had developed that condition.

New section 112Q provides for the Director-General to designate persons as screening programme evaluators, and to specify the particular evaluation functions that they are to perform. *Subsection (3)* gives the Director-General power to limit the type of information that a screening programme evaluator may have access to, depending on the functions that the screening programme evaluator is to perform.

New section 112R sets out the criteria that must be met before the Director-General may designate a person as a screening programme evaluator if that person is an employee of the Ministry of Health, and *new section 112S* sets out the criteria that must be met if the person is not a Ministry employee.

New section 112T provides that a screening programme evaluator may only access information and specimens, under the next 3 provisions in the Bill, for the purpose of performing the screening programme evaluator's functions. However, under *new section 112Z*, if the screening programme evaluator is also an employee working in the relevant screening programme, he or she may also access some of the information referred to in those sections, such as information held by the programme, for the purposes of performing his or her functions as an employee.

New section 112U gives a screening programme evaluator access to certain information about, and specimens taken from, persons who are enrolled in the screening programme that is being evaluated, and persons who have developed the condition to which that programme relates. The information and specimens that may be obtained are—

- records and specimens held by a laboratory:
- records and specimens held by a hospital:
- information held by the screening programme:
- information on the cancer registry.

The clause makes it clear, however, that a screening programme evaluator's access to the information and specimens is only to the extent that that access is not restricted by regulations made under *new section 112ZD(2)(c) or (d)* or by limits imposed on that screening programme evaluator's access by the Director-General under *new section 112Q(3)*.

New section 112V gives a screening programme evaluator access to other health information that is held by providers of health services if the person to whom that information relates, or their personal representative, gives consent. The Director-General may specify the manner and form in which that information must be provided to the screening programme evaluator.

New section 112W allows the Director-General to require any person to make health information available to a screening programme evaluator if that information relates to the treatment of a person who has been diagnosed as having the condition to which a screening programme relates. The Director-General may only do this if he or she is satisfied that, despite reasonable efforts having been made, it has not been possible to obtain consent because the person has not been found or, if the person has died, his or her personal representative has not been found.

New section 112X sets out certain duties on screening programme evaluators. Generally these duties are designed to limit what may be done with information and specimens relating to an identifiable individual that are obtained by a screening programme evaluator under *new Part 4A* (**evaluation material**). The general rule is that evaluation material may only be used or disclosed by a screening programme evaluator for the purpose of performing the screening programme evaluator's functions. However, there are 5 exceptions under *new section 112X(2)*. A screening programme evaluator may—

- disclose evaluation material to a person who requires that material to assist the evaluator to perform the evaluator's functions; and
- use and disclose evaluation material for the purpose of referring a concern about the competence of a health professional to the appropriate registering body; and
- disclose evaluation material to the ACC or to the Health and Disability Commissioner for the purpose of assisting an investigation into the competence of a health professional; and
- use and disclose evaluation material for the purpose of advising the person in charge of the screening programme that a particular person who is enrolled in the programme may benefit from follow-up action; and
- use evaluation material to prepare academic articles and papers for publication in accordance with *new section 112Z* (which, amongst other things, provides that no identifiable person may be referred to in an article without their consent).

Under *new section 112X(3)*, a screening programme evaluator is required to protect evaluation material by—

- taking appropriate measures to safeguard it from unauthorised use or disclosure:
- reporting cases of unauthorised use or disclosure to the Director-General:
- returning the material to the person who supplied it as soon as it is no longer required, and destroying all copies:

- advising all persons to whom the screening programme evaluator discloses evaluation material of the restrictions that apply to the screening programme evaluator, and to that person.

In addition, *new section 112X(4)* imposes 2 reporting duties on screening programme evaluators who are not employed by the Ministry. An external evaluator must, at the end of the evaluation, provide a written report of the results of the evaluation to the Director-General. In addition, if the Director-General so requests, an external evaluator must provide a statutory declaration as to whether or not he or she has met the requirements of *new section 112X(3)(a) to (c)*.

New section 112Y sets out the duties of persons who are given evaluation material to enable them to assist a screening programme evaluator. Those persons must—

- use that material only for the purpose for which it was provided:
- take appropriate measures to safeguard it from disclosure to any other person:
- return material that is in hard copy or electronic form as soon as it is no longer required, and destroy all copies of it.

These duties are, however, subject to *new section 112ZC*, which allows the employees of a screening programme to retain, access, use, and disclose information to the extent necessary to perform their functions.

New section 112Z allows a screening programme evaluator to publish academic papers or articles that are based on evaluation material, as long as the paper or article does not identify any individual person without their consent. In addition,—

- the screening programme manager must consent to publication of the paper or article, and to the timing of the publication; and
- the publication must be in accordance with any regulations that are made under *new section 112ZD(2)(f)* that restrict an evaluator's ability to publish academic papers or articles.

The screening programme manager may only withhold consent to publication if he or she believes, on reasonable grounds, that publication would pose a serious risk to the effective operation of the screening programme.

Duties to provide information to screening programme evaluators

New section 112ZA obliges the person in charge of a laboratory or other premises where specimens are held to make certain records and specimens available to a screening programme evaluator. The records and specimens that must be provided are those that relate to persons who are enrolled in the relevant screening programme, and those that relate to persons who have been diagnosed as having the condition to which that programme relates.

New section 112ZB imposes the same obligation to provide records and specimens on the person in charge of a hospital.

Miscellaneous

New section 112ZC allows a person who is an employee of a screening programme to retain, access, use, and disclose information and evaluation material to the extent necessary to perform his or her functions as an employee of the screening programme. The section applies to all employees, whether or not they are also appointed as screening programme evaluators, and it overrides any provisions in the Bill that appear to provide to the contrary.

New section 112ZD is a regulation-making power that has substantially been carried over from current section 74A(7) of the principal Act. However, the language has been modified to make it more general, so that regulations may be made that apply not only to the NCSP but also to other screening programmes to which the provisions of this Bill may be extended. In addition, 2 new regulation-making powers have been added as follows:

- a power to make regulations imposing restrictions on the publication by screening programme evaluators of academic papers or articles that are wholly or partly based on evaluation material obtained during an evaluation; and
- a power to make regulations specifying the standards that must be met by persons who provide screening, diagnostic, and treatment services that are relevant to a screening programme.

New section 112ZE sets out 2 categories of offences. First, it is an offence to fail to comply, without reasonable excuse, with the following obligations:

- the obligation on a person, under *new section 112K(1)*, not to disclose certain information held by the NCSP except in specified circumstances:
- the obligation of a screening programme evaluator, under *new section 112X(1)*, not to use evaluation material for an unauthorised purpose:
- the obligation of a screening programme evaluator, under *new section 112X(3)(d)*, to advise a person to whom he or she gives information of the requirements to protect that information:
- the obligation of a screening programme evaluator who is not employed by the Ministry, under *new section 112X(4)(b)*, to provide a statutory declaration to the Director-General on request:
- the obligations, under *new section 112Y*, of a person to whom a screening programme evaluator gives information to protect that information:
- any obligation imposed by regulations made under *new section 112ZD*, the breach of which is specified to be an offence.

Under section 136 of the principal Act, the penalty for these offences is a fine not exceeding $500 and, if the offence is a continuing one, a further fine of up to $50 per day.

The second category of offences are offences that relate to a failure to provide information to a screening programme evaluator. The offences are set out in *new section 112ZE(2)*, and are as follows:

- failure of a health care provider, under *new section 112V*, to provide certain information to a screening programme evaluator once consent has been obtained:
- failure of a person, under *new section 112W(4)*, to provide certain information to a screening programme evaluator when required to do so by the Director-General:
- failure of a person in charge of a laboratory, under *new section 112ZA*, to provide certain records and specimens to a screening programme evaluator:
- failure of a hospital, under *new section 112ZB*, to provide certain records and specimens to a screening programme evaluator.

The penalty for these offences is a maximum fine of $10,000.

New section 112ZF allows the Governor-General, after appropriate consultation, to extend the provisions of *new Part 4A* to other screening programmes by Order in Council.

Clause 5 amends section 121A of the principal Act, which confers the power to make regulations for the retention of health information. The amendment extends that regulation-making power so that regulations may, in the future, be made that will require specimens to be retained.

Clause 6 is a transitional clause that provides for the continuation of the current NCSP register, and for the persons who operate it to be deemed to have been appointed to operate the NCSP under the provisions of this Bill. It also provides that—

- every woman who has results on the NCSP register when this Bill comes into force is deemed to be enrolled in the NCSP under the provisions of this Bill; and
- if the NCSP manager knows that a woman has opted off the NCSP register before this Bill comes into force, the NCSP manager must take reasonable steps to deal with her information as if she had cancelled her enrolment in the NCSP; and
- the NCSP manager must take reasonable steps to ensure that information about the programme, and about the effect of this Bill (when it is enacted), is available to women who are deemed to be enrolled in the programme.

Regulatory impact and compliance cost statement

Statement of problem and need for action

Organised screening programmes are proactively initiated by the health sector. They aim to provide benefits at a population level but cannot guarantee individual benefits. Screening tests can identify most of the people with the relevant condition, as well as most who do not, but there is an inherent risk of some false results. The highest quality service must therefore be provided to ensure that population benefits are maximised and individual harms minimised. Unlike personal health services, any deficiency in screening programmes are likely to affect many individuals. Effective monitoring and evaluation of screening programmes are therefore essential.

The current system presents significant barriers to effective and efficient monitoring, evaluation, and audit of the NCSP because the information required for routine evaluation and monitoring activities cannot be adequately collected or is difficult to access. Without the ability to comprehensively evaluate the NCSP, it would be difficult to assess whether the programme is operating with optimal safety and efficiency.

The objective of the Bill is to enable the NCSP to be evaluated on an ongoing basis by NCSP staff and also by external evaluators. The Bill aims to make sure that the necessary levels of information are available. This involves enabling the NCSP to collect the data that is required, and enabling appropriately qualified and designated evaluators to have access to the necessary information.

Statement of public policy objective

The objective is to ensure that the NCSP operates as safety and effectively as possible, and can be comprehensively and efficiently evaluated on a routine and ongoing basis.

The *Ministerial Inquiry into the Under-Reporting of Cervical Smear Abnormalities in the Gisborne Region* recommended that legislative change be made in order to ensure that there are no legislative barriers to the comprehensive evaluation of the NCSP.

Options for achieving desired objective

Non-regulatory measure

Evaluation of the NCSP can be partially achieved by means that do not involve changes to the present regulatory framework, through conducting periodic audits. This would involve having teams of appropriately qualified persons to identify the women whose records are required. These women may be identified from the Cancer Registry, which records the incidence of all cancers in New Zealand, and from NCSP Register data. Persons evaluating the programme would then attempt to trace these women, where possible, and seek their informed consent and authorisation to access their relevant medical records, slides, and NCSP Register data where this is available.

As a means of evaluating the NCSP, this option is inadequate for several reasons. First, undertaking periodic audits with the requirement to get the informed consent of all women involved is costly and unlikely to generate sufficiently comprehensive results. Some of the

addresses held by the Cancer Registry are out of date and, in some cases, it is clear that women have moved away from the region. In a few instances, the address held on the Cancer Registry is almost certain to be unhelpful (eg, c/o a named Post Office). There are particular difficulties in relation to those women who have died. The Cancer Registry does not normally hold details of next of kin. The evaluation team would therefore have to embark on detective work to find out who the next of kin are and where they currently reside. It is expected that tracing the women involved or their next of kin would take several months. If a substantial number of women could not be traced, or decided to withhold consent, the whole value of the exercise would be questionable.

The process of attempting to trace women is likely therefore to be a relatively costly and time-consuming exercise, with no guarantee that sufficient numbers of women will be able to be traced for the exercise to be successful. This means that the ability to evaluate the NCSP is unlikely to be effective.

The undertaking of periodic evaluations alone is also unsatisfactory as a means of evaluating the NCSP. Ideally, quality control should be an ongoing activity that is fully integrated into the NCSP, rather than a series of one-off projects. Routine evaluation in this sense will be facilitated by the regulatory changes provided in this Bill.

Regulatory measures

The alternative is to make amendments to the current legislation to allow the NCSP to be effectively evaluated using the full range of information that is currently collected by the NCSP, and to ensure access to cervical specimens, hospital records, and Cancer Registry data as required. Consent would be sought before accessing and using an individual woman's non-hospital records (eg, primary care records), which may be required for specific evaluations, such as the periodic evaluation of cases of invasive cervical cancer. The Bill requires that the people or organisations that hold such information make it available to evaluators designated by the Director-General of Health.

Net benefits of this proposal

Benefits

It is widely accepted that the NCSP needs to be routinely evaluated to ensure that the programme is operating in a clinically safe manner. This was a key recommendation of the *Ministerial Inquiry into the Under-Reporting of Cervical Smear Abnormalities in the Gisborne Region.*

The introduction of appropriate legislation allowing the effectiveness and safety of the NCSP to be evaluated has the benefit of enabling the NCSP to identify potential systemic issues before these become a serious ongoing risk to the clinical safety of those women who are enrolled on the NCSP.

The Crown will also benefit by being able to evaluate and monitor the NCSP in an efficient and cost-effective manner. The more accessible the information is for the screening programme evaluators, the less cost will be involved in carrying out evaluation activities.

Costs

There is some loss of privacy for certain women in relation to hospital records accessed for evaluation purposes, given that consent is not a requirement for such access. However, the Bill sets out clear provisions to protect disclosure of this information so that risks to privacy are minimised.

If the proposed changes are put in place, there will be ongoing operational costs to the Ministry when evaluating the NCSP. While many of these costs would be administrative in nature, there will be costs incurred in the analysis of data that is created in the course of particular evaluations undertaken by contracted evaluators.

If the changes are not put in place, there is a significant risk that the NCSP will not be able to be effectively evaluated. If that is the case, the cost for some women may be difficulties in identifying and assessing the systemic issues that may put their health at risk.

In general, the Bill will mean that, for evaluation that involves women on the programme, data collection costs will be minimal as all NCSP data will be available to evaluators. For the evaluation of women with invasive cervical cancer, there will still be substantial data collection costs associated with the process to obtain consent to access non-hospital primary care records, which will require the informed consent of the women concerned.

Business compliance costs

The implementation of the proposals is likely to result in some costs for health professionals and laboratories involved in the NCSP. For a small number of health professionals and specialists there may be some compliance costs resulting from requests to provide medical records to persons carrying out evaluation activities. There may be ongoing costs for smear takers and colposcopists, who will be required to provide information to women about the NCSP. Such compliance costs will be reduced with provision by the NCSP of relevant Programme information (pamphlets, etc), which can be used by smear takers and specialists to provide the specified information.

Colposcopists will face some costs in addition to those currently incurred when providing colposcopic services to women. These costs will generally be met within the contracts that the NCSP has with District Health Boards for the provision of these services. Any additional costs incurred in private practice will fall to the client.

There are likely to be few additional compliance costs for laboratories as a result of this amendment. Additional information will be required to be provided to the NCSP, however laboratories already process this information and provide it to the relevant health professionals. The provision of duplicates of this information to the NCSP is unlikely to incur significant additional costs. While it may appear that there will be some compliance costs for laboratories if they are required to store cervical slides for a minimum period, laboratories already store these slides for a lengthy period, and it is not anticipated that the regulatory regimen will create any new costs for laboratories.

Further possible regulations, in particular those relating to standards, will be the subject of their own separate consultation and regulatory impact statement/business compliance cost statement processes.

Consultation

A public discussion document was released, with 101 submissions received from key stakeholders, and members of the public. Consultation has been undertaken during the drafting of the Health (Screening Programmes) Amendment Bill with government departments and agencies and selected professional and women's groups.

The following government departments and statutory agencies have also been consulted during the development of this Bill:

Government departments:

Ministry of Consumer Affairs

Ministry of Justice

Ministry of Pacific Island Affairs

Ministry of Women's Affairs

Te Puni Kōkiri

Other statutory agencies:

Office of the Health and Disability Commissioner

Office of the Privacy Commissioner

Medical Council of New Zealand

Nursing Council of New Zealand

Hon Annette King

Health (Screening Programmes) Amendment Bill

Government Bill

Contents

The Parliament of New Zealand enacts as follows:

1 Title

(1) This Act is the Health (Screening Programmes) Amendment Act **2002**.

(2) In this Act, the Health Act 1956[1] is called "the principal Act".

[1] 1956 No 65

Part 1
Preliminary provision

2 Commencement

This Act comes into force on **1 July 2003**.

Part 2
Amendments to principal Act and transitional provision

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 IV, the following Part:

"Part 4A
"Screening programmes

"112A **Purpose**

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

"(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; and

"(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,—

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

"**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

"(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

"(ii) 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**

"**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**, for the purposes of **sections 112U, 112V, 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)**

"**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

"**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

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

"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.

"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.

"(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.

"(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.

"112E **Objectives of NCSP**

The objectives of the NCSP are to—

"(a) promote high quality cervical screening, assessment, and treatment services 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 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; and

"(ii) safely stored, including on the NCSP register.

"112F **Enrolment in NCSP**

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

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

"(b) undergoes a colposcopic examination, 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—

"(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 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

"(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 112H(1)**.

"(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, if that result relates to a woman who is enrolled in the NCSP.

"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.

"(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—

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

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

"(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)(b)**, 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 Act.

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

"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.

"112K **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 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

"(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

"(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

"(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.

"(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), 112ZA(2), and 112ZB(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*

"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—

"(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

"(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**.

"(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.

"112N **Duty of persons performing colposcopy examinations**

"(1) Every person who performs a colposcopy examination 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 NCSP 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 112H**; and

"(d) cause a report in relation to that colposcopy 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.

"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

"(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
"(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.

"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 so as to promote the fulfilment of the objectives of that screening programme by determining whether there are any systemic issues to address within that programme or quality improvements that may be made to that programme.

"(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 (whether or not they have developed the condition to which the programme relates); and
"(b) any persons who have developed the condition to which the screening programme relates (whether or not those persons are enrolled in that programme); and
"(c) any deceased persons to whom **paragraph (a) or paragraph (b)** applied at the time of death.

"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.

"(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.

"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—

"(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.

"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—

"(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.

"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.

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

"112U **Power of screening programme evaluators to access certain specimens and information**

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

"(a) a person who is enrolled in a screening programme that is being evaluated by a screening programme evaluator; or

"(b) a person who is not enrolled in that programme but who has developed the condition to which that programme relates; or

"(c) a deceased person 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,—

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

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

"(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.

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

"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—

"(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.

"(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.

"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.

"(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

"(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.

"(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.

"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—

"(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; 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 professional; and

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

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

"(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) 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**.

"(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 112ZC**.

"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—

"(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.

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

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

"(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—

"(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 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 112ZD(2)(f)**.

"(2) The person in charge of a screening programme 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.

"Duties to provide information to screening programme evaluators

"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 and specimens that relate to a relevant person.

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

"112ZB **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 records and specimens that relate to a relevant person.

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

"*Miscellaneous*

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

"(1) Nothing in this Part prevents any employee of a screening programme 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 that programme; 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 screening programme by a screening programme evaluator during or following an evaluation.

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

"112ZD **Regulations**

"(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**.

"(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 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:

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

"(d) prohibiting the use, disclosure, and publication of information from a screening programme register, or derived from the operation of a screening programme, 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 a screening programme or to the matters referred to in **paragraphs (b) and (d)**:

"(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:

"(g) prescribing standards that must be met by providers of screening, diagnostic, and treatment services relevant to a screening programme, 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),—

"(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.

"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.

"(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), 112ZA**, and **112ZB**.

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

"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-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),—

"(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.

"(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; and

"(b) provide that the extension is to take effect subject to any exceptions or conditions specified in the Order in Council.

"(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.

"(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

(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) The NCSP register is the same register that was maintained under section 74A of the principal Act immediately before the commencement of this Act.

(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**.

(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.

(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)**.

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

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