Health (National Cervical Screening Programme) Amendment Bill

Government Bill

As reported from the Health Committee

Commentary

Recommendation

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

The bill as introduced

The bill seeks to amend Part 4A of the Health Act 1956, which provides for the National Cervical Screening Programme (NCSP).

The key amendment is in clause 6 of the bill, which seeks to replace section 112J in governing how, and for what purpose, information on the NCSP register can be accessed, used, retained, and disclosed.

Currently, when cervical screening providers need to access clinical information about individual patients, they do so by fax. NCSP staff fax the information to them. The amendments would allow providers to look up the information directly, using secure, log-on access via the internet.

New section 112J(2)(a) and (c) would allow health practitioners and their administration staff to directly look up a woman's information to help provide cervical screening services to her. Under new section 112J(2)(b), (c), and (d), colposcopy and laboratory service providers, their administrative staff, and certain district health board staff would also be able to look up information on the register.

New section 112J(2)(e) would allow access to the register by people providing support services to women who were experiencing barriers to accessing cervical screening services.

Access to the register by providers would be view-only, so that providers could see information but not change it. Under new section 112JA(4), only people authorised to do so by the NCSP manager could amend information on the register. Clause 8, new section 112ZP(1), would make it an offence to amend the register without the authorisation of the NCSP manager.

Proposed amendments

This commentary covers the main amendments we recommend to the bill as introduced. We do not discuss minor or technical amendments.

Definitions should refer to vagina as well as cervix

The NCSP screens for cancer in the vagina as well as the cervix. However, definitions in the Act only refer to the cervix. We recommend inserting new subclauses (1AAA) and (4) into clause 5 to amend the definitions of "diagnostic test" and "specimen" in section 112B so that they refer to cancer of the vagina and vaginal cytology.

Wider definition of "screening test"

Currently, a patient's first screening test is cytology (examining cells). We understand that, in future, this is likely to change to primary screening for human papillomavirus (HPV). We consider it appropriate to amend the definition of "screening test" to provide for this change. We recommend inserting subclause (3) into clause 5, setting out a new definition of "screening test" which includes reference to the HPV test.

Screening males for HPV

HPV also infects men and can lead to some forms of cancer in men. We acknowledge the shift in recent years to provide boys with free vaccination against HPV. This is a positive move. Although it would be outside the scope of the NCSP, we note that there may be a time in the future when screening for cancers caused by the HPV virus could be available to men. We look forward to such developments.

Kaitiaki Regulations

The Health (Cervical Screening (Kaitiaki)) Regulations 1995 were made under section 74A of the Act, which was later repealed. They establish a National Kaitiaki Group which can approve the disclosure, use, and publication of certain information from the register about Māori women. The Kaitiaki Group must have regard to the matters set out in regulation 5(3), namely:

- the sanctity of Te Whare Tangata
- the need for culturally appropriate protection for the taonga of the information covered by the regulations
- the need to ensure that the information is used for the benefit of Māori women.

We were advised that existing provisions about the Kaitiaki Regulations were carried over to the bill.

Ministry's adherence to Kaitiaki Regulations

However, some submitters said that the Ministry of Health does not comply with the Kaitiaki Regulations. They submitted that the ministry exempts itself from the requirement to seek approval from the National Kaitiaki Group. They said that protection offered by the regulations are lost because the ministry extracts data without seeking Kaitiaki Group approval.

We note that section 112ZE of the Act means that the Kaitiaki Regulations do not prevent NCSP employees from retaining, accessing, using, or disclosing any information to the extent necessary to perform their functions as employees of the programme.

In 2003, the Health Select Committee of the 47th Parliament reported to the House on the Health (Screening Programmes) Amendment Bill. We note the committee's comment that the Kaitiaki Regulations require any disclosure, use, and publication of aggregate data about Māori women, including for evaluation purposes, to be approved by the Kaitiaki Group.

Submitters told us that in 2015, the ministry obtained legal advice about the application of the Kaitiaki Regulations to the NCSP. The advice was that the NCSP did not have to apply to the Kaitiaki Group to retain, access, use, or disclose information to perform routine programme functions, provided the information was dealt with by an employee of the NCSP, the action was necessary for them to perform their functions as an employee, and the NCSP was pursuing its statutory duties. Among other things, the advice said that the NCSP did not need to apply to the Kaitiaki Group to disclose information to external researchers and programme evaluators if facilitating that research was consistent with the NCSP's statutory objectives. It said that external researchers and programme evaluators should apply to the group before:

- disclosing information that identifies individuals as Māori (without identifying them individually) where the purpose of the disclosure is to compile and publish non-identifiable statistics
- disclosing, using, or publishing non-identifiable information that identifies Māori.

It also said that researchers from an Australian organisation could be engaged to perform functions in relation to the operation of the NCSP following appointment made by the Director-General of Health.

Submitters told us that, after 2015, the Ministry of Health stopped applying to the Kaitiaki Group for approval to use data from the database.

The ministry commented that there are varying understandings of section 112ZE, and it is keen to work to resolve the issues that arise from these. We encourage it to prioritise this work as a matter of urgency.

We were heartened to hear that the ministry is working to develop a sustainable and inclusive framework to govern the use of data, with a particular focus on the security, protection, and management of Māori data. The ministry acknowledged that it needs to collaborate more widely with stakeholders to address the considerations and inter-

ests of Māori in data governance. We encourage the ministry to progress this important work.

We believe that the Kaitiaki Regulations should increase Māori participation in the programme, by assuring Māori women that their information is important and that it will be kept confidential.

At the same time, we acknowledge that experts need to access Māori data in order to monitor the success of the NCSP and reduce the incidence of cervical cancer among Māori. Obviously, both the NCSP and Māori would wish to work together to achieve these goals. We encourage the ministry to nurture and support the relationship between the NCSP and the National Kaitiaki Group.

We consider it appropriate for the ministry's data use to be subject to the approval of the Kaitiaki Group as outlined in the Kaitiaki Regulations. We recommend inserting new clause 6A to amend section 112ZE. Our amendment would provide that section 112ZE(1) does not override the requirements of the Kaitiaki Regulations.

Disclosure of register information for statistical purposes

Under clause 6, new section 112J(4)(d), the NCSP manager could authorise a person to disclose register information for the purpose of enabling the compilation and publication of statistics. This provision is based on existing section 112J(1)(h). Disclosure under the existing section is "subject to" regulations. Disclosure under the new section would be "in accordance with" the regulations.

We believe the phrase "in accordance with" could be taken to imply that regulations could authorise disclosures not otherwise permitted under the Act. Also, the phrase does not take into account the possibility that future regulations could prohibit disclosure (as opposed to simply establishing additional procedural requirements).

We recommend amending clause 6, new section 112J(4)(d), to make it clear that disclosure under that paragraph would not be allowed if regulations prohibited disclosure. We recommend replacing the words "in accordance with" with "unless the disclosure is prohibited by" regulations.

Definition of register updated

Clause 5(1) would amend the definition of "NCSP register" by inserting a reference to any part of the register that is replaced. We recommend making the same change to the definition in the Kaitiaki Regulations by inserting clause 9(1A) into the bill.

Appendix

Committee process

The Health (National Cervical Screening Programme) Amendment Bill was referred to the committee on 20 March 2018. The closing date for submissions was 3 May 2018. We received and considered 16 submissions from interested groups and individuals. We heard oral evidence from three submitters.

We received advice from the Ministry of Health.

Committee membership

Louisa Wall (Chairperson)

Dr Liz Craig

Matt Doocey

Anahila Kanongata'a-Suisuiki

Dr Shane Reti

Hon Nicky Wagner

Angie Warren-Clark

Hon Michael Woodhouse

Key to symbols used in reprinted bill

As reported from a select committee

<u>text inserted unanimously</u>

~~text deleted unanimously~~

Hon Julie Anne Genter

Health (National Cervical Screening Programme) Amendment Bill

Government Bill

Contents

The Parliament of New Zealand enacts as follows:

1 Title

This Act is the Health (National Cervical Screening Programme) Amendment Act **2018**.

2 Commencement

This Act comes into force on the day after the date on which it receives the Royal assent.

3 Principal Act

This Act amends the Health Act 1956 (the **principal Act**).

4 Section 112A amended (Purpose)

(1) In section 112A(b)(ii), after "that programme", insert "; and".

(2) After section 112A(b)(ii), insert:

(iii) enabling access to information by specified classes of persons for the purpose of providing cervical screening, assessment, and treatment services and by researchers.

5 Section 112B amended (Interpretation)

(1AAA) In section 112B, definition of **diagnostic test**, after "cervix", insert "or vagina".

(1) In section 112B, definition of **NCSP register**, after "section 112C", insert ", and includes any part of the register that is replaced".

(2) In section 112B, insert in their appropriate alphabetical order:

cervical screening service means any service provided for the purpose of providing cervical screening, assessment, and treatment services in relation to a particular woman as part of the NCSP

NCSP information means—

(a) register information; and

(b) information held by the NCSP as a result of an evaluation conducted in accordance with this Part

register information means information held on the NCSP register

(3) In section 112B, replace the definition of **screening test** with:

screening test means a test, such as a high-risk HPV test or a cervical or vaginal cytology test, designed to identify women who may have, or are at higher risk of developing, cervical cancer or a precursor to cervical cancer

(4) In section 112B, definition of **specimen**, after "cervical", insert "and vaginal".

6 Section 112J replaced (Certain information held by NCSP must not be disclosed)

Replace section 112J with:

112J Restriction on access to, and use, retention, and disclosure of, NCSP information

(1) No person may access, use, retain, or disclose NCSP information if that information identifies a woman, except as provided by this section.

(2) The following persons may access register information by directly accessing the NCSP register:

(a) a health practitioner engaged by or on behalf of a woman to provide cervical screening services to that woman, for the purpose of providing cervical screening services in relation to that woman:

(b) a health practitioner engaged to provide cervical screening services in relation to the woman by or on behalf of a health practitioner referred to in **paragraph (a)**, for the purpose of providing cervical screening services in relation to that woman:

(c) administrative support staff engaged by a health practitioner referred to in **paragraph (a) or (b)** who access the information at the direction of the health practitioner, for the purpose of providing cervical screening services in relation to that woman:

(d) district health board NCSP team staff performing the functions of NCSP register administrators and any other person or class of persons authorised for that purpose by the NCSP manager, for the purpose of supporting the operation of the NCSP:

(e) a person engaged by the Ministry of Health or a district health board, and any other person or class of persons authorised for that purpose by the NCSP manager, for the purpose of providing support services to women experiencing barriers to accessing cervical screening services:

(f) a person authorised by the NCSP manager, for the purpose of providing information to any person authorised to receive it under **subsection (3) or (4)**.

(3) Register information may be disclosed by a person referred to in **subsection (2)(f)**, to—

(a) a person authorised to access the NCSP register under **subsection (2)**, for the authorised purpose; or

(b) a person engaged by the Ministry of Health or a district health board, and any other person or class of persons authorised for that purpose by the NCSP manager, for the purpose of enabling results from a screening test or a diagnostic test to be followed up; or

(c) a person engaged by the Ministry of Health or a district health board, and any other person or class of persons authorised for that purpose by the NCSP manager, 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.

(4) NCSP information may be accessed and disclosed by a person authorised for that purpose by the NCSP manager, if the disclosure is—

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

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

(c) for the purpose of research, in accordance with regulations made under section 112ZF(1)(a); or

(d) 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, ~~in accordance with~~unless the disclosure is prohibited by any regulations made under section 112ZF(1)(b).

(5) Any person who accesses or receives information in accordance with **subsection (2), (3), or (4)** may use and retain the information for the purpose of that subsection and any directly related purpose.

112JA Further provisions relating to NCSP information

(1) Nothing in **section 112J** prevents any person from accessing, using, retaining, or disclosing NCSP information about a particular woman with the consent of that woman or her personal representative.

(2) Nothing in **section 112J** prevents any person from accessing, using, retaining, or disclosing NCSP information in accordance with this Part (*see*, for example, sections 112Q, 112X, 112Y, and 112ZE).

(3) Access to the NCSP register is subject to any conditions and procedures that the NCSP manager thinks necessary to impose or establish for the purpose of ensuring privacy and security of the material or information.

(4) No person may amend the information stored on the NCSP register unless authorised for that purpose by the NCSP manager.

6A Section 112ZE amended (Screening programme employees may retain, access, use, and disclose information to perform functions)

After section 112ZE(1), insert:

(1A) Despite subsection (1), that subsection does not override the Health (Cervical Screening (Kaitiaki)) Regulations 1995.

7 Section 112ZF amended (Regulations)

In section 112ZF(1)(b), replace "section 112J(1)(h)" with "**section 112J(4)(d)**".

8 Section 112ZP amended (Offences)

Replace section 112ZP(1) with:

(1) Every person commits an offence against this Act who, without reasonable excuse,—

(a) fails to comply with the requirements of section 112Y(3)(e) or (4)(b) or 112Z; or

(b) accesses, uses, retains, or discloses any NCSP information or evaluation material in contravention of section **112J(1)** or 112Y(1); or

(c) amends any information stored on the NCSP register, without authority from the NCSP manager under **section 112JA(4)**.

9 Health (Cervical Screening (Kaitiaki)) Regulations 1995 amended

(1) This section amends the Health (Cervical Screening (Kaitiaki)) Regulations 1995.

(1A) In regulation 2(1), definition of **Register**, after "for this purpose", insert ", and includes any part of the Register that is replaced".

(2) In regulation 3(1), replace "section 74A(5)(f)" with "**section 112J(4)(d)**".

(3) In regulation 11(a), replace "section 74A(5)(f)" with "**section 112J(4)(d)**".

Legislative history

22 February 2018	Introduction (Bill 26–1)
20 March 2018	First reading and referral to the Health Committee

Wellington, New Zealand:
Published under the authority of the House of Representatives—2018