Australian Government

Department of Health

Notification requirement for the National Cervical Screening Program (NCSP)

Frequently Asked Questions (FAQs) for Pathology Practitioners

1 December 2017 marks the commencement of the renewed NCSP which will be supported by the National Cancer Screening Register (the Register).

From 1 December 2017, pathology practitioners will be required to notify prescribed cervical screening information to the Commonwealth Chief Medical Officer (CMO) through the Register.

The Rules

What is the legal basis for mandatory notification of cervical screening information?

The *National Cancer Screening Register Act 2016* (the NCSR Act) includes a requirement for certain individual healthcare providers to notify cervical screening information to the CMO within a specified timeframe. The Register provides the capability for pathology practitioners to notify prescribed information to the CMO in an approved form. The details of the information to be notified to the Register are intended to be contained in the legislative instrument, the National Cancer Screening Register Rules 2017 (the Rules).

What is the purpose of the Rules?

The Rules provide a legislative basis for the collection of individuals' cervical screening test results, results of relevant follow-up procedures up to and including the diagnosis (or clearance) of cancer, and treatment in relation to pre-cancerous abnormalities to be notified to the Register.

The Rules have been developed to implement the mandatory notification to the CMO under section 13 of the NCSR Act and prescribe the types of cervical 'screening tests' and, for each type of screening test:

a) the individual healthcare provider who must notify the information; and
b) the information that must be notified to the CMO through the Register; and
c) the timeframe for notifying the information.

The notification requirement supports the screening processes and clinical pathways and the monitoring of program quality, safety and effectiveness, and provides a safety net function for the renewed NCSP.

Prescribed healthcare provider

How do I know if I need to notify information to the CMO?

Mandatory notification applies where an individual healthcare provider, or approved pathology practitioner who is an individual healthcare provider, undertakes a type of screening test associated with cervical cancer. For pathology laboratory notification, a screening test includes a HPV test, a cytology test or a histopathology test carried out in an accredited pathology laboratory, and that screening test is a pathology service of a kind for which the laboratory is accredited.

The NCSR Act defines an individual healthcare provider as an individual who:
(a) has provided, provides , or is to provide, healthcare; or
(b) is registered by a registration authority as a member of a particular health profession.

Approved pathology practitioner, *accredited pathology laboratory* and *pathology service* have the same meaning as in the *Health Insurance Act 1973* (the HI Act*)*.

What if the screening test is conducted as part of a clinical trial?

Screening tests carried out as part of a clinical trial approved by an ethics committee (within the meaning of the *Therapeutic Goods Act 1989)* are exempted from the mandatory notification requirement.

As per the *Therapeutic Goods Act 1989*, an ethics committee means a committee:

(a) constituted and operating as an ethics committee in accordance with guidelines issued by the CEO of the National Health and Medical Research Council as in force from time to time; and
(b) which has notified its existence to the Australian Health Ethics Committee established under the *National Health and Medical Research Council Act 1992*.

An example of a clinical trial exempted from the notification requirement is the Compass trial.

Who is responsible for notifying the required pathology information?

The approved pathology practitioner who performs the screening test (which is a pathology service) is responsible for notifying prescribed information to the CMO.

Under the Rules, a pathology service is taken to be carried out on behalf of an approved pathology practitioner if the service is rendered on behalf of the approved pathology practitioner for the purposes of the HI Act.

This means that the approved pathology practitioner is responsible for notifying the results of the screening test, notwithstanding this was undertaken by an individual healthcare provider on their behalf.

Prescribed information

What prescribed information will pathology practitioners need to notify?

The Rules give effect to the notification requirement in the NCSR Act thereby requiring information on screening tests carried out by or on behalf of an approved pathology practitioner to be notified to the CMO in an approved form. Attachment A details the required screening test information. This includes:

- the individual's demographic information
- information about the pathology practitioner and accredited pathology laboratory
- information about the screening test, including type of screening test and date of screening test
- test result, including cancer risk and recommendation
- specific information about the HPV test, cytology (including conventional Pap smears and LBC) and histopathology.

'Screening test' for the purpose of the Rules means a test or procedure as part of screening, such as a HPV test, cytology test, or histopathology test, including unsatisfactory and negative results.

Screening test in this context also includes HPV and cytology tests performed as part of the test of cure and cervical histology. It also includes Pap tests undertaken after 1 December 2017.

Results of penile or anal HPV and clinical trial screening test results are not required to be reported to the Register.

How was the prescribed information determined?

The reporting requirements have been based on the National Pathology Accreditation Advisory Council *Requirements for Laboratories reporting Tests for the National Cervical Screening Program (First Edition 2017)* (the NPAAC Requirements).

The data items have been determined to enable reporting against agreed quality standards.

Prescribed timeframe

How long do I have to notify the screening test result to the CMO?

Pathology practitioners are required to notify prescribed information to the CMO through the NCSR within 14 days. The 14 days commences after the screening test is completed. That is;

- HPV test and LBC test (if required) – the 14 day period commences immediately after the lab has received, tested and issued a combined report.
- Histology – the 14 day period commences immediately after the lab has completed their testing (ie multiple examinations on the tissue) and issued a report.

The 14 days aligns with the NPAAC Requirements which require laboratories to issue a report (following receipt and testing of specimens) on 90% of all cervical screening specimens within 10 days of receipt (S6.5).

Commencement of notification requirement

When do I need to start notifying prescribed information to the NCSR?

The Rules will commence on 1 December 2017. The requirement to notify prescribed information to the CMO commences on 1 December 2017 to coincide with the commencement of the renewed NCSP.

How to notify

How do pathologists notify the CMO?

The Register provides the capability for pathology practitioners to notify prescribed information to the CMO in an approved form.

Reporting electronically

Reporting by or on behalf of approved pathology practitioners can be via direct laboratory integration to the Register using the HL7 messaging format, in accordance with the NCSR Provider Integration Guide (see below 'Connecting to the Register' and 'what is the Provider Integration Guide') or via a Commonwealth approved alternate electronic solution.

Paper based reporting

Non-electronic means of transmitting results to the Register, including by paper or fax, is also an approved form for the purpose of these Rules (in accordance with the 'Prescribed Information' above and Attachment A).

What can I do to prepare for the commencement of the mandatory notification requirement?

It is important that pathology practitioners familiarise themselves with the NPAAC *Requirements for Laboratories Reporting Tests for National Cervical Screening Program (First Edition 2017)* (the NPAAC Requirements). The NPAAC Requirements set out the minimum requirements for best practice in relation to HPV NAT and gynaecological LBC services by laboratories participating in cervical screening program.

To prepare for the commencement of the mandatory notification requirement, pathology practitioners should check that the process for connecting their pathology laboratory to the Register has been completed. Refer to 'Connecting to the Register' below.

Connecting to the Register

How does a pathology laboratory directly connect to the Register?

Pathology laboratories connection to the Register is being coordinated by Telstra Health, the contracted service provider for the Register, to implement the connection process with pathology laboratories. Pathology laboratories that are yet to commence the connection process are requested to contact Telstra Health for the necessary forms and guides at ncsrpathology@team.telstra.com.

Connection to the Register requires agreement to the Pathology Provider Interface – Integration Terms and Conditions (Terms and Conditions). The Terms and Conditions provide access to the Register Test System and the Register Pathology Provider Interface and have been drafted as an agreement between the pathology laboratory and the Commonwealth as represented by the Department of Health (Health). Pathology laboratories that have feedback or questions regarding the Terms and Conditions may contact Health directly at NCSRProject@health.gov.au.

Once the pathology laboratory has signed the Terms and Conditions, Telstra Health will be able to progress the prescribed laboratory solution to report to the Register.

What is the Provider Integration Guide?

Telstra Health's Provider Integration Guide provides information for healthcare provider information systems intending to electronically connect directly with the Register and has been developed in consultation with the pathology sector to support the modification of the pathology laboratory HL7 interface.

The data fields that are relevant to pathology practitioners are articulated in the Provider Integration Guide including recommended use of LOINC and SNOMED coding to support streamlined reporting.

The Provider Integration Guide serves as a guide to point out the sections of the Australian HL7 standard that are relevant for laboratories participating in the NCSP. It highlights and clarifies only those specific aspects of standard HL7 communication messages that are required to communicate with the Register. All the fields in the Provider Integration Guide are relevant for the NCSP as per the NPAAC Requirements and the *NCSP: Guidelines for the management of screen-detected abnormalities, screening in specific populations and investigation of abnormal vaginal bleeding (the NCSP 2016 Guidelines)*.

Privacy and security

How is personal information held in the Register protected?

Any data uploaded to the Register is subject to the range of information protections set out in the NCSR Act and the *Privacy Act 1988* (the Privacy Act).

The NCSR Act provides the legislative framework to safeguard protected information, that is, personal information and commercial-in-confidence information, in the Register. The NCSR Act limits the use and disclosure of protected information to those that are related to the purposes of the Register, or as authorised by the NCSR Act. The limited authorisations ensure that protected information is only recorded, used or disclosed to or from the Register for specific purposes.

The NCSR Act includes an offence for the unauthorised recording, use or disclosure of protected information in the Register. The NCSR Act also requires notification to the Information Commissioner if there is a data breach.

How is information held in the NCSR kept secure?

Telstra Health as the contracted service provider for the Register has obligations to:

- build and operate the Register in accordance with Commonwealth cybersecurity guidelines for new ICT infrastructure, taking into consideration sensitivity and classification of the information it stores;
- at all times comply with and adhere to the stringent controls of the Commonwealth Protective Security Policy Framework which sets out mandatory requirements to:
  - manage security risks to their people, information and assets;
  - provide assurance to the government and the public that official resources and information provided to the Register are safeguarded; and
  - incorporate protective security into the culture of the Register; and
- at all times, comply with the Information Security Manual and the National Identity Security Strategy.

Information in the Register is stored within Australia in secure data storage facilities.

Penalties

Is there a penalty for not complying with the notification requirement?

The NCSR Act includes an offense for non-compliance with the notification requirement. The maximum fine per offence is 30 penalty units. A penalty unit is currently $210 (effective from 1 July 2017).

The penalty commences from 1 May 2018. The period between December 2017 and May 2018 provides a grace period for prescribed healthcare providers to transition to the national mandatory notification regime.

What happens if I fail to notify?

The Department recognises that encouraging compliance and raising awareness regarding the requirement to notify will help minimise the need to enforce regulatory action.

Where considered appropriate, the Department of Health will provide sufficient notice through warning letters prior to enforcing regulatory action.

For more information

More information regarding the Rules and mandatory notification is available on Health's website.

ATTACHMENT A

Information for pathology laboratory screening tests

1. Individual's details
   a) Medicare number (If known)
   b) Name
   c) Date of birth
   d) Sex and gender
   e) Indigenous status (If known)
   f) Country of origin (If known)
   g) Preferred language (If known)
   h) Address

2. Pathology practitioner details
   a) Provider number Name
   b) Name
   c)
3. Accredited pathology laboratory details
   a) Name
   b) Address
   c)
4. Information about the screening test
   a) Type of screening test
   b) Date of screening test
   c) Cancer risk
   d) Recommendation

5. HPV test
   a) Collection method
   b) Specimen site
   c) Reason for test
   d) Result
   e) Name of test
   f) Collection media
   g) Batch information

6. Cytology test
   a) Specimen type
   b) Specimen site
   c) Reason for test
   d) Result

7. Histopathology test
   a) Specimen site
   b) Procedure used for obtaining specimen
   c) Result

Proposed additional information for pathology laboratory screening tests (if known)

1. Individual's details
   a) IHI

2. Information about the requesting provider
    a) Address
    b) Provider number
    c) HPI-I
    d) HPI-O

3. Information about the cervical sample collector
    a) Address
    b) Provider number
    c) HPI-I
    d) HPI-O