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THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

HOUSE OF REPRESENTATIVES

NATIONAL CANCER SCREENING REGISTER BILL 2016

EXPLANATORY MEMORANDUM

(Circulated by authority of the Minister for Health and Aged Care/Minister for Sport,
the Hon Sussan Ley MP)

NATIONAL CANCER SCREENING REGISTER BILL 2016

OUTLINE

This Bill, the National Cancer Screening Register Bill 2016, creates a legislative framework for the establishment and ongoing management of the National Cancer Screening Register (the Register).

The Australian Government committed to the establishment of the Register as part of the 2015-16 Budget and set aside funding, subject to approval of an ICT business case that considered market-tested solutions for a cost-effective register to replace the existing National Bowel Cancer Screening Program (NBCSP) register, operated by the Department of Human Services, as well as the eight State and Territory registers supporting the National Cervical Screening Program (NCSP), at the discretion of each State and Territory. As part of the 2016-17 Budget, the Australian Government approved the Register's business case.

The need for this Bill arose from the 2015-16 Budget announcement to improve cancer detection, treatment and prevention through innovative measures that ensure Australia remains a world leader in the field. This announcement included funding to implement a renewed NCSP following the Australian Government's acceptance of the evidence-based Medical Services Advisory Committee recommendation to replace the two-yearly Pap test with a new five-yearly cervical screening test. Once implemented, the changes to the NCSP are expected to prevent an additional 140 cervical cancers each year. In addition, the announcement included a commitment to establish the Register to meet the needs of the renewed NCSP and the expansion of the NBCSP.

As part of the 2014-15 Budget, the Australian Government committed to accelerate the expansion of the NBCSP to a biennial screening interval for Australians 50-74 years of age by 2020. Evidence from clinical trials has shown that biennial screening using faecal occult blood testing can prevent 300-500 deaths per year.

The Bill provides for the establishment of the Register, national electronic infrastructure for the collection, storage, analysis and reporting of cancer screening program data for both the renewed NCSP and the NBCSP. The Register will facilitate invitations, sending out of test kits, recall and clinical decision-making. The design of the Register will enable improved software integration with general practice, specialists and pathology laboratories, as well as improved quality and accessibility of data and rate of data capture and data matching. Over time it will help increase program participation rates and the effectiveness of the screening programs. Australia's organised approach to population-based screening will be underpinned by the Register which has the ability to be expanded to support other cancer screening programs in the future.

It authorises the collection, use and disclosure of information for the purposes of the Register and mandates reporting of prescribed cancer screening information to the Register to ensure routine collection of information that is crucial for the screening processes and clinical pathways. The details of the reporting obligations, including who is obliged to report and what information is to be reported, will be prescribed in the rules.

FINANCIAL IMPACT STATEMENT

The Australian Government committed to the establishment of a National Cancer Screening Register as part of the 2015-16 Budget and set aside funding, subject to approval of an ICT business case that considered market-tested solutions for a cost-effective register to replace the existing NBCSP register, as well as the eight State and Territory registers supporting the NCSP.

As part of the 2016-17 Budget, the Australian Government approved the Register and provided additional funding of \$29.9 million over four years to address the unanticipated increase in Australia Post rates and additional costs associated with the market's response to Health's tender. The total funding for the measure is \$178.3 million over four years to 2019-20, which takes into account saves from the discontinuation of the existing NBCSP register, as well as approximately \$10 million per annum being provided back to consolidated revenue through saves from the NBCSP from 2017-18.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

National Cancer Screening Register Bill 2016

This Bill is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Bill

This Bill, the National Cancer Screening Register Bill 2016 (the Bill), creates a legislative framework for the establishment and ongoing management of the National Cancer Screening Register (the Register).

The need for this Bill arose from the Federal Budget 2015-16 announcement to improve cancer detection, treatment and prevention through innovative measures that ensure Australia remains a world leader in the field. This announcement included a commitment to implement a renewed NCSP and establish the Register following the Australian Government's acceptance of the evidence-based Medical Services Advisory Committee recommendation to replace the two-yearly Pap test with a new five-yearly cervical screening test. Once implemented, the changes to the NCSP are expected to prevent an additional 140 cervical cancers each year.

As part of the 2014-15 Budget, the Australian Government committed to accelerate the expansion of the NBCSP to a biennial screening interval for Australians 50-74 years of age by 2020. Evidence from clinical trials has shown that biennial screening using faecal occult blood testing can prevent 300-500 deaths per year.

The Bill provides for the establishment of the Register, a national electronic infrastructure for the collection, storage, analysis and reporting of cancer screening program data for both the renewed NCSP and the expanded NBCSP. The Register will facilitate invitations, sending out of test kits, recall and clinical decision-making and increase program participations rates and the effectiveness of the screening program. Australia's organised approach to population-based screening associated with cervical cancer and bowel cancer will be underpinned by the Register which will also have the ability to be expanded to support other cancer screening programs in the future.

It authorises the collection, use and disclosure of information for the purposes of the Register and mandates reporting of prescribed cancer screening information to the Register to ensure routine collection of information which is crucial for the screening processes and clinical pathways. The details of the reporting obligations, including who is obliged to report and what information is to be reported, will be prescribed in the rules.

Human rights implications

This Bill engages the following rights:

- protection of privacy and reputation (Article 17 of the *International Covenant on Civil and Political Rights* (ICCPR)); and

- right to health (Article 12(1) of the *International Covenant on Economic, Social and Cultural Rights* (ICESCR)).

Protection of privacy and reputation

Article 17 of the ICCPR prohibits arbitrary or unlawful interference with an individual's privacy, family, home and correspondence. For interferences with privacy not to be arbitrary, they must be reasonable in the particular circumstances. Reasonableness, in this context, incorporates notions of proportionality to the end sought and necessity in the circumstances.

The Bill engages Article 17 of the ICCPR by the provisions that allow the Register to collect, record, use and disclose personal information for various purposes associated with the Register.

Section 11 of the Bill provides for the Register to include individuals' key information, including personal identifying information, and information about individuals' screening tests, diagnosis with a designated cancer or precursor to a designated cancer and nominated healthcare provider.

These authorised collections, recordings, uses and disclosures are designed to ensure the NCSP and NBCSP function effectively by allowing the appropriate sharing of information.

The Bill includes provisions allowing individuals to opt off participation in the screening programs. Requests about participation in the Register are described in Division 4, section 14.

Persons cannot make a record of, disclose or otherwise use this information if this is contrary to such a request. The specific circumstances where collecting, recording, using or disclosing protected information from the Register is authorised are provided in subsection 17(3) of the Bill. The authorised categories are:

- an officer or employee of the Commonwealth (or of an authority of the Commonwealth), a person engaged by the Commonwealth to perform work related to the purposes of the Register or prescribed body where the collection, recording, disclosure or use is for the purposes of the Register;
- a healthcare provider where the information is about screening or diagnosis associated with a designated cancer in relation to an individual and the collection, recording, disclosure or use is for the purposes of providing healthcare to the individual in relation to the designated cancer;
- a participating State or Territory authority, or an officer or employee of a participating State or Territory authority where the collection, recording, disclosure or use is required or permitted by the law of the State or Territory;
- where the person does so for the purposes of performing the person's functions, or exercising the person's powers under this Bill;
- where the collection, recording, disclosure or use is required or authorised by or under a law of the Commonwealth or of a State or Territory;
- where the information is disclosed to the person under this section and the collection, recording, disclosure or use is for the purposes for which the information was disclosed to the person;
- the Secretary where the collection, recording, disclosure or use is for the purpose of disclosing information to a professional disciplinary body or child

protection officer and the Secretary reasonably believes that the information will enable or assist them to perform or exercise any of their functions or powers;

- where the person does so for the purposes of court or tribunal proceedings, or in accordance with an order of a court or tribunal;
- where the person does so for the purposes of a coronial inquiry, or in accordance with an order of a coroner.

These limited authorisations ensure that personal information is only collected, recorded, used or disclosed to the Register or collected, recorded, used or disclosed from the Register where it is associated with the Register.

The Bill prohibits the use and disclosure of personal information collected by the Register outside of the circumstances described above and creates an offence arising from the unauthorised disclosure of personal information contained in the Register as described in section 18. Persons who record, use or disclose protected information and are not authorised to do so under section 17 of the Bill are subject to imprisonment for two years or 120 penalty units, or both. These sanctions are designed to maintain privacy protections by ensuring that protected information is not shared where it is not for a legitimate purpose.

The authorisations for the use and disclosure of personal information are reasonable, appropriate and necessary for the objectives and purposes of the Bill and adequately describe persons who require access to the Register to achieve the objectives of the Register or for other legitimate public purposes, such as assisting professional disciplinary bodies and child protection officers investigate matters that are within their remit that come to the attention of the Register through its operations. To mitigate loss of privacy, the Bill allows individuals to request that the Register not collect, store, use or disclose any information about them. The Bill also allows the Register to use a pseudonym for individuals at their request. As described above, there are safeguards included in the Bill to protect an individual's right to privacy, including limitations on the collection, recording, disclosure or use of information in the Register. The Bill is very clear in describing when collection, recording, disclosure and use are authorised. The purposes for which information can be disclosed are a reasonable and proportionate limitation on an individual's right to privacy since the authorised disclosures are for legitimate purposes and limited to what is required to achieve the purposes of the NCSP and NBCSP. The offence provision for unauthorised disclosure provides appropriate safeguards to protect against arbitrary and unlawful interference with privacy.

Right to health

The Bill engages Articles 2 and 12 of the ICESCR by assisting the progressive realisation of the right of everyone by all appropriate means to the enjoyment of the highest attainable standard of physical and mental health. The Bill assists the advancement of this human right by establishing the Register for the purpose of supporting early detection and prevention of cancer through screening.

According to the World Health Organization, the aim of screening for a disease or a risk marker for a disease is "to reduce the burden of the disease in the community, including incidence of disease, morbidity from the disease or mortality. This is achieved by intervening to reduce individual risk of the disease or detecting the

disease earlier on average than is usually the case in the absence of screening and thereby improving disease outcome.” A ‘positive’ screening test identifies people who are at increased likelihood of having the condition and who require further investigation to determine whether or not they have the disease or condition. The Bill establishes a national infrastructure that supports the renewed NCSP and the expanded NBCSP, with the ability to be extended to other cancer screening programs in the future. The Register will facilitate invitations and sending out of test kits to increase participation rates in these programs. It will capture individuals’ screening test results/outcome data and results of relevant follow-up procedures, up to and including the diagnosis of cancer.

The Register’s interoperability with clinical information systems will improve the quality and accessibility of patient data and facilitate clinical decision-making by healthcare providers thereby leading to better health outcomes for individuals as well as the larger community.

Conclusion

The Bill is compatible with human rights because it advances the protection of human rights as outlined above and, to the extent that it may limit human rights, those limitations are reasonable, necessary and proportionate.

Minister for Health and Aged Care/Minister for Sport, the Hon Sussan Ley MP

NATIONAL CANCER SCREENING REGISTER BILL 2016

NOTES ON CLAUSES

Part 1: Preliminary

Clause 1 – Short Title

Clause 1 provides for the short title of the Act to be the *National Cancer Screening Register Act 2016*.

Clause 2 – Commencement

This clause provides that commencement of the Bill's provisions, except for clause 13 relating to the requirement to notify, will be the day after Royal Assent.

This clause provides that clause 13 commences on 1 May 2017.

Clause 3 – Simplified outline of this Act

This clause provides a simplified outline of the Act and summarises the provisions set out in the Act.

While a simplified outline is included to assist readers to understand the substantive provisions, the outline is not intended to be comprehensive. It is intended that readers should rely on the substantive provisions.

Clause 4 – Definitions

This clause provides definitions of the terms used within the Bill.

The definitions are:

- *approved form* – means a form approved under subclause 25(1). Various provisions in the Bill provide for an approved form to be used, for example, clause 14 provides for an approved form to be used by individuals when making certain requests. Subclause 25(1) provides for the Minister to approve forms.
- *child protection officer* – means an officer or employee of a State or Territory or State or Territory authority who has functions, powers or duties in relation to the care, protection or welfare of children. This definition covers officers in State and Territory child protection agencies.
- *civil penalty provision* – has the same meaning as in the Regulatory Powers Act. The Regulatory Powers Act is defined as the *Regulatory Powers (Standard provisions) Act 2014*. Subsection 79(2) of the *Regulatory Powers (Standard provisions) Act 2014* provides that a provision is a civil penalty provision if either the provision imposes a pecuniary penalty indicated by the words 'civil penalty' or if another provision in the Act or a legislative instrument provides that it is a civil penalty provision or that a person is liable for a civil penalty for breach of that provision.
- *claims information* – means information about claims for Medicare benefits under *Part II of the Health Insurance Act 1973*, or treatment, other than information that

relates to compensation or benefits, provided under legislation administered by the Minister for Veterans Affairs.

- *commercial-in-confidence* – has the meaning given in clause 5 of the Bill. Commercial-in-confidence information does not include an individual’s health information but information relating to an organisation that the organisation may seek to protect that is not personal information.
- *designated cancer* – means, for the purposes of this Bill, bowel cancer or cervical cancer.
- *enforcement body* – means enforcement body within the meaning of subclause 6(1) of the *Privacy Act 1988*.
- *entity* – means a person, a partnership, any other unincorporated association or body, a trust or a part of another entity.
- *healthcare* – means health service within the meaning of subclause 6(1) of the *Privacy Act 1988*.
- *healthcare provider* – means an individual healthcare provider or a healthcare provider organisation.
- *healthcare provider organisation* – means an entity that has conducted, conducts, or will conduct, an enterprise that provides healthcare (including healthcare provided free of charge). This includes the relevant government authorities that operate public hospitals.
- *individual healthcare provider* – means an individual who has provided, provides, or is to provide healthcare, or is registered by a registration authority as a member of a particular health profession.
- *key information* means an individual’s name, address, contact details, date of birth, gender and other identifying information as listed in relation to this definition, information in the Register relating to screening associated with cervical cancer such as the individual’s sex and human papillomavirus (HPV) vaccination status, and any other information prescribed by the rules for the purposes of this definition.

Key information is information that the Register requires in order to fulfil its purposes. The definition includes any other information prescribed by the rules to accommodate new developments in technology and treatment, so that the Register is provided with up-to-date and relevant information in order to fulfil its broader purposes. In relation to the NCSP the intention is to screen all individuals with a cervix including those who do not identify as female. For this reason, the key information for the NCSP includes information about an individual’s sex as well as gender.

- *nominated healthcare provider* means the healthcare provider an individual has requested be recorded for screening associated with that designated cancer in a request that is in effect under clause 14. An individual may have a different nominated healthcare provider for each of the designated cancers or multiple nominated healthcare providers for a designated cancer.
- *parent* – means the parent of another person if the other person is a child of the person within the meaning of the *Family Law Act 1975*. This defines the meaning of parent for the purposes of the definition of “personal representative”.
- *participating State or Territory* – means a State or Territory that has agreed with the Commonwealth to participate in the Register. This definition is used to ensure that the Register does not operate in the States and Territories that have not agreed to transition from their current State and Territory based cervical screening registers to the Register. In those States and Territories that do not

agree to transition, their existing cervical screening registers will continue operation. Clause 17 of the Bill authorises disclosure of Register information to participating States and Territories.

- *personal information* – has the same meaning as in the *Privacy Act 1988*.
- *personal representative* – means a parent or guardian of the individual, a trustee of an individual's estate if the individual is under a legal disability, a person who holds an enduring power of attorney granted by an individual or a person nominated by the individual for the purpose of managing the individual's affairs in relation to screening associated with a designated cancer. This definition sets out who is authorised to act on an individual's behalf when interacting with the Register. The first three categories of personal representative apply where the individual cannot manage their own health affairs. The fourth category applies where the individual can manage their own health affairs but chooses to nominate another person to interact with the Register on their behalf. An example is where an individual from a non-English speaking background who might choose to nominate someone who can translate for them to interact with the Register.
- *prescribed body* – means a person prescribed by the rules for the purposes of this definition. Prescribed bodies are additional entities authorised to handle protected information for the purposes of the Register.
- *professional disciplinary authority* – means a registration authority, the Health Care Complaints Commission established under the *Health Care Complaints Act 1993* (NSW), the Health Ombudsman appointed under the *Health Ombudsman Act 2013* (Qld), and any other authority that is responsible for investigating complaints about the professional conduct of healthcare providers. This definition covers all the bodies responsible for regulating or investigating complaints about the various health professions, such as the Australian Health Practitioner Regulation Agency.
- *protected information* – means personal information or information that is commercial-in-confidence that is included in the Register or obtained under or in accordance with this Bill. It includes information derived from a record of information, or disclosure or use of information, that was included in the Register or obtained under or in accordance with this Bill.

Protected information includes information originally collected elsewhere before the commencement of the Register which is subsequently included in the Register. It covers data transfers from the Department of Human Services in relation to the NBCSP and the States and Territories cervical screening registers for the purpose of the NCSP to enable pre-population of the Register.

Information in a healthcare provider's file that has not been uploaded to the Register or information obtained elsewhere by a healthcare provider about a designated cancer is not protected information as it is not information that has been included in the Register, derived from information included in the Register or derived from information obtained under or in accordance with this Bill.

This definition provides the scope of the operation of the offence in clause 18 of the Bill.

- *purposes of the register* – means the purposes set out in clause 12 of the Bill.
- *register* – means the National Cancer Screening Register established under clause 9.

- *registration authority* – means an entity that is responsible under a law for registering members of a particular health profession. This definition is used for defining who is an individual healthcare provider and as part of the definition of professional disciplinary body.
- *Regulatory Powers Act* – means the *Regulatory Powers (Standard Provisions) Act 2014*.
- *rules* – means the rules made under clause 28.
- *screening* – means a process in which an individual undergoes testing or procedures in order to determine whether the individual has a designated cancer, a precursor to a designated cancer or any indicator such as genetic markers or cell abnormalities that may lead to cancer. This definition encompasses not just tests or procedures used to diagnose cancer but includes other tests or procedures that may indicate that an individual is at increased risk of developing cancer. The broad definition ensures that the term encompasses the range of tests and procedures that are used as part of the NCSP and NBCSP now and that may be used in the future.
- *screening test* – means a test or procedure as part of the screening pathway.
- *State or Territory authority* – has the same meaning as in the *Privacy Act 1988* which includes various bodies associated with the States and Territories such as Ministers, Departments and bodies and offices established under legislation.
- *Veterans' Affairs Department* – means the Department administered by the Minister administering the *Veterans' Entitlement Act 1986*. Currently, this is the Department of Veterans Affairs.

Clause 5– Meaning of commercial-in-confidence

This clause sets out factors for the Minister to consider when deciding whether information is commercial-in-confidence. These include whether release of information that is not in the public domain, is not disclosable or readily discoverable and that is not required to be disclosed under a law of the Commonwealth, or of a State or Territory would cause competitive detriment to the person. This clause is used for the purpose of the definition of “protected information” and defines what information apart from personal information will be subject to the offence in clause 18.

Clause 6– Act binds the Crown

This clause provides that the obligations in the Bill apply to the Crown in each of its capacities, and therefore applies to the Crown in right of the Commonwealth and each of the States and Territories, but that the Crown cannot be liable to be prosecuted for any offences under the Bill.

The exception to the application of the Bill to the Crown ensures that the Commonwealth or a State or Territory entity cannot be prosecuted if it breaches the offence in section 18 by recording, using or disclosing protected information where not authorised.

Clause 7 Act extends to every external Territory

This clause provides that the Bill (once enacted) extends to every external Territory. This is to ensure that individuals in the external territories can participate in the Register and therefore have access to the NCSP and NBCSP.

Part 2: Register

Division 1–Simplified outline

Clause 8– Simplified outline of this Part

This clause provides an outline of Part 2 of the Bill. While a simplified outline is included to assist readers to understand the substantive provisions, the outline is not intended to be comprehensive. It is intended that readers should rely on the substantive provisions in the Bill.

Division 2–Establishment, contents and purposes

Clause 9– Establishment of the register

The Bill provides a legal framework for the collection, use and disclosure of particular information. Although the Bill does not address issues of ownership or custodianship of information, the Commonwealth will be the custodian of data in the Register.

Subclause 9 (1) states that the Commonwealth must establish and keep a register to be called the National Cancer Screening Register.

Subclause 9(2) allows for screening and program data within the Register to be compartmentalised. This means that information related to the NCSP can be kept separate from those relating to the NBCSP to prevent unnecessary disclosure.

Subclause 9(3) is included to make clear that the Register is not a legislative instrument within the meaning of section 4 of the *Legislation Act 2003*. This is because the Register merely contains information relating to the NCSP and NBCSP, as set out in the contents of the Register (clause 11), and does not determine or alter the law.

Clause 10– Coverage of the register

This clause sets out the scope of coverage of data collected for the purposes of the Register.

The Register may include information about individuals in connection with screening associated with bowel cancer and cervical cancer.

Clause 11– Contents of the register

This clause describes the types of information that may be collected by the Register.

These include:

- the individual's key information;
- the individuals' nominated healthcare provider for screening associated with a designated cancer including the healthcare provider's healthcare identifier (within the meaning of the *Healthcare Identifiers Act 2010*);

- information about screening tests undergone (including outcomes such as benign, inflammatory and negative results) or to be undergone by the individual;
- the individual's diagnosis with a designated cancer or pre-cursor to a designated cancer;
- claims information that may indicate screening or diagnostic tests already undergone or that should be undergone by the individual;
- details of requests or withdrawals related to participation in the Register; and
- any other information relevant to the purposes of the register and prescribed by the rules.

Medicare claims information (as in the definition of clause 4) of individuals who are within the coverage of the Register (as defined in clause 10) will be collected as part of the establishment and ongoing operation of the Register. Updates to individuals' personal information recorded in Medicare, in particular address details, will be regularly provided to the Register to ensure that the record in the Register is kept up to date.

An individual's key information can be:

- registered or updated by the individual using the Register's self-service function in relation to identifying information such as address, contact details, nominated healthcare provider and indigenous status;
- registered or updated by the GP/test provider/other healthcare provider;
- sent to the Register electronically by the pathologist; or
- registered or updated by the register operator after receiving contact from the individual.

When a healthcare provider uploads screening test results associated with a designated cancer to the Register, that information will be matched to the individual's record stored in the Register, unless the individual has requested that their screening test results not be included in the Register (paragraph 14(1)(c)). Where an individual is not enrolled in Medicare (or not eligible for Medicare), their details will also be collected by the Register.

Once Medicare information is recorded in the Register, it will become protected information (as defined in clause 4) and will be subject to the offence provision in Part 3 of this Bill.

Collection of an individual's Medicare number and healthcare identifier is necessary to facilitate data matching. The individual's data collected by the Register that are likely to change over time include their name (in the case of marriage or change in gender), address and other contact details, and nominated healthcare provider for screening associated with a designated cancer. This means that the two key elements of the individual's information that will not change in the Register are the date of birth and the healthcare identifier. The use of individuals' unique healthcare identifiers will ensure that the right information is associated with the right individual in the Register thus ensuring that healthcare providers have the correct information when using information from the Register in providing healthcare to an individual. It also increases the chances of capturing a larger number of identification matches and decreases the risk of duplication of records.

Subclause 11(b) provides for the details of the individual's nominated healthcare provider for screening associated with a designated cancer, if any, and their healthcare identifier (within the meaning of the *Healthcare Identifiers Act 2010*) to be recorded in the Register. This provision recognises the role of the nominated healthcare provider for screening associated with a designated cancer in delivering clinically appropriate advice, services, treatment and care, and providing data on participants and their outcomes to the Register. Collection of a healthcare provider's healthcare identifier ensures that the Register can clearly identify healthcare providers who are providing information to the Register. While other details about a nominated healthcare provider may change, their healthcare identifier will remain the same allowing accurate matching.

For the National Bowel Cancer Screening Program, GPs encourage those who receive a test kit to participate in screening, assess those with a positive result and refer them for further examination as clinically indicated, for example a colonoscopy, and recommend individuals at average risk to screen at least once every two years from the age of 50 to 74. They also identify individuals who are at increased risk of bowel cancer in accordance with the National Health and Medical Research Council Guidelines – these individuals are not recommended for population screening.

For the National Cervical Screening Program, it recognises that GPs and non-medical healthcare providers are critical to the success of the program as they provide cervical screening services and opportunistically encourage women to participate in cervical screening, particularly those who are under-screened.

Subclause 11(c) provides for information about screening tests associated with a designated cancer undergone or to be undergone by the individual to be collected and recorded in the Register. Subclause 11(d) provides for information about a diagnosis with a designated cancer or a diagnosis with a precursor to a designated cancer relating to an individual to be collected and recorded. These provisions authorise the Register to capture and report on individuals' screening test results/outcome data and results of relevant follow-up procedures, up to and including the diagnosis (or clearance) of cancer.

Subclause 11(e) provides for Medicare or other claims information, which may indicate whether or not the individual has undergone or should undergo screening associated with a designated cancer, to be collected and recorded in the Register. This information will be used to identify individuals who are to be sent an invitation or reminder to screen for a designated cancer (paragraph 12(1)(d)).

Claims information may also be used in deciding whether an individual should not be invited to undergo screening under the NCSP or NBCSP. An example of this is where claims information may be used to identify those individuals who have had a colonoscopy and where it would therefore be inappropriate for them to be invited to undertake the Faecal Occult Blood Test (FOBT) as part of the NBCSP. Another example is where claims information may be used to identify those women who have undergone a hysterectomy who may not be required to undergo screening under the NCSP.

Subclause 11(f) provides for the details of any request made by an individual under clause 14 to not participate, or to limit participation, in the Register to be collected and recorded in the Register. For example, an individual may have requested that no

invitation to undergo screening associated with a designated cancer should be provided to the individual (paragraph 14(1)(b)(i)), or no advice should be provided to the individual about when they may need to take action after a screening test (paragraph 14(1)(b)(ii)).

Provision has also been allowed in subclause 11(g) to collect other information of a kind prescribed by the rules. Subclause 11(g) allows incidental information that would not normally be captured by the Register to be recorded in the Register to fulfil the stated purposes of the Register. For example, the Register may collect information about an individual's partial hysterectomy status which may require her to undergo screening if advised by her healthcare provider as part of the clinical management.

With rapidly advancing technology or changes in screening tests, the range of information that needs to be collected may also change and is difficult to predict. This provision allows rules to prescribe additional classes of data to form part of the contents of the Register that is considered necessary to be included in the Register for the purposes of the Register.

Clause 12 – Purposes of the register

This clause sets out the purposes of the Register.

Paragraph 12(1)(a) provides that a purpose of the Register is to establish and keep an electronic database of records relating to screening and diagnosis associated with the designated cancers.

The Register will be a national electronic infrastructure for the collection, storage, analysis and reporting of cancer screening program data to support designated cancers. It will contain the types of information as set out in clause 11 to support the screening pathway and fulfil its purposes as set out in this clause.

The Bill sets out bowel cancer and cervical cancer as the designated cancers. This enables the Register to be expanded in the future to support the screening pathway for other cancers.

Paragraph 12(1)(b) provides that a purpose of the Register is to allow for the collection, analysis and publishing of statistics and other information in relation to screening and diagnoses associated with the designated cancers.

The Register will have a reporting capability that will facilitate a number of reporting types to authorised users: standardised and self-service (de-identified) reporting; ad hoc analytics; and identifiable (raw) data, a proportion of which will be accessible through Health's Enterprise Data Warehouse.

An important purpose of the Register, as provided for in paragraph 12(1)(c), is to monitor the effectiveness, quality and safety of screening and diagnoses associated with the designated cancers.

The analysis of data collected and stored in the Register will contribute to a formal approach for the ongoing monitoring and evaluation of the screening programs. Over time, appropriate measurable indicators will be identified for which data may be

collected to monitor the safety and quality of the program, as well as screening participation rates, screening results, follow-up investigations and outcomes. The Register will contribute to identifying reporting milestones (e.g. annually, or related to stages of screening rollout), changing patterns in program indicators, and timeframes or circumstances that would necessitate program review or re-orientation.

Statistical data may be used to inform government policy, identify emerging trends and support new policy initiatives and directions using measurable indicators. Statistics may also be used to measure the impact of screening programs in improving the burden of disease in target populations and for benchmarking and forecasting.

Paragraph 12(1)(d) provides that a purpose of the Register is to provide invitations to individuals to undergo screening for a designated cancer. Invitations include re-invitations, follow-ups and reminders. Persons who may be provided invitations include those who have reached the age qualifying birthday who are newly eligible to participate in a screening program, those who meet the criteria for screening but have never screened, those who have previously screened but are due or overdue for re-screen, or those who meet the criteria for screening and their screening has been brought forward by their healthcare provider.

Where the individual has authorised a personal representative, invitations and follow up correspondence may also be sent to the address of the personal representative if requested by the individual.

Those individuals who would otherwise meet certain criteria to participate in a screening program who are identified in the Register as not requiring screening will be excluded from receiving an invitation and will not be sent an invitation.

Paragraph 12(1)(e) provides that a purpose of the Register is to provide an individual with a test kit.

The NBCSP involves testing for bowel cancer in people in the program target group who do not have any obvious symptoms of the disease. The aim is to find cancers early when they are easier to treat and cure. Screening can also find polyps, which may develop into cancer over time. People identified as meeting certain criteria to participate in a screening program are sent a bowel screening kit (FOBT Kit) by mail with instructions on how to take samples and send the completed test back to the laboratory for analysis.

Paragraph 12(1)(f) provides that a purpose of the Register is to advise an individual when the individual is due to undergo screening or when action may need to be taken after screening.

A reminder letter will be sent to individuals who do not undertake a screening test within a specified time frame in accordance with an agreed national follow-up protocol, or who do not return a completed FOBT Kit to the Contracted Pathology Laboratory for testing within a specified timeframe. Reminders will also be sent to nominated healthcare providers (where this is known) of those individuals who do not return for further testing, or have a positive screening test result and have not visited their healthcare provider. This is to ensure that individuals are encouraged to take the relevant screening test and to ensure that they receive appropriate follow-up if they receive a positive screening test result.

Paragraph 12(1)(g) provides that a purpose of the Register is to advise the individual's nominated healthcare provider when the individual is due to undergo screening, or when action may need to be taken after screening.

Where the details of an individual's nominated healthcare provider is known, the Register may notify the healthcare provider that an invitation has been sent to assist the individual's participation in the Register.

If an individual has nominated a healthcare provider, the Register may also contact the healthcare provider if the individual has not visited the healthcare provider after a positive screening test result to ensure that the individual receives appropriate follow-up.

Paragraph 12(1)(h) provides that a purpose of the Register is to advise a participating State or Territory when action may need to be taken after a screening test for an individual residing in the State or Territory. This is an important provision allowing State and Territory health departments to receive information about participating individuals in their respective jurisdictions to enable follow up action.

Paragraph 12(1)(i) provides that a purpose of the Register is to allow an individual to access information relating to themselves in the Register about screening and diagnoses associated with a designated cancer. Individuals will be able to access information related to their screening and diagnosis history via My Health Records and may be able to access certain information from the Register directly.

Paragraph 12(1)(j) provides that a purpose of the Register is to allow healthcare providers access to information about screening and diagnosis related to an individual for the purposes of providing healthcare to the individual. This is for the purposes of clinical decision making and to encourage participation in the relevant program.

Healthcare providers will be able to update the Register with details about the individual's screening test. For example, when the healthcare provider updates their patient information system, this will send an update to the Register.

When a pathology laboratory receives an individual's cervical screening sample, they will check the Register for the individual's screening history through electronic data exchange. Screening and histopathology results (both bowel and cervical) will be recorded by the specialists in their pathology laboratory information management system and updated in the Register via electronic data exchange.

Following a positive screening test and colposcopy or colonoscopy procedure, the colposcopist or colonoscopist will update the individual's information in the Register electronically where possible. This may include any adverse events from the procedure, removal of abnormal tissue, biopsy or treatment undertaken. When the individual's information is updated electronically, this will facilitate an update to the Register with the details of the outcomes of the colposcopy or colonoscopy procedure.

Paragraph 12(1)(k) provides that a purpose of the Register is to provide participating States and Territories access to information relating to individuals residing in the State or Territory in connection with screening and diagnoses associated with the designated cancers.

This provision reflects the ongoing role of States and Territories in implementing the NBCSP and the NCSP in their respective jurisdictions, including developing and providing information and support for participants across all aspects of the screening pathway.

This provision will ensure that State and Territory officers (or sub-contractors) performing the NBCSP Participant Follow-up Function can access information on the Register for the purpose of encouraging individuals to progress along the screening pathway. The officers can contact the individual and the healthcare provider (if nominated) by phone if no follow up activity occurs following the individual's positive FOBT.

Paragraph 12(1)(l) provides that a purpose of the Register is to facilitate planning, delivering and promoting healthcare and services in relation to the designated cancers.

The Register will contribute to improved cancer detection, treatment and prevention through capturing and reporting on individuals' screening test results/outcome data and results associated with a designated cancer at a national level. The data collected will assist in planning for service delivery based on local circumstances and address projected needs and demands as the participation rates and target population increase. Service planning supports organisations to respond to the health needs of the community and to take a proactive population health approach.

Paragraph 12(1)(m) provides that a purpose of the Register is reporting to international organisations in relation to the designated cancers. This provision recognises the importance of sharing information with international organisations such as the World Health Organization in helping to reduce the global burden of cervical and bowel (colorectal) cancer.

Paragraph 12(1)(n) provides that a purpose of the Register is research relating to healthcare, screening or a designated cancer.

The Department of Health will ensure that the community realises the greatest possible value from data held by the Register through better use of existing datasets for research, community information, policy development and policy evaluation, consistent with meeting its legal and contractual obligations to respect privacy, recognise intellectual property and manage risks. Access, release and use of information and data held in the Register must comply with the Bill as well as with privacy and freedom of information legislation.

Where research requires identifiable information from the Register, and it is impracticable to obtain individuals' consent, researchers will be required to comply with the guidelines under sections 95, 95A or 95AA of the *Privacy Act 1988* (as applicable) to obtain access to that information. These guidelines, issued by the National Health and Medical Research Council and approved by the Information Commissioner, provide a framework for Human Research Ethics Committees to assess researchers' proposals to use personal information without consent.

Paragraph 12(1)(o) provides that a purpose of the Register is anything incidental to the purposes of the Register as specified in paragraphs 12(1)(a)-(n). This provision is

included in the Bill to facilitate any associated purposes that relate to the other purposes in clause 12.

Subclause 12(2) extends the operation of the purposes in paragraphs 12(1)(d), (e), (f) and (i) so that information that could be provided to an individual can be provided to a personal representative.

Division 3–Notification to register

Clause 13 – Requirement to notify

The requirement to report to the Register will allow individuals' screening test results/outcome data and results of relevant follow-up procedures up to and including the diagnosis (or clearance) of cancer (collectively referred to as screening test or diagnosis) to be routinely reported to the Register. Complete and accurate data will allow the screening processes and clinical pathways to operate safely, efficiently and effectively. High quality data will also help inform policy for national screening programs and service delivery at the local level.

Clause 13 provides for rules to be made prescribing the individual healthcare providers who are required to notify prescribed information for a type of screening test or diagnosis by the prescribed timeframe. The information is required to be notified to the Chief Medical Officer in the approved form.

The effect of this clause is that:

- the reporting obligation applies to the type of healthcare provider prescribed by the rules;
- the reporting obligation is triggered when an individual undergoes a type of screening test or diagnosis prescribed by the rules; and
- the prescribed healthcare provider must report the prescribed screening test results or diagnosis in the approved form within a prescribed timeframe.

Subclause 13(2) provides that a person is liable to a civil penalty of 30 penalty points if the person contravenes subclause (1). The civil penalty applies to individual healthcare providers and not to organisations.

A grace period of 12 months will apply from 1 May 2017, as set out in the National Cancer Screening Register (Consequential and Transitional Provisions) Bill 2016 during which no regulatory action will be taken for not complying with the requirement to report to the Register. This is to allow time for prescribed healthcare providers who will be required to report to the Register to first become familiar with the new Register. Regulatory action will commence from 1 May 2018.

Division 4–Requests about the register

Clause 14 – Requests about participation in the register

To protect individual privacy, the Bill allows individuals to request that the Register not collect, store, use or disclose any information about them. It also provides individuals the choice of not participating, or limiting their level of participation, in the screening programs.

Individuals may elect to opt off from, or defer, receiving invitations to screen, test kits, or reminders to rescreen or undergo follow-up tests or procedures. Individuals may also elect not to have information relating to their screening test or diagnosis to be recorded in the Register.

An individual may opt-off from or defer screening for a designated cancer by using the Register self-service facility, contacting the register operator, or during a consultation with their healthcare provider. Individuals have the option to opt-off screening for a designated cancer at any point and opt back in whenever they choose.

Subclause 14(1) specifies the type of requests that an individual may make using an approved form.

Paragraph 14(1)(a) allows for an individual to nominate their healthcare provider for screening associated with a designated cancer. This allows an individual to choose the healthcare provider who will receive copies of results and other correspondence from the Register related to the individual. An individual may have a different nominated healthcare provider for each of the designated cancers or multiple nominated healthcare providers for a designated cancer.

Paragraph 14(1)(b) allows an individual to elect not to receive at all, or for a period of time (i) any invitation to undergo screening or a test kit for screening associated with a designated cancer or (ii) any advice about when the individual is due to undergo a screening test or when action may need to be undertaken after a screening test associated with a designated cancer.

Paragraph 14(1)(c) allows an individual to elect not to have information notifiable under clause 13 included in the Register.

This provision operates prospectively, that is, any information related to the individual that has already been collected by the Register prior to receiving the request from the individual will remain in the Register. This will allow consistent, complete and accurate data for reporting and statistical purposes to ensure Register data is not compromised by retrospective removal of information.

Paragraph 14(1)(d) allows individuals participating in the NCSP to change the date recorded as the due date for undergoing screening.

Paragraph 14(1)(e) allows individuals to request that the Register use a pseudonym for their record in the Register. This enables an individual to protect their privacy while continuing to participate in the Register.

Subclause 14(2) provides that an individual may withdraw any request made under subclause 14(1) using an approved form for the purpose of the Register.

Subclause 14(3) provides that the Commonwealth must action a request or withdrawal made under clause 14 as soon as practicable. This provision aims to provide confidence to individuals by creating an obligation for the Commonwealth to comply as soon as practicable with individuals' requests about participation under clause 14(1).

Subclause 14(4) provides that an individual's personal representative may make or withdraw a request under clause 14 on behalf of the individual.

Division 5–Alternative constitutional bases

Clause 15 Alternative constitutional bases

This clause sets out the different heads of power in the constitution that are relied upon to support the operation of the Register.

These constitutional powers are the pharmaceutical and sickness benefits power, medical services power, census and statistics power, powers relating to postal, telegraphic, telephonic and other like services, external affairs power, powers in relation to a Territory or a Commonwealth place, implied nationhood power, executive power of the Commonwealth, corporations power and matters incidental to the execution of any of the legislative or executive powers of the Commonwealth.

Part 3: Dealing with information in the register

Clause 16 Simplified outline of this Part

This clause provides an outline of Part 3 of the Bill. While a simplified outline is included to assist readers to understand the substantive provisions, the outline is not intended to be comprehensive. It is intended that readers should rely on the substantive provisions.

Clause 17 Authorised dealings with information

Healthcare providers and other authorised bodies (including State and Territory health departments and contractors or other persons authorised by State and Territory health departments) will be able to access personal information, key information, or commercial-in-confidence information from the Register in order to perform functions or duties relating to the purposes of the Register. This will facilitate clinical decision-making for healthcare providers in relation to their patients' screening or diagnosis associated with the designated cancer. It will enable the register operator, who will be engaged by the Commonwealth to perform work relating to the purposes of the Register, to identify individuals who are due, coming due or overdue for screening, or to receive a test kit, associated with a designated cancer (paragraph 12(1)(d) and (e)).

Subclause 17(1) provides that a person may collect, make a record of, disclose or use information if it is for the purposes of uploading the information in the Register. Information that is within the scope of this provision is personal information, key information for an individual, or information that is commercial-in-confidence. This provision authorises information to be provided to the Register and for information to be collected by the Register in order for the information to be included in the Register.

Subclause 17(2) provides that subclause (1) does not apply to information notified under clause 13 to the extent that collection, recording, disclosure or use under the subsection would be contrary to an individual's request made under clause 14 relating to participation in the Register. This ensures that such information is not disclosed to or collected by the Register where the collection, recording, disclosure or use would be inconsistent with a request made by the individual (Clause 14). For example,

where an individual has requested that their information not be included in the Register, a healthcare provider will not be able to rely on subclause 17(1) to authorise them to disclose the individual's information to the Register and the register operator would not be authorised to collect information related to that individual.

Subclause 17(3) authorises certain collections, recordings, uses and disclosures of protected information or key information. This subclause applies to information that has been uploaded to the Register. Once personal information has been included in the Register it becomes protected information in the Register

Paragraph 17(3)(a) authorises the following persons to collect, make a record of, disclose or use information for the purposes of the Register identified in clause 12:

- an officer or employee of the Commonwealth;
- person engaged by the Commonwealth or by an authority of the Commonwealth to perform work relating to the purposes of the Register;
- an officer or employee of, or engaged by, a person who is engaged by the Commonwealth or by an authority of the Commonwealth to perform work relating to the purposes of the Register;
- a prescribed body.

In particular, this provision authorises the register operator to collect, record, use and disclose information where associated with their functions in operating the Register.

Paragraph 17(3)(b) authorises a healthcare provider to collect, make a record of, disclose or use information if the information is about an individual's screening or diagnosis associated with a designated cancer, and the collection, recording, disclosure or use is for the purposes of providing healthcare to that individual. This provides authority for healthcare providers to obtain information from the Register in providing healthcare to an individual who has undergone screening.

Paragraph 17(3)(c) provides that a participating State or Territory authority, or an officer, employee, contractor, or other persons authorised by a participating State, Territory or State or Territory authority may collect, make a record of, disclose or use information if it is required or permitted by State or Territory law.

This provides flexibility for participating States and Territories in handling information obtained from the Register to fulfil their functions. For example, this provision would allow States and Territories to use information in developing or implementing health policies where the law in that State or Territory does not prohibit that use. This paragraph provides the authority for States and Territories to collect, use or disclose information where State or Territory law does not prohibit the collection, use or disclosure.

Once information is disclosed to a participating State or Territory, that State or Territory may provide the information to a non-state organisation as it sees fit, if required or permitted by applicable State or Territory legislation. In this regard, participating States and Territories may establish enduring data linkages to ensure that information they collect from the Register is automatically passed from them to the non-state organisation, provided such linkages are not prohibited by State or Territory law.

Paragraph 17(3)(d) authorises a person to collect, make a record of, disclose or use information for the purposes of performing the person's functions, or exercising the person's powers under the Bill.

Paragraph 17(3)(e) authorises a person to collect, make a record of, disclose or use information if required or authorised to do so by or under Commonwealth or State or Territory law. For example, if a government agency has a power to compel the provision of documents under another law, a person is authorised to comply with a request that involves the provision of documents including information in the Register. Another example is if collection, use or disclosure for research complies with the guidelines under sections 95, 95A or 95AA of the *Privacy Act 1988* then the collection, use or disclosure for that research will be authorised for the purposes of paragraph 17(3)(e).

Paragraph 17(3)(f) provides that if the information is disclosed to the person under clause 17, the collection, recording, disclosure or use of the information is authorised where it is for the same purpose for which the information was disclosed to the person. For example, if a healthcare provider obtains information for the purposes of providing healthcare to an individual, that healthcare provider could share the information with another healthcare provider where disclosure of the information is associated with providing healthcare to the individual.

Paragraph 17(3)(g) authorises the Secretary to collect, record, disclose or use information for the purpose of disclosing to a professional disciplinary body, child protection officer or enforcement body if the Secretary reasonably believes that the information will enable or assist the professional disciplinary body, child protection officer or enforcement body in performing or exercising their functions or powers. For example, this would authorise the Secretary to disclose information in relation to a healthcare provider to the Australian Health Practitioner Regulation Agency if information in the Register brings up potential issues with the professional conduct of a healthcare provider.

Paragraph 17(3)(h) and (i) authorises a person to collect, make a record of, disclose or use information for the purposes of, or in accordance with an order of, a court or tribunal proceedings, or for the purposes of a coronial inquiry, or in accordance with an order of the coroner, respectively. This allows persons to provide information from the Register to assist a court, tribunal or coroner in considering a matter and to comply with the orders of a court, tribunal or coroner.

Subclause 17(4) provides that subclause 17(3) does not authorise the collection, recording, disclosure or use of information if the collection, recording, disclosure or use of information would be inconsistent with an individual's request made under clause 14 relating to participation in the Register. For example, information cannot be used to send an invitation to an individual where the individual has requested not to receive any invitations.

Collections, disclosures and uses permitted by this clause constitute an authorisation for the purposes of the *Privacy Act 1988* and other laws.

Clause 18 Offence relating to protected information

This clause creates an offence where a person makes a record of, discloses or uses protected information where it is not authorised by clause 17.

A maximum penalty of two years imprisonment, or 120 penalty units, or both, applies for a contravention of this offence. This is appropriate considering the potential damage that unauthorised recording, disclosure or use of protected information could cause to a person or commercial establishment.

Under subsection 4B(3) of the *Crimes Act 1914* a court can impose a penalty up to five times this amount for an offence committed by a body corporate.

There are certain exceptions to clause 18 which are set out in clauses 19, 20, 21 and 22 of the Bill.

Clause 19 Exception for use in good faith

This clause provides an exception to the offence in clause 18 if a person makes a record of, discloses or uses protected information in good faith and in purported compliance with clause 17. This clause ensures that the offence does not apply to unintentional non-compliance with the authorisations in clause 17.

The defendant has the evidential burden in relation to this exception, which means that the defendant bears the burden of adducing or pointing to evidence that suggests a reasonable possibility that the exception has been met. It is then up to the prosecution to establish the offence. It is the defendant's responsibility to provide evidence that they were acting in good faith to satisfy this exception. It is appropriate to put the evidential burden on the defendant since the matters required to satisfy this exception would be peculiarly within the knowledge of the defendant.

Clause 20 Exception if unaware information is commercial-in-confidence

This clause provides an exception to the offence in clause 18 if a person makes a record of, discloses, or uses information that is commercial-in-confidence and the person does not know that the information is commercial-in-confidence. This clause ensures that the offence does not apply if a person is unaware that information they have recorded, disclosed or used has been designated as commercial-in-confidence.

The defendant has the evidential burden in relation to this exception, which means that the defendant bears the burden of adducing or pointing to evidence that suggests a reasonable possibility that the exception has been met. It is then up to the prosecution to establish the offence. To satisfy the exception, it is the defendant's responsibility to provide evidence that they were not aware the information was commercial-in-confidence. It is appropriate to put the evidential burden on the defendant since the matters required to satisfy this exception would be peculiarly within the knowledge of the defendant.

Clause 21 Exceptions relating to the person to whom the protected information relates

This clause provides an exception to the offence under clause 18 if a person discloses protected information to the person to whom the information relates. This clause also provides an exception to the offence if a person makes a record, discloses or uses protected information with the consent of the person to whom the information relates. This exception allows a person to be provided with their own information and authorises persons to handle protected information as consented to by the person to whom the information relates where it would not otherwise be authorised by clause 17.

The defendant has the evidential burden in relation to this exception, which means that the defendant bears the burden of adducing or pointing to evidence that suggests a reasonable possibility that the exception has been met. It is then up to the prosecution to establish the offence. To meet the exception, it is the defendant's responsibility to provide evidence that the information was disclosed to the person to whom the information relates, or with consent. It is appropriate to put the evidential burden on the defendant since the matters required to satisfy this exception would be peculiarly within the knowledge of the defendant.

Clause 22 Exception for disclosure to person who provided the information

This clause provides an exception to the offence under clause 18 if a person discloses protected information to the person who provided the information. This allows a person to receive protected information that they have provided to another person. For example, if a healthcare provider has provided information to the Register related to an individual as part of providing healthcare to that individual, the Register can provide, at a later stage, that information back to the healthcare provider even if they are no longer providing healthcare to the individual.

The defendant has the evidential burden in relation to this exception, which means that the defendant bears the burden of adducing or pointing to evidence that suggests a reasonable possibility that the exception has been met. It is then up to the prosecution to establish the offence. To satisfy the exception, it is the defendant's responsibility to provide evidence that the disclosure was to the person who provided the information. It is appropriate to put the evidential burden on the defendant since the matters required to satisfy this exception would be peculiarly within the knowledge of the defendant.

Part 4: Other matters

Clause 23 Simplified outline of this Part

This clause provides an outline of Part 4 of the Bill. While a simplified outline is included to assist readers to understand the substantive provisions, the outline is not intended to be comprehensive. It is intended that readers should rely on the substantive provisions.

Clause 24 Civil penalty provisions

Clause 24 provides the details for the enforcement of the civil penalty in clause 13 for non-compliance where there was a requirement to notify as prescribed in the rules.

Subclause 24(1) provides that the civil penalty is enforceable under Part 4 of the *Regulatory Powers (Standard Provisions) Act 2014*.

Subclause 24(2) provides that the Secretary or a Senior Executive Service (SES) officer in the Department of Health are the authorised applicants to bring civil penalty proceedings under clause 13.

Subclause 24(3) provides that the Federal Court of Australia, the Federal Circuit Court of Australia and relevant State and Territory courts that have jurisdictions are the relevant courts in which civil penalty proceedings under clause 13 may be instituted.

Subclause 24(4) extends the enforcement of the civil penalty provision to every external territory. This ensures that healthcare providers in the external territories interacting with the Register are subject to the same requirements to notify as other healthcare providers in Australia.

Subclause 24(5) ensures that civil penalty proceedings cannot be brought against the Commonwealth or a State or Territory.

Clause 25 Approved forms

This clause provides authority for the Minister or the delegate, by writing, to approve a form for the purposes of a provision in the Bill.

It also provides that a request or a withdrawal of a request, as set out in clause 14, must be given to the person specified in the form for that purpose.

Clause 26 Agreements

This clause provides authority for the Minister, on behalf of the Commonwealth, to engage a person under a written agreement to perform services for on behalf of the Commonwealth in connection with the functions of the Commonwealth, the Minister or the Chief Medical Officer under this Bill.

This clause will allow a register operator, contracted by the Department of Health, to build, maintain and operate the Register, as authorised by the Minister and on behalf

of the Commonwealth, to support the implementation of the renewed NCSP and expanded NBCSP.

Clause 27 Delegation

This clause provides that the Minister may delegate the powers or functions conferred under clause 5, clause 25 and clause 26 to an SES employee or an acting SES employee in the Department of Health.

This clause also provides that the Secretary (for subclause 17(3)(g)) may delegate the powers or functions conferred under clause 5, clause 25 and clause 26 to an SES employee or an acting SES employee in the Department of Health.

Any persons exercising the powers or functions as a delegate of the Minister or Secretary must comply with any directions of the Minister or Secretary, respectively.

Clause 28 Rules

Subclause 28(1) provides that the Minister may, by legislative instrument, make rules to prescribe matters required or permitted to be prescribed, or necessary or convenient to be prescribed to give effect to the Bill.

Relevant matters required or permitted to be prescribed by the rules are:

- additional types of key information;
- additional contents for the Register;
- the healthcare providers required to notify the Chief Medical Officer, the information to be notified, including the type of screening test or diagnosis, and the timeframe for providing the notification; and
- prescribed bodies who are authorised to collect, record, use or disclose information for the purposes of the register.

Subclause 28(2) provides that the rules may not create an offence or civil penalty, provide powers of arrest or entry, search or seizure, impose a tax, set an amount to be appropriated from the Consolidated Revenue Fund or directly amend the text of the Bill. This sets appropriate limits on the scope of the rules.