

2013 - 2014 - 2015

THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

HOUSE OF REPRESENTATIVES

AUSTRALIAN IMMUNISATION REGISTER BILL 2015

EXPLANATORY MEMORANDUM

(Circulated by authority of the Minister for Health, The Hon Sussan Ley MP)

AUSTRALIAN IMMUNISATION REGISTER BILL 2015

OUTLINE

The Australian Immunisation Register Bill 2015 creates a new consolidated legislative framework for the operation of Australian immunisation registers. Consequential to the establishment of the new legislation, Part IVA of the *Health Insurance Act 1973* (HIA) – Australian Childhood Immunisation Register (ACIR) and Part 9BA of the *National Health Act 1953* (NHA) – The National HPV Vaccination Program Register (HPV Register) is to be repealed.

The need for this Bill arose from a number of announcements made by the Australian Government as part of the Federal Budget 2015-2016. Prior to 1 January 2016, the ACIR recorded vaccines given only to children aged less than seven years. Approval has been given for the expansion of the ACIR to become the **Australian Immunisation Register (AIR)**, which will capture all vaccines given, from birth to death, through General Practice and community clinics.

The ACIR will be expanded in two stages. From 1 January 2016, it will be expanded to collect and record vaccinations given to young individuals under the age of 20 years. This is required to implement the Government's *No Jab No Pay* Budget measure. From late 2016, it will be expanded further to cover all vaccinations given from birth to death. This is to accommodate the addition of zoster virus (shingles) vaccine (Zostavax) to the National Immunisation Program for persons aged 70 years.

Approval was also given through the *Improving Immunisation Coverage Rates* Budget measure to broaden and improve immunisation data capture to assist vaccination providers to boost coverage rates. This includes expanding the HPV Register to become the **Australian School Vaccination Register (ASVR)**, which will capture all adolescent vaccinations given through school programs from the start of the 2017 school year. The HPV Register currently only captures administration of the HPV vaccine. Other adolescent vaccinations administered through the school programs that would be captured in the ASVR include Varicella (chickenpox) and the Diphtheria, Tetanus and Pertussis (whooping cough) booster.

The Bill will have amendments that commence in three stages:

Amendments commencing on 1 January 2016 include repealing Part IVA (relating to the ACIR) and associated offence provisions of the *Health Insurance Act 1973*, minor amendments to the *National Health Act 1953* and consequential amendments to other legislation including the *A New Tax System (Family Assistance) Act 1999*, the *Freedom of Information Act 1983*, the *Healthcare Identifiers Act 2010*, the *Child Support (Registration and Collection) Act 1988*, the *Human Services (Medicare) Act 1973* and the *Human Services (Centrelink) Act 1997*. In addition, the Rule made under this Bill, which defines the bodies to which register information may be provided, will commence.

Amendments commencing in September 2016 will reflect the expansion of the ACIR to collect vaccination information for all individuals from birth to death, not just

individuals under 20 years of age. The *Healthcare Identifiers Act 2010* is to be amended to refer to the new *Australian Immunisation Register Act 2015* (AIR Act).

Finally, from 1 January 2017, the provisions of the AIR Act will apply equally to the AIR and the ASVR and Part 9BA of the *National Health Act 1953* (relating to the HPV Register) will be repealed.

Other amendments

- Repeal Regulation 22A and Schedule 1A of the *Health Insurance Regulations 1975* which currently lists prescribed bodies to whom ACIR data can be provided (to be replaced by the new Rule).

The Bill:

- describes the provisions under which the ACIR will be operated;
- authorises the collection and use of Commonwealth assigned identifiers, such as the Medicare number;
- establishes the ACIR and details the types of information that may be recorded in the Register, including relevant identifying information about an individual; information about the vaccinations they have received or information about a natural immunity to a disease or a medical contraindication to a vaccine;
- allows for authorised persons to make a record of, use or disclose protected information recorded in the ACIR if the person does so for one of the purposes of the Register listed in the Bill;
- authorises the disclosure of personal information for the purpose of other laws, including the Australian Privacy Principles;
- provides for individuals whose details are recorded in the Register to request that they not receive correspondence from the ACIR or that their personal information not be disclosed from the ACIR;
- describes the sanctions that protect the unauthorised disclosure of personal information contained within the ACIR; and
- authorises the transfer of immunisation status information from the Australian Immunisation Register to the Centrelink payment system for the purposes of determining eligibility for family assistance and child care payments which are linked to immunisation. The information to be shared includes:
 - those who meet the requirements due to being fully immunised, including those who meet the requirements through a valid exemption (natural immunity; medical contraindication; or being an active participant in a vaccine trial); and
 - those who do not meet the requirements due to being not fully immunised.

This Bill will lay the foundations for future work to move towards one integrated system that captures and reports on all vaccines given in Australia from birth to death, providing one ‘front door’ for consumers and immunisation providers.

Financial Impact Statement

Funding to expand the Australian Childhood Immunisation Register (ACIR) and the National HPV Vaccination Program Register (HPV Register) was approved by Government as part of the 2015-16 Federal Budget, as follows:

- As part of the *Improving Immunisation Coverage Rates* Budget measure, \$9.2 million over four years for broader and better immunisation data capture by expanding the HPV Register to become an Australian School Vaccination Register (ASVR). The ASVR will collect data from all adolescent vaccinations delivered nationally in schools as part of the National Immunisation Program (NIP), including the Diphtheria, tetanus and acellular pertussis (dTpa) booster, Human Papillomavirus (HPV) vaccine and Varicella (chickenpox).
- The *Shingles Vaccination Programme* will provide shingles vaccination to 70 year olds, with a five-year catch-up program for 71-79 year olds. This measure includes funding of \$27.2 million over four years to expand the ACIR to capture adult immunisation data for those vaccines delivered under the NIP, thus becoming a birth to death vaccination register. This expansion will commence on 1 January 2016, with an initial stage to collect immunisation details for persons under 20 years of age (currently seven years of age) to support the *No Jab, No Pay* Budget measure.

Statement of Compatibility with Human Rights

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

AUSTRALIAN IMMUNISATION REGISTER BILL 2015

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 Australian Immunisation Register Bill 2015, creates a new consolidated legislative framework for the operation of Australian immunisation registers. Consequential to the establishment of the new legislation, Part IVA of the *Health Insurance Act 1973* (HIA) – Australian Childhood Immunisation and Part 9BA of the *National Health Act 1953* (NHA) – The National HPV Vaccination Program Register is to be repealed.

The need for this Bill arose from a number of announcements made by the Australian Government as part of the Federal Budget 2015-2016. Prior to 1 January 2016, the ACIR recorded vaccines given only to children aged less than seven years. Approval has been given for the expansion of the Australian Childhood Immunisation Register (ACIR) to become the **Australian Immunisation Register (AIR)**, which will capture all vaccines given, from birth to death, through General Practice and community clinics.

The ACIR will be expanded in two stages. From 1 January 2016, it will be expanded to collect and record vaccinations given to young individuals under the age of 20 years. This is required to implement the Government's 'No Jab No Pay' Budget measure. From late 2016, it will be expanded further to cover all vaccinations given from birth to death. This is to accommodate the addition of zoster virus (shingles) vaccine (Zostavax) to the National Immunisation Program for persons aged 70 years.

Approval was also given through the *Improving Immunisation Coverage Rates* Budget measure to broaden and improve immunisation data capture to assist vaccination providers to boost coverage rates. This includes expanding the HPV Register to become the **Australian School Vaccination Register (ASVR)**, which will capture all adolescent vaccinations given through school programs from the start of the 2017 school year. The HPV Register currently only captures administration of the HPV vaccine. Other adolescent vaccinations administered through the school programs that would be captured in the ASVR include Varicella (chickenpox) and the Diphtheria, Tetanus and Pertussis (whooping cough) booster.

The National Immunisation Committee includes immunisation coordinators from all jurisdictions who have indicated their support for the proposed amendments.

Human rights implications

The Bill engages Articles 2 and 12 of the *International Covenant on Economic, Social and Cultural Rights (ICESCR)* by assisting with the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The Bill assists the advancement of this human right by providing access for eligible people to the Australian registry that records vaccine administered. Enhancing the mechanism in which vaccinations are recorded will contribute to an enriched monitoring and provides invaluable statistics on health-related issues. This is a positive step towards attaining the highest standard of health for all Australians, by protecting individuals and the community through enhanced monitoring of vaccine preventable disease.

Current legislation describing immunisation registers is described within the *Health Insurance Act 1973* and the *National Health Act 1953* (NHA) and provides for immunisation records for children up to the age of seven (Australian Childhood Immunisation Register) and HPV vaccine given in schools (HPV Vaccine Register). The new legislation and the expansion of the Register promote the right to health and the accessibility of individual records for whole of life, not just the young. The Bill describes individual access to information about them recorded on the Register. The process for accessing immunisation information will be the same throughout life providing a consistent approach for individuals and healthcare providers.

The Bill is also consistent with the advancement of Article 1 of the ICESCR. Since vaccination is not mandatory in Australia this enables and promotes the right to self-determination.

This Bill engages Article 17 the *International Covenant on Civil and Political Rights (ICCPR)* by the provision that the Register can collect, store, use and disclose personal information. Part 2, Subsection 9(a) of the Bill provides for the collection of relevant identifying information for individuals who had or could have, a relevant vaccination. Personal Information from the Medicare database is disclosed to the register under the secrecy provisions contained within s130 of the *Health Insurance Act 1973* to pre-populate the Register with personal information of individuals. This information is then deemed as protected information under this Bill and protected under the secrecy provisions in Part 4, which maintains the protection of personal information. Individual privacy is maintained and not diminished within this proposed Bill.

Individuals may request that personal information is not disclosed from the Register as described in Subsection 11(2). Persons cannot make a record of, disclose or otherwise use this information if this is contrary to such a request. Limitations on disclosure of personal information are expressed within Subsection 22(2) of the Bill. A person may only disclose personal information to third parties, if the persons does so for the purposes of the register described in Section 10 of the Bill and is a listed person described under Subparagraph 22(2). The authorised categories of persons in proposed Subsection 22(2) are persons who are an employee of the Commonwealth (or authority of the Commonwealth), a prescribed body, a recognised Australian vaccination provider, if the person is a parent/guardian (or legal representative) of a child or is an officer or employee engaged by the Commonwealth to perform work relating to the

purposes of the Register. Authorised persons may only disclose personal information for limited purposes including if, the person does so in accordance with the purpose under the Act, the person is required to do so by the law, the person does so for the purpose of a coronial inquiry. The expressed limitation on who can access and disclose personal information is explicit to the purposes of the Register and those authorised dealings with protected information under Subparagraph 22(2)(b).

The Minister (or his or her delegate) may also disclose personal information if they are satisfied that it is in the public interest to do so. An example is where a child protection agency requests information when investigating the welfare of a child. Section 23 of the Bill creates an offence for making a record, using or disclosing personal information where not authorised. In the 2014-2015 financial year, more than 18,000 authorisations occurred for this purpose.

Persons who obtain information or disclose information and are not authorised to do so under Subsection 22(2) of the Bill are subject to imprisonment for 2 years or 120 penalty units, or both. Specific exemptions to this offence relates to the person to whom the protect information relate to is described in Section 27. These sanctions are described and designed to encourage adherence to the intent of the Bill whilst maintaining privacy provisions.

The authorisations of used and disclosure of personal information are reasonable, appropriate and necessary for the objectives and purposes of the Bill and adequately describes persons who are requiring access to the immunisation Register to achieve the objectives of the Register. The provisions in the Bill also provide individuals with freedom to access their own personal information. The limiting provisions surrounding the access of personal information are well described. The limitations for purposes for which the information can be disclosed are a reasonable and proportionate use of individual's personal information.

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 also limit human rights, those limitations are reasonable, necessary and proportionate.

The Hon Sussan Ley MP, the Minister for Health

AUSTRALIAN IMMUNISATION REGISTER BILL 2015

NOTES ON SECTIONS

Part 1: Preliminary

Section 1 – Short Title:

This Section provides that the Bill, once enacted, may be cited as the *Australian Immunisation Register Act 2015*.

Section 2 – Commencement:

The Bill will commence on 1 January 2016.

Section 3 – Simplified outline of this Act

This section provides a simplified outline of the Act. It summarises the provisions set out in the Act.

Whilst 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.

Section 4 – Definitions

This Section provides definitions of the terms used within the Act.

The definitions include;

- ACI Register – means the Australian Childhood Immunisation Register.
- Approved Form – is a form approved under subsection 29(1). This form will allow individuals to actively manage personal information that is contained on the register.
- Arrangement- means and includes a contract or deed.
- Chief Executive Medicare – has the same meaning as in the *Human Services (Medicare) Act 1973*.
- Commercial-in-confidence – is defined in section 5 of the Act.
- Family assistance - has the same meaning within the *A New Tax System (family Assistance) Act 1999*.
- General Practitioner - has the same meaning as in the *Health Insurance Act 1973*.
- Parent- means someone who is a parent based on the definition of child.
- Personal information - has the same meaning as in the *Privacy Act 1988*.
- Prescribed bodies - prescribed bodies refers to the definition set out in the *Australian Immunisation Register Rule 2015*.
- Protected information- means personal information, relevant identifying information or information that is commercial-in-confidence obtained under the Act or derived from information obtained or disclosed under the Act.
- Purposes of the ACI register – means the purposes listed in section 10 of the Act.

- Recognised vaccination provider – Medicare General Practitioners which would include general practitioners (GPs) can access information recorded in the register and notify vaccination information to the register. Other individuals or organisations can register as a vaccination provider for the purposes of sending information to the register, and checking information contained in the register. This is done by completing a registration form and seeking endorsement from their respective state or territory health department.
- Relevant identifying information – is identifiable information about an individual. This includes, name, contact details, date of birth, gender, indigenous status, Medicare number, individual healthcare identifier and name of parent or guardian.
- Relevant vaccination- is any vaccination administered in Australia or outside of Australia if the information is notified to a recognised vaccination provider.
- Rules – means the rules under section 31 of the Act.
- Vaccine preventable disease – is any disease listed as a vaccine preventable disease in the latest edition of the Australian Immunisation Handbook.
- Young individual – defined as a person under the age of 20 years.

Section 5 – Meaning of *commercial-in-confidence*

This Section sets out factors, for the Minister to consider when deciding whether information is commercial-in-confidence. This provision provides similar protections to that currently provided in the ACIR to commercial information in the *Health Insurance Act 1973*.

Section 6 – Act binds the Crown

This Section provides that the obligation in the Act apply to the Crown but that the Crown cannot be prosecuted for any offence under the Act.

Part 2: Australian Childhood Immunisation Register

Division 1 – Simplified outline

Section 7 – Simplified outline of this Part

This provides an outline of Part 2 of the Act. Whilst 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.

Division 2 – Establishment, contents and purposes

Section 8 – Establishment of the register

This section states that (1) the Commonwealth must establish and keep a register, (2) parts of the register can be kept separate and (3) the register is not a legislative instrument.

Subsection 8(2) allows for the Australian School Vaccination Register (ASVR) to be maintained and operated on a separate register platform, whilst still being covered by the provisions of this Bill from 1 January 2017 onwards. The ASVR will record immunisation data for all adolescent vaccines given through the school based programs.

Currently, states and territory health departments are responsible for implementing vaccination programs delivered in schools, including the collection and reporting of immunisation status information. The states and territories use a wide variety of systems to collect and transfer data to the HPV Register.

Section 8(3) is included to inform readers that the Register is not a legislative instrument within the meaning of Section 5 of the *Legislative Instruments Act 2003*.

Section 9 – Contents of the register

This section describes the type of information that may be collected for the purposes of the Register.

Paragraph 9(a) provides for relevant identifying information for each individual to be recorded in the Register. This includes the individual's name, contact details, gender, date of birth, indigenous status, healthcare identifier and medicare number.

Individuals will be automatically registered on the Register once they are enrolled in Medicare. Relevant personal information recorded in Medicare will be synchronized daily with information kept on the Register to ensure that the record is kept up to date. When a recognised vaccination provider notifies the Register about a vaccination that has been administered, that information will be matched to the individual's record stored in the Register. Where an individual is not enrolled (or not eligible) for Medicare, their details will be included on the Register once the Register receives notification of their first vaccination from a provider.

Once Medicare information is recorded in the Register, it will become protected information as defined in Section 4 of this Bill, and will be subject to the offence provision under Part 4 of this Bill. Medicare enrolment information will also be used by the Register as the population denominator to calculate vaccination coverage rates.

Collection of an individual's Medicare number and healthcare identifier is necessary to facilitate updating of personal information on the Register which has the capacity to become outdated over the course of time. In an individual's lifetime a number of elements of the data collected at the time of vaccination will change. These can include their name, the Medicare number for example when they become independent of their parents or in the event of marriage. The address will certainly change several times. This means that the only element of information that will not change on the register is the date of birth and the healthcare identifier. The use of these unique identifiers will also enable future linkage of data between the AIR and ASVR.

Paragraph 9(b) describes the type of information that is collected and recorded in the Register about vaccinations. This includes the day of the vaccination; information about the vaccine administered such as the brand name and dose number; and the

name and contact details of the Australian recognised vaccination provider who administered the vaccine. If a vaccine was administered outside Australia, the individual must discuss the details of the vaccination with an Australian recognised vaccination provider who will need to notify the Register that this vaccination has taken place. This information will be used to compile statistics on immunisation rates by geographical area and assist in the identification of persons who are due or overdue for vaccinations, directly contributing to the purposes of the Register.

Recognised vaccination providers can send vaccination information to the Register using the following mechanisms:

- directly via state and territory based vaccination registers and databases;
- online claiming via a software application known as Practice Management Software that allows data to be sent from the vaccination provider's desktop;
- via a secure website; or
- manually using a hard copy notification form.

Subparagraph 9(c)(i) provides that the Register may collect and record information for an individual if a General Practitioner assesses that the individual does not require a vaccination because the individual has contracted a disease, and as a result has developed a natural immunity, or that the individual has a medical contraindication to a vaccine, and has been clinically advised not to receive a vaccination. Information about a natural immunity or medical contraindication can only be notified to the Register by a General Practitioner. Natural immunity can only be notified for a limited type of diseases, which includes measles, mumps, rubella, varicella and Hepatitis B.

Paragraph 9(d) details the type of information that may be included in the Register about the assessment relating to a natural immunity or medical contraindication, including details of the General Practitioner who made the assessment, the vaccine relevant to the assessment and date that the assessment was made.

Provision has also been allowed in Paragraph 9(e) to collect other information relating to vaccinations of individuals.

Section 10 – Purposes of the register

This Section sets out the purposes of the Register.

Paragraph 10(1)(a) provides that a purpose of the Register is for the establishment and keeping of an electronic database of records relating to the vaccination status of individuals.

Paragraph 10(1)(b) provides that a purpose of the Register allows for the collecting, analysing and publishing of statistics, and other information, in relation to vaccination coverage. The Commonwealth, via the Immunise Australia website, publishes data which shows the proportion of children and adolescents who are fully immunised at key age milestones, according to the National Immunisation Program schedule. Only de-identified aggregated data is published on this website, which maintains personal privacy and prevents the identification of individuals. A range of statistical coverage reports across various population cohorts and geographical areas of Australia are also

produced and made available to state and territory health departments who are responsible for implementing immunisation programs in their respective jurisdictions. Research bodies, such as the National Centre for Immunisation Research and Surveillance, the National Health Performance Authority and the Australia Institute of Health and Welfare, also have an interest in the surveillance of vaccine preventable diseases and vaccination uptake across Australia. This involves the compilation and publishing of information and statistics about vaccinations in Australia, including maps showing levels of coverage in different areas of Australia.

An important purpose of the Register, as provided for in Paragraph 10(1)(c), is to monitor vaccination coverage across Australia and geographical areas within Australia. Part of implementing a successful vaccination program requires continual monitoring of vaccination coverage across different age cohorts. In areas where vaccination coverage is low, targeted vaccine delivery and promotion can be directed in that region to increase vaccination rates.

Paragraph 10(1)(d) provides for information contained in the Register to be used to monitor the effectiveness of vaccines and the success of Commonwealth and state and territory immunisation programs in reducing the incidence of vaccine preventable diseases.

The Register, as stated in Paragraph 10(1)(e) through analysis of vaccine preventable disease burden and data contained within the ACI Register, will be used in the identification of Australians at risk of contracting vaccine preventable disease. In instances where a vaccine preventable disease outbreak has been detected, vaccination providers and prescribed bodies can actively target individuals recorded on the Register as being not fully immunised and at risk, to encourage vaccination of those individuals to protect the community more broadly.

Paragraph 10(1)(f) provides that a purpose of the Register is for an individual or a recognised vaccination provider to check the vaccination status of an individual recorded on the Register. A parent or guardian is also able to check the immunisation status of the individual if they are incapable of managing their own health affairs, such as young children (Paragraph 10(2)(a)).

Recognised vaccination providers, prescribed bodies and authorised persons will be granted access to personal information recorded in the Register about the vaccination status of an individual via:

- an individual search facility on the secure website (exact match search);
- a number of identified reports which are accessible via the secure website (allows providers to identify children who are due, coming due or overdue for their vaccinations); and
- the Register information phone line.

Paragraph 10(1)(g) allows the Commonwealth to perform a check of an individual's vaccination status recorded in the Register and share this information with the Centrelink payment system for the purpose of determining eligibility for family assistance and child care payments which are linked to immunisation. The information to be shared includes:

- those who meet the requirements due to being fully immunised, including those who meet the requirements through a valid exemption (natural immunity; medical contraindication; or being a participant in an approved vaccine trial); and
- those who do not meet the requirements due to being not fully immunised.

Paragraph 10(1)(h) allows the Register to establish a mechanism to contact individuals (or the parent/guardian or legal representative)(Section 10(2)(b)) when they are due for a vaccination. At specified milestones the Register will generate notices to individuals who are recorded in the Register advising them when a dose of vaccine is due to be administered or reminding them if a dose of vaccine is overdue to be administered. These notices may be made in writing or via electronic messaging, including email and SMS.

Paragraph 10(1)(i) allows a purpose of the Register to provide individuals with a record of vaccinations that they have received. A vaccination history/completion statement will be generated at key milestones and be available electronically from a secure website. The history statement can also be requested over the phone. At the completion of a course of vaccination, or at any time at the request of an individual (or parent/guardian for those not capable of managing their own health affairs such as young individuals or individuals suffering mental limitations rendering them incapable of handling their affairs), the register will have the capacity to generate a letter of certification that a course of vaccination has been completed, and will contain the details of the brand of vaccine and the dates on which each dose was administered. This will provide a record of vaccination for the individual concerned. The history statement can be used as proof of vaccination for entry to child care, school and for family assistance payment purposes.

Paragraph 10(1)(j) provides that it is a purpose of the Register to support notification mechanisms about new developments associated with vaccines and the National Immunisation Program to individuals (or a parent/guardian) and recognised vaccination providers. This could include any material of an informative, technical or statistical nature relating to vaccine preventable diseases, new and emerging vaccines or matters relating to the immunisation programs. De-identified statistical information may also be published to raise awareness in the general population about vaccine preventable diseases and to promote immunisation programs.

Similarly, the advancement of the scientific knowledge base and potential technological advancements globally may aid research into vaccine preventable diseases and vaccinations in Australia. This purpose is detailed in Paragraph 10(1)(l).

Paragraph 10(1)(k) allows the Commonwealth to make payments to recognised vaccination providers when they notify the Register of a vaccination. This will ensure the vaccination information relating to individuals is as current and as comprehensive as possible.

Section 10(1) allows for information to be used and disclosed for relevant purposes related to vaccination including individuals who are conducting research in relation to immunisation or vaccine preventable disease within Australia.

Paragraph 10(1)(m) sets out that anything incidental to the above purposes of the Register can also be included as a permissible function under the Act. This provision is included in the Bill to facilitate any associative purposes that relate to the provisions described within 10(1)(a-l).

Subsection 10(2) outlines that if an individual is incapable of managing his or her health affairs, the parent or guardian of the individual (or legal representative) may check the vaccination status of the individual. An example of someone who cannot manage their own affairs includes young children and individuals suffering mental limitations rendering them incapable of handling their affairs. Individuals who are capable of managing their own health affairs can access their own immunisation information from the Register directly.

Division 3 – Requests about personal information in the register

Section 11 - Requests about personal information in the register

Individuals (or a parent or guardian of an individual) can request that they not be provided with information from the Register (for example, a reminder that the person is due for a vaccination) and that the Register no longer disclose personal information about them (for example, to a recognised vaccination provider). There will be no capability for an individual to request complete destruction of records about them that are held by the Register.

The request will be required to be made using an approved form and the Commonwealth will be required to comply with the written request as soon as practicable. The form will articulate that a request for the Register to no longer disclose information about an individual will not prevent information being shared with Centrelink for the purpose of assessing eligibility for family assistance payments which are linked to vaccination.

Division 4—Payments relating to the register

Section 12- Payments relating to vaccinations

One of the purposes of the Register is to allow the Commonwealth to make administrative payments to recognised vaccination providers when they notify the Register of a vaccination (Paragraph 10(1)(k)). Section 12 gives the Commonwealth authority to make payments for the purposes described in the Bill.

To be eligible for a payment described in 12(1)(a) the notification must be in relation to a vaccination that completes one of the six childhood immunisation schedule points (e.g. 2, 4, 6, 12, 18 and 48 months of age). This will ensure the vaccination information relating to these individuals is as current and as comprehensive as possible.

From March 2016, an additional incentive payment (described in paragraph 12 (1)(b)) will be made to recognised vaccination providers who proactively follow up children who are more than two months overdue for their vaccinations and call them in to

receive the required catch up vaccinations. The incentive payment is payable in relation to vaccinations that are administered to children under seven years of age. Payments are made monthly via Electronic Funds Transfer into the provider's nominated bank account. A statement of payment is sent each month to vaccination providers.

Division 5—Alternative constitutional bases

Section 13- Alternative constitutional bases

This section sets out the different heads of power in the constitution that provide constitutional support for the operation of the Register. These constitutional powers are the pharmaceutical benefits power, the medical services power, census or statistics, external affairs power, executive power of the Commonwealth, implied nationhood power, powers in relation to a Territory or a Commonwealth place and matters incidental to the execution of any of the legislative or executive powers of the Parliament.

There is a deliberate interruption to numbering which will allow for future insertion of provisions relating to the proposed National Australian Cancer Screening Register.

Part 4 – Dealing with protected information in the register

Section 21 – Simplified outline of this Part

This section provides an outline of Part 4 of the Bill. Whilst 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.

The definition of protected information means that the offence in section 23 can apply to on-disclosure/use by persons who have received register information. To avoid committing an offence, such persons can only on-disclose/use the information if they are authorised under section 22(2) to do so, or if they come within an exception in section 24 to 27.

This division provides the confidentiality of information contained in the Register. It sets out the circumstances in which personal and commercial-in-confidence information may be collected, recorded, used or disclosed. It will be an offence to disclose personal or commercial-in-confidence information other than in certain circumstances.

Section 22 – Authorised dealings with protected information

This section provides that protected information may be collected for inclusion in the Register and sets out the circumstances in which the protected information may be recorded, disclosed or used. It allows the Minister for Health or delegate to authorise persons to make records of, use or disclose protected information for a permissible purpose (a purpose that promotes the objectives of the Act) in specific circumstances.

A person, as defined in Paragraph 22(2)(a), may make a record of, disclose or use protected information for a permissible purpose, in performing functions or duties and exercising powers under the Act.

Recognised vaccination providers and prescribed bodies (including state and territory health departments) will be able to access protected information from the Register, including the vaccination status of an individual, via an individual search facility (exact match search); by phoning the Register information line or by accessing a number of identified reports available via a secure website. This enables recognised vaccination providers and prescribed bodies to identify individuals who are due, coming due, or overdue for their vaccinations (Paragraph 10(1)(g)).

Subsection 22(3) also allows the Minister for Health (or delegate) to authorise a person to make a record of or use protected information, or to disclose protected information to a specified person or to a specified class of persons. This authorisation must be in writing. This will enable information to be disclosed to persons who may not be listed in section 22 or relating to a purpose not specified in section 10, in cases where it is deemed to be in the public interest. An example is where a child protection agency requests information when investigating the welfare of a child.

The Bill does not limit the disclosure of de-identified information from the Register.

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

These uses and disclosures are authorised where it is for one or more of the purposes described in Section 10.

Section 23 – Offence relating to protected information

This section creates an offence where a person obtains protected information, and makes a record of, discloses or uses the information without authorisation. A maximum penalty of two years imprisonment or 120 penalty units, or both, applies for contravention of this offence, which is considered appropriate due to the damage that could be done to a person or company as a result of unauthorised disclosure of protected information. Exceptions to this offence are provided in Sections 24 through to 27.

Section 24 – Exemption for use in good faith

This section provides an exception to the offence under Section 23 if the person obtains protected information for a permissible purpose and the person discloses, makes a record of or uses the information in good faith and in purported compliance with the Act.

The defendant's evidential burden of proof is in accordance with Section 13.3 of the *Criminal Code Act 1995*, 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. That

is, the defendant must provide evidence that they were acting in good faith to meet the exception.

Section 25 – Exception if unaware information is commercial-in-confidence

This section provides an exception to the offence under section 23 if the person makes a record of, discloses, or uses protected information that is commercial-in-confidence and the person does not know that the information is commercial-in-confidence.

The defendant's evidential burden of proof is in accordance with section 13.3 of the *Criminal Code Act 1995*, 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. That is, the defendant must provide evidence that they did not know that the information is commercial-in-confidence to meet the exception.

Section 26 – Exceptions relating to the person to whom the protected information relates

This section provides an exception to the offence under section 23 if the person obtains protected information for a permissible purpose and discloses the information to the person to whom the information relates. This section also provides an exception to the offence if a person obtains protected information and makes a record, discloses or uses the information with the consent of the person to whom the information relates.

The defendant's evidential burden of proof is in accordance with section 13.3 of the *Criminal Code Act 1995*, 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. That is, the defendant must provide evidence that the information was disclosed to the person to whom information relates, or with their consent, to meet the exception.

Section 27 – Exception for disclosure to person who provided the information

This section provides an exception to the offence under section 23 if the person obtains protected information for a permissible purpose and discloses the information to the person who provided the information.

The defendant's evidential burden of proof is in accordance with section 13.3 of the *Criminal Code Act 1995*, 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. That is, the defendant must provide evidence that the disclosure was to the person who provided the information to meet the exception.

Part 5 – Other matters

Section 28 – Simplified outline of this Part

This section provides an outline of Part 5 of the Bill. Whilst 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.

Section 29 – Approved forms

This section provides authority for the Minister, by writing, to approve a form for the purposes of a provision of this Act.

Section 30 – Delegation

This section provides that the Minister is permitted to delegate, in writing, the functions or powers relating to specific sections within the Bill.

The Minister may delegate the powers or functions conferred under subsection 22(3) to a person holding the SES Band 3 position or higher within the Department of Health or the Chief Executive Medicare who is an officer within the Department of Human Services.

Additionally, the Minister may delegate the functions or powers under section 5 (about commercial-in-confidence information), section 12 (about payments relating to vaccinations) and section 29 (relating to approved forms), to an SES employee or an acting SES employee in the Department of Health and to the Chief Executive Medicare.

Any persons exercising the powers or functions as a delegate for the Minister must also comply with any directions of the Minister.

Section 31 – Rules

The Minister may through a legislative instrument make rules to prescribe matters associated with the Bill. Disclosure of protected information contained within the Register is permissible as stated in subparagraph 22(2)(a)(iv) to prescribed bodies. The prescribed bodies are to be listed in the Rules.

However, the Rules may not create an offence or civil penalty (Section 31(2)), 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.