

EXPLANATORY STATEMENT

Australian Immunisation Register Act 2015

Australian Immunisation Register Amendment (Reporting) Rules 2021

Authority

Section 31 of the *Australian Immunisation Register Act 2015* (the AIR Act) provides that the Minister may make rules prescribing matters required or permitted by the AIR Act to be prescribed by the rules or necessary or convenient to be prescribed for carrying out or giving effect to the AIR Act.

Purpose

This instrument provides for rules to support amendments to the AIR Act contained in the *Australian Immunisation Register Amendment (Reporting) Act 2021* (the Amending Act).

Section 10A of the AIR Act requires vaccination providers to report information relating to certain relevant vaccinations to the Australian Immunisation Register.

Subsection 10A(5) of the AIR Act provides that a person is liable to a civil penalty if the person contravenes subsection 10A(1) or (3).

The civil penalty applicable for contravention of subsection 10A(1) or (3) of the AIR Act is 30 penalty units.

Pursuant to subsection 10A of the AIR Act, the *Australian Immunisation Register Amendment (Reporting) Rules 2021* (the Rules) prescribe that if the vaccination is of a kind and administered in the circumstances, set out in the rules, then the provider must report:

- in the manner so prescribed;
- the information so prescribed; and
- in the timeframe so prescribed.

Background

The need for the Amending Act arose from the significant investment made and to be made by the Government in the purchase and introduction of COVID-19 vaccines. In order to monitor the safety and efficacy of the vaccines, tracking and tracing of every dose delivered and administered to the Australian population is essential.

Combined with the reporting of influenza and National Immunisation Program (NIP) vaccines, more accurate coverage reporting will be available providing a broader understanding of any risks to public health due to COVID-19 or other vaccine

preventable diseases outbreaks. The effect of the amendments in the Amending Act is to make it mandatory for all vaccination providers to report vaccines given, including any COVID-19 vaccine, to the AIR. The details of the reporting obligations, including the relevant vaccines, the information to be reported and the manner and timeframes for reporting are prescribed in the *Australian Immunisation Register Rule 2015*.

Details

Details of the Rules are set out in the Attachment.

Consultation

The department undertook a public consultation seeking stakeholder, and the broader public's, views on the proposed amendments. The scope of consultation included feedback on changes to the AIR Act including any required changes to the AIR Rule. In addition, the department consulted directly with the Communicable Diseases Network Australia, Australian Health Protection Principal Committee, and General Practitioner, nursing and midwifery, and pharmacy peak bodies, who are supportive of the measure.

Responses to the public consultation paper were received from 5301 respondents, 179 organisation affiliated and 5122 individual submissions. Analysis indicates that key stakeholders, including health peak bodies, are supportive of the move to mandatory reporting. The majority of the 4957 individuals who responded that they do not agree with the proposed legislation amendment provided views regarding mandatory vaccination as opposed to mandatory reporting of vaccination.

Key health stakeholder feedback centred primarily on proposed compliance measures for the amendments. Many suggested an 'escalating approach', with tougher measures such as civil penalties used as a last resort for repeat offenders. This feedback was considered in the development of the Amending Act and specifically the drafting of the Bill to allow a staged approach of which vaccines are required to be reported. Specifically the approach outlined in 9(1)(b) of the Amending Act.

The Rules commence the day after registration on the Federal Register of Legislation.

The Rules are a legislative instrument for the purposes of the *Legislation Act 2003*.

Details of the Australian Immunisation Register Amendment (Reporting) Rules 2021

1 Name

Section 1 states that the name of the amending instrument is the *Australian Immunisation Register Amendment (Reporting) Rules 2021*.

2 Commencement

Section 2 states that these amendments commence on the day after this instrument is registered.

3 Authority

Section 3 states that this instrument is made under the authority of the *Australian Immunisation Register Act 2015* (the AIR Act).

4 Schedule

Section 4 states each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1 Amendments

Australian Immunisation Register Rule 2015

Item 1 Section 4 (after the heading)

This item provides a note stating that a number of expressions used in the *Australian Immunisation Register Amendment (Reporting) Rules 2021* are defined in the AIR Act.

Item 2 (at the end of the instrument)

This item provides reporting requirements relating to vaccinations. It outlines what information recognised vaccination providers are required to report to the Australian Immunisation Register. This rule prescribes that recognised vaccination providers must report all COVID-19 vaccines upon commencement of this rule and from 1 March 2021 all influenza vaccines.

Providers are required to report relevant vaccinations within 24 hours of administration, if practical to do so, and no later than 10 business days after the vaccine is administered.

The vaccination information should be reported to the AIR electronically, if practical to do so, and contain the following details relating to the individual vaccinated:

- Name

- Contact details
- Date of birth
- Gender
- Medicare number (if the individual is registered with Medicare)
- Health care identifier (if known)

Providers are also required to report their provider identification information, as defined by the Act and the day of vaccination.

Providers are also required to report product details relating to the vaccine administered including the brand name, dose number and batch number. For COVID-19 vaccines, the vial serial number must also be reported, if it is known.

At this time, no Rules are prescribed in relation to section 10A(3) of the Amending Act. Recognised vaccination providers are able (but not required) to report vaccines administered overseas to ensure their patients have a complete AIR record.

Understanding what vaccines the Australian public has received in Australia and overseas is an important element for the Australian Government to manage and monitor the public health risk of vaccine preventable disease.

Statement of Compatibility with Human Rights

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

This Rule 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*.

Section 31 of the *Australian Immunisation Register Act 2015* (AIR Act) provides that the Minister may make rules prescribing matters required or permitted by the AIR Act to be prescribed by the rules or necessary or convenient to be prescribed for carrying out or giving effect to the AIR Act.

Section 10A of the AIR Act, outlines reporting requirements for vaccination providers. The Rule prescribes that if the vaccination is of a kind and administered in the circumstances, set out in the rules, then the provider must report:

- in the manner so prescribed;
- the information so prescribed; and
- in the timeframe so prescribed.

The types of information to be collected under the Rule are the same as those previously collected on a voluntary basis under the AIR Act.

Human rights implications

This Rule engages the following human rights:

International Covenant on Economic, Social and Cultural Rights (ICESCR)

The Rule engages Article 12 of the 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 Rule provides legislative infrastructure to assist in the Australian Government's policy objective of protecting the health of individuals and the community more generally by enhanced monitoring of vaccine preventable disease.

It assists the advancement of this human right by standardising the quality of information in the Australian register that records vaccines administered. Enhancing vaccination reporting will contribute to 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.

Right to protection or privacy and reputation

The Rule engages Article 17 of the *International Covenant on Civil and Political Rights*.

The proposed amendments in this Rule do not change the existing provisions and are consistent with the secrecy provisions in Part 4 of the AIR Act, which controls the use

and disclosure of information stored on the Register and who can use and disclose this information.

Further, existing provisions in the AIR Act regulate the uploading of personal information or of ‘relevant identifying information’ for the purposes of including such information in the Register. They also regulate using or disclosing such information for the purposes of the Register by setting out particular identified categories of persons who may make a record of, disclose or otherwise, use such information.

Conclusion

The Rule is compatible with human rights.

The Hon Greg Hunt MP, Minister for Health and Aged Care