



Department for Health and Wellbeing

# Organisations delivering immunisation programs

## Information guide

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## Version control

Version	Effective from	Effective to	Change summary
V 1.0	21 June 2021	12 July 2021	Original version
V 1.1	9 August 2021	9 June 2022	Updated legislative information, organisation requirements and email address
V 1.2	10 June 2022	20 October 2022	Removed statement on age restrictions in a pharmacy setting. Removed S4 licence requirements and updated information. Included information regarding Aboriginal and Torres Strait Islander Health Practitioners.
V 1.3	21 October 2022	Current	Updated QCPP documentation required for pharmacies.

## Glossary of terms

The Act	<i>Controlled Substances Act 1984 (SA)</i>
AEFI	Adverse Event Following Immunisation
AHPRA	Australian Health Practitioner Regulation Agency is the national body responsible for the regulation of registered health practitioners in Australia
ATAGI	Australian Technical Advisory Group on Immunisation is a Ministerial appointed body of experts providing advice on immunisation matters to the Federal Minister for Health and Aged Care
ATSIHP	Aboriginal and Torres Strait Islander Health Practitioner
Basic life support – cardio-pulmonary resuscitation	Basic life support – cardio-pulmonary resuscitation. Adult, child and infant cardio-pulmonary resuscitation basic life support training according to the Australian Resuscitation Guidelines, must be successfully completed each year.
CPD	Continuing Professional Development is the ongoing, systematic learning process that registered health practitioners undertake to maintain their competence to practice and to enhance their professional and personal skills and knowledge
PRASA	The Pharmacy Regulation Authority SA
QCPP	Quality Care Pharmacy Program
The Code	The current Vaccine Administration Code published by the South Australian Department for Health and Wellbeing
The Department	South Australian Department for Health and Wellbeing
The Minister	The South Australian Minister for Health and Wellbeing
NIP	National Immunisation Program
NMBA	Nursing and Midwifery Board of Australia
PBA	Pharmacy Board of Australia
The Regulations	The Controlled Substances (Poisons) Regulations 2011 (SA)

## 1. Background

Vaccines aim to protect people against specific diseases. Vaccines are S4 drugs under the Controlled Substances (Poisons) Regulations 2011<sup>1</sup>.

In South Australia, section 18(1d)(a)(iii) of the *Controlled Substances Act 1984* (the Act) authorises a registered health practitioner to administer a prescription drug (not being a drug of dependence), hereafter referred to a S4 drug, to a person if the practitioner is acting in the ordinary course of the practitioner's profession and the practitioner is authorised to administer the drug under the relevant regulations.

For the purposes of section 18(1d)(a)(iii) of the Act, regulation 18(3) of the Controlled Substances (Poisons) Regulations 2011 (the Regulations) provides that registered health practitioners as determined by the Minister may administer S4 drugs which are vaccines if they comply with all of the requirements in regulation 18(3).

To meet the requirements of the legislation:

- the vaccine must be administered by a registered health practitioner of a class of health practitioner approved by the Minister; and
- the registered health practitioner must have successfully completed an approved immunisation training program; and
- the vaccine must be listed in the Vaccine Administration Code (the Code) or be approved by the Minister; and
- the registered health practitioner must work for an organisation approved by the Minister; and
- the drug must be administered:
  - as part of an immunisation program delivered by the organisation; and
  - in accordance with the Code; and
- the vaccine is administered as part of a specified immunisation program.

Registered practitioners administering vaccines under the requirements listed above are referred to hereafter as authorised registered health practitioners. Currently the only practitioners who may be authorised registered health practitioners under the Code are registered nurses, midwives, Aboriginal and Torres Strait Islander Health Practitioners, and pharmacists.

APHRA registered medical practitioners working within their scope of practice are able to vaccinate independently of the Code.

**On an ongoing basis, approved organisations; may be subject to audits of their immunisation services and may be requested to submit evidence of their policies and procedures.**

## 2. Organisations delivering immunisation programs

Incorporated hospitals, the SA Ambulance Service, councils and council subsidiaries do not need to seek approval from the Minister for the purposes of regulation 18(3)(c)(ii).

Other organisations employing authorised registered health practitioners to deliver immunisation programs without a medical order require approval from the Minister.

Approved organisations must ensure the following minimum requirements are in place to support delivery of safe, high quality immunisation services by authorised registered health practitioners within their organisation:

- A process for employment and ongoing clinical credentialing requirements for authorised registered health practitioners immunising in accordance with regulation 18(3).
- Policies and procedures governing the provision of immunisations by authorised registered health practitioners that are consistent with the requirements of regulation 18(3).
- Accreditation with a relevant recognised peak regulatory or representative body. Re-accreditation is required to support ongoing approval, and it is a requirement of the organisation to provide evidence of accreditation.

### 2.1 Application to be an approved organisation

To apply to become an approved organisation:

1. Complete the application form '[Application for approval as an organisation delivering immunisation programs](#)'.
2. The proprietor, executive or manager of the organisation must sign the Executive Declaration of the form. Pharmacy applications must be signed by the proprietor.
3. Forward a PDF version of the completed application and supporting documents to [Health.CDCBOrganisationApprovals@sa.gov.au](mailto:Health.CDCBOrganisationApprovals@sa.gov.au).

Please note:

- Approval of an organisation is granted for a maximum term of three (3) years from the date of approval.
- Approval of the organisation is linked to the signatory of the Executive Declaration (proprietor, executive or manager).
  - Re-application is required within three months after any change of the signatory of the Executive Declaration to remain an approved organisation, except in the following circumstance;
  - in the instance of a group of proprietors, if the signatory leaves the group, only the Executive Declaration must be re-signed and submitted.

To update signatory proprietor details complete and submit the '[Update proprietor details and executive declaration for organisations delivering immunisation programs](#)' form.
- At the discretion of the Minister or delegate, temporary approval of an organisation may be issued whilst a previously approved organisation is seeking reaccreditation.

- Notification of any change of organisational details is required, such as name or address, to ensure accurate records are maintained online.

To notify SA Health of any changes complete and submit the [‘Update organisation details for approved organisations delivering immunisation programs’](#) form.

- Where a single proprietor, or the same group of proprietors, has multiple sites delivering immunisation services each individual site must be listed but one application will cover all sites.
- The application process may take up to 8 weeks. Details of the application outcome will be sent to the proprietor, executive or manager of the organisation in an electronic format.

## 2.2 Application to register as a vaccination provider with the Australian Immunisation Register

The Australian Immunisation Register (AIR) is a national register that records details of vaccinations given to an individual. All individuals eligible for a Medicare card are automatically listed on the AIR. Under the *Australian Immunisation Register Act 2015* (Cth), all COVID-19 vaccines, influenza vaccinations, and all National Immunisation Program (NIP) vaccinations, must be reported to the AIR. A civil penalty may apply under the *Australian Immunisation Register Act 2015* if an organisation fails to report a vaccination to the AIR.

It is important that all vaccines administered are reported to the AIR. National immunisation coverage rates are the percentage of persons in Australia who have received vaccines recommended and/or administered. Coverage rates are calculated using reported data from National Immunisation Registers. A national immunisation coverage target provides a goal against which Australia can measure its immunisation coverage.

Organisations must register as a vaccination provider with the AIR by completing the [‘Australian Immunisation Register - Application to register as a vaccination provider form’](#) and submit as directed.

## 2.3 Conditions for ongoing approval

Pharmacies to maintain currency of:

- SA Health approval as an organisation delivering immunisation programs. Re-accreditation is required every three years.
- Professional indemnity insurance that includes a level of cover not less than \$20 million for any single claim (that is, for each claim), or for all claims in the aggregate, that may be made against you.

Refer to the Pharmacy Board of Australia [‘Registration standard: Professional indemnity insurance arrangements’](#).

- Pharmacy Regulation Authority SA (PRASA) registration
  - *Pharmacy Services Provider Registration* certificate or evidence of current Australian Health Practitioner Regulation Agency (AHPRA) registration if an individual/sole trader
  - *Premises Registration* certificate

Certificates must be emailed to SA Health annually when new registration certificates are issued.

- Accreditation with a relevant recognised peak regulatory or representative body such as Quality Care Pharmacy Program (QCPP).

The QCPP *Accreditation Schedule* and *Pharmacy Services* certification document (including certification for 'Vaccination Services in the Pharmacy') must be emailed to SA Health biennially when the pharmacy is issued a new certificate of accreditation. If confirmation of re-accreditation is pending, you must provide evidence of this to SA Health.

PRASA registration certificates, and/or AHPRA registration certificates and QCPP re-accreditation documents should be emailed to [Health.CDCBOrganisationApprovals@sa.gov.au](mailto:Health.CDCBOrganisationApprovals@sa.gov.au) in PDF format. The accompanying email should clearly identify the pharmacy, using the organisation name on the approval notice.

Other organisations to maintain currency of:

- SA Health approval as an organisation delivering immunisation programs. Re-accreditation is required every three years.
- Professional indemnity insurance that includes a level of cover not less than \$20 million for any single claim (that is, for each claim), or for all claims in the aggregate, that may be made against you.
- Accreditation with a relevant recognised peak regulatory or representative body. Please view details at: [Approved organisations for delivering specified immunisation programs](#)  
Evidence of re-accreditation must be emailed to SA Health prior to expiry.

Evidence of re-accreditation to confirm currency should be emailed to [Health.CDCBOrganisationApprovals@sa.gov.au](mailto:Health.CDCBOrganisationApprovals@sa.gov.au) in PDF format. The accompanying email should clearly identify the organisation, using the organisation name on the approval notice.

### 3. Relevant legislative and licensing requirements for the delivery of an immunisation program

#### 3.1 Professional practice standards, codes and guidelines

Under AHPRA, health professionals have a legal obligation to perform within their scope of practice according to the education and training they have received and within any regulatory or legislative frameworks.

Employers and organisations are responsible for providing sufficient resources to enable health practitioners to provide safe and competent care. This includes policies and procedures that support the development of a risk management framework, to meet the needs and expectations of the client.

#### 3.2 Registered Nurses and Midwives

The Decision Making Framework for Nurses and Midwives (Framework), approved by the Nursing and Midwifery Board of Australia (NMBA), provides guidance for nurses, midwives and employers to ensure that clinical practice decisions are made in accordance with a risk management, professional, regulatory and legislative framework.

The Framework ensures that those who are authorised to make decisions, where professional knowledge and experience are needed, are competent to do so. The scope of practice is defined as "that which the individual is educated, authorised and competent to perform".<sup>2</sup> The Framework states that to practice within the full scope of practice of the profession may require

the registered nurse to update or increase their knowledge, skills or competence.

The Framework ensures registered nurses and midwives, as registered health practitioners, work within their scope of practice, maintain their competence to practice, and update their knowledge and clinical skills. The Framework ensures that nursing practice is regulated to protect the public, identifying the minimum standards expected of the registered health practitioner.

The following NMBA professional codes and guidelines are examples of documents that govern the practice of nurses and /or midwives providing an immunisation service:

- [Guidelines for registration standards](#)
- [Professional practice guidelines](#)

### 3.3 Pharmacists

The following competency standards, codes and guidelines are examples of documents that govern the practice of pharmacists providing an immunisation service:

- [National Competency Standards Framework for Pharmacists in Australia](#)
- [Pharmaceutical Society of Australia Professional Practice Standards](#)
- [Pharmaceutical Society of Australia Code of Ethics](#)
- [Pharmacy Board of Australia Registration Standards](#)
- [Pharmaceutical Society of Australia - Practice guidelines for the provision of immunisation services](#)

### 3.4 Aboriginal and Torres Strait Islander Health Practitioners

The Aboriginal and Torres Strait Islander Health Practitioner (ATSIHP) role is regulated under the National Registration and Accreditation Scheme implemented by AHPRA, ensuring consistent, high quality, national professional standards.

Under AHPRA, health professionals have a legal obligation to perform within their scope of practice according to the education and training they have received and within any regulatory or legislative frameworks.

The following codes, frameworks and guidelines are examples that govern the practice of ATSIHP's providing an immunisation service:

- [SA Health Aboriginal and Torres Strait Islander Health Practitioner Immunisation Clinical Guideline](#)
- [Aboriginal and Torres Strait Islander Health Practice Board - Professional capabilities for registered Aboriginal and Torres Strait Islander Health Practitioners](#)
- [Aboriginal and Torres Strait Islander Health Practice Board - Codes and guidelines](#)
- [National Framework for Determining Scope of Practice for the Aboriginal and/or Torres Strait Islander Health Worker and Health Practitioner Workforce](#)
- Guidelines as published time to time by the [Aboriginal Health Council of South Australia](#)



### 3.5 Licence to supply or possess S4 drugs

Organisations that are approved to deliver immunisation programs under the Code do not require a licence to supply or possess S4 drugs, for the purposes of the Code.

For organisations that are not approved to deliver immunisation programs under the Code please refer to [Vaccine standing drug orders](#).

Under regulation 21(1) of the Regulations a council, council subsidiary or health service facility does not need to hold a licence for the supply of S4 drugs under immunisation programs that it runs.

## 4. Clinical governance and risk management

Clinical governance is the system of collecting all the activities that promote, review, measure and monitor the quality of patient care into a unified and coherent model. It delivers systematic and integrated approaches to ensuring services are accountable for delivering quality health care. Clinical governance is delivered through a combination of strategies that include clinical competence, clinical audit, education and training, risk management, use of information and staff management.<sup>3</sup>

The organisations employing authorised registered practitioners must be appropriately accredited for service provision. Accreditation provides quality and performance assurance for owners, managers, staff and consumers.

### 4.1 Credentialing for registered health practitioners

The Australian Commission on Safety and Quality in Health Care describes credentialing as a process used by employers to verify the qualifications and experience of health practitioners to determine their clinical competence and ability to provide safe, high quality health care services within a specific health care setting. Credentialing can improve patient safety by ensuring clinicians practice within the bounds of their training and competency levels, and within the capacity of the health service in which they are employed.<sup>4</sup>

Employers have a duty of care to employ competent, suitably qualified and experienced registered health practitioners to deliver their immunisation service. This includes ensuring the registered health practitioner is currently registered under AHPRA and holds a current certificate or statement to verify the successful completion of an approved training program. It also involves ongoing monitoring to ensure registered health practitioners have completed updates in line with the legislation and the organisational policies.

There are a number of documents and guidelines that can be used to assist employers in the development of organisational policies and processes on credentialing and defining the scope of clinical practice for authorised registered health practitioners.

See <https://www.safetyandquality.gov.au/publications-and-resources>

### 4.2 Ongoing performance reviews and competency assessments

Registered health practitioners have an obligation to advise employers if they are not competent and must participate in ongoing performance reviews and competency assessments.

The ongoing competence and safety may be assessed by employers through the following:

1. The registered health practitioner is participating in Continuing Professional

Development (CPD). National health practitioner boards regulate the practice of all registered health professionals in Australia and one of its key roles is to ensure the safety of the public by ensuring all health practitioners are suitably qualified to practice in a competent and ethical manner. It is mandatory for all registered health practitioners to complete a minimum number of CPD hours directly relevant to the health practitioner's context of clinical practice.

2. The authorised registered health practitioner compliance with the Recency of Practice registration standard published by the NMBA and the Pharmacy Board of Australia (PBA).
3. Review of all incidents, reports, complaints, and compliments.
4. Ongoing performance management, where written evidence may be presented.
5. The authorised registered health practitioner acting as an effective clinical resource to other staff, providing education and updates as required.
6. Ensuring the authorised registered health practitioner is knowledgeable and credible in the delivery of immunisation information to clients.
7. Ensuring clinical practice complies with current key elements of safe and quality immunisation practice set out in the online *Australian Immunisation Handbook*, Australian Government Department of Health immunisation procedures and guidelines, SA Health immunisation procedures and guidelines and, where relevant, the Pharmaceutical Society of Australia - [Practice Guidelines for the provision of immunisation services](#)
8. Ensuring immunisation providers successfully complete annual basic life support - cardio-pulmonary resuscitation training.

### 4.3 Risk management framework

The management of risk is recognised as an integral part of good management practice and an essential component of good corporate and clinical governance. Organisations are responsible for ensuring there are sufficient resources to enable safe and competent care for the clients accessing health care. This includes the development of broader policies and guidelines to support a clinical governance framework.

An example of how risk management is incorporated into a clinical governance policy framework is provided in the *Victorian clinical governance policy framework* made available through VicHealth at: <https://www2.health.vic.gov.au/hospitals-and-health-services/quality-safety-service/clinical-risk-management/clinical-governance-policy>.

## 5 Immunisation practice standards

Immunisation practice standards are to cover all aspects of the delivery of high-quality immunisation services. Policies and procedures are to be in place that support practice and are to include at a minimum:

- storage and handling of vaccine, including cold chain monitoring;
- pre-vaccination screening;
- patient exclusion and referral to a general practitioner or other NIP service;
- consent process;
- vaccine administration;

- anaphylaxis response kit;
- managing anaphylaxis and vaso-vagal episodes;
- adverse events management and reporting;
- vaccination documentation and record keeping, including reporting to the Australian Immunisation Register;
- handling of sharps, maintaining infection control including management of needle stick injury and exposure to blood or body fluids;
- sharps and clinical waste disposal; and
- management of staff training and credentialing.

The following resources provide information on practice standards:

- The online Australian Immunisation Handbook, available at: <https://immunisationhandbook.health.gov.au/>
- The National Vaccine Storage Guidelines: Strive for 5, available at: <https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5>
- Australian Immunisation Register (AIR) and reporting vaccination information available at: <https://www.humanservices.gov.au/health-professionals/services/medicare/australian-immunisation-register-health-professionals>
- Documentation legislative requirements information available at: <http://www.archives.sa.gov.au/alias/recordkeeping>. A completed personal record card of vaccines administered must be given to each person vaccinated. Approved organisations should retain vaccination records in accordance with organisational policies and with legislative requirements.
- The Pharmaceutical Society of Australia - Practice guidelines for the provision of immunisation services within pharmacy. The Pharmaceutical Society of Australia provides resources for pharmacists to support practice as an immuniser <https://www.psa.org.au/resource/immunisation-resources/>.
- Quality Care Pharmacy Program (QCPP) - a quality management system designed to assist business owners. QCPP provides its members with support and guidance on professional health services and pharmacy business operations.

## 6 Information support

Clinical information and advice are available from specialist immunisation nurses in the Department's Immunisation Section within the Communicable Disease Control Branch. The Immunisation Section can be contacted on 1300 232 272 on working days 8.30am - 5.00pm.

**These guidelines and additional resources will assist organisations to meet these requirements. In addition, the organisation needs to consider the existing national and state immunisation legislation.**

## 7 References

1. Government of South Australia. Attorney Generals Department. Controlled Substances (Poisons) Regulations 2011, under the *Controlled Substances Act 1984*. Available at: <https://www.legislation.sa.gov.au/index.aspx>.
2. Nursing and Midwifery Board of Australia, *National framework for the development of decision making tools for nursing and midwifery practice*. September 2007. Available at: <http://www.nursingmidwiferyboard.gov.au/Codes-Guidelines-Statements/Frameworks.aspx>.
3. Phillips, C.B, Pearce, C.M. Hall, S., Travaglia, J., de Lusignan, S., Love, T. & Kljakovic, M. 2010. *Can clinical governance deliver quality improvement in Australian general practice and primary care? A systematic review of the evidence*. Medical Journal Australia, 2010; 193(10), 602-607. Available at: <https://www.mja.com.au/journal/2010/193/10/can-clinical-governance-deliver-quality-improvement-australian-general-practice>
4. Australian Commission on Safety and Quality in Healthcare. *Australian Safety and Quality Framework for Health Care*. December 2010. Available at: <https://safetyandquality.gov.au/wp-content/uploads/2012/04/Australian-SandQ-Framework1.pdf>.

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### For more information

**Communicable Disease Control Branch**  
**Department for Health and Wellbeing**  
**Telephone: 1300 232 272**  
[www.sahealth.sa.gov.au](http://www.sahealth.sa.gov.au)

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