



Department for Health and Ageing

# Organisations delivering immunisation programs

## Information guide

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# Contents

|  |    |
|--|----|
| Glossary of terms .....  | 3  |
| 1. Introduction.....   | 4  |
| 2. Approved organisations .....  | 4  |
| 2.1 Application to be an approved organisation .....   | 5  |
| 3. Relevant legislative and licensing requirements for the delivery of an immunisation program ..... | 6  |
| 3.1 Professional practice standards, codes and guidelines .....                                      | 6  |
| 3.2 Registered Nurses.....   | 6  |
| 3.3 Pharmacists.....   | 7  |
| 4. Clinical governance and risk management .....   | 7  |
| 4.1 Credentialing for registered health practitioners .....  | 7  |
| 4.2 Ongoing performance reviews and competency assessments.....                                      | 7  |
| 4.3 Risk management framework.....   | 8  |
| 5. Minimum immunisation practice standards.....  | 8  |
| 5.1 Procedures and guidelines.....   | 9  |
| 6. Information support .....   | 9  |
| 7. References.....   | 10 |
| 8. Appendix 1: Application for approval as an organisation delivering immunisation programs.....     | 11 |
| 9. Appendix 2 .....  | 14 |

## Glossary of terms

|                       |  |
|-----------------------|--|
| The Act               | <i>Controlled Substances Act 1984 (SA)</i>   |
| AEFI                  | Adverse Event Following Immunisation   |
| AHPRA                 | Australian Health Practitioners Regulation Agency is the national body responsible for the regulation of registered health practitioners in Australia.   |
| ANMAC                 | The Australian Nursing and Midwifery Accreditation Council is a peak national nursing and midwifery organisation which works with the national, state and territory nursing and midwifery boards to produce national standards to assist nurses and midwives to deliver safe and competent care. |
| ATAGI                 | Australian Technical Advisory Group on Immunisation is a Ministerial appointed body of experts providing advice on immunisation matters to the Minister for Health and Ageing.   |
| Continuing Competence | The ability for nurses to demonstrate that they have maintained their competence in their current area and context of practice   |
| 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.   |
| CPR                   | Cardio Pulmonary Resuscitation.<br>Adult, child and infant CPR training according to the Australian Resuscitation Guidelines, must be successfully completed each year.  |
| The Code              | The current Vaccine Administration Code published by the South Australian Department for Health and Ageing   |
| The Department        | South Australian Department for Health and Ageing  |
| The Minister          | The Minister for Health and Ageing   |
| NIP                   | National Immunisation Program  |
| NMBA                  | Nursing and Midwifery Board of Australia   |
| PBA                   | Pharmacy Board of Australia  |
| The Regulations       | The Controlled Substances (Poisons) Regulations (SA)   |

## 1. Introduction

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 authorisation for registered health practitioners as determined by the Minister, to administer specified vaccines without a medical order if the following requirements are met.

- The registered health practitioner has, not more than 3 years before the administration of the drug, successfully completed a training program approved by the Minister for the purposes of regulation 18(3).
- The vaccine is listed in the Vaccine Administration Code (the Code) published by the South Australian Department for Health and Ageing (the Department). Listed vaccines can be given either singly or in combination.
- The vaccine is administered as part of an immunisation program delivered by an incorporated hospital; or South Australian Ambulance Service; or a council or council subsidiary; or an immunisation program delivered by an organisation approved by the Minister for the purposes of regulation 18(3).
- The drug is administered in accordance with the Code; and in the case of a drug administered as part of the National Immunisation Program in accordance with the National Immunisation Program Schedule and the Australian Immunisation Handbook; or in any other case in accordance with requirements specified by the Minister (i.e. any immunisation procedures and guidelines published by the Department).

Registered practitioners administering vaccines under the specifications 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 and pharmacists.

## 2. Approved organisations

Local Health Networks that are part of SA Health, SA Ambulance Service, councils and council subsidiaries are recognised health facilities and 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.

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. Other organisations that do not meet the definition of a health service facility under Regulations may need to hold a licence to supply or possess S4 drugs for administration under the immunisation programs that they run. These organisations should contact the Department's

Controlled Substances Licensing Section to find out if they need to obtain a licence – telephone 8226 7117 or email [controlledsubstances@sa.gov.au](mailto:controlledsubstances@sa.gov.au).

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

- 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);
- a documented clinical risk management strategy in relation to immunisation services; and
- professional indemnity insurance cover which is appropriate for the immunisation service.

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

**Approved organisations will be subject to random audits of their immunisation services and may be requested to submit copies of their policies and procedures.**

## 2.1 Application to be an approved organisation

To apply to become an approved organisation:

1. Find the appropriate form '*Application for approval as an organisation delivering immunisation programs*' in Appendix 1.
2. Complete the application form. The proprietor must sign the completed form.
3. Forward a PDF version to [healthimmunisationadministration@sa.gov.au](mailto:healthimmunisationadministration@sa.gov.au).

Please note:

- Where a single organisation has multiple sites delivering immunisation services (for example a pharmacy proprietor with several pharmacy outlets), 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 of the organisation in an electronic format.

### 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 the health practitioners to provide safe and competent care. This includes policies and practices that support the development of a risk management framework, to meet the needs and expectations of the client.

#### 3.2 Registered Nurses

The Decision Making Framework for Nurses, approved by the NMBA, provides guidance for nurses and employers to ensure that clinical practice decisions are made in accordance with a risk management, professional, regulatory and legislative framework.

This 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> This 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 Decision Making Framework for Nurses ensures registered nurses, as registered health practitioners, work within their scope of practice, maintain their competence to practice, and update their knowledge and clinical skills. This framework ensures that nursing practice is regulated to protect the public, identifying the minimum standards expected of the registered health practitioner.

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

- Competency Standards for Registered Nurses
- Guidelines for Professional Indemnity Insurance Arrangements for Nurses
- Code of Ethics for Nurses
- Code of Professional Conduct for Nurses
- National Framework for the development of decision-making tools for Nursing and Midwifery Practice
- Guidelines for advertising of regulated health services
- Guideline for Mandatory Notifications

These resources are available from the Nursing and Midwifery Board of Australia at the following link: <http://www.nursingmidwiferyboard.gov.au/Codes-Guidelines-Statements/Codes-Guidelines.aspx>.

### 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 within pharmacy*

## 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>

### 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.

<http://www.safetyandquality.gov.au/our-work/credentialing/>

### 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 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 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 current *Australian Immunisation Handbook*, Department immunisation procedures and guidelines and where relevant the *Pharmaceutical Society of Australia Practice - Guidelines for the provision of immunisation services within pharmacy*.
8. Participation and competence in annual CPR 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 the 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. Minimum immunisation practice standards

Minimum immunisation practice standards cover all aspects of the delivery of high quality immunisation services including:

- vaccine storage;
- pre-vaccination screening;
- vaccination administration;
- vaccination documentation;
- adverse events following immunisation (AEFI) and AEFI reporting; and
- vaccination registers.

The following resources provide information on these minimum standards:

- The Australian Immunisation Handbook
- The National Vaccine Storage Guidelines: Strive for 5
- Australian Childhood Immunisation Register (ACIR) and reporting vaccination information is available at: <http://www.humanservices.gov.au/health-professionals/services/australian-childhood-immunisation-register/>.
- National Human Papillomavirus Vaccination Program Register (HPV Register) and reporting information is available at: <http://www.hpvregister.org.au/>.
- Documentation legislative requirements information is 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.

## 5.1 Procedures and guidelines

The Department has in place a number of procedures and guidelines that support specific immunisation programs.

- **Procedures** - each organisation should have in place their own set of procedures to support the best practice immunisation service delivery. A list of recommended procedures is provided in Appendix 2.
- **Immunisation Guidelines** for Health Care Workers can be accessed at: <http://www.sahealth.sa.gov.au/immunisationprovider>.
- **School Immunisation Protocols** provide clinical governance to assist immunisation providers to meet their professional responsibilities and community expectations for a quality and safe school based immunisation service delivery and can be accessed at: <http://www.sahealth.sa.gov.au/immunisationprovider>.

### **The Pharmaceutical Society of Australia - Practice guidelines for the provision of immunisation services within pharmacy**

The Pharmaceutical Society of Australia provides a set of guidelines for pharmacists to support best practice and the delivery of high quality immunisation services in pharmacy.

<http://www.psa.org.au/archives/21565>

## 6. Information support

Clinical information and advice is available from expert immunisation nurses in the Department's Immunisation Section. The Immunisation Section can be contacted on 1300 232 272 Monday to Friday 8.30am - 5.00pm.

## 7. References

1. Government of South Australia. Attorney Generals Department. Controlled Substances (Poisons) Regulations 2011, under the *Controlled Substances Act 1984*. Version: 11.7.2013. 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.  
<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: <http://www.safetyandquality.gov.au/wp-content/uploads/2012/04/Australian-SandQ-Framework1.pdf>.

## 8. Appendix 1: Application for approval as an organisation delivering immunisation programs

Application for approval as an organisation to deliver immunisation programs for the purposes of regulation 18(3)(c)(ii) of the Controlled Substances (Poisons) Regulations 2011 and section 18(1d)(a)(iii) of the *Controlled Substances Act 1984*

**Please print clearly**

Name of organisation \_\_\_\_\_

Address of organisation \_\_\_\_\_

\_\_\_\_\_

Phone number (work) \_\_\_\_\_

Fax number (work) \_\_\_\_\_

S4 Drug Licence No (if applicable) \_\_\_\_\_

**1. Indicate the vaccination programs your organisation plans to offer**

- National Immunisation Program – Childhood schedule
- National Immunisation Program – Adolescent schedule
- National Immunisation Program – Adult schedule
- New Arrival Refugee Immunisation Program schedule
- Occupational Health Program
- Seasonal Influenza Program
- Maternal Pertussis Program
- Other vaccine program

(please specify) \_\_\_\_\_

2. **If you intend administering funded vaccines to eligible groups under the National Immunisation Program, to access the vaccines you will require a customer identification number that can be provided by contacting the Vaccine Distribution Centre on 7425 7139.**

VDC ID number: \_\_\_\_\_

3. **Does the organisation have policies and procedures available in each setting that support the delivery of immunisation services in accordance with the current edition of the Australian Immunisation Handbook, National Vaccine Storage Guidelines and relevant SA Department for Health and Ageing procedures and guidelines?**

Yes       No

4. **Does the organisation has in place a policy to support regular checking of validity of clinical credentials of authorised registered health practitioners?**

Yes       No

5. **Does the organisation have policies and procedures in place to support a clinical risk management strategy and plan in relation to immunisation services?**

Yes       No

6. **Does the organisation have sufficient professional indemnity insurance cover appropriate to their immunisation services?**

Yes       No

**PHARMACIES ONLY**

7. **Is the organisation registered with Pharmacy Registration Authority South Australia (PRASA)?**

Yes       No

8. Provide the details of the person ultimately responsible for oversight of the provision of immunisation services (**proprietor**)

Name \_\_\_\_\_

Phone number \_\_\_\_\_

Mailing address \_\_\_\_\_

Email address \_\_\_\_\_

**Executive declaration**

I (print full name), \_\_\_\_\_ the **proprietor** of  
the organisation/company listed below (print name of organisation)

\_\_\_\_\_

**Declare that:**

- I have read and understood the information in the attached guidelines;
- the information I have provided in this application is true and correct;
- I am aware that I will be subject to random audits of the immunisation service and may be required to submit copies of my organisation's policies and procedures;
- I have provided a copy of this completed application form and the guidelines to each individual involved in the delivery of the vaccination program; and
- I will inform the Department's Immunisation Section if significant changes occur in my organisation such as change of ownership or any other matter which may impact the ability of the organisation to provide a safe immunisation service.

Signed \_\_\_\_\_

Dated \_\_\_\_\_

Once you have completed and signed your application please forward a PDF version to [healthimmunisationadministration@sa.gov.au](mailto:healthimmunisationadministration@sa.gov.au).

Please note: Email receipt confirmation will be sent. The application process may take up to 8 weeks. Details of the application outcome will be sent to the proprietor of the organisation in an electronic format.

## 9. Appendix 2

### **Suggested list of policies and/or procedures to support best practice immunisation service delivery**

- Checking of anaphylaxis response kit
- Monitoring of vaccine storage systems
- Managing the transport of vaccines when providing clinics off site
- How to respond to a cold chain breach
- Back-up plan for vaccine storage during power failures
- Pre-screening assessment process
- Consent process
- When and how to seek further advice following outcome of screening process
- Responding to a needle stick injury
- Responding to adverse event reports
- Managing anaphylaxis and vaso-vagal episodes
- Documentation and record keeping including GP notification
- Disposing of infectious waste