Controlled Substances Licensing of First Aid Service Providers

Framework for assessing drug licence applications from first aid service providers

June 2012

Government of South Australia

SA Health

Introduction

This Controlled Substances Licensing assessment framework has been developed to provide guidance on assessing drug licence applications from first aid service providers. It ensures consistency and timely assessment of applications, as well as demonstrating equitable procedures in assessing applications and granting drug licences.

Controlled Substances Licensing (CSL), Scientific Services, Public Health & Clinical Systems, Department for Health and Ageing SA administers licensing provisions of the *Controlled Substances Act 1984* (the Act) and *Controlled Substances (Poisons) Regulations 2011*. CSL is also known as the 'licensing authority'.

The legislation regulates the manufacture, sale, possession, supply and administration of schedule 4 and schedule 8 drugs by registered health practitioners e.g. medical practitioners, dentists and nurses acting in the ordinary course of their profession, or veterinary surgeons acting in the ordinary course of their profession. There is provision under the Act to licence or permit a person (including a body corporate) who is not a registered health practitioner, or who has a genuine need to act outside the ordinary course of their profession, to possess and administer scheduled drugs.

This assessment framework entails the Department for Health and Ageing SA policy for assessing licence applications to possess and administer schedule 4 and/or schedule 8 drugs from a range of service providers who provide first aid in various settings (e.g. occupational, public events, private functions) where high risk activities are undertaken.

Staff employed by these service providers are commonly members of unregulated professions (e.g. paramedics, first aiders) for which there is no overseeing professional association or body with disciplinary powers, or for which there are no nationally recognised competency standards. For those staff who are registered health practitioners (e.g. nurses), the scope of activities required to be undertaken may not fall within the ordinary course of their profession. Service providers may operate from a fixed site (e.g. occupational first aid rooms), or at various temporary sites (e.g. public events, private functions).

The primary reference for developing this framework has been the clinical governance framework model of the SA Ambulance Service (SAAS). The Department for Health and Ageing SA drug list contained within the '*Clinical protocols for the provision of non-emergency ambulance services*', with the addition of adrenaline, has been used as a 'starting point' for the most basic drug list. SAAS clinical protocols provided the framework for creating the extended drug lists and for determining qualification categories. Considerations and references also include policies and codes of practice of other relevant authorities and service providers e.g. SafeWork SA, Country Health SA, SA Immunisation Coordination Unit, the Royal Flying Doctor Service (RFDS).

Guiding principles

- The tenet of the Act is that in terms of public health outcomes and patient safety it is preferable that a patient is assessed by a person who is authorised to prescribe prescription drugs and for a pharmacist to dispense the prescription for the patient. If a prescription drug is not dispensed on prescription for the patient only a specified registered health practitioner may administer the drug to the patient. Licences provide mechanisms for deviating from these preferred relationships where necessary, but are not intended to replace them. Matters of convenience are not accepted as valid reasons for deviating from these preferred relationships.
- In terms of administering drugs, the role of any first aid provider is to provide appropriate treatment or care to someone suffering an injury or sudden illness until more advanced medical care is accessed (e.g. attendance by SAAS or RFDS, presentation of patient at hospital emergency department).
- It is not the normal role of first aid providers to administer drugs to treat chronic or non-emergency medical conditions; to act as de facto medical practitioners, pharmacists or nurses; or, in the case of registered health practitioners, to act outside the ordinary course of their profession.

Using the Assessment Framework

The Risk Matrix and Drug Lists contained within this assessment framework are intended to provide general guidance on the range of drugs the licensing authority considers appropriate for most first aid providers according to two key risk assessment criteria:

- **the level of risk (primarily location in relation to the proximity to medical assistance or emergency patient transport services), and**
- **qualifications of first aid personnel required to administer drugs.**

Other considerations include, but are not limited to:

- The 'type' of service to be provided. This allows for some reasonable assumptions to be made with regard to the appropriate inclusion of particular drugs under licence. The type of first aid service provided usually falls into one of two categories; 'Events' and 'Occupational'.
  - A typical Events first aid provider operates predominantly out of vehicles or from temporary sites/structures at Low or High risk sites.
  - A typical Occupational first aid provider has a dedicated occupational first aid room, provides services to employees accommodated onsite at or adjacent to a High or Very High risk site, or to non-accommodated employees at a Low or High risk site, and often has a clearly defined established relationship with SAAS and/or the RFDS.
- Clinical support levels and procedures (e.g. procedures for the remote clinical management of emergencies) and clinical governance and review systems (e.g. auditing, sentinel or serious adverse event review mechanisms).
- Availability of a RFDS Medical Chest.
- Whether there are any arrangements or Memorandums of Understanding with SAAS for providing additional off-site support to SAAS.

The list of drugs approved for possession and administration under licence is at the discretion of the licensing authority, and may comprise all or some of the drugs listed in the Drug Lists.

Definitions

1. **LOW** risk typically refers to a site:

   a) located within the Adelaide metropolitan area; or

   b) located in reasonably close proximity to an emergency department; and

   c) located in reasonably close proximity (i.e. approximately less than 20 - 30 minutes drive by the shortest route) to a SAAS service location, and

   d) is where high risk activities are undertaken.

2. **HIGH** risk typically refers to a site:

   a) from which there is likely to be some delay in accessing an emergency department; and

   b) is where high risk activities are undertaken.

3. **VERY HIGH** risk typically refers to a site:

   a) that is remote; and

   b) is where high risk activities are undertaken.

4. **Remote** means a site:

   a) from which there is likely to be a major delay in accessing the accident and emergency section of a public or private hospital (e.g. where aero-medic evacuation would **usually** be required), and

   b) is usually located within an unincorporated area.

5. **Emergency department** means a public or private hospital that provides emergency service levels of at least those described for a 'District' in Appendix A of *'Country Health SA: Strategy for Planning Country Health Services in SA, December 2008'* (at http://www.publications.health.sa.gov.au/spp/82/), including:

   - 24 hour, 7 day/week emergency triage and assessment,
   - 24 hour, 7 day/week emergency trauma and resuscitation, initial management,
   - appropriately staffed and supported by medical and nursing staff.

6. **High risk activities** are those which could reasonably be foreseen to result in a serious and sudden injury or illness that would require not only immediate first aid but also:

   a) further assessment or treatment at an emergency department; and/or

   b) may cause permanent disability or disfigurement, or death.

7. Serious and sudden injuries or illness include (but are not limited to):

- amputation of any body part
- serious head injury
- cardiac arrest
- spinal injury
- serious electric shock
- serious eye injury
- narcotic overdose
- a major bleeding wound
- a serious burn
- heat stroke

8. **Unincorporated area** means any area located outside municipalities or districts administered under the *Local Government Act, 1999*. The following SA Local Government Association website contains interactive maps and links to further information: http://www.lga.sa.gov.au/site/page.cfm?u=209

9. **Direction from a medical practitioner** includes direction from a dentist or an authorised medical officer of SAAS or the RFDS, and means direct instruction, usually verbal, to administer a drug to a particular patient. It is expected that the person who gives the direction(s) to administer a drug will provide written verification for direction(s) given within a reasonable time to the person to whom they give the direction(s).

10. A **standing order** is a written document which details the circumstances under which a particular drug should be administered. A standing order should include: a physical description of the drug, indications and contraindications, dose rates, and method/s of administration. Standing order documents should have version control, be signed by a medical practitioner (or the chair of a clinical governance panel or drug advisory group if available), and provide an indication of when the standing order is due to be reviewed.

11. **Administration** of a drug means giving a patient a single dose of medication (e.g. a tablet to ingest, administering an injection) by, or in the presence of, the person authorised to administer that drug. To give a patient medication to take away for self-administration is defined as **supply** under the Act and **is not permitted** (with conditional exceptions for nurse practitioners, nurses and midwives whose registration has the appropriate Nursing and Midwifery Board of Australia endorsement of their registration, or for specified registered health practitioners who are acting in the ordinary course of their profession). The supply of drugs by a pharmacist is called **dispensing**, and only a pharmacist can dispense a prescription.

Risk Matrix

QUALIFICATION CATEGORIES (highest qualification level available onsite during *all* working hours/events)	LEVEL OF RISK (location)		
	LOW	**HIGH**	**VERY HIGH**
CATEGORY A Basic First Aid	No drug licence issued (use of First Aid Kit and/or RFDS Medical Chest only)		
CATEGORY B Cert II in Emergency Medical Service First Response (HLT21107) eg: > Senior First Aid Certificate > Occupational First Aider‡	Drug List: 1	Drug Lists: 1 + 2*	Drug Lists: 1+ 2*
	Drugs administered in accordance with conditions of licence. Generally, no drugs may be administered under standing orders.		
CATEGORY C Enrolled Nurse, Cert IV in Health Care Ambulance(HLT41007) eg: > SAAS Ambulance Officer > St John Volunteers > Emergency Medical Technician‡	Drug List: 1	Drug Lists: 1 + 2*	Drug Lists: 1 + 2* + 3*
	Drugs administered in accordance with conditions of licence. Generally, List 2 and 3 drugs to be administered under directions from a medical practitioner only.		
CATEGORY D Paramedic (Degree)	Drug Lists: 1 + 2*	Drug Lists: 1 + 2* + 3* + 5 on request	Drug Lists: 1 + 2 + 3* + 5 on request
	Drugs administered in accordance with conditions of licence. Generally, List 3 drugs to be administered under directions from a medical practitioner only.		
CATEGORY E Registered Nurse, Intensive Care Paramedic (SAAS recognised: PL3, ICP)	Drug Lists: 1 + 2 + 3* + 5 on request	Drug Lists: 1 + 2 + 3 + 4* + 5 on request	Drug Lists: 1 + 2 + 3 + 4* + 5 on request
	Drugs administered in accordance with conditions of licence. Nurses can only implement a standing order within the scope of their professional practice. Generally, List 3 & 4 drugs to be administered under directions from a medical practitioner only.		

Risk Matrix Notes:

- The Risk Matrix is to be used as a guide only, and should be read within the context of this policy in its entirety.
- Position titles marked with a '‡' are not protected or defined and qualification levels should not be assumed to be as indicated in the Risk Matrix.
- Generally, Drug Lists marked with a '*' in the Risk Matrix will only be considered for Occupational first aid providers who are able to provide (on request) written justification for inclusion.

Drug Lists

Drug List 1:	*Form*	*Indications*	*Notes*
Adrenaline *LIMITED USE*	Injectable (including auto injector)	Limited to treatment of anaphylaxis/severe allergy and severe asthma only	*Limited* indications when in Drug List 1
Aspirin	300 mg tablets	Angina; chest pain or discomfort	Platelet inhibition
Glucagon	Injectable (incl auto injector)	Diabetic coma, hypoglycaemia	
Glucose	Powder or paste	Hypoglycaemia	
Glyceryl trinitrate (GTN)	Buccal or sublingual - spray	Angina; chest pain or discomfort	
Methoxyflurane	Inhaler	Analgesia for trauma pain	
Oxygen	Gas	Hypoxia, shock, poor perfusion	Delivered by mask or nasal-specs
Salbutamol	Nebulising solution	Respiratory distress, wheeze	Requires nebuliser

Drug List 2:	*Form*	*Indications*	*Notes*
Benzylpenicillin	Injectable	Symptoms of meningococcal meningitis; suspected meningitis	
Ipratropium bromide	Nebulising solution	Respiratory distress including wheeze, bronchospasm in COPD and children	Requires nebuliser
Midazolam	Injectable	Major tranquilizer, anticonvulsant, pre-op sedation	
Naloxone	Injectable	Reversal of opioid overdose	

Drug List 3:	*Form*	*Indications*	*Notes*
Adrenaline	Injectable (including auto injector)	Anaphylaxis, acute allergic reaction, severe asthma bronchospasm, cardiac arrest, paediatric croup etc	Extended indications when in Drug List 3 May require nebuliser
Adenosine	Injectable	Cardiac arrest, VF, pulseless VT	Requires ECG
Amiodarone	Injectable	Cardiac arrest, refractory ventricular fibrillation, pulseless VT	Requires ECG
Atropine	Injectable	Organophosphate poisoning, bradycardia	ECG should be monitored
Diazepam	Tablets	Major tranquilizer, sedative	
Hydrocortisone	Injectable	Anaphylaxis, severe allergic reaction, severe asthma	
Lignocaine	Injectable	Cardiac arrest – VT or VF following reversion	Requires ECG
Metoclopramide	Injectable	Nausea and vomiting including prophylaxis	
Morphine	Injectable	Narcotic analgesic for severe pain	Maximum 10 x 10mg/mL ampoules

Drug List 4:	*Form*	*Indications*	*Notes*
Requested schedule 4 and schedule 8 drugs - justification required	As per specified S4 or S8 drug		
General note:	Maximum quantities apply for all schedule 8 drugs and certain schedule 4 drugs		

Drug List 5:	*Form*	*Indications*	*Notes*
Vaccines (schedule 4)	As per specified vaccine		

Drug List Notes:

- The licensing authority reserves the right to review and amend the list of drugs approved under licence as it sees fit, and will advise the licensee in writing of any significant changes. Factors that may trigger a review of drugs held under licence include: staffing changes (e.g. from a higher qualification category to a lower one); in response to new or emerging trends in clinical pharmacology or emergency medicine; as a response to specific issues.
- Only drugs legitimately required should be requested in the application.
- Licence holders are advised that only drugs approved under a current licence may be possessed for administration in accordance with conditions of licence, regardless of any non-statutory authorisation conferred e.g. an 'authority to practice' conferred by a training provider or any other person (including registered health practitioners).
- Written requests to amend the list of drugs approved under licence may be submitted at any time (e.g. drugs may be added to the licence), but amendments may only be made by the licensing authority.
- Where adrenaline is held under licence as part of Drug List 1 it must not be used to treat any conditions other than those listed under the 'Indications' in Drug List 1.
- Indications listed above are intended as a general guide, and use of drugs will be limited to standing orders and/or directions from a medical practitioner.
- Generally, ipratropium will be only be considered for approval where first aid is likely to be provided to members of the general community.
- Licences issued with morphine included in the approved list of drugs will also include naloxone regardless of whether or not naloxone was requested.
- Several drugs appearing in the Drug Lists are either unscheduled, schedule 2 or schedule 3 (depending on drug and/or pack size) and a licence is not required for these drugs/substances. They have been included in order to simplify ordering from suppliers, and/or because they may be included in existing clinical protocols.
- Applicants are advised that drugs approved on interstate licences are not automatically approved under licence in SA, and all licences, authorities or permits are valid only in the State/Territory in which they were issued.

How to apply for a licence

It is recommended the applicant contact CSL to discuss their application prior to submitting the application form or paying the fee.

The applicant needs to submit:

1. A fully completed and current Department for Health and Ageing SA *'Application for Licence to Possess an S4 or S8 Drug for Administration'* form signed by the applicant (the person with the responsibility to be making the application on behalf of the organisation – usually the person in charge of the first aid facility or service),
2. Interstate applicants will generally need to provide a valid South Australian address e.g. where drugs are to be stored, a branch office,
3. Payment of the appropriate fee i.e. for a 1 year or 3 year licence period for schedule 4 and/or schedule 8 drugs,
4. Supporting information or documentation that justifies the need for drugs based on the level of risk associated with activities to be carried out at the site(s), remoteness of location(s), and qualification levels of persons undertaking the first aid involving the administration of drugs. The type of information CSL will request includes:
    - The location, or types of locations (if a mobile service), at which services are to be provided,
    - The highest qualification level of staff who will be available onsite during **all** working hours of every working day (e.g. for Occupational first aid providers), or at **all** events/functions (e.g. for Events first aid providers),
    - Details of clinical governance structure and procedures, and clinical support systems e.g. system for obtaining remote medical practitioner advice or direction, proposed interactions or arrangements with SAAS and/or the RFDS,
    - Security and storage provisions for the drug(s),
    - Drug stock and administration recording and reporting procedures.

Note: All supporting information and documentation should be clear and concise. The submission of excessive, irrelevant or ambiguous information has the potential to complicate and slow down the assessment process.

Conditions of licence

All licences issued by CSL have conditions which must be complied with in addition to relevant provisions under the Act and regulations. There are additional conditions of licence where schedule 8 drugs are included.

Licences will generally reflect a single qualification category as indicated in the Risk Matrix i.e. the highest qualification category available onsite during all working hours of every working day and/or all events/functions.

Conditions of licence include, but are not limited to, requirements relating to the following:

- When or how specified drugs may be administered e.g. under standing orders and/or at the direction of a medical practitioner.
- Drug storage, security, efficacy and record keeping requirements, and ensuring the availability of records for inspection by authorised persons.
- Requirement to comply with the Department for Health and Ageing SA policy "*Suspected Theft or Loss of Drugs or Substances from Licence or Permit Holders"* .
- The requirement for the Minister's approval of all standing orders for schedule 8 drugs.

Licence amendments

Licence amendments requests may be made at any time by submitting a written request to CSL. Amendment requests should include a brief explanation of reason(s) why the amendment is required. You will be contacted if further information or clarification is required. Approved amendments are provided in the form of a 'Letter of Amendment to the Licence' and changes are incorporated when the licence is renewed and re-issued.

Decision review

Where an applicant or licensee considers that this policy has not been properly applied in assessing their licence application or amendment request or a variation of conditions of licence by CSL, a review of the decision may be requested. Decision review requests should be submitted in writing to the Director, Scientific Services Branch, Department for Health and Ageing SA, PO Box 6, Rundle Mall, SA, 5000, and should clearly and concisely outline how the decision conflicts with this policy. The applicant or licensee will be notified in writing of the findings of the decision review and, where required, the licence will be amended.

Other options

A complaint can be made to the Ombudsman SA about any action or inaction by an agency of the SA Government. The Ombudsman may conduct investigations to determine whether the agency's process was reasonable and fair, and that the decision is not unreasonable or unlawful.

If considering lodging an appeal in the District Court (Administrative and Disciplinary Division) against a decision of the Department for Health and Ageing SA it is recommended the advice of a legal practitioner is obtained.

Contact Controlled Substances Licensing:

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