AMENDMENTS TO THE *CONTROLLED SUBSTANCES (POISONS) REGULATIONS 2011* | 11 JULY 2013

Complete details of the requirements under the *Controlled Substances (Poisons) Regulations 2011* are available at http://www.legislation.sa.gov.au/LZ/C/R/CONTROLLED%20SUBSTANCES%20(POISONS)%20REGULATIONS%202011.aspx

Regulation	Change	Notes
12(2)	There is an exemption for a council, council subsidiary or health service facility from the requirement to hold a licence to supply the S3 poison adrenaline if the supply is for administration to a person as part of an immunisation program run by the council, council subsidiary or health service facility.	Councils, council subsidiaries and health services need to be able to supply adrenaline injection to the immunisation clinics they run. A council, council subsidiary or health service does not need to hold a licence to supply adrenaline injection for administration as part of an immunisation program that it runs.
18(1)	A dental therapist, dental hygienist or oral health therapist or podiatrist is authorised to administer the S4 drug articaine.	There is widespread use of the new local anaesthetic articaine in dental practice.
18(3)	There is an authorisation for a registered health practitioner of a class determined by the Minister for Mental Health and Substance Abuse to administer a Schedule 4 (S4) drug to a person if the administration is in accordance with the Vaccine Administration Code (the Code) published by the South Australian Department for Health and Ageing (the Department) and provided all the	The registered health practitioner must meet specified requirements about training, vaccines, immunisation schedules and organisations that deliver immunisation programs. Registered nurses are a class of registered health practitioners determined by the Minister for the purpose of the authorisation under regulation 18(3). A registered nurse may initiate administration of a vaccine provided that: • The registered nurse has successfully completed a training program approved by the Minister and must update his or her training every three years; and • The vaccine is listed in Schedule 1 of the Code or is a vaccine approved by the Minister; and • The vaccine is administered in accordance with the recommendations in the current edition of The Australian Immunisation Handbook published by the Commonwealth Department of Health and Ageing (the Australian

	other requirements of regulation 18(3) are met.	Immunisation Handbook) and any policies on vaccines or immunisation programs that are published by the Department; and • The vaccine is administered as part of an immunisation program delivered by a local health network that is part of SA Health, or the SA Ambulance Service or a council or council subsidiary, or an organisation approved by the Minister; and • If the drug is administered as part of the National Immunisation Program, the administration is in accordance with the National Immunisation Program Schedule and the current edition of the Australian Immunisation Handbook; and • If the vaccine is not administered as part of the National Immunisation Program the drug must be administered in accordance with the requirements specified by the Minister. Additional information about the authorisation, approved training programs and applying for approval as an organisation that delivers immunisation programs for the purposes of the new regulation, is available on the SA Health website at www.sahealth.sa.gov.au/immunisationprovider.
20	Regulation 20 has been deleted.	Regulation 20 restricted a midwife whose registration is endorsed under section 94 of the *Health Practitioner Regulation National Law* as qualified to prescribe scheduled medicines (a scheduled medicines endorsement) to prescribing the prescription drugs listed in the regulation. The drugs listed were those that an eligible midwife is permitted to prescribe under the Pharmaceutical Benefits Scheme. The restriction on prescribing by a midwife whose registration is endorsed with a scheduled medicines endorsement has been removed. A midwife acting in the ordinary course of his or her profession whose registration is endorsed with a scheduled medicines endorsement is authorised to prescribe scheduled medicines in accordance with that endorsement. Eligible midwives must be in a collaborative arrangement as specified in the *National Health (Collaborative arrangements for midwives) Determination 2010* (Cth) available at http://www.comlaw.gov.au/Details/F2010L02105/Download. The *Prescribing Formulary for Eligible Midwives with a Scheduled Medicines Endorsement* available at http://www.nursingmidwiferyboard.gov.au/Registration-and-Endorsement/Endorsements-Notations.aspx#EligibleMidwife lists the S4 and Schedule 8 (S8) medicines approved by the Nursing and Midwifery

		Board of Australia for prescribing by eligible midwives whose registration is endorsed with a scheduled medicines endorsement.
21(1)	The exemption for a council or health service facility from the requirements to hold a licence for supply of S4 drugs under the immunisation programs that they run applies to all types of immunisation programs run by councils, council subsidiaries and health services.	The previous exemption applied to community immunisation programs. The exemption has been broadened to cover all types of immunisation programs run by councils, council subsidiaries and health service facilities, for example, supply of vaccines to school and work place immunisation programs is now covered under the exemption.
21(2)(g)	A pharmacist may sell or supply an S4 drug without dispensing a prescription if the drug is a pharmaceutical benefit that may be supplied under the Continued Dispensing Program. The sale or supply of the drug must be made in accordance with the conditions specified in the National Health (Continued Dispensing) Determination. The current determination is available at http://www.comlaw.gov.au/Details/F2012L01465/Download	The amendment enables implementation of the Continued Dispensing Program under the Fifth Community Pharmacy Agreement between the Pharmacy Guild of Australia and the Australian Government. The drugs that may be supplied under the Continued Dispensing Program are a maximum quantity under the Pharmaceutical Benefits Scheme for: • A statin for the treatment of high cholesterol; • The oral contraceptive pill. Conditions of the Continued Dispensing Program include: • The pharmacist must not supply the medicine unless the person has previously had a valid prescription and the person's therapy is stable; • A person is only able to get one requested supply of the medicine under the program in a twelve month period; • The pharmacist is required to provide information about the supply to the most recent prescriber. The Continued Dispensing Program does not replace existing emergency supply provisions, it complements them. The options for a pharmacist who receives a request for supply of an S4 drug without a prescription are: • Dispense the drug after receiving a prescription from the prescriber (a prescription given by telephone or fax or some other form of electronic transmission), with a written prescription provided in confirmation as soon as practicable. A written prescription does not need to be provided in confirmation if the prescriber endorsed the

		prescription given by fax with the name and address of a single pharmacy at which the prescription may be dispensed. • Provide an emergency supply of the drug (usually limited to a maximum of 3 days dosage) if the criteria specified in regulation 21(2)(f) are met. A follow up prescription is not required. • Supply the medicine under the Continued Dispensing Program. A Pharmaceutical Benefits Scheme claim can be made without the need for a follow up prescription. • Refer the person to a prescriber without supplying the drug.
33(7), 34(4)	There are exemptions from the requirements of regulations 33 and 34 about how prescriptions are given and written for a prescriber who gives a medication chart prescription for a medicine that may be supplied under the Medication Charts Program, in accordance with the conditions specified in the National Health (Residential Medication Chart) Determination. The current determination is available at: http://www.comlaw.gov.au/Details/F2012C00798/Download	The amendments enable implementation of the Medication Charts Program under the Fifth Community Pharmacy Agreement between the Pharmacy Guild of Australia and the Australian Government. The exemptions take account of the following elements of the Medication Charts Program: • The prescriber will not give the pharmacist the original medication chart prescription. The medication chart prescription will be faxed or scanned and e-mailed to the pharmacy; • The medication chart prescription will not include the total amount of drug to be supplied each time the prescription is dispensed, or the total number of times the drug may be dispensed. The National Health (Residential Medication Chart) Determination specifies the applicable pharmaceutical benefits that may be supplied under the program. The pharmaceutical benefits excluded from supply under the Medication Charts Program are: • Drugs of dependence (e.g. morphine, fentanyl) • Section 100 drugs • Authority prescription drugs, except if the authority requirements include a streamlined authority code. The determination also specifies the information that must be included on a residential medication chart.

35(12)	There is an exemption from the requirements of regulation 35 (other than subregulations (1)(b) and 7(a) and (b)) if a pharmacist or medical practitioner dispenses a medicine that may be supplied under the Medication Charts Program on a medication chart prescription and the supply is in accordance with the conditions specified in the National Health (Residential Medication Chart) Determination. The current determination is available at: http://www.comlaw.gov.au/Details/F2012C00798/Download	The exemptions take account of the fact that under the Medication Charts Program the pharmacist or medical practitioner will be dispensing from a copy of the medication chart prescription and the prescriber does not have to provide the original medication chart prescription to the pharmacist or medical practitioner. The maximum period of validity of a residential medication chart under the Medication Charts Program is four months. The pharmacist or medical practitioner may supply up to a maximum Pharmaceutical Benefits Scheme quantity of the medicine more than once on the basis of a particular medication chart prescription only if: • The medication chart prescription indicates that ongoing supply is authorised for the period of validity of the chart; or • The medication chart prescription indicates a stop date for the supply and, based on the dose and frequency of administration indicated in the prescription, more than one supply of a maximum quantity of the pharmaceutical benefit is needed before the stop date is reached. If the above criteria do not apply the pharmacist or medical practitioner may only supply the quantity needed to give effect to the prescription, up to a maximum quantity of the medicine permitted under the Pharmaceutical Benefits Scheme. A standard National Residential Medication Chart is being developed by the Australian Commission on Safety and Quality in Health Care as part of the Medication Charts Program. The chart is currently being trialled in selected residential aged care services in New South Wales. It is expected that the final version of the chart will be available by the end of 2013. The changes to the regulations will enable implementation of the Medication Charts Program in South Australia when it becomes operational on a national basis (expected date, January 2014). A pharmacist or medical practitioner who dispenses a medicine under the Medication Charts Program still has to comply with the requirements under regulations 35(1)(b) and 35(7)(a) and (b) to: • record specified details about the prescriber, the resident and the drug when he or she dispenses a drug on a medication chart prescription; • not dispense a drug— (a) if the prescription for the drug— o is presented more than 12 months after the date on which the prescription was written; or o has been cancelled; or

		o is partly or wholly illegible; or o does not comply with the Act or these regulations; or (b) if there are reasonable grounds for suspecting that the prescription has been altered, forged or obtained by false pretences.
37(2)	The requirement that a registered health practitioner must first examine the person if the practitioner is prescribing or supplying a drug of dependence for use by a person, unless the prescribing or supply is in the circumstances of a verifiable emergency is removed.	It is a matter of clinical judgement for a registered health practitioner to decide if it is appropriate to prescribe or supply a drug of dependence for use by a person without first examining the person. Medical practitioners need to take account of the Technology-Based Patient Consultations Guidelines (the Guidelines) published by the Medical Board of Australia when deciding if it is appropriate to prescribe or supply a drug of dependence for use by a person without first examining the person. The Guidelines are available at: http://www.medicalboard.gov.au/Codes-Guidelines-Policies.aspx. The Guidelines include requirements for the medical practitioner to: • Make a judgment about the appropriateness of a technology-based consultation and in particular whether a direct physical examination is necessary • Confirm to his or her satisfaction the identity of the patient at each consultation • Make appropriate arrangements to follow the progress of the patient and inform the patient's general practitioner or other relevant practitioners • Keep an appropriate record of the consultation.
45(1)(a)(v)	A person who has been authorised in writing by the Chief Executive of the SA Ambulance Service to administer drugs of dependence may witness the destruction of a drug of dependence.	The persons who may witness the administration of a drug of dependence are: (i) an authorised officer; or (ii) a police officer; or (iii) a registered health practitioner; or (iv) a veterinary surgeon; or (v) a person who has been authorised in writing by the Chief Executive of the SA Ambulance Service to administer drugs of dependence