

ACAM PROTOCOL FOR SUPERVISED DELEGATED INJECTORS: USE OF SCHEDULE 4 MEDICATIONS AND DEVICES FOR COSMETIC PROCEDURES BY SUPERVISED DELEGATED INJECTORS

This protocol has been developed by the Australasian College of Aesthetic Medicine (ACAM) and should be read in conjunction with the following Medical Board of Australia publications: *Guidelines For Registered Medical Practitioners Who Perform Cosmetic Medical And Surgical Procedures* and *Good Medical Practice: A code of conduct for doctors in Australia*.¹

It is the responsibility of the prescribing practitioners or authorised individual to be aware of the relevant poisons and therapeutic goods regulations and guidelines (or similar), for the state(s) and territory(s) in which they conduct their practice(s).²

This document may not contain links to all the relevant legislation, guidelines and regulations that a prescribing practitioner or authorised individual may require adherence to within each state or territory. It is the responsibility of the prescribing practitioner or authorised individual to ensure they are practicing to the standard required within each jurisdiction.

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¹Medical Board of Australia Medical Board of Australia *Guidelines For Registered Medical Practitioners Who Perform Cosmetic Medical And Surgical Procedures* <https://www.medicalboard.gov.au/Codes-Guidelines-Policies/Cosmetic-medical-and-surgical-procedures-guidelines.aspx>; Medical Board of Australia *Good Medical Practice: A code of conduct for doctors in Australia* <https://www.medicalboard.gov.au/codes-guidelines-policies/code-of-conduct.aspx>

² Refer to NSW Poisons and Therapeutic Goods Amendment (Cosmetic Use) Regulation 2021 concerning definition of prescribing practitioners or authorised individual <https://www.health.nsw.gov.au/patients/cosmetic/Pages/amendments.aspx>

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1. Background

Cosmetic injectables are categorised as S4 medications or devices by the Therapeutic Goods Administration (TGA). Prescribing practitioners or authorised individuals under the legislation can be supplied with these medications.³ Cosmetic injectables and devices can be administered to a patient by a supervised delegated injector under the supervision of a prescribing practitioner or authorised individual with recorded, patient-specific authorisation to administer the drug.

A prescribing practitioner or authorised individual may not supply an S4 medications or device to a supervised delegated injector for administration to a patient who is not under the direct care of that medical practitioner. A supervised delegated injector may not administer an S4 medications or device to a patient unless written authorisation has been given by a prescribing practitioner or authorised individual to administer the substance to that specific patient.

2. Supervision

A supervised delegated injector administering cosmetic injectables or devices must be under direct supervision by a prescribing practitioner or authorised individual.

2.1 *Direct supervision.*

ACAM recommends the prescribing practitioner or authorised individual be physically onsite with the ability to immediately respond to any difficulties, or adverse event the supervised delegated injector may encounter.

Supervision by video conferencing/Telehealth is **not** recommended by ACAM. Supervision and patient assessment by telephone/instant messaging/email is not recommended by ACAM. It is strongly recommended that the prescribing practitioner or authorised individual consult the regulations and guidelines of each state and territory where they intend to conduct cosmetic procedures.

³ Therapeutic Goods Administration (www.tga.gov.au)

2.2 Video Supervision

As the name suggests, video supervision (Telehealth) is the delivery of related supervision activities that use any form of video technology, as an alternative to in-person face-to-face consultations. In respect of Telehealth, medical practitioners should follow existing guidelines. For example, the seminal text *Good Medical Practice: A code of conduct for doctors in Australia* is equally valid for video supervisions/consultations as it is for traditional face-to-face consultations.⁴

There is no one preferred software for video supervision, but it must be in accordance with each professions' Code of Conduct or equivalent including expectations about confidentiality and privacy, informed consent, good care, communication, health records and culturally safe practice.⁵

A prescribing practitioner or authorised individual can only conduct video consultation, supervision and S4 medications and device prescribing in the jurisdiction in which they are registered. The prescribing practitioner or authorised individual must make appropriate notes concerning the patient, including history, diagnosis and treatment plan, including dosage and location of treatment. The prescribing practitioner or authorised individual must not utilise Medicare/Telehealth rebatable codes for any cosmetic consultation.

The video technology requirements must be of a high standard, with clear audio, without time lag, and appropriate for the visual consultation and the supervision. It must not interfere with a prescribing practitioner or authorised individual's ability to conduct consultations/supervision to a high standard.

If technical difficulties are encountered, the prescribing practitioner or authorised individual should delay the consultation/supervision until the technical difficulties are overcome. The consultation is to be documented. For guidance consult: *Telehealth Guidance for Practitioners and Guidelines for Technology-based Patient Consultations*.⁶

3. Training requirements

3.1 Supervisor (Prescribing practitioner or authorised individual):

- (a) A minimum of one year of aesthetic medicine experience gained within Australia;
- (b) Be a current financial member of ACAM or a current ACAM Fellow;
- (c) Completion of an infection control course;⁷

⁴ Medical Board of Australia *Good Medical Practice: A code of conduct for doctors in Australia* <https://www.medicalboard.gov.au/codes-guidelines-policies/code-of-conduct.aspx>

⁵ Medical Board of Australia *Good Medical Practice: A code of conduct for doctors in Australia* <https://www.medicalboard.gov.au/codes-guidelines-policies/code-of-conduct.aspx>

⁶ Medical Board of Australia <https://www.medicalboard.gov.au/Codes-Guidelines-Policies/Technology-based-consultation-guidelines.aspx>

⁷ ACAM recommends Australia Commission on Safety and Quality in Health Care Courses <https://www.safetyandquality.gov.au/> Downloadable workbook <https://www.safetyandquality.gov.au/sites/default/files/2019->

- (d) Prescribing practitioner or authorised individual should be aware of and comply with the requirements of their state(s) or territory(s) drug and poisons (or equivalent) legislation and regulations for Schedule 4 (S4) cosmetic injectables and devices. Including but not limited to requirements relating to permits, supply, storage, medical notes and transport;
- (e) The supervising prescribing practitioner or authorised individual is required to have demonstrated appropriate training, expertise, and experience to perform the procedure, manage all routine aspects of care including suboptimal outcomes and complications;
- (f) Prescribing practitioner or authorised individual has the responsibility to be familiar with relevant legislation, regulations and standards of the jurisdiction in relation to facilities where the procedure will be performed;
- (g) Prescribing practitioner or authorised individual has the responsibility to be aware of the drugs and poisons (or equivalent) regulations, guidelines and legislation for the state(s) or territory(s) where they provide services;
- (h) The responsibility for procedures conducted remains with nominated supervisor who is required to have appropriate medical indemnity insurance to cover the procedures they are offering and supervising; and
- (i) The prescribing practitioner or authorised individual who is responsible for the patient's treatment should be readily identifiable and contactable by the patient, who in the event of an adverse or suboptimal outcome, is able to contact the prescribing practitioner or authorised individual for care and advice.

3.2 Supervised Delegated Injector

- (a) Should have appropriate demonstrated, training experience and capability to carry out all the injections delegated to him/her;
- (b) Had training in the particular procedure/s conducted, pre- and post- care of the procedure conducted, management of immediate and delayed complications, and ensure appropriate medical notes are recorded and retained for the MBA mandated period of seven years;
- (c) Have successful certification regarding emergency treatment (CPR/BLS/ALS) and is competent to manage emergencies such as anaphylactic reactions to drugs;
- (d) Have the necessary CPR/BSL/ALS drugs and equipment in good working order, at the location of the procedure;
- (e) Have training and certification for the administration of each individual medication or device that is used;
- (f) Have completed training in the area infection control and have knowledge of safety and sterility protocols relevant to injections; and

- (g) Supervised delegated injectors administering the prescribed S4 medications are required to be familiar and comply with relevant state(s) and territory(s) drugs and poisons legislation, guidelines and regulations regarding using, obtaining, selling, storing, prescribing, administering, recording of medical notes and their storage and supplying of scheduled medicines.

The prescribing practitioner or authorised individual must satisfy themselves that:

- (a) The supervised delegated injector holds registration with the appropriate registration board and the activities they will undertake are within their scope of practice as defined by their registration board;
- (b) The supervised delegated injector has the required and appropriate indemnity insurance for the procedures they will undertake; and
- (c) The supervised delegated injector holds current certification and training evidence for the points listed in 3.2 of this protocol. Training and certification is not limited to the items listed in 3.2 of this protocol.

4. Prescribing practitioner or authorised individual obligations and responsibilities:

- (a) The prescribing practitioner or authorised individual is responsible for ensuring the supervised delegated injector administering the prescribing practitioner or authorised individual's prescribed S4 medications or device, has appropriate qualifications, training and experience;
- (b) The prescribing practitioner or authorised individual retains responsibility for the patient who receives the treatment they have prescribed.

4.1 Professional responsibilities

Prescribing practitioners or authorised individual's must practise in accordance with the national board's regulatory standards, codes and guidelines, specifically ensuring they will: act in accordance with the standards set out in the Code of Conduct or equivalent document including, but not limited to: expectations about confidentiality and privacy, informed consent, good care, communication, health records and culturally safe practice.⁸

Prescribing practitioners or authorised individuals must be aware of, and comply with: state(s) and territory(s) legislative requirements including, but not limited to, authorities that regulate health records and digital image privacy legislation and/or any other relevant privacy requirement.

⁸ Medical Board of Australia *Good Medical Practice: A code of conduct for doctors in Australia*
<https://www.medicalboard.gov.au/codes-guidelines-policies/code-of-conduct.aspx>

Prescribing practitioners or authorised individuals must only supervise within their scope of practice.

4.2 Registration responsibilities⁹

- a) Prescribing practitioners or authorised individuals must have current medical registration with MBA with good standing (i.e. no disciplinary actions);
- b) Prescribing practitioners or authorised individuals' registration should not be subject to conditions or undertakings that would impact on their ability to effectively supervise the supervisee.

4.3 Professional indemnity responsibilities

Prescribing practitioners or authorised individuals are required to have appropriate professional indemnity insurance (PII) arrangements in place for all aspects of their practice, including but not limited to disclosure of:

- (a) Supervision of supervised delegated injectors off-site, detailing the use of videoconferencing technology arrangements;
- (b) The nature of the supervised procedure and training of the supervised delegated injector to conducting the procedure;
- (c) The total value of cosmetic billings supervised;¹⁰
- (d) The type of S4 medications or devices prescribed in practice.

4.4 Patient safety responsibilities

- (a) Consent
 - (i) The prescribing practitioners or authorised individual must be familiar with the relevant legislation of their jurisdiction in relation to restrictions on cosmetic procedures for patients under the age of 18;
 - (ii) The prescribing practitioners or authorised individual must assess and be satisfied by the patient's capacity to consent to the procedure;
 - (iii) The prescribing practitioners or authorised individual should be satisfied that the patient has made an informed consent.
- (b) Identification
 - (i) The prescribing practitioners or authorised individual should be satisfied with the identification of the patients by a 3-point ID check. Face match with the photo ID and their name and DOB;
 - (ii) The prescribing practitioners or authorised individual should make their own identity clear to the patient. Stating their name, role and

⁹ aafp.org/dam/AAFP/documents/news/NP_Info_GlinesNP-060710.pdf

¹⁰ Prescribing practitioners or authorised individuals should clarify the definition of billings in their indemnity policies, it is generally considered the total cost amount of the procedure conducted, not, for example the total payment for scripts written.

make clear to the patient their qualifications and accreditations to the patient if asked. The prescribing practitioners or authorised individual should not make any false claims.

- (c) The prescribing practitioners or authorised individual should ensure written instructions / protocols on the premises for supervised delegated injector in relation to:
 - (i) Treatment plan;
 - (ii) Complications;
 - (iii) Infectious control;
 - (iv) Emergencies;
 - (v) Patient satisfaction.

4.5 Documentation responsibilities

The prescribing practitioners or authorised individual must document clearly:

- (a) Patient's clinical record including allergies, medications and previous cosmetic medicine treatments;
- (b) Full name of the injector and location of administration;
- (c) History and examination;
- (d) Informed consent and their assessment of suitability of consent;
- (e) Treatment and management plan;
- (f) Prescribed medication:
 - (i) Indication of treatment;
 - (ii) Dosage and location of administration;
 - (iii) Methodology of administration (i.e. direct needle, canula etc.)
 - (iv) Type of medication or device, recording brand, lot number and expiry date, dilution and date of dilution if applicable;
 - (v) Premises of administration.
- (g) If there were any immediate adverse events evident (i.e. bruising);
- (h) Date of planned review;
- (i) Documentation should note down the written information provided to the patient including but not limited to:
 - (i) Post procedure care;
 - (ii) Patient education for complications;
 - (iii) Instructions and point of contact for concerns, complications and emergencies.

5. Premises for Injection

S4 medications and devices should be administered in an appropriate setting, with adequate equipment and protocols in place.

The premises must be properly equipped for emergency treatment and life support, including potentially life threatening anaphylactic reactions.

The premises must provide facilities and procedures for infection control principles, safe injection practices and aseptic technique. Premises, such as homes or non-medical rooms without the necessary emergency equipment, and appropriate infection control environment; are not recommended by ACAM. The premises must have any local council or regulatory permits in place to offer medical services.

6. Protocols and procedures

1. *Initial consultation*

Initial consultation should be with the prescribing practitioners or authorised individual. The patient is assessed by the prescribing practitioners or authorised individual *as per* a holistic medical consultation, including but not limited to a clinical history, a record of the patient's current and past medications, allergies, and previous cosmetic treatments and cosmetic medical interventions.

A plan of management must include a discussion of potential side effects and complications of any procedures, devices or drugs considered for treatment. The patient must give informed consent before undergoing any procedures. The patient must be lucid, not intoxicated or under the influence of any substance at the time of providing consent or undertaking a procedure.

2. *Administration of S4 medications and devices*

When the prescribing practitioners or authorised individual has determined a plan of management, an appropriately trained and qualified supervised delegated injector (see below) may administer S4 medications or devices according to the prescribing practitioners or authorised individual written instructions.

The prescribing practitioners or authorised individual prescription should incorporate a precise script (e.g., the number of units of botulinum toxin) for a specific treatment area in which the medication is to be used. The prescribing practitioners or authorised individual should be immediately contactable to deal with any problems that may occur related to the administration of the drug.

3. *Prescribing practitioners or authorised individual planned review of patient*

It is recommended that the prescribing practitioner or authorised individual review the patient in the following circumstances:

3.1: When a new S4 medication or device is scripted;

3.2: When an adverse event or unexpected outcome is experienced by the patient; and

3.3: When the regulated standing order period has elapsed.¹¹

The supervised delegated injector may only carry out the written instructions of the prescribing practitioners or authorised individual. The supervised delegated injector should record in the patient's notes how and where the S4 medications or device(s) was administered, the dose, dilution date if applicable and dilution substance. It is recommended that supervised delegated injector do not inject permanent fillers or devices.

7. References

1. AAFP aafp.org/dam/AAFP/documents/news/NP_Info_GlinesNP-060710.pdf
2. Medical Board of Australia *Good Medical Practice: A code of conduct for doctors in Australia* <https://www.medicalboard.gov.au/codes-guidelines-policies/code-of-conduct.aspx>
3. Medical Board of Australia *Guidelines For Registered Medical Practitioners Who Perform Cosmetic Medical And Surgical Procedures* <https://www.medicalboard.gov.au/Codes-Guidelines-Policies/Cosmetic-medical-and-surgical-procedures-guidelines.aspx>
4. Medical Board of Australia *Guidelines For Technology-based Patient Consultations* <https://www.medicalboard.gov.au/Codes-Guidelines-Policies/Technology-based-consultation-guidelines.aspx>
5. Poisons and Therapeutic Goods Amendment (Cosmetic Use) Regulation 2021 <https://www.health.nsw.gov.au/patients/cosmetic/Pages/amendments.aspx>

¹¹ Prescribing practitioners or authorised individuals are responsible for consulting the regulations, legislation and guidelines for each state(s) or territory(s) in which the prescribing practitioners or authorised individual may find themselves providing treatments, as they vary between jurisdictions.