

**Submission
No 16**

COSMETIC HEALTH SERVICE COMPLAINTS IN NEW SOUTH WALES

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SUBMISSION

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Inquiry into the Cosmetic Health Service Complaints

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Introduction and Background – Co-regulatory environment

The National Registration and Accreditation Scheme (the National Scheme) for health practitioners in Australia commenced on 1 July 2010, under the *Health Practitioner Regulation National Law Act* (the National Law) as in force in each state and territory.

In New South Wales (NSW), under the National Law, the Nursing and Midwifery Board of Australia (NMBA) is responsible for the registration of the nursing and midwifery professions and is supported in this role by the Australian Health Practitioner Regulation Agency (AHPRA). The NMBA has approved registration standards, codes, guidelines, and standards for practice that together form a Professional Practice Framework (PPF). The PPF determines the requirements and expectations which guide the professional practice of nurses and midwives in Australia. In March 2018, the NMBA issued a Position Statement for nurses about cosmetic procedures.

The Nursing and Midwifery Council of New South Wales (NSW) is a co-regulator with the Health Care Complaints Commission, for the management of complaints about registered nurses and midwives who have a principal place of practice in NSW. The number of complaints received by the Council has been increasing since 2010. The Council currently receives approximately 600+ complaints per year. A small proportion of those are related to the cosmetic industry ie 79 complaints have been received about 64 nurses from July 2010 to December 2017. Although the number of complaints related to the cosmetic industry each year is small (2-28), there appears to be an increasing trend since 2013-14.

Under the Health Care Complaints Act, the HCCC conduct an initial assessment of a complaint and then consults with the Council to determine whether the matter is serious (at the level of unsatisfactory professional conduct or professional misconduct) and requires referral to the HCCC for an independent investigation. The Council can, on receipt of any information which indicates concerns about safety of the public, consider whether it is necessary to take immediate action (ie impose conditions or suspension) for the safety of the public under the National Law.

The matter is referred to the Council at consultation, if it is considered to be a performance, health, or minor conduct issue which is suitable for remediation through one, or more, of the Council's processes. In the performance stream these include referral to professional counselling, performance interview, performance assessment and if necessary referral to a Performance Review Panel. A panel will consider whether the registered nurse has demonstrated unsatisfactory professional performance which requires conditions on registration. The panel can, for example, impose conditions requiring supervision, education and further assessment, to ensure practice has improved and is within professional standards. The Council may also order an inspection of premises by an Authorised Person. To ensure that appropriate health standards and legislative requirements within the facility are being maintained such as infection control, record keeping, maintenance and cleaning of equipment, and appropriate policies and procedures are in place.

The Council may also manage cases in the health stream using processes such as health assessment and referral to an Impaired Registrants Panel to consider whether a practitioner may have an impairment. The panel may recommend to the Council and seek agreement from a practitioner to suspend or impose conditions on registration. The Council can impose voluntary conditions if a panel has recommended, and the practitioner has agreed, to the conditions or suspension.

The Council may only use these processes while the practitioner continues to be registered under the National Law. The HCCC may deal with unregistered and unregulated individuals working in health services.

The Code of Conduct for Unregistered Health Practitioner¹ provides guidance for unregistered health practitioners about the standards expect of them. The HCCC can also take action when there has been a serious breach of the code which impacts on public safety and place an interim prohibition order.

The HCCC Code defines a 'health practitioner' as a natural person who provides a health service whether or not the person is registered under the National Law. 'Health Service' is also defined as the following public and private services:

- a) Medical, hospital, nursing and midwifery services
- b) Dental services
- c) Mental health services
- d) Pharmaceutical services
- e) Health education services
- f) Community health services
- g) Health education services
- h) Welfare services necessary to implement any services related to paragraphs a-g
- i) Services in connection to Aboriginal and Torres Strait Islander practices and medical radiation practices
- j) Chinese medicine, chiropractic, occupational therapy, optometry, osteopathy, physiotherapy podiatry and psychology services
- k) Optical dispensing, dietitian, massage therapy, naturopathy, acupuncture, speech therapy, audiology, and audiometry services
- l) Services provided in other alternative health care fields
- m) Forensic pathology services
- n) A service proscribed by the regulations as a health service for the purposes of the Health Care Complaints Act

It does not appear that the cosmetic and beauty industry clearly fits within the health services identified in the Code and therefore whether individuals in the cosmetic industry can be defined as an unregistered 'health practitioner'. Furthermore, many of the treatments offered within the beauty and cosmetic industry may, in some instances, not be meeting the items within the code

- Must not accept financial inducements or gifts for referring clients to other health practitioners or to suppliers of medications or therapeutic goods.
- Must not diagnose or treat an illness or condition without adequate clinical basis
- Must not engage in any form of misinformation or misrepresentation in relation to the products or services provided
- Must not make claims either directly or in advertising and or promotional material about the efficacy of treatment or services provided if those claims cannot be substantiated
- Must comply with the relevant privacy laws

While the Council can work with the HCCC in relation to complaints about registered health professionals, it cannot deal with any matter where the practitioner is unregistered. The National Board is responsible for prosecuting matters in relation to the inappropriate use of a protected title but otherwise not able to deal with unregistered health providers.

¹ <http://www.hccc.nsw.gov.au/Information/Information-for-Unregistered-Practitioners-> accessed 4 April 2018

The HCCC, may take interim action for a period of 8 weeks and investigate the unregistered 'Health worker'. Following an investigation, the HCCC may place a prohibition order on practice. The Council has concerns the HCCC may not have the range of powers to deal with the range of different complaints that are received about people who provide cosmetic services. The Council is also concerned that workers from the cosmetic industry, may not meet the definition of 'health practitioner' as defined in the Code.

The Cosmetic and Beauty industry

A wider range and number of people are spending more money on their appearance, and the cosmetic and beauty industry has grown accordingly. Cosmetic procedures are surgical operations and other procedures that revise or change the appearance, colour, texture, structure, or position of normal bodily features with the dominant purpose of achieving what the patient or client perceives to be a more desirable appearance or to boost the patient's self-esteem². Although the outcomes of research in relation to this is variable.

The range of services provided by the industry has also grown from relatively non-invasive topical treatments such as, brightening, tightening, detoxing, scrubs, wraps, hydro-microdermabrasion and endermology to those techniques and treatments where if wrongly applied may cause significant harm eg Light therapy, intense pulsed light (IPL), and Laser treatments. Increasingly injectables are being used and include, for example, Botox and fillers. Day surgery and anaesthetics may be provided for simple and sometimes even more complex surgical procedures in some clinics.

The Medical Board of Australia provide the following description of the range of clinical procedures that may be carried out by medical practitioners in the industry³.

BOX 1: Extract – Guidelines for Registered Medical Practitioners who Perform Cosmetic Medical and Surgical Procedures

Minor (non-surgical) cosmetic medical procedures do not involve cutting beneath the skin but may involve piercing the skin. Examples include: non-surgical cosmetic varicose vein treatment, laser skin treatments, use of CO₂ lasers to cut the skin, mole removal for purposes of appearance, laser hair removal, dermabrasion, chemical peels, injections, micro sclerotherapy, and hair replacement therapy.

Major cosmetic medical and surgical procedures ('cosmetic surgery') involve cutting beneath the skin. Examples include: breast augmentation, breast reduction, rhinoplasty, surgical face lifts and liposuction.

There are a range of possible harms and different levels of risks that may occur from these procedures, including minor allergies to anaphylaxis, skin redness and itching, lumps, asymmetry, skin necrosis and ulceration, changes in skin colour, scarring, pain, burns,

² Guidelines For Registered Medical Practitioners Who Perform Cosmetic Medical And Surgical Procedures - <http://www.nursingmidwiferyboard.gov.au/Codes-Guidelines-Statements/Position-Statements/nurses-and-cosmetic-procedures> - accessed 25 March 2018

³ Ibid

infections, brushing, partial facial paralysis, blindness, muscle weakness, difficulty swallowing, bleeding. There have also been reports of death during minor operations conducted in cosmetic clinics.

The service provider may be an unregulated worker who has certificate III or certificate IV qualifications (in the case of the non-invasive topical treatments) or may be regulated practitioners such as registered nurses or medical practitioners (as relevant) who are authorised to prescribe or administer injections or conduct surgery when required. It is difficult to estimate the number of nurses currently working within the Cosmetic Industry, as this data is not collected as part of workforce data collection at the time of annual registration. There do however appear to be many job adverts for beauty therapists and cosmetic nurses in NSW, listed over the last 30 days on IT platforms.

Nursing scope of practice in the Cosmetic Industry

In cosmetic nursing practice, the clinical scope of practice for nurses falls into a few primary domains: assessing the client, ensuring appropriate information is provided to clients, obtaining informed consent, and planning and delivering appropriate care. This may include, infection control and administering medication such as muscle relaxants and dermal fillers only when an authorized person appropriately prescribes these. Nurses may also assist medical practitioners during minor or more complex cosmetic surgery. They are required to document treatment in a timely fashion and monitor, follow-up and evaluate outcomes. Increasingly nurses are operating their own clinics with cooperative arrangements with medical practitioners.

Nurses may perform laser, IPL, and other related therapies, as well as recommend and apply cosmeceuticals. A registered nurse may also assist a medical practitioner / surgeon / anaesthetist when necessary during surgical procedures. They may be required to appropriately store any drugs or poisons⁴ used in their procedures and ensure that relevant infection control mechanisms⁵ are in place for the protection of clients and themselves.

The activities undertaken by a nurse and the level of autonomy and supervision required by the nurse will depend on: registration status; the division of nursing in which a nurse is registered; whether they have endorsement as a nurse practitioner and scope of practice. This will be explained in more detail later in this submission.

The NMBA has developed principles for decision making about scope of practice and level of supervision. This includes

- Ensuring that the practitioner has lawful authority and professional consensus and evidence to support their practice
- Risk management and risk minimization procedures are in place
- Organisational support developing policy and planning to support the activity
- Preparation and experience ie the practitioner has the knowledge, skills, and confidence to undertake the activity
- Readiness to accept delegation and accountability only when that is appropriate
- Appropriate level of supervision and oversight

⁴ Poisons and Therapeutic Goods Act 1966

⁵ Health Practitioner Regulation (New South Wales) Regulation 2016

- Evaluation of outcomes

These principles apply to RNs, ENs and nurse practitioners

All registered nurses, enrolled nurses and nurse practitioners must know and comply with the requirements of their state or territory drugs and poisons (or equivalent) legislation for schedule 4 (prescription only) cosmetic injectables. For example, requirements relating to permits, supply, storage, and transport.

Relevant Laws and professional guidance documents for nurses working in the cosmetic industry

1. Relevant laws include but are not limited to:

- Health Practitioner Regulation National Law
- Health Practitioner Regulation (New South Wales) Regulation 2016
- Poisons and Therapeutic Goods Act 1966 and its regulations

Nurses working in the area of cosmetic procedures are required to know and comply with relevant state / territory drugs and poisons legislation and ensure they are compliant with local policies and protocols that are consistent with the law.

2. NMBA documents

The Nursing and Midwifery Board of Australia Position statement⁶ acknowledges that nurses obtain and develop qualifications and expertise throughout the course of their careers.

It is expected that nurses practise within scope of practice ie they are educated and competent in the specific area of practice in which they have chosen to work and comply with the NMBA standards.

These standards include but are not limited to:

- Relevant Registration Standards
- Registered Nurse Standards of Practice⁷
- Enrolled Nurse Standards for Practice
- Nurse Practitioner Standards for Practice

⁶ Position Statement on Nurse and Cosmetic Procedures, NMBA March 2018
<http://www.nursingmidwiferyboard.gov.au/Codes-Guidelines-Statements/Position-Statements/nurses-and-cosmetic-procedures> - accessed 25 March 2018

⁷ <http://www.nursingmidwiferyboard.gov.au/Codes-Guidelines-Statements/Professional-standards.aspx> - accessed 25 March 2018

Box 2: RELEVANT LAWS

HEALTH PRACTITIONER REGULATION NATIONAL LAW 86

94 Endorsement for scheduled medicines

- (1) A National Board may, in accordance with an approval given by the Ministerial Council under section 14, endorse the registration of a registered health practitioner registered by the Board as being qualified to administer, obtain, possess, prescribe, sell, supply, or use a scheduled medicine or class of scheduled medicines if the practitioner—
- (a) holds either of the following qualifications relevant to the endorsement—
 - (i) an approved qualification;
 - (ii) another qualification that, in the Board's opinion, is substantially equivalent to, or based on similar competencies to, an approved qualification; and
 - (b) complies with any approved registration standard relevant to the endorsement.

Note.

The endorsement of a health practitioner's registration under this section indicates the practitioner is qualified to administer, obtain, possess, prescribe, sell, supply, or use the scheduled medicine or class of medicines specified in the endorsement but does not authorise the practitioner to do so. The authorisation of a health practitioner to administer, obtain, possess, prescribe, sell, supply, or use scheduled medicines in a participating jurisdiction will be provided for by or under another Act of that jurisdiction. (see section 17A Poisons and Therapeutic goods Act 1966)

Health practitioners registered in certain health professions will be authorised to administer, obtain, possess, prescribe, sell, supply, or use scheduled medicines by or under an Act of a participating jurisdiction without the need for the health practitioners to hold an endorsement under this Law.

- (2) An endorsement under subsection (1) must state—
- (a) the scheduled medicine or class of scheduled medicines to which the endorsement relates; and
 - (b) whether the registered health practitioner is qualified to administer, obtain, possess, prescribe, sell, supply, or use the scheduled medicine or class of scheduled medicines; and
 - (c) if the endorsement is for a limited period, the date the endorsement expires.

POISONS AND THERAPEUTIC GOODS ACT 1966 - SECT 17A

17A Authorisation of possession, use, supply or prescription of substances by nurses and midwives

- (1) A nurse is authorised to possess, use, supply or prescribe a poison, restricted substance or drug of addiction for the purposes of the practice of nursing, if:
- (a) the nurse's registration has an endorsement of a kind referred to in section 94 of the Health Practitioner Regulation National Law (NSW) that qualifies the nurse to possess, use, supply or prescribe that poison, restricted substance or drug of addiction, or
 - (b) the nurse is a nurse practitioner who is authorised in writing by the Secretary to possess, use, supply or prescribe that poison, restricted substance or drug of addiction.

Midwives have similar provisions

- Code of Conduct for Nurses²
- Guidelines for advertising regulated health services⁸, and
- National framework for the development of decision making tools in nursing and midwifery practice⁹
- Safety and Quality framework for Nurse Practitioner (when relevant)

3. Other documents

NSW Nurse Practitioner Formulary approved by the Director General Ministry of Health. It should be noted that Privately Practising Nurse Practitioners and those working in non-government or private facilities are required to get approval for their formulary from the Director General or their delegate (Chief Nursing and Midwifery Officer of NSW)

The NMBA also specifies that nurses working within the cosmetic industry should be aware of Medical Board of Australia's (MBA) Guidelines for registered medical practitioners who perform cosmetic medical and surgical procedures.

Type of registered nurses in the cosmetic industry

There are many unregulated individuals who work and conduct business within the cosmetic industry. There is a high likelihood that clients may be unaware of the qualifications and experience of the person providing a service to them or whether the person is regulated. They may also not be aware of their rights should a service which is provided to them causes harm. This process may differ depending on the person who is providing them with the service.

The Council is unable to comment on the practice of unregulated workers in the cosmetic industry. It is a concern that unregulated workers in the cosmetic industry may be conducting invasive procedures without adequate qualifications or skills or maybe using the title of nurse in communications with the general public.

A description of the three different types of nurses who are registered or endorsed under the Australian National Regulation and Accreditation Scheme their level of education, supervision and authority is provided below: ie

- enrolled nurses – division 2 (EN);
- registered nurses – division 2 (RN)
- nurse Practitioner (NP)

1. Enrolled Nurse – Division 2

Enrolled nurses – division 2 (EN) undertake 12-18 months training, including 120 clinical placement hours to achieve a Diploma of Nursing. ENs can administer appropriately prescribed medications under the supervision of a registered nurse if they have the knowledge and skills to do so. The exceptions to this is if there is a notation or condition on the register not to administer medications on the Health Professional Register held by AHPRA and available on its website.

⁸ <http://www.nursingmidwiferyboard.gov.au/Codes-Guidelines-Statements/Codes-Guidelines.aspx> - accessed 25 March 2018

⁹ <http://www.nursingmidwiferyboard.gov.au/Codes-Guidelines-Statements/Frameworks.aspx> - accessed 25 March 2018

The EN works with a registered nurse (division 1) (RN) or a nurse practitioner (NP) as part of the health care team and demonstrates competence in the provision of care. Core practice generally requires the EN to work under the direct or indirect supervision of an RN/NP¹⁰. At all times, the EN retains responsibility for their actions and remains accountable in providing delegated nursing care. To ensure patient safety, an EN should have a named RN or NP accessible in all contexts of care for support and guidance.

The level of supervision required by an EN will depend on the acuity and complexity of the tasks the EN is undertaking; and the support needs of the EN in relation to qualifications, experience, and competence.

Indirect supervision is a model of clinical supervision where the RN “works in the same facility or organisation as the supervised”¹¹ EN, “but does not constantly observe their activities”¹². The RN “must be available for reasonable access”. If direct supervision is necessary, there should be an RN who “is actually present and personally observes, works with, guides and directs” the EN who is being supervised.¹³

2. Registered nurse - Division 1

Registered Nurses (division 1) may also be employed within the cosmetic industry. Programs of study leading to registration as a nurse (division 1) in Australia must be at Bachelor or Masters degree level and include a minimum of 800 hours workplace experience.

Specific training in relation to cosmetic nursing is not specified in the Accreditation standards approved by the NMBA, however all ENs, RNs and NPs are expected to have relevant training to practise in the area of nursing in which they are working.

Like ENs, RNs in cosmetic practice in NSW may administer medication such as topical anaesthetics, dermal fillers and muscle relaxants if prescribed by an authorized person as specified in the Poisons and Therapeutic Goods Act 1966. In all states and territories, they are able to independently operate all classes of laser with the exception Queensland where when using a Class 4 laser must do so under the supervision of a doctor or in Western Australia where Class 4 is restricted to a medical practitioner or a nurse practitioner.¹⁴

3. Nurse practitioner

A nurse practitioner is a registered nurse who meets the following criteria and is so endorsed by the National Board

- Current registration as a registered nurse with no restrictions
- Equivalent of three years' full-time experience (5,000 hours) at the clinical advanced nursing practice level, within the past six years

¹⁰ Standards for practice for the Enrolled nurse - <http://www.nursingmidwiferyboard.gov.au/Codes-Guidelines-Statements/Professional-standards/enrolled-nurse-standards-for-practice.aspx> - accessed 25 March 2018

¹¹ Standards for practice for the Enrolled nurse - <http://www.nursingmidwiferyboard.gov.au/Codes-Guidelines-Statements/Professional-standards/enrolled-nurse-standards-for-practice.aspx> - accessed 25 March 2018

¹² Ibid

¹³ Ibid

¹⁴ <http://aestheticmedicalpractitioner.com.au/features/cosmetic-practice/clinical-scope-practice-nurses/> Accessed 25 March 2018

- Successful completion of: an NMBA-approved program of study leading to endorsement as a nurse practitioner, usually at a postgraduate masters level practitioner, or substantially similar program as determined by the NMBA.
- Compliance with the NMBA's *Nurse practitioner standards for practice*.
- Meets the standards for registration including recency and ongoing Continuing professional development

Scope of practice for the nurse practitioner:

While the area of practice is not notated on a NP endorsement on the register, it is nevertheless an expectation that the NP will only practice in that specific area in which they have the training and experience, and in accordance with the Safety and Quality Framework (SQF) included in the *Guidelines on endorsement as a nurse practitioner*¹⁵. The scope of practice for an NP may change over time. If an NP decides to expand or change their scope of practice to meet the needs of their client group, then the NP is expected to complete further postgraduate education and skill development to meet those needs.

Endorsement allows the NP to assess using diagnostic capability, initiate diagnostic investigations, prescribe medications, and make referrals. NPs work at an advanced practice level and are educated and authorised to function autonomously and collaboratively in an extended clinical role.

The NMBA Safety & Quality Framework outlines the professional standards (registration and practice), codes, legislative requirements and collaborative arrangements within which NPs must practice, ensuring ongoing competence and safe practice

NPs are authorised by law to prescribe independently. This authority is based on educational preparation that develops an in-depth knowledge of pharmacology and pharmacokinetics related to the relevant practice specialty. As independent prescribers, NPs are responsible and accountable for the assessment of patients with both undiagnosed and diagnosed conditions and for decisions regarding appropriate clinical management including prescribing.

Prescribing decisions for NPs in NSW are no longer required by law to be tied to 'approved clinical practice guidelines' of NPs working in public hospital facilities. The Scope of Practice defines the 'practice of nursing' for which a NP is authorised to possess, use, supply or prescribe a poison, restricted substance, or drug of addiction under the Poisons and Therapeutics Goods Act 1966¹⁶.

Approved formulary in NSW

The Director-General, in accordance with s17a of the Poisons and Therapeutic Goods Act 1966, has approved a list of poisons, restricted substances and drugs of addiction as the NSW Nurse Practitioner Formulary. This list reflects the national formulary approved for Nurse Practitioner prescribing listed on the Pharmaceutical Benefits Schedule (PBS) but does not infer the ability

¹⁵ Standards for endorsement as a nurse practitioner and Safety and quality guidelines for a nurse practitioner - <http://www.nursingmidwiferyboard.gov.au/Registration-Standards/Endorsement-as-a-nurse-practitioner.aspx> - accessed 25 March 2018

¹⁶ Nurse Practitioners in NSW Guideline GUIDELINES (GL2012_004) Issue date: May 2012 Page 31). <http://www.health.nsw.gov.au/nursing/practice/Pages/nurse-practitioner.aspx> - accessed 24 March 2018

to prescribe these as PBS subsidised items (Guideline 10.6)¹⁷. The NSW Nurse Practitioner Formulary is updated from time to time, as required, to include other poisons, restricted substances, and drugs of addiction to reflect expanding scopes of practice (Guideline section 10.1)¹⁸.

Nurse Practitioners (under s 94 of the Health Practitioner Regulation National law) are qualified to administer, obtain, possess, prescribe, supply, medications when endorsed by the NMBA and authorised to do so under the Poisons and Therapeutics Goods Act 1966 (NSW) and in accordance with section s17A.

Private and non-government organizations

The NSW Nurse Practitioner Formulary does **not** apply to Nurse Practitioners in private practice or those employed by non-government organisations (NGOs). Under s21 of the Health Administration Act, the responsibility for authorising a Nurse Practitioner to prescribe, possess, use, and supply a poison, restricted substance or drug of addiction is also delegated by the Director-General to the Chief Nursing and Midwifery Officer (CNMO) NSW. These NPs are required to submit a separate formulary appropriate to their scope of practice to the CNMO for approval. Requirements for submitting a formulary for approval can be found on the Nursing and Midwifery Office (Ministry of Health) website¹⁹. If the NP has a formulary approved which includes drugs related to the Cosmetic industry they are an Approved Prescriber for the administration of those drugs.

Common drugs injected during cosmetic procedures.

Many medical products used in cosmetic procedures, such as botulinum toxin (Botox), collagen, hyaluronic acid (Hylaform, Restylane), other non-permanent fillers and lignocaine, are classified in the Poisons Schedule as S4 drugs. Their use is controlled in NSW by the Poisons and Therapeutic Goods Act (1966) to protect the health and welfare of the community.

The drugs used in the cosmetic industry are, generally, not found on the NSW Nurse Practitioner Formulary approved by the Director-General. Lignocaine appears to be the only drug currently specified for use by the NSW Nurse Practitioner Formulary. NPs working in both public and facilities and in private organizations are unable to prescribe these drugs unless they apply to the Director-General or delegate to approve the addition of these drugs to their approved formulary.

NPs, as well as RNs and ENs, can also administer these medications on receipt of a valid prescription from a medical practitioner or dentist if they have the knowledge and skills to do so.²⁰

¹⁷ Ibid

¹⁸ Nurse Practitioners in NSW Guideline GUIDELINES (GL2012_004) Issue date: May 2012 Page 31).

<http://www.health.nsw.gov.au/nursing/practice/Pages/nurse-practitioner.aspx> - accessed 24 March 2018

¹⁹ www.health.nsw.gov.au/about/ministry/Pages/namo.aspx

²⁰ Poisons and Therapeutic Goods Act 1966

Prescribing and administering schedule 4 (prescription only) cosmetic injectables^{21 22}

If the NP is an Authorised Prescriber for cosmetic medications, they must know and comply with the requirements of their state or territory drugs and poisons (or equivalent) legislation for schedule 4 (prescription only) cosmetic injectables. For example, requirements relating to permits, supply, storage, and transport.

Authorised prescribers must not prescribe schedule 4 (prescription only) cosmetic injectables unless they have had a consultation with the patient, either in person or by video. Remote prescribing of cosmetic injectables by phone or email (or equivalent) is not appropriate.

If the 'prescription only' cosmetic injectable is administered by another registered health practitioner, who is not an authorised prescriber (such as a RN, EN, or NP), the authorized prescriber must be contactable and able to respond if required.

Nurse Practitioner prescribing under Continuing Treatment Only and Shared Care Models²³

Continuing Treatment Order and shared care prescribing models are a compulsory requirement for NPs prescribing some PBS subsidised medications. NPs may also considered using continuing treatment orders and shared care models of prescribing in situations where such models are not compulsory. 'Continuing treatment only' is where the patient treatment and prescription of a medicine has been initiated by a medical practitioner, but prescribing is continued by a Nurse Practitioner. 'Shared care' is where care is shared between a Nurse Practitioner and a medical practitioner in a formalised arrangement with an agreed treatment plan, in a patient centred model of care.²⁴

NPs may also considered using continuing treatment orders and shared care models for prescribing in situations where such models are not compulsory. When NPs use these prescribing models, they may only do so if they are competent and authorised to initiate and prescribe these drugs independently.

Complaints made about nurses who work in the cosmetic industry

Anyone may make a complaint to the Council about the health, performance of conduct of nurses. Under the Health Practitioner Regulation National Law, registered health practitioners, employers and education providers must make a mandatory notification if a registered nurse's practice meets the defined criteria requiring mandatory notification. These criteria relate to putting the public at risk of harm due to a significant departure from expected standards; impairment which may place the public at substantial risk of harm; sexual misconduct in the practice of the profession; and practising the profession while intoxicated with drugs or alcohol.

There has been a trend of increasing numbers of complaints received by the Nursing and Midwifery Council since national regulation commenced in July, 2010. The number of

²¹ Poisons and Therapeutic Goods Act 1966

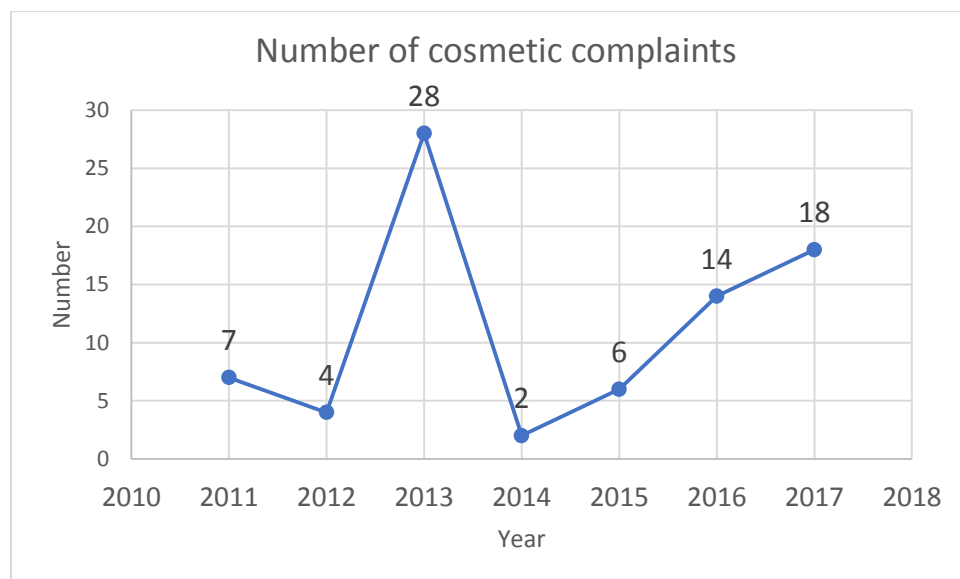
²² Guidelines For Registered Medical Practitioners Who Perform Cosmetic Medical And Surgical Procedures - <http://www.nursingmidwiferyboard.gov.au/Codes-Guidelines-Statements/Position-Statements/nurses-and-cosmetic-procedures> - accessed 25 March 2018

²³ Nurse Practitioners in NSW - Guideline for Implementation of Nurse Practitioner Roles - http://www1.health.nsw.gov.au/pds/ActivePDSDocuments/GL2012_004.pdf - accessed 24 March 2018

²⁴ Ibid

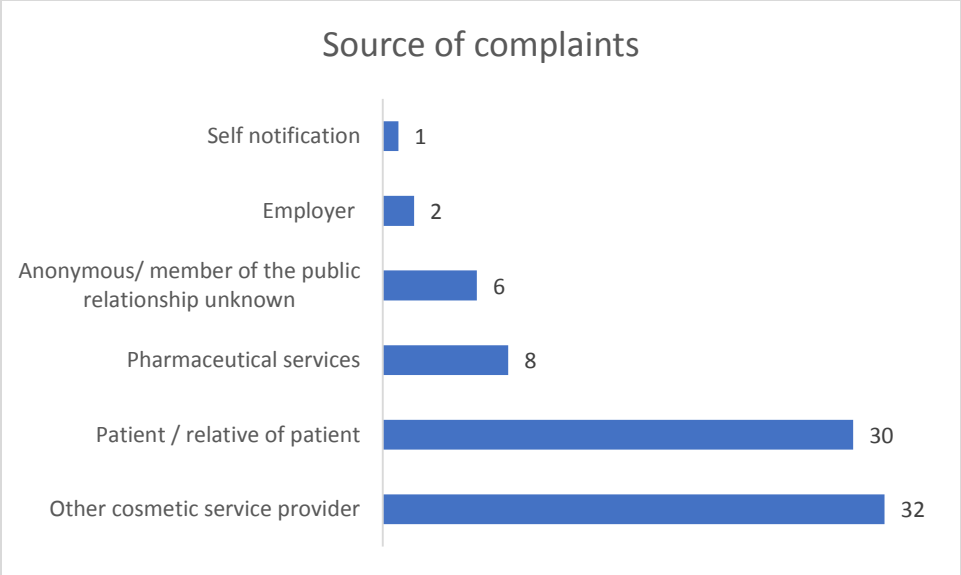
complaints received range from 250 to 680. During this time, the Council has received 79 complaints about 64 nurses working in the cosmetic industry. None of these have been mandatory notifications. The number of complaints related to nurses working in the cosmetic industry per year varies from 2 to 28. There was a peak in complaints in 2013, when other service providers in the cosmetic industry reported 21 RN's for allegedly working outside the S4 drug guidelines by consulting and administering botulinum toxin and dermal fillers without the patient having ever seen a doctor. There appears to be a trend of increasing cosmetic complaints since 2013 although the number of complaints received is small in comparison to the overall complaints received.

Most of the nurses reported to the Council only received one complaint. There were 6 nurses who received 2 complaints and 3 nurses who received more than 2 complaints. The highest number of complaints received about a nurse was five.

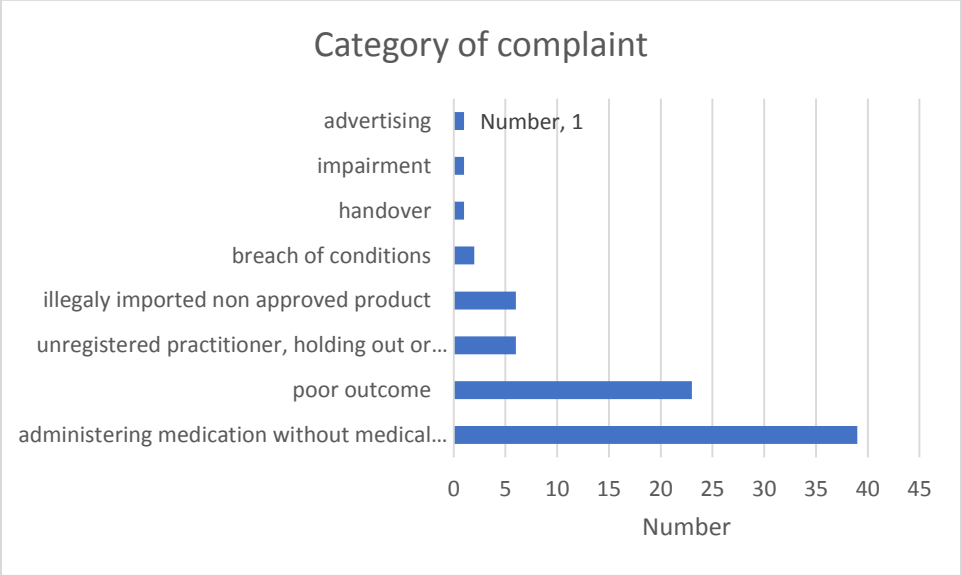


Source of complaint

Other cosmetic service providers were the most frequent source of complaints. This may be reflective of the competitive nature of the cosmetic industry. These were largely related to the administration of cosmetic medications without medical assessment. However, a large number of complaints were also from either patients or their relatives (30/79) who complained about poor outcome, failure to provide adequate information and lack of informed consent. The Pharmaceutical Regulation Unit has reported several practitioners who were using unauthorized or illegally imported cosmetic substances. Two employers reported poor professional practice (inadequate handover and breach of conditions). A nurse also made a self-notification about a health issue.



Type of complaint



Outcomes of complaints

Of the 68 complaints which have been finalised, five registrants had restrictions applied to their registration because of the complaint. Seven were referred either to the National Board (for improper use of title) or the Pharmaceutical Service Unit for further assessment. More than half the complaints were closed due to insufficient evidence – most of these related to working outside the S4 drug guidelines by injecting consulting and administering botulinum toxin and dermal fillers without the patient having ever been seen by a doctor.

Outcome	Frequency
Suspended	1
Conditions on registration	4
Referred to AHPRA (inappropriate use of protected title)	6
referred to pharmaceutical services unit	1
Counseling a letter or advice	7
Discontinued at initial assessment	45
Complaint withdrawn	3
individual no longer registered	1
total	68

Concerns about the cosmetic industry

Although a relatively small number of complaints are received in relation to nurse working in the cosmetic industry, the Council has concerns that clients within the cosmetic industry who have experienced harm may be unaware of their rights. They also may not know who to report to about specific issues ie what may be reported to the health professional regulators, or to other regulators relevant to the industry such as Fair Trading and the Consumer Protection Act. For this reason, there may be significant underreporting of harms which are occurring in a largely unregulated industry, where there is potential for serious harm due to potentially unnecessary treatment.

A review of the Cosmetic Industry in the UK, "...exposed woeful lapses in product quality, after care and record keeping. It also drew attention to widespread use of misleading advertising, inappropriate marketing and unsafe practices right across the sector...non-surgical interventions, which can have major and irreversible adverse impacts on health and wellbeing, are almost entirely unregulated."²⁵

Also of concern, is the number of younger people having cosmetic treatments and their vulnerability in being persuaded to have treatments. One study found that "...children and teenagers are being exposed to cosmetic interventions at an early age due to the wide availability of, and their exposure to, TV programmes and magazines that include interventions as part of their core material."²⁶ Other research states "...that a wide range of influences, including media coverage of celebrities and their cosmetic interventions, reality TV programmes and the wider broadcasting of cosmetic procedures, alongside the increasing availability of and access to cosmetic interventions, are coming together to create a climate in which having a cosmetic procedure is increasingly regarded as normal and the associated risks are often underestimated. These factors also result in changing aspirations and ideals regarding body image, with some evidence that this results in greater salience for cosmetic intervention among the young".²⁷

²⁵ Review of the Regulation of Cosmetic Interventions - Final Report (2013) – Department of Health UK www.gov.uk/dh https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/192028/Review_of_the_Regulation_of_Cosmetic_Interventions.pdf - accessed 31 march 2018

²⁶ Regulation of Cosmetic Interventions- Research amongst teenage Girls (2013)– Department of Health UK www.gov.uk/dh https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/192030/Report_on_research_among_teenage_girls.pdf - accessed 31 March 2108

²⁷ Regulation of Cosmetic Interventions Research among the General Public and Practitioners (2013) - Department of Health UK www.gov.uk/dh, accessed 31 March 2018.

Improper use of title and scope of practice

'Nurse', 'registered nurse', 'nurse practitioner', 'enrolled nurse', are protected titles under Section 113 of the Health Practitioner Regulation National Laws. This means that these titles, (amongst others listed in the Law) may only be used by individuals who are appropriately registered in those the professions under the law. It is an offence to knowingly or recklessly use a protected title in a way that could induce a belief that a person is registered in a profession under the Law, when they are not. Health professional registration assures the public that the person who holds a protected title is appropriately educated and capable of maintaining professional standards.

Unregulated Beauty Clinics, when they employ individuals who claim to be a registered health professional, may not be aware of, or check, the AHPRA register, to confirm registration status. Individuals and organizations may also be contravening the law by inappropriately using the titles of 'nurse', 'registered nurse' and 'nurse practitioner' in advertising when a person is not registered.

The Council has received five cases where the person was believed to be a registered nurse and was alleged to be injecting substances. One of whom, it is alleged, advertised that he was an 'independent nurse consultant' although he was not on the AHPRA professional register.

The public may also not be fully aware of the differences in scope of practice between ENs, RNs, and Nurse Practitioners. The complaints about 3 enrolled nurses alleged that the EN claimed to be a registered nurse (Div. 1), worked outside of scope of practice or demonstrated poor practice with an inappropriate level of supervision.

The Council has also received a complaint about an individual who had his registration cancelled by a Tribunal and who was employed as a 'registered nurse' as he did not disclose that he was unregistered, and the clinic did not check whether he was on the register.

The public expect that registered health professionals meet the professional standards, are suitably qualified to provide accurate and complete information and implement safe procedures to those who need it in their area of practice.

Administering medications which are not appropriately prescribed.

As stated previously, the most common reasons for which RNs and ENs are reported are allegations that the nurse is administering cosmetic medications that have been inappropriately prescribed as the medical practitioner has not appropriately assessed the client prior to prescribing. Most of these complaints have been discontinued as there is insufficient evidence to support the allegations, as the nurses, in most of these cases appear to have a collaborative arrangement with a medical practitioner who prescribes following a video conference with the client.

There has, however been one case prosecuted by the HCCC - HCCC V Piper [2014] NSWCATOD 62; (12 June 2014)²⁸ – see case study below

Poor outcomes

The second most common reason for a complaint being made was due to poor or unexpected outcomes of the cosmetic procedure provided. These were described as: a lop sided and lumpy face, bruising and dark marks under the eyes, eye brows ‘drooping’ on one side, an infection, adverse injuries (unspecified), scarring on legs and pigmentation on face, burns, adverse reaction to the medication injected, pain and swelling. Several complainants were also displeased with the results of treatment. Some of these outcomes are known potential outcomes for the procedures and may indicate inadequate informed consent and discussion about the potential complications

Online availability of illegal drugs and medications

Access to and importation of drugs and medication from other countries is difficult to identify. Nurses, have been reported to the HCCC by the Pharmaceutical Regulation Unit for importing large supplies of illegal medications from other countries. Due to competition within the cosmetic industry, there is likely to be pressure to minimize costs and maximise profits by identifying sources of cosmetic drugs that may be cheaper, and potentially have poorer quality and standards of production compared to those sourced through legal channels. These drugs will have inherent and unknown risks when they are used. The Council has received eight complaints where the practitioner is alleged to have used substances which were not legally obtained, were used incorrectly or were ‘watered down’.

Offers of financial inducement

The Council has also received a report about clinics offering bonuses to workers to upsell products which may be unnecessary and not initially requested by the client. This was not investigated as it was not related to the case being dealt with by the Council or the HCCC. It is possible that registered nurses working in the industry may be involved and participating in such practice. Such behavior is defined under the law as unsatisfactory professional conduct.

BOX 3 – EXTRACT HEALTH PRACTITIONER REGULATION NATIONAL LAW

139B (1) (g) Accepting benefit for recommendation of health product

Accepting from a person who supplies a health product (or from another person on behalf of the supplier) a benefit as inducement, consideration, or reward for recommending that another person use the health product but does not include accepting a benefit that consists of ordinary retail conduct.

²⁸ <http://www.austlii.edu.au/cgi-bin/sinodisp/au/cases/nsw/NSWCATOD/2014/62.html?stem=0&synonyms=0&query=piper%20HCCC> – accessed 2 April 2018

Infection control and standard precautions

Several complaints reported to the Council alleged that the practitioner was providing services from their own home or from unlicensed premises which lack cleanliness and where infection control procedures and universal standard precaution may not have been met. The Council has conducted one inspection and identified that standards for infection control and record keeping were not being met. One patient reported needing hospitalization for several days and antibiotics following a procedure.

Case study 1– supply of drugs without written authority

HCCC V Piper [2014] NSWCATOD 62; (12 June 2014)²⁹

The registered nurse started working in cosmetic medicine more than a decade ago. For nearly two and a half years, a medical practitioner obtained cosmetic medications for her that were restricted substances under the Poisons and Therapeutic Goods Act 1966(NSW) (the PTGA). The nurse supplied and administered the restricted substances to patients at the medical practitioner's surgery and at a day spa 30 kilometres away.

The nurse entered into an arrangement with a specialist plastic surgeon who has a surgery. The doctor obtained the cosmetic injectable medications and provided them to the nurse. The nurse reimbursed the doctor for the cost of the medications with a sizeable share of the fee she received from the patients receiving injections from her. She worked one day per week as a nurse injector at the doctor's clinic. The nurse also took the drugs to premises a day spa and supplied and administered the medications to clients of the spa

The seven medications administered by the nurse, included hyaluronic acid or botulinum toxins which are restricted substances within schedule 4 of the PTGA.

A medical practitioner may supply an S4 drug to a nurse to administer to a patient if the patient is under the direct care of the medical practitioner and a specific patient authorisation to administer the drug has been given to the nurse. A medical practitioner may not supply an S4 drug to a nurse for administration to a patient who is not under the direct care of that medical practitioner. Further, a nurse may not administer any drug to a patient unless written authorisation has been given by a medical practitioner to administer the substance to that specific patient.

Under the protocol, any patient receiving an S4 drug should initially be assessed by a medical practitioner, so a clinical history and record of the patient's medications and allergies can be noted. The management plan must include a discussion of potential side effects or any complications of the drugs being administered. Once the plan of management has been determined, the nurse may administer the drugs according to the medical practitioner's recent

²⁹ <http://www.austlii.edu.au/cgi-bin/sinodisp/au/cases/nsw/NSWCATOD/2014/62.html?stem=0&synonyms=0&query=piper%20HCCC> – accessed 2 April 2018

instructions. The medical practitioner should be immediately contactable to deal with any problems arising from the administration of the medication.

The protocol states that medical practitioners who supply S4 drugs to nurses but have no input into the clinical management of the patient, or no physical presence on the premises at which the drugs are injected, contravene the law and are liable to prosecution. Nurses are also advised that if they function autonomously to store, prescribe and dispense S4 drugs purchased for them by medical practitioners, they contravene the PTGA. Further, this conduct is outside the nursing scope of competency and practice.

The document also warns nurses practising outside the protocol's terms that they may find they are not appropriately protected, professionally or industrially if a claim is made. The Tribunal was surprised, in asking the nurse about her professional indemnity insurance arrangements, to be informed by her that she had a policy which provided coverage for her work as a nurse injector, particularly at the day spa.

Australasian College of Cosmetic Surgery Protocol for Delegated Cosmetic S4 Injections notes that it is not uncommon for cosmetic injections to be administered by nurse injectors and if so, the supervising medical practitioner has ultimate responsibility for the training and skills maintenance of the nurse and for the patients' safety and overall care.

The nurse supplied the medications obtained by the doctor to 97 patients on more than 230 occasions at the day spa without authority or written direction from a medical practitioner. The nurse also administered the medications without a medical practitioner being involved in the consultations.

The nurse denied that she had administered Botox from her home. In terms of her work at the day spa, the nurse stated the treatment was under the supervision of the doctor and that patients' photos and records were reviewed by him. Further, since the nurse had become aware of the complaint, she had ceased administering Botox at the day spa and would only administer such treatments at the Doctors clinic. Around this time the nurse also began working at Anti-Aging Associates, a group of cosmetic clinics providing dermal fillers and other "anti-ageing" treatment.

The nurse said that she did not know where the "rules" about the supply and administration of S4 drugs came from. She also was not certain if "fillers" were an S4 drug. She advised that she ceased administering Juvederm or Botox without supervision at the end of 2011. She said that she did not cease the treatment when she first became aware of the complaint because of pressing financial issues.

The nurse would obtain blank prescription and consent forms from the Doctors secretary prior to seeing a patient. After the nurse's treatments these would be given to the doctor for his signature. The doctor would usually not see the Botox or dermal filler patients unless they required surgery or if the treatment required was beyond the scope of the injecting treatment.

The Pharmaceutical Services unit provided evidence and had concerns that some medical practitioners were failing to adequately consult and review patients and empowering nurses or

other unauthorised persons to administer and make clinical decisions about restricted substances, without authority or supervision. The use of multidose vials on more than one patient with the risks of microbial contamination and cross infection is also raised as a concern.

In commencing work at the doctor's clinic, the nurse reported that she adopted the system that had been in place for the previous 18 years and that most of the clients were long-standing and had been treated by the previous nurse injector. The nurse gave evidence that she presumed, in taking over the practice of the previous nurse injector at the clinic, that the practice was appropriate. She knew of the doctor's reputation as a respected medical practitioner. She said that she recognised that she should have been more assertive so that the doctor saw all the patients and wrote the scripts for the S4 medication.

The Tribunal's view was "the requirements in the PTGA and the protocols developed to assist practitioners working in cosmetic medicine, leave little ambiguity of the procedures which must be followed by nurses and medical practitioners. It is imperative nurses working in this area access and understand the requirements for the supply and administration of S4 drugs or they practise at their peril. As the subject nurse has found, assuming or hoping that her treatment of patients was within the law because it had the support of a medical practitioner does not protect her from serious consequences."

Tribunal found the nurse guilty of unsatisfactory professional conduct and serious misconduct. The nurse was reprimanded and suspended for three months following which conditions on registration were imposed in relation to practice restrictions, education and audit

Case Study 2 – Enrolled nurse establishing Beauty Clinic – unsupervised and unsatisfactory professional performance

The individual was registered as an enrolled nurse (EN) in 2014. Prior to becoming registered, she had worked in the beauty industry for over 20 years. The EN had aspirations to progress to cosmetic injecting, which she could only do if she became a qualified nurse with AHPRA registration. The EN was not successful in gaining a position on a new graduate program and did not have the opportunity to consolidate her skills, knowledge and experience as an enrolled nurse.

The EN worked for cosmetic clinics, administering cosmetic injections after qualifying, whilst building her own business. When the EN left her place of employment, she concentrated on her own business which had rooms in a medical centre. Within her business, she worked as a sole practitioner with a prescribing medical practitioner via Skype. As an EN, she was required to work under the supervision of a registered nurse, but up until she was first reported to the Council, she practiced unsupervised.

In 2016, two notifications were received from the EN's employer alleging that the registrant was:

- working from home (providing cosmetic injections);
- selling S4 medications without authorisation;
- working without professional indemnity insurance; and

- uploading photos of patients on her Instagram page without permission from the patients or the company.

A further notification was received a month later alleging the EN was falsely advertising, on her business cards, that she was a Clinical Nurse Specialist.

The EN was directed to attend professional counselling by a Committee of the Council. The counselling focused on:

- the use of protected titles (e.g. EEN, RN, Clinical Nurse Specialist)
- clarification regarding the nature of her work and scope of practice
- use of social media and privacy
- code of Professional Conduct for Nurses
- code of Ethics for Nurses
- Enrolled Nurse Standards for Practice

The EN provided a response to the notification, evidence of continuing professional development (CPD), a self reflection log and a 12 month learning plan. The Counselling Committee requested that the EN submit further documentation relating to professional indemnity insurance and CPD before a further decision would be made on the matter.

Two months later, further complaints were received from three separate clients alleging the EN:

- ‘watered down’ her lip filler medications and products;
- was aggressive and swore at the client when she made a direct complaint to her;
- failed to administer lip numbing cream prior to the procedure; and
- charged the client in excess of \$1250 for three failed lip treatments

As a result of these complaints, the EN was ordered to attend a performance assessment and an inspection of her workplace.

In 2017, an inspection of the EN’s workplace was carried out. There were issues identified in relation to privacy, consent process, lack of supervision, infection control, and lack of standard procedures for: medication administration, privacy and complaints management.

The EN also attended a performance assessment, where serious concerns were raised in relation to her practice as an enrolled nurse.

The assessors’ preliminary findings raised serious concerns about her competency and ability to practice. It was recognised that The EN’s current practice relates to cosmetic procedures and this role requires the application of skills and knowledge of an enrolled nurse. She was required to undertake continuing professional development to maintain her knowledge base as an EN, regardless of the setting in which she practices.

The assessors provided examples where they considered the EN did not meet the standards required. A selection is listed below:

- Infection control and universal precautions
 - Did not consistently attend to the ‘5 moments of hand hygiene’
 - Used non-sterile gloves during procedures

- Did not perform a clean of her trolley prior to administering the lip injections
- Care of the deteriorating patient/escalation of care
 - Was delayed in identifying the client's health deterioration
 - Was unable to determine the level of dyspnoea or conduct a respiratory assessment for a client in respiratory distress
 - Administered oxygen at a sub-therapeutic rate for a deteriorating patient who was short of breath
 - Did not seek the assistance of a RN at any stage
 - Did not follow the elements of the DRABCD algorithm for resuscitation
 - Did not correctly open the airway of the client
 - Did not demonstrate correct chest compression technique
 - Did not demonstrate documentation of the deterioration or resuscitation of the client
- Medication administration
 - Did not administer the lip fillers using the 'five rights of medication administration'
 - Did not correctly document the medication administration
 - Did not wear sterile gloves during the procedure
 - Did not recognise the risks of bleeding with Ibuprofen use
 - Was unable to demonstrate an ability to complete medication calculations although she is required to maintain her competency in this area
 - Achieved 5% score in the drug calculation section
 - Could not articulate the actions required of an EN working within her scope of practice
- Documentation
 - Did not note times on progress notes or when medication was administered
 - Did not correctly document CPR and use of the defibrillator
 - Left gaps in her notes
 - Notes were at times illegible
- Patient assessment and care planning
 - Unable to demonstrate skills such as observation, interview, physical examination and measurement, failing to perform a comprehensive nursing assessment of the client who presented for consultation for lip fillers
 - Did not demonstrate anatomy and physiology knowledge in line with her area of specialty
 - Delivered a clinical handover to a paramedic about her client without providing required information
- Informed consent
 - Did not identify that the consent form had not been witnessed before or after the procedure was performed

It was noted that the EN worked with no restrictions in an unstructured and unsupervised environment. The assessment identified significant deficits in the EN's current practice. The assessors consider she has demonstrated limited insight into these deficits and is a risk to the public and unsafe to practice at this time.

A risk assessment was undertaken and the matter referred to the s150 Committee for consideration of urgent action. A response was requested from The EN. Interim immediate action was taken by the Council. The EN was ordered not to practice until the conditions imposed on practice were reviewed by the Council and the condition removed. In order to

maintain her business during this time, the EN employed two registered nurses to perform the cosmetic procedures whilst she is unable to work.

The EN was also referred to a Performance Review Panel to determine whether she demonstrated unsatisfactory performance.

The EN acknowledged she requires continuing education in many of the areas where a deficiency was identified. She outlined a number of courses she will commence in the near future to address some of these concerns. The EN intended to practice as an enrolled nurse only within the Cosmetic Treatment Industry in the foreseeable future. She stated that she had become accustomed to a lower standard of documentation in the industry through her former employers. The EN believed that she was competent and this was demonstrated by the success of her business and the positive feedback she receives from clients on Instagram and Facebook.

The PRP were not satisfied with the EN's responses and were of the view that her performance was unsatisfactory. They required the EN to only work supervised and to undertake a number of courses and a further performance assessment on completion of the courses.

The EN was monitored by the Council. In early 2018, a further complaint was received indicating the EN was not practising under the supervision of a registered nurse. This allegation was confirmed following a further inspection. An interim suspension has been placed on the EN's registration and she has been referred as a complaint to the HCCC as required by the Law.

BOX 4: Information provided by the Department of Health Therapeutic Goods Administration

Advertising cosmetic services that include schedule 4 substances

Related information

[Advertising cosmetic injections](#)

[Advertising health services with schedule 3, schedule 4 or schedule 8 substances](#)

16 August 2017

The following advice is for health professionals and cosmetic/beauty clinics who advertise cosmetic services that involve therapeutic goods containing Schedule 4 (prescription-only) substances.

These groups are reminded that advertising of prescription-only products to consumers is illegal. Generally, it is an offence under section 42DL(1)(f) of the *Therapeutic Goods Act 1989* (the Act) for a person to publish or broadcast an advertisement about therapeutic goods that contains a statement referring to goods, or substances or preparations containing goods, included in Schedules 3, 4 or 8 of the [Standard for the Uniform Scheduling of Medicines and Poisons \(SUSMP\)](#) (the Poisons Standard). This offence attracts a maximum penalty of \$12,600 for an individual and \$63,000 for a body corporate.

The Act broadly defines an advertisement in relation to therapeutic goods as including any statement, pictorial representation, or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods.

The issue

Some health professionals and cosmetic/beauty clinics are advertising, to the public, therapeutic goods or substances that are designated 'prescription-only' items. These products include cosmetic injections such as:

Anti-wrinkle injections

Botox, Dysport (botulinum toxin)

Dermal Fillers

Restylane, Perlane, Dermalive, Juvéderm, Emervel, Sub Q, Esthelis, Belotero (hyaluronic acid)

Hylaform (hyaluronan, sodium hyaluronate)

Collagen, Zyderm, Zyplast, Cosmoplast, Cosmoderm (collagen)

Newfill, Nufill, Sculptra (polylactic acid)

Aquamid (polyacrylamide)

Radiesse (calcium hydroxyapatite)

Ellansé (polycaprolactone)

Improvement of the appearance of submental fat

Belkyra, Kybella, ATX-101, Lipodissolve (deoxycholic acid)

These products are generally administered for temporarily removing/reducing wrinkles and lines on the face, around the eyes, forehead (anti-wrinkle injections and dermal fillers), lips and neck (dermal fillers only) or for improving the appearance of submental fat (deoxycholic acid).

The products listed above contain substances that are in Schedule 4 of the current Poisons Standard and the products are therefore regulated as:

Prescription Only substances - includes substances, the use or supply of which should be by, or on the order of medical practitioners and should be available from a pharmacist on prescription.

Some of the cosmetic injections listed above may be compounded by a pharmacy for an individual patient rather than supplied by a manufacturer as a finished product. The advertising of compounded cosmetic injections that contain prescription-only substances to the public is also prohibited.

See [Advertising: extemporaneously compounded medicines](#) for more information.

Acceptable general terms

To enable health professionals and cosmetic/beauty clinics to continue promoting their businesses and services to consumers, while also complying with the regulatory advertising requirements for therapeutic goods, the Therapeutic Goods Administration (TGA) advises that there should be no reference in advertisements to individual Schedule 4 items. However, the following acceptable general terms and phrases may be used in advertising (noting a therapeutic good must not be advertised for an indication or intended purpose that is not accepted in relation to the inclusion of the good on the ARTG):

cosmetic injections (anti-wrinkle injections, dermal fillers, and submental fat)
anti-wrinkle injections/treatments (anti-wrinkle injections and dermal fillers)
wrinkle injections/treatments (anti-wrinkle injections and dermal fillers)
injections/treatments for lips (dermal fillers)
injections/treatments for fine lines/folds/age lines (anti-wrinkle injections and dermal fillers)
wrinkle and lip enhancement/fulfilment/augmentation (dermal fillers)
injections to enhance pouting of the lips (dermal fillers)
injections which reduce the depth of fine lines/wrinkles around the face/lips (dermal fillers)
injections to improve the appearance of chin/neck/jaw line (dermal fillers)
injections for improving the appearance of submental fat/fullness under the chin. (submental fat)

Other words and phrases with similar meaning may also be used, if they do not refer to specific products or ingredient names. It is not acceptable to use acronyms, nicknames, abbreviations, or hashtags of the medicine's name (or some part thereof), which may be taken by a consumer to be a "reference" to a specific medicine or substance.

Advertisers, businesses, and service providers are also reminded of their obligations under the *Competition and Consumer Act 2010* and state and territory fair trading/consumer affairs legislation.

More information

Further enquiries may be addressed to:

The Director
Advertising Compliance Unit
Regulatory, Practice, Education and Compliance Branch
Therapeutic Goods Administration