



The Australasian College of Dermatologists

**Submission to the NSW Parliamentary Inquiry into
cosmetic health service complaints in New South Wales**

April 2018



NSW Parliamentary Inquiry into cosmetic health service complaints in New South Wales

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About the Australasian College of Dermatologists

The Australasian College of Dermatologists (ACD) is the sole medical college accredited by the Australian Medical Council for the training and continuing professional development of medical practitioners in the specialty of dermatology. The College is the leading authority in Australia for dermatology, providing information, advocacy and advice to individuals, communities, government and other health stakeholders on dermatological practice in Australia.

As the national peak membership organisation, the College represents over 500 specialist dermatologist Fellows (FACD) and 100 trainees across the country. In 2017, there were 138 dermatologists practicing across the New South Wales public and private sector, with 38 dermatology registrars in training.

Dermatologists specialise in the diagnosis, treatment and management of all skin diseases and conditions. Dermatologists' skills and expertise span medical, surgical and procedural dermatology; including laser technologies and injectable treatments which can be used for cosmetic purposes. Dermatologists are at the forefront of research and innovation in this field and the College is well placed to provide expert guidance to governments to inform policy and regulation of cosmetic health services.

Executive summary

As the Australian authority in the medical speciality of dermatology, the Australasian College of Dermatologists commends the New South Wales Parliamentary Committee on the Health Care Complaints Commission (HCCC) for undertaking this inquiry into the regulatory framework for cosmetic health service complaints.

As the medical craft group specialising in complex skin conditions, dermatologists are attending to an increasing number of patients presenting with complications as a result of cosmetic procedures being performed by underqualified or untrained practitioners. If left unchecked, this may amount to a serious public health issue given the rapid expansion of this industry. Consumers now have an extensive array of choice in cosmetic health service providers and procedure types. While the College has no objections to the growth of this emerging market, ensuring that safeguards are in place for consumer protection is paramount. Certain parts of this industry are freely operating without existing NSW regulation, while others appear to be showing a flagrant disregard to safety and quality standards. The College welcomes this Inquiry into the adequacy of the Health Care Complaints Commission and the existing regulatory framework, and looks forward to a government-led solution to address the poor patient outcomes increasingly observed across this sector.

Terms of Reference of the Inquiry into cosmetic health service complaints in NSW

According to the Terms of Reference, the Committee on the Health Care Complaints Commission (HCCC) will inquire into and report on the regulatory framework for complaints concerning cosmetic health service providers in New South Wales, with particular reference to:

- A. The roles and responsibilities of the HCCC relative to the roles and responsibilities of Commonwealth and other state regulatory agencies;
- B. The adequacy of the powers and functions of the HCCC to improve outcomes for the public in the cosmetic health services sector;
- C. The opportunities for collaboration with other agencies, organisations and levels of Government to improve outcomes for the public in the cosmetic health services sector; and
- D. Any other related matters.

A. Roles and responsibilities of the HCCC and other state and Commonwealth agencies

The HCCC acts to protect public health and safety by dealing with complaints about health service providers in NSW. According to the *Health Care Complaints Act 1993*, a health practitioner is defined as a person 'who provides a health service (whether or not the person is registered under the Health Practitioner Regulation National Law)'. Cosmetic health service providers range from practitioners registered with the Australian Health Practitioners Regulation Agency (AHPRA), such as doctors, nurses and dentists, as well as non-registered professionals i.e. beauty therapists or laser operators.

Complaints about registered and non-registered health practitioners are dealt with differently by the HCCC. Under the *Health Care Complaints Act 1993*, investigation and prosecution of serious complaints relating to registered practitioners are undertaken in consultation with relevant professional councils, i.e. the Medical Council of NSW. For non-registered practitioners, no such professional standards bodies exist and these practitioners are held to account according to the Code of Conduct, *Public Health Act 2010* and *Public Health Regulation 2012*. Serious complaints for registered practitioners can lead to cancellation of registration. For non-registered practitioners, a public warning or prohibition warning can be given. For both registered and non-registered practitioners, criminal charges can be laid where prosecution is warranted according to the Director of Public Prosecutions.

While the most severe outcome of criminal prosecution applies to both registered and non-registered practitioners, it is the lack of a professional standards body or an accreditation process for non-registered practitioners which is of concern. There is no mechanism for professional counselling or performance management or other remediation action, which may act to prevent minor incidents escalating to a major threat to patient or public safety. In contrast, medical, dental and nursing practitioners must not only demonstrate the skills and expertise required to gain qualifications throughout the course of their undergraduate education and post-graduate training where required, but must also undertake continuing professional development to maintain AHPRA registration. Thus there are several additional layers of oversight and while it can be argued that this is commensurate with the complexity of the health service they are providing, the increasingly risky and technologically-driven cosmetic procedures being performed by non-registered practitioners

strongly suggests that more stringent or rigorous oversight is needed for this group of professionals. It is questionable whether the majority of non-registered practitioners would even be aware of the existing Code of Conduct. Evidence provided by the HCCC on its promotion and uptake would be very informative in this regard.

Other national government agencies and independent bodies play a critical role in maintaining public health and safety and each with their own remit, including the Therapeutic Goods Administration (TGA), the Australian Commission for Safety and Quality in Health Care (ACSQHC), the Medical Board of Australia (MBA) and Australian Radiation Protection and Nuclear Safety Agency (ARPANSA). The reach of these bodies does not extend to beauty or other non-medical clinics, although products and devices used at these locations must be listed on the Australian Register of Therapeutic Goods (ATRG) held by the TGA. The recent raids across a number of Sydney-based beauty salons uncovering non-TGA approved goods is evidence of a significant gap in regulatory control with respect to importation. Furthermore, the MBA guidelines relating to cosmetic medical and surgical procedures apply only to registered medical practitioners; and only those practicing in day surgeries are required to comply with the National Health and Safety Quality Standards for ACSQHC accreditation. Thus, given the burgeoning non-medical cosmetic market, a cohesive framework is needed to address the considerable regulatory gaps which have allowed questionable and unsafe practices to occur.

The MBA guidelines for registered medical practitioners stratify procedures according to the degree of invasiveness i.e. minor (non-surgical) vs major. Many minimally invasive procedures have an excellent safety profile when performed by competent and qualified practitioners, both registered and non-registered. The type of product or energy device and its manufacturing quality (e.g. TGA approved vs 'black-market') has a bearing on procedural outcomes and risks – beyond practitioner/practice competency and adherence to guidelines. It is at this regulatory interface where the HCCC and other regulatory bodies such as the TGA have a critical role to play. In this regard, establishment of a professional council with oversight of non-registered practitioners could assist the HCCC manage complaints for this group, potentially using a stratified approach based on procedural risk.

B. Adequacy of the powers and functions of the HCCC to improve outcomes

A review the HCCC website indicates that over the last five years, a total of seven registered and three non-registered health practitioners have been the subject of public statements or warnings relating to cosmetic procedure complaints. Anecdotal evidence from College Fellows suggests that cosmetic services requiring post-procedure medical intervention are being performed at a rate much greater than would be implied by these statistics. The College is of the view that the HCCC does not currently have adequate powers to enforce and police issues in the cosmetic health sector.

There are two main obstacles facing the HCCC in performing its duties according to its charter: namely, lack of regulation and lack of visibility.

Lack of regulation

Laser / intense pulsed light (IPL)

Unlike certain other jurisdictions, in NSW there are no minimum requirements to operate lasers or intense pulsed light (IPL) machines, nor are there restrictions around the purchasing of these devices. In effect this means that any operator can purchase and run a laser system. There are some inherent controls based on laser companies being unwilling to sell certain equipment to non-medical practitioners, but this is inappropriate de-facto regulation and relies on self-imposed standards upheld by the vendor. The lack of defined training for operators continues to be of concern to the College, due to incidences of patients requiring treatment for laser burns. As this technology is increasingly available and procedures continue to gain in popularity amongst consumers, regulation is critically needed.

ARPANSA released a Regulatory Impact Statement (RIS) for the use of IPL sources and lasers for public consultation in 2015, in an attempt to examine options for the promotion of safe use of cosmetic lasers and IPLs across the industry. Options included education, self-regulation and accreditation, or licensing of practices; the final option was supported by this College in its submission to ARPANSA. ARPANSA concluded that there was insufficient evidence to proceed with a decision statement and rather are in the process of developing non-mandatory guidance material to support a national uniform approach to the laser and IPL industry. While commendable, this was perhaps a wasted opportunity to implement a national regulatory response, given that regulation only exists currently in Queensland, Western Australia and Tasmania, and is different in each of these states. The College is of the view that in NSW, laser safety officer certification/licencing should be compulsory as a minimum, and interstate accredited providers should have their status recognised in NSW. Licencing categories should accommodate for the variation in procedural complexity and operator skill required.

Injectable treatments

Access to injectable treatments, i.e. Botulinum toxin and fillers, in contrast, is governed by S4 regulation (prescription only) to only be injected by doctors, dentists or nurses under supervision. However it is evident as previously noted that access to these restricted substances is occurring through importation or other mechanisms and thus these regulations are being flaunted.

Whilst the recent publication of the MBA's guidelines for cosmetic medical and surgical procedures has been important to provide overarching standards to registered practitioners, in the absence of legislation these guidelines may be inadequate to ensure patient safety and the delivery of high quality care according to best practice. For example, the guidelines state 'Medical practitioners must not prescribe schedule 4 (prescription only) cosmetic injectables unless they have had a consultation with the patient, either in person or by video'. It is the view of the College that video consultations are an inadequate form of consultation for cosmetic procedures. As patients are not often aware that initial pre-procedure consults are a minimum requirement, there are occasions where these do not take place, even via videoconferencing or skype, or where cosmetic clinic operators may be consulting with medical practitioners interstate to obtain prescriptions. This raises considerable

concern for patient safety and access to appropriate health networks, especially in the case of intravascular injections. Should videoconferencing continue to be allowable by AHPRA, a minimum standard for consultations should be enforced, including a requirement to have review consultations at defined periods, and restrictions around product and laser use. Furthermore, there should be no diagnosis of lesions by videoconferencing unless accompanied by clinical diagnostic images deemed of suitable quality according to ACD teledermatology guidelines (in development).

Lack of visibility

Cosmetic procedures are increasingly being performed in a variety of business or clinic settings; from small back rooms or private residences to corporatised chains. There is a lack of transparency around clinical and corporate governance approaches being implemented in these settings. With no accreditation requirements, the public cannot be assured of adherence to safety and quality standards. There is anecdotal evidence of certain highly questionable practices, such as contracted nurses being offered financial incentives to up-sell customers and increase the volume of product used. Extreme scenarios include individuals, who may or may not be overseas trained doctors, advertising through social media, entering the country, performing procedures in private residences, and departing before authorities are alerted. The recent high profile incident which led to the death of a NSW women is one such example. A targeted approach involving multiple government agencies and jurisdictions is essential to combat this illegal activity.

It is important that the corporatisation of cosmetic and laser clinics does not obscure clinical governance approaches and individual practitioner accountability. Non-medical groups are able to directly advertise to consumers, refer to glowing testimonials (which are not allowable to medical practitioners) and offer discounts as inducements. Product suppliers enhance their capacity to discount by selling product at heavily discounted rates to non-medical “chain clinics” that are able to buy in bulk because of their size. Injectable product supply companies and laser companies are more than willing to sell product at much lower price than what is accessible by an average medical clinic; the College suggests that supplier discounting should be closely examined as it may be inadvertently contributing to upselling to consumers. By contrast, registered practitioners regardless of training or specialty are not allowed to offer inducements under MBA guidelines and have significant restrictions on direct marketing. This makes it harder to compete, but also makes the other operators appear more reputable through their marketing campaigns. There is an enduring public opinion that all cosmetic procedures are safe, regardless of the operator. Challenging this belief and raising awareness of the importance of safe practices is difficult for the medical profession, who must use other means to provide evidence-based education to patients and consumers.

The current class action suit against The Cosmetic Institute is worth highlighting. It is alleged that breast augmentation surgery was being performed across several locations in NSW and one in Queensland with inadequate infection control procedures, a lack of emergency surgical or medical assistance, no capacity to legally administer general anaesthesia and utilised a self-credentialing process.

Finally, both registered and non-registered practitioners have a duty of care to their patients or clients. Doctors and nurses are held to the highest level of duty of care and are accountable to

several codes and standards of practice. It is alarming that some operators are working in the cosmetic space without insurance or adequate training to manage issues or adverse events that may arise. It then falls to the medical profession to rectify poor outcomes and manage complications, in certain cases within the public system and thus at the expense of the tax payer. The cosmetic tourism industry also contributes to the burden on Australia's medical practitioners. A multi-pronged approach of tighter regulation spanning professional training requirements, restrictions on purchasing of devices and a greater focus on both the individual as well as the corporate service provider is required, supported by a public education campaign.

C) Opportunities for collaboration with other agencies, organisations and levels of Government to improve outcomes for the public in the cosmetic health services sector

According to the report on Proceedings before the Committee on the Health Care Complaints Commission on March 12th 2018, a new national body – the Consumer Health Regulators Group – is to be established. Membership will include the TGA, the Australian Competition and Consumer Commission (ACCC), AHPRA, the Private Health Insurance Ombudsman, and state regulators such as Fair Trading NSW and the HCCC. The College is encouraged by the formation of this group, which in theory should facilitate greater jurisdictional and Commonwealth interconnectivity and help to drive appropriate policy development at a national level.

It has been almost 20 years since the publication of the HCCC's *The Cosmetic Surgery Report* (1999). Inadequate data collection continues to be a significant barrier to gaining a complete picture of the cosmetic health services industry, both medical and non-medical. As cosmetic services are not claimable on Medicare, national data on the numbers and types of procedures is not available, nor can information about practitioners performing these services be accurately or readily obtained. There is no register of cosmetic services adverse outcome data which could be used to inform policy development. ARPANSA's Australian Radiation Incident Register may be useful in this regard. The College would be open to further discussions with the HCCC or other relevant bodies on finding solutions to the data gap.

As mentioned, there is a lack of public awareness of the risks involved in cosmetic procedures and the range of practitioners providing these services. A NSW Government-led targeted education campaign to raise awareness of these issues will lead to more empowered consumers who are able to make better cosmetic health choices, in turn improving outcomes.

Links (last accessed April 2018)

Health Care Complaints Commission. <http://www.hccc.nsw.gov.au/Home>

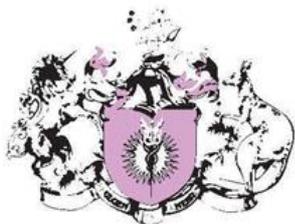
Medical Board of Australia. *Guidelines for registered medical practitioners who perform cosmetic medical and surgical procedures*. October 2016. <http://www.medicalboard.gov.au/Codes-Guidelines-Policies/Cosmetic-medical-and-surgical-procedures-guidelines.aspx>

Australian Radiation Protection and Nuclear Safety Agency. *Cosmetic and beauty IPL/lasers Regulatory Impact Statement*. <https://www.arpansa.gov.au/news/cosmetic-and-beauty-ipllasers-regulatory-impact-statement>

Parliament of New South Wales. *Hearing 12/03/2018 - Review of the Health Care Complaints Commission Annual Report 2016-17*. March 2018. <https://www.parliament.nsw.gov.au/committees/inquiries/Pages/inquiry-hearing.aspx?pk=7168>

Health Care Complaints Commission. *The Cosmetic Surgery Report: Report to the NSW Minister for Health*. October 1999. <http://www.hccc.nsw.gov.au/ArticleDocuments/158/Cosm%20report.pdf.aspx>

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