

**COSMETIC MEDICAL AND SURGICAL PROCEDURES  
A NATIONAL FRAMEWORK**

**FINAL REPORT**

**INTER-JURISDICTIONAL COSMETIC SURGERY WORKING GROUP  
CLINICAL, TECHNICAL AND ETHICAL PRINCIPAL COMMITTEE**

**AUSTRALIAN HEALTH MINISTERS' ADVISORY COUNCIL**

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## EXECUTIVE SUMMARY

The Australian Health Ministers' Conference requested an examination of the adequacy of consumer safeguards in relation to cosmetic medical and surgical procedures.

The Australian Health Ministers' Advisory Council referred the matter to its Clinical, Technical and Ethical Principal Committee, which established the Inter-jurisdictional Cosmetic Surgery Working Group to undertake the review.

The Working Group was tasked with identifying, and reviewing the adequacy of, consumer safeguards in relation to cosmetic medical and surgical procedures and in particular, safeguards relating to advertising, marketing and recruitment; information available to consumers and informed consent (including any specific issues for persons under 18 years of age); regulatory coverage; and professional/clinical standards of practice.

The Working Group was requested to make recommendations to the Australian Health Ministers' Conference on the need for and nature of additional safeguards for consumers and to identify options for progressing such safeguards through a national framework or baseline of requirements.

For the purpose of scoping its task, the Working Group defined cosmetic surgery as a procedure performed to reshape normal structures of the body or to adorn parts of the body, with the aim of improving the consumer's appearance and self-esteem.

Reconstructive surgery, being surgery which is performed on abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumours or disease, was excluded. This is usually done to improve functions, but may also be done to approximate a normal appearance.

The project excluded gender reassignment surgery; tattooing; body piercing and cosmetic dentistry.

### **The overall picture**

Cosmetic medical and surgical procedures, depending on the nature of the procedure, are mostly performed by medical practitioners, with nurses and beauty therapists also playing a role.

Procedures are performed in a variety of settings, including hospitals, day procedure centres and medical practitioners' rooms. Cosmetic surgical procedures are increasingly being performed in day procedure centres, and with rapidly changing technology providing alternatives to traditional surgical procedures, many procedures (such as liposuction, laser skin treatments and sclerotherapy [injection of a solution

into unwanted varicose and spider veins]) are now being done in medical practitioners' rooms.

Non-surgical procedures are a burgeoning area of activity – laser hair removal, injections, microdermabrasion and light and medium skin peels are being performed in medical practitioners' rooms and in beauty salons.

It is a rapidly growing and changing industry which is difficult to quantify. Industry estimates suggest that cosmetic surgery is now a billion-dollar industry and non-surgical procedures have seen about a 40-50% increase over the last five years.

“Cosmetic tourism” is another growing area – increasingly, individuals are travelling to other countries, such as in south-east Asia, in search of low cost treatment, often as part of “package tour” deals where the cosmetic procedure forms an incidental part of the trip.

It is not possible to estimate how many Australians travel overseas for cosmetic medical and surgical procedures. Overseas reports indicate that the market in medical tourism is currently estimated to be between 20 and 40 billion US dollars annually, predicted to reach 100 billion within two years.

The current regulatory framework within which cosmetic medical and surgical procedures are practised around Australia consists of a combination of –

- professional (practitioner) registration;
- private health facilities licensing;
- public health measures (eg infection control);
- regulation of some of the devices and substances used in performing the procedures;
- independent health complaints mechanisms; and
- more general consumer legislation, including in some jurisdictions, specific protection in relation to children.

Not all jurisdictions have all of the above measures in place and where they do have them in place, they are not necessarily consistent.

### **Consumer safeguards and their adequacy**

Cosmetic medical and surgical procedures are lifestyle choices, undertaken to enhance appearance to achieve what patients perceive to be more desirable and to boost self-esteem and confidence – they are not driven by medical need.

The cosmetic medical and surgical industry has become a multi-million dollar entrepreneurial industry. Rapid and ad hoc growth has opened the way for unregulated practices and some questionable methods of promotion, posing ethical dilemmas for some members of the medical profession, consumers and legislators.

Advertising and promotion of cosmetic medical and surgical procedures focus on the benefits for the consumer, downplaying or not always mentioning the risks. Different “boundaries” are tolerated for promotion of these procedures (which are not driven by medical need and where there is significant opportunity for financial gain by those promoting them) than is the case for “mainstream” medical procedures.

Factual, easily understood information for consumers contemplating cosmetic medical or surgical procedures from a source that is independent of practitioners and promoters is not always readily available.

While cosmetic medical and surgical procedures are undertaken by some medical practitioners who have completed advanced specialist surgical or medical training, current regulatory provisions allow any registered medical practitioner to set up in practice and call themselves a cosmetic surgeon or physician, conveying the impression that they are specifically qualified or specialise in the area.

In other areas of medicine, the general practitioner (GP) is the ‘gatekeeper’ for referral to surgeons. Where the cosmetic surgery industry sells procedures directly to the public, a GP referral is not required. This means the GP is not able to offer an independent view on the procedure unless specifically sought by the patient. The GP is also potentially uninvolved in post-procedural care.

Unregistered practitioners in the industry are largely able to operate independently, without a common code of conduct or a common set of core practice standards. Use of Schedule 4 substances (eg Botox) in their work raises issues related to access to what are prescription-only substances and the qualifications training and oversight of those who administer them. Use of devices such as lasers and intense pulsed light sources in their work is not regulated in all jurisdictions and training is variable.

It is difficult to assess the extent to which the current regulatory framework provides or maintains consumer safeguards because there are few sources of information. Medical insurance claims data suggests that medical practitioners working in the area of cosmetic practice have a higher claims frequency, which has increased at a much higher rate over the last ten years, than the average for all insured doctors. The most common reason for claims was dissatisfaction with the results.

## **A National Framework**

Where jurisdictions have moved to implement specific measures in relation to the cosmetic medical and surgical industry, it has usually been in response to local concerns about safety and quality of procedures and promotional methods. As the industry continues to expand rapidly across jurisdictions in an ad hoc way and consumer demand continues its dramatic increase, those concerns have become more widespread.

Australia implemented a national scheme of registration and accreditation for health professionals from 1 July 2010. It is also moving towards a national model of safety and quality accreditation for health care organisations, including a set of national safety and quality health service standards. It is producing recommendations for nationally uniform regulation of lasers and intense pulsed light sources. It is undertaking a national examination and consultation on options for regulation of unregistered practitioners.

To that extent, the die is already cast for a national approach or framework covering many aspects of the cosmetic medical and surgical industry.

The Working Group considered that a baseline of requirements within a national framework would provide consumers with some assurance of consistency in standards of conduct in the cosmetic medical and surgical industry across the country.

It considered that there were five interdependent elements that formed the linchpins for the national framework – the procedures, the promotion of the procedures, the practitioner, the patient and the place. Enhancement of consumer safeguards requires all five to work together. Recommendations are made in relation to each of the five elements.

Since the Working Group commenced the project, significant progress has been made in advancing the national initiatives. That has clarified the national context within which the project has been undertaken and has defined the mechanisms through which many of the recommendations can be progressed.

The national registration boards under the national registration and accreditation scheme for health professionals have been established. Two of the boards – the Medical Board of Australia and the Nursing and Midwifery Board of Australia – have jurisdiction over the two main groups of registered practitioners involved in cosmetic medical and surgical procedures – medical practitioners and nurses. Many of the recommendations are directed for the boards' attention.

The cosmetic medical and surgical industry is a rapidly growing and changing industry. In that sense, the Working Group's recommendations are a "work-in-progress". It recommends that the national boards keep the situation under review.



## SUMMARY OF NATIONAL FRAMEWORK FEATURES AND RECOMMENDED ACTIONS

### National Framework

- There should be a national framework covering cosmetic medical and surgical procedures, which includes a baseline of requirements.
- The national framework should be based on five interdependent elements – the procedures, the promotion of the procedures, the practitioner, the patient and the place.

### The Procedures - definition

#### Framework Feature:

*There should be consistency in the definition of cosmetic medical and surgical procedures*

#### RECOMMENDED ACTION -

- The term "cosmetic medical and surgical procedures" be the terminology used to capture cosmetic procedures within the national framework. That term is further defined as

"operations and other procedures that revise or change the appearance, colour, texture, structure or position of normal bodily features with the sole intention of achieving what the patient perceives to be a more desirable appearance or boosting the patient's self-esteem"

## The Promotion of the Procedures

### Framework Feature:

*There should be restrictions on advertising specific to cosmetic medical and surgical procedures by both registered professions and unregistered practitioners*

*Offering of cosmetic medical and surgical procedures as a prize should be prohibited*

### RECOMMENDED ACTION:

- The Medical Board of Australia monitor compliance with its recent Advertising Guidelines, particularly in relation to cosmetic medical and surgical practice.
- The Nursing and Midwifery Board of Australia monitor compliance with its recent Advertising Guidelines, particularly in relation to nurses practising independently and offering cosmetic medical and surgical procedures.
- When the National Law is next subject to substantive amendment, consideration be given to the need to further strengthen its provisions to prohibit the offering of gifts and inducements to attract people to undergo cosmetic medical and surgical procedures, and particularly to prohibit time-limited discounts.
- The offering of cosmetic medical and surgical procedures as a prize be prohibited (noting that this had been achieved under Lotteries legislation in three jurisdictions).

**Note** – in relation to unregistered practitioners, recommendations for further work are grouped at the end of the Recommendations section.

## The Practitioner

### Framework Feature:

*Treatment should only be provided if the practitioner has appropriate training, expertise and experience in the procedure;*

*In relation to follow-up care, the medical practitioner should be available personally or have a formal arrangement with another suitably qualified practitioner who has full access to the patient's history and these arrangements should be made known to the patient;*

*In relation to medical practitioners, the use of the title "specialist" should be restricted to those having specialist recognition;*

*Medical practitioners should be prevented from entering into financial incentive arrangements with agents who refer patients;*

*In relation to nurses, treatment should only be provided if the nurse has appropriate training, expertise and experience in the procedure;*

*Where nurses are administering scheduled drugs or undertaking other high risk procedures in relation to cosmetic medical and surgical procedures, some as independent practitioners, this should be done in accordance with applicable laws, protocols and best practice standards;*

*Where unregistered practitioners are involved in providing cosmetic medical and surgical procedures, they should be provided in a safe and ethical manner.*

## **RECOMMENDED ACTION -**

### **Medical Practitioners -**

- The Medical Board of Australia consider supplementing the Code “*Good Medical Practice: A Code of Conduct for Doctors in Australia*” with Supplementary Guidelines specifically covering cosmetic medical and surgical practice. (Attachment 2 provides a full draft of possible content of the proposed Supplementary Guidelines.) In particular, the proposed Supplementary Guidelines should emphasise that -
  - Treatment should only be provided if the medical practitioner has the appropriate training, expertise and experience in the particular cosmetic procedure being performed to deal with all routine aspects of care and any likely complications;
  - The medical practitioner is responsible for ensuring he or she has the necessary training, expertise and experience to perform a particular cosmetic procedure with reasonable care and skill.
- The Medical Board of Australia, in collaboration with medical colleges and professional associations, undertake a review of the minimum training and accreditation standards for medical practitioners performing cosmetic medical and surgical procedures -
  - The review process could be informed by the Australian Medical Council processes;

- The review should encompass the need for processes to be in place to ensure that medical practitioners undertaking cosmetic medical and surgical procedures are part of a program of peer review and ongoing audit.
- In association with the review of training and accreditation standards, the Medical Board of Australia give further consideration to the use of titles, lists of qualifications and memberships so that the public is not misled into believing that someone who specialises in a particular form of treatment is in fact a "specialist" if not so recognised through established processes. Use of titles, qualifications and memberships should not imply that the practitioner is more skilled or has greater experience than is the case.
- The Medical Board of Australia consider including in the Supplementary Guidelines to the Code "*Good Medical Practice: A Code of Conduct for Doctors in Australia*" provisions in relation to after-care. The provisions should make explicit the responsibility of the medical practitioner carrying out the cosmetic procedure to ensure there are protocols in place to cover all aspects of post-operative (post-procedural) care, including the full range of complications. The patient should be provided with specific written information on post-operative (post-procedural) instructions and after-care arrangements.
- The Medical Board of Australia consider including in the Supplementary Guidelines to the Code "*Good Medical Practice: A Code of Conduct for Doctors in Australia*" more explicit provisions to achieve the following:
  - Medical practitioners be prevented from entering into financial incentive arrangements with agents who recruit patients for procedures (eg payment of a commission for patients recruited).
  - Medical practitioners be prevented from offering financing schemes to patients (other than credit card facilities), either directly or through a third party, such as loans, as part of their cosmetic medical or surgical services.

#### **Nurses -**

- The Nursing and Midwifery Board of Australia consider the need for the development of supplementary guidelines to its code of professional conduct, specifically dealing with cosmetic medical and surgical procedures (including, for example, guidelines or a protocol for cosmetic Schedule 4 injections).

## Unregistered practitioners -

- Nationally uniform regulation of lasers and intense pulsed light sources (IPLs) should capture unregistered practitioners. The work of the ARPANSA working group tasked with producing such recommendations should be concluded as soon as possible.

## The Patient

### Framework Feature:

*There should be restrictions relating to the performance of cosmetic medical and surgical procedures on children;*

*There should be specific requirements relating to obtaining consent for the performance of cosmetic medical and surgical procedures on adults;*

*There should be reliable, accessible information available to consumers to assist them in making an informed choice about whether or not to undergo a cosmetic medical or surgical procedure;*

*The patient should recognise their responsibility to truthfully disclose their medical history, to enable the practitioner to accurately assess each patient's risk;*

*There should be accessible avenues for complaint, irrespective of whether the practitioner is a registered health professional or an unregistered practitioner.*

## RECOMMENDED ACTION –

- The Medical Board of Australia consider including in the Supplementary Guidelines to the Code “*Good Medical Practice: A Code of Conduct for Doctors in Australia*” specific provisions relating to the undertaking of cosmetic medical and surgical procedures to achieve the following -

In relation to adults:

- the first consultation should be with the operating medical practitioner, not with an agent/patient adviser
- there must be an assessment of the person's motivation for seeking treatment
- there is a need to ensure the person has realistic expectations

- there should be an opportunity for a person to be referred for psychological evaluation
- informed written consent should be obtained at a pre-procedure consultation within a reasonable time period before the day of the procedure and re-confirmed on the day of the procedure
- a cooling-off period between the initial consultation and performance of the procedure should be encouraged (but not mandated)

In relation to persons under 18 years of age, the above provisions should be supplemented or replaced (where the intent is inconsistent) by the following:

- if the requested surgery/procedure has no medical justification there must be a 'cooling off' period of 3 months, followed by a further consultation during which the request is further explored. The requested surgery/procedure should not be scheduled at the initial consultation.
- the person should be encouraged to discuss their desire for the surgery/procedure and any concerns with their general practitioner during the cooling off period.
- in addition, there should be a requirement for the person to be assessed by an appropriately qualified health professional (eg psychiatrist, psychologist or specialist counsellor)
- The above provisions also be referred for the attention of the Nursing and Midwifery Board of Australia, for potential inclusion (as appropriate) in supplementary guidelines to its code of conduct, specifically dealing with cosmetic medical and surgical procedures, to cover those situations where nurses are practising independently.
- There should be broader availability of factual, easily understood information for consumers contemplating cosmetic medical or surgical procedures from a source that is independent of practitioners and promoters. The consumer information resource being produced in Victoria be reviewed when available and considered for adoption nationally.
- The patient's responsibility to truthfully disclose their medical history, to enable the medical practitioner to accurately assess each patient's risk, be clearly stated in consumer information packages. "Medical history" includes allergies, current medications (including complementary and alternative therapies), social habits and previous operations.
- The consumer information resource include specific information relevant to cosmetic 'tourism' along the lines of the ISAPS/ASAPS guidelines or The Australasian Society of Aesthetic Plastic Surgery's Position Statement on Cosmetic Tourism included as Attachments 3 and 4.

- Arrangements for handling complaints against registered practitioners under the new national registration scheme be monitored as the scheme is consolidated.

## **THE PLACE**

### **Framework Feature:**

*No matter where a medical practitioner undertakes cosmetic medical and surgical procedures, infection control and other standards should apply*

*Similar standards should apply in relation to higher risk procedures undertaken by unregistered practitioners*

### **RECOMMENDED ACTION -**

- Jurisdictions use their best endeavours to ensure their legislation will enable the implementation of the proposed new national model of safety and quality accreditation being developed by the Australian Commission on Safety and Quality in Health Care, so that cosmetic medical and surgical procedures, wherever they occur in Australia, must be in accordance with key national safety and quality health service standards (eg infection control).

## **GENERAL**

- The Medical and Nursing and Midwifery Boards of Australia maintain a 'watching brief' on developments in the cosmetic medical and surgical industry as they relate to registered practitioners under their jurisdiction.

## **RECOMMENDATIONS FOR FURTHER WORK**

### **UNREGISTERED PRACTITIONERS**

There is to be a national project and consultation process on the regulation of unregistered health practitioners. The scope of the project as it proceeds to consultation is understood to be broad. The Working Group has made a number of observations where it believes that, in the interests of consumer protection, there should be consistency in the requirements on unregistered practitioners undertaking higher risk cosmetic medical and surgical procedures, such as beauty therapists, with those recommended for registered practitioners.

- It is therefore recommended that this report be made available to the project group undertaking the national project.
- In particular, the following points are recommended for consideration –
  - services should be provided in a safe and ethical manner;
  - advertising constraints consistent with those outlined in relation to the registered professions (medical practitioners and nurses) should also apply to unregistered practitioners where they are offering cosmetic medical and surgical procedures;
  - the requirements outlined in relation to the registered professions for assessment, ensuring realistic expectations, cooling-off periods, informed consent and consumer information should be taken into consideration in relation to those cosmetic medical and surgical services of beauty therapists which are higher risk and can cause physical responses potentially requiring medical intervention;
  - appropriate standards should apply to premises where cosmetic medical and surgical procedures are carried out;
  - robust and accessible complaints mechanisms should be available in relation to unregistered practitioners where they are offering cosmetic medical and surgical procedures.



## BACKGROUND TO THE PROJECT

### **Establishment and Terms of Reference -**

The South Australian Minister for Health submitted an agenda paper to the July 2008 Australian Health Ministers' Conference (AHMC) seeking support for investigation by the Australian Health Ministers' Advisory Council (AHMAC) of measures that could be taken to regulate the cosmetic surgery industry to provide greater consumer protection.

The agenda paper was prompted by concerns about the growth in advertising and marketing of cosmetic surgical and medical procedures and its potential to create confusion in the community about titles, memberships and qualifications. There was also concern about the potential for public demand for such procedures to drive inappropriate business activities to meet the demand, and for the increased possibility of unrealistic and unmet expectations of the public.

Of further concern, two States in recent years had recorded the deaths of young adults following a cosmetic procedure (liposuction in both cases), both of which were subject to Coronial investigation.

AHMC agreed to an investigation, with the matter being referred to the Clinical, Technical and Ethical Principal Committee (CTEPC) of AHMAC to progress. South Australia was requested to take the project lead and to establish an Inter-jurisdictional Working Group. The Working Group consisted of members from Health Departments and the Australian Commission on Safety and Quality in Health Care with backgrounds in clinical care, medical administration, clinical and health policy, safety and quality, workforce and legislation.

The Terms of Reference of the Working Group were:

1. To identify, and review the adequacy of, consumer safeguards in relation to cosmetic medical and surgical procedures and in particular, in relation to –
  - Advertising, marketing and recruitment
  - Information available to consumers and informed consent (including any specific issues for persons under 18 years of age)
  - Regulatory coverage
  - Professional/clinical standards of practice
2. To make recommendations to the Australian Health Ministers' Conference (AHMC), through the Clinical, Technical and Ethical Principal Committee (CTEPC) of the Australian Health Ministers' Advisory Council (AHMAC), on the need for and nature of additional safeguards for consumers

3. To identify in the report to AHMC options for progressing such safeguards through a national framework or baseline of requirements

## Scope

The Working Group was aware of *The Cosmetic Surgery Report - Report to the NSW Minister for Health - October 1999*<sup>1</sup>. Taking into account the relative recency of the report, its Australian context and its comprehensive nature - arguably the most comprehensive review on the topic undertaken in Australia to date - the Working Group used that report as a reference point. For the purposes of scoping the project, the Working Group used the following definition of cosmetic surgery (noting that the *Cosmetic Surgery Report* had used a similar definition):

*“a procedure performed to reshape normal structures of the body or to adorn parts of the body, with the aim of improving the consumer’s appearance and self-esteem”*

noting that -

- The notion of ‘improvement of appearance’ is a subjective one, defined by the consumer;
- Cosmetic surgical and medical procedures are initiated by the consumer, not by medical need;
- Cosmetic surgical and medical procedures include any cosmetic treatment, including invasive cosmetic surgery, cosmetic injections (pharmaceuticals), and other cosmetic procedures (ie lasers)

“Cosmetic surgery” excludes reconstructive surgery, being surgery which is performed on abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumours or disease. This is usually done to improve functions, but may also be done to approximate a normal appearance.

The project excluded gender reassignment surgery; tattooing; body piercing and cosmetic dentistry. Gender reassignment surgery was excluded because of the complex clinical issues involved. It was also noted that gender reassignment in some jurisdictions is covered by specific law, which sets parameters around the conduct of such procedures and/or enables a person to be legally identified as the opposite sex to that identified by a birth certificate. Tattooing, body piercing and associated body modification activities were excluded taking into account that they are generally covered by public health legislation dealing with skin penetration procedures, which may require businesses to be registered with local councils and infection control measures to be in place. Cosmetic dentistry was excluded as it had not been a core consideration in the initiation of the project.

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<sup>1</sup> The Cosmetic Surgery Report - Report to the NSW Minister for Health - October 1999, page 1

However, during the course of its deliberations the Working Group became aware of the increasing popularity of tooth whitening (bleaching) and the apparent increasing number of practitioners (registered and unregistered) undertaking such procedures, which had the potential to cause mottling and marbling of teeth, gum ulcerations and chemical burns. Its attention was drawn to a Victorian Magistrates' Court decision in September 2009 which found that tooth whitening was an invasive and irreversible procedure that should only be performed by registered dental care providers. The finding preceded the introduction of national registration and accreditation of health professionals but given that the National Law adopted by jurisdictions contains similar provisions to those considered in the Court proceedings, the Working Group wrote to the Chair of the new Dental Board of Australia, drawing attention to the Court's findings.

Given the timeframe for the project, the Working Group also considered it necessary to limit its scope to regulated professions (medical practitioners and nurses) who perform the majority of cosmetic medical and surgical procedures. Non-regulated groups such as beauty therapists and aestheticians were excluded, except to the extent that some of their activities, such as the provision of laser treatment and scheduled pharmaceuticals including injectables, could be captured by other regulatory mechanisms.

However, the Working Group left the way open to make recommendations as appropriate, particularly in relation to unregulated practitioners, with regard to future work outside the scope of this project.

## **Methodology**

The Working Group was mindful that, since the *NSW Cosmetic Surgery Report<sup>2</sup>*, a number of measures have been put into place in some parts of Australia and internationally to enhance consumer protection, some as a result of regulatory or other reviews which included extensive consultation. Developments have included practice standards, advertising guidelines, specific regulation in relation to children and enhanced consumer information. Attachment 1 summarises some of those developments.

The Working Group was also aware that several major national pieces of work of direct relevance to its deliberations were being undertaken concurrently with this project and were likely to have an impact on its recommendations.

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<sup>2</sup> Ibid

Accordingly, it undertook a mapping exercise to capture what was already in place or under development and could be drawn upon, rather than duplicating significant bodies of work.

The Working Group was also aware that segments of the cosmetic medical and surgical industry itself had been seeking to raise standards within their areas of operation and had sought to pursue that objective via submissions to the Australian Competition and Consumer Commission (in relation to a code of practice) and the Australian Medical Council (in relation to recognition as a medical specialty). Both of those processes had been public submission processes, with large numbers of submissions from an extensive range of organisations and individuals available on public websites. The National Health and Hospitals Reform Commission processes had also elicited some submissions that were relevant to aspects of the Working Group's deliberations and were available on the public website.

Taking all of the above into consideration, the Working Group was therefore in the advantageous position of having a wide range of very recent views and supporting material available to it that covered much of the scope of the project.

For those reasons, the Working Group did not undertake a public submission process. It prepared a draft consultation document for targeted consultation with a group of key stakeholders. The consultation included -

- Chairs of the new Medical and Nursing and Midwifery Boards of Australia
- Australian Medical Council
- Commonwealth Chief Medical Officer
- Commonwealth Chief Nurse and Midwifery Officer
- Health Departments
- Therapeutic Goods Administration
- Australian Radiation Protection and Nuclear Safety Agency's (ARPANSA)
  - Radiation Health Committee
- Australian Commission on Safety and Quality in Health Care
- National peak bodies including –
  - Medical Colleges
  - Medical Associations/Societies
  - Nursing organisations
  - Beauty therapy industry
  - Consumers

Twenty-six responses were received covering the range of stakeholders. Overall, there was a high level of support (much of it coming from medical organisations) for a national framework, with suggestions for refinement or enhancement of some recommendations.

The feedback was used to review and refine the document and finalise it for subsequent submission to CTEPC, AHMAC and AHMC for approval. The Final Report is more robust as a result of the constructive feedback.

## COSMETIC SURGICAL AND MEDICAL PRACTICE

### What is it?

*The Cosmetic Surgery Report – Report to the NSW Minister for Health, October 1999*<sup>3</sup> considered the cosmetic surgery industry in detail. It remains arguably the most extensive study undertaken in Australia. While there have been other jurisdictional reviews of the area since that time, they have tended to use *The Cosmetic Surgery Report* as their reference point. Information from that report is used in this report.

*The Cosmetic Surgery Report* noted that, while cosmetic surgery is difficult to define precisely, it has a number of key characteristics. It involves reshaping normal structures of the body using surgical and non-surgical techniques.

A central characteristic of cosmetic surgery is that it is initiated by the consumer to improve their appearance and self-esteem. Other medical procedures are performed for therapeutic reasons, as a result of medical need. However, delineating procedures performed for therapeutic reasons from those that are performed for cosmetic reasons is difficult. Another important feature is the subjective nature of judgements about improvement in appearance.

Cosmetic surgery covers a range of procedures, including surgical procedures, non-surgical procedures and dental procedures. Surgical procedures include breast enlargement, rhinoplasty (nose surgery), surgical face-lifts, abdominoplasty (tummy tuck) and liposuction. Procedures such as chemical peels, collagen injections, laser skin resurfacing, vein removal and laser hair removal are collectively referred to as cosmetic medicine.

### Who does it?

Cosmetic medical and surgical procedures, depending on the nature of the procedure, are mostly performed by medical practitioners, with nurses and beauty therapists also playing a role. *The Cosmetic Surgery Report* noted that medical practitioners performing cosmetic procedures include plastic surgeons, cosmetic surgeons, cosmetic physicians, general practitioners, dermatologists, ophthalmologists (eye surgeons), otolaryngologists (ear, nose and throat specialists) and to a lesser extent, oral and maxillofacial surgeons. As the Report noted,

Plastic surgeons have specialist surgical training and experience in plastic and reconstructive procedures, and perform cosmetic surgery.

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<sup>3</sup> *ibid*

Cosmetic surgeons do not necessarily have specialist surgical qualifications, and tend to be specifically trained in cosmetic procedures, usually in the USA.

Dermatologists have specialist training and experience in the skin and may perform dermabrasion, injections, peels and laser resurfacing, in combination with liposuction, cheek implants and other surgical procedures. Ophthalmologists have specialist training in eye surgery and most perform blepharoplasty (eyelid surgery), eye lifts and some brow lifts. Otolaryngologists have specialist training and experience in the ear, nose and throat and they perform facelifts, brow lifts and rhinoplasty (nose surgery) and laser skin treatments.

GPs performing cosmetic medicine may provide injections of fillers as well as Botox, peels, laser skin treatments and dermabrasion.

Nurses also play a significant role in the cosmetic surgery industry. In addition to their traditional roles, nurses also perform some cosmetic procedures and provide patient counselling in some plastic and cosmetic surgery clinics. A large number of practitioners who use injections in cosmetic medicine are nurses. They also provide some laser skin treatments, dermabrasion and peels, mostly under supervision of medical practitioners.

Beauty therapists are a third industry group, providing removal of unwanted hair and facials. The techniques used by beauty therapists have changed in recent years with the use of new equipment and techniques used in cosmetic medicine, such as lasers and IPL for removal of unwanted hair.<sup>4</sup>

Dermal therapists are beauty therapists trained in paramedical procedures, and specialise in treatment of high strength peels, microdermabrasion and laser treatments.<sup>5</sup>

The following professional groups, most of whom were identified in the Cosmetic Surgery Report, represent the range of medical practitioners involved in the cosmetic medical and surgical industry in Australia:

**Royal Australasian College of Surgeons (RACS)** – provides training and education in the nine surgical specialties into which it admits surgeons to fellowship (cardiothoracic surgery; general surgery; neurosurgery; orthopaedic surgery; otolaryngology head and neck surgery; paediatric surgery; plastic and reconstructive surgery; urology; vascular surgery; there are also fellows in ophthalmology and obstetrics and gynaecology).

RACS is accredited by the Australian Medical Council for the delivery of specialist medical education and training and professional development programs.

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<sup>4</sup> ibid pages 4 and 5

<sup>5</sup> Dermal Therapies, Faculty of Health, Engineering and Science, Victoria University, Melbourne.

**Australian Society of Plastic Surgeons (ASPS)** – provides training in plastic and reconstructive surgery and cosmetic surgery and publishes guidelines for standards of practice and research. It works closely with the Board of Plastic and Reconstructive Surgery of the Royal Australasian College of Surgeons, which is responsible for selection, training and supervision of plastic surgeons. ASPS members are Fellows of the Royal Australasian College of Surgeons in the specialty of plastic and reconstructive surgery.

**The Australasian Society of Aesthetic Plastic Surgery** – formed more than 30 years ago to provide education in aesthetic plastic surgery and to provide training in cosmetic surgery for plastic surgeons. It also promotes research in aesthetic cosmetic plastic surgery. Members are specialist plastic surgeons with a special interest in cosmetic or aesthetic surgery.

**Australasian Academy of Facial Plastic Surgery** – formed in 1990 to provide education to its specialist members in the field of facial plastic surgery. Membership includes otolaryngologists, head and neck surgeons, ophthalmologists, plastic surgeons, facio-maxillary surgeons and dermatologists who have an interest in plastic and reconstructive surgery of the head and neck. The AAFPS runs a four year training programme in facial cosmetic surgery.

**The Australian Society of Otolaryngology Head and Neck Surgery** – forms the Surgical Board in otolaryngology/head and neck surgery jointly with the Royal Australasian College of Surgeons. There is a long tradition of facial plastic surgery being performed by otolaryngologists and it is included in the curriculum and examined by the Board.

**Royal Australian and New Zealand College of Ophthalmologists** – trains and accredits specialist eye surgeons who are trained in dealing with the structure of the eye, vision and diseases of the eye. Education and training involves a period of at least two years of basic training in the specific technical skills of the specialty followed by successful training for the sub-specialty of ocular plastic surgery. Ophthalmologists perform some cosmetic surgery – blepharoplasty (eyelid surgery), eye lifts and some brow lifts. Complementary surgery such as rhinoplasty and facelifts is usually performed in collaboration with other surgeons.

**Australasian College of Dermatologists** – trains and accredits specialists with primary expertise in the skin. Education and training involves a period of at least two years of basic training in the specific technical skills for the specialty, two years training in a teaching hospital, followed by successful completion of advanced clinical training for four years and examination.

**The Royal Australian College General Practitioners (RACGP)** – is the specialty medical college for general practice in Australia, responsible for standards and curriculum for education. The College has a training role within a spectrum of less interventional cosmetic dermatological procedures which improve skin and facial health and appearance.

**Australian College of Rural and Remote Medicine (ACRRM)** – is the peak professional organisation for rural medical education and training in rural general practice in Australia.

It is one of two colleges responsible for setting and arbitrating standards for the medical specialty of general practice.

**The Australasian College of Cosmetic Surgery (ACCS)** – formed in 1999 in order to provide training and ethical standards for cosmetic surgery and related disciplines. Its members are registered medical practitioners and its membership base includes general surgeons, plastic surgeons, dermatologists, ear nose and throat surgeons, ophthalmologists and other medical practitioners who practise in cosmetic surgery.

**Cosmetic Physicians Society of Australasia** – formed in 1998 with the aim of providing standards for education and accreditation of its members. Members must be medical practitioners and must have practised in at least one area of cosmetic procedure for at least 12 months. Membership includes plastic surgeons and other specialists including general surgeons and dermatologists but most are general practitioners. All full members must have completed 12 months preceptorship with a suitable member of the Society to obtain ordinary membership.

**The Australasian College of Phlebology** – established in 1993 initially as the Sclerotherapy Society of Australia, to offer training and improve the standard of care related to venous disease. It is an association of medical practitioners and other health professionals such as scientists and sonographers.

**Australasian College of Aesthetic Medicine** – described as a fellowship of medical practitioners whose strategic objectives include: to promote education of college members and other persons directly associated with laser and aesthetic medicine activities; to promote the advancement of aesthetic medicine, its practice and integrity and to produce medical practitioners who are safe, skilled and competent in the management of all aspects of aesthetic medicine.

### **Where is it done and how much is done?**

Cosmetic medical and surgical procedures are performed in a variety of settings, including hospitals, day procedure centres and medical practitioners' rooms. In line with general trends, cosmetic surgical procedures are increasingly being performed in day procedure centres and, with rapidly changing technology providing alternatives to traditional surgical procedures, many procedures (such as liposuction, laser skin treatments and sclerotherapy [injection of a solution into unwanted varicose and spider veins]) are now being done in medical practitioners' rooms.

Non-surgical procedures are a burgeoning area – laser hair removal, injections, dermabrasion and light and medium skin peels are being performed in medical practitioners' rooms and in beauty salons.

It is a rapidly growing and changing industry which is difficult to quantify. Currently in Australia, no legislative requirement exists for the centralised collection of data or statistics relating to cosmetic medical and surgical procedures, invasive or otherwise.

Data that is captured is usually collected through licensed health facilities reporting and this data does not clearly define the nature of the cosmetic procedure.



There is also the probability of inconsistencies and discrepancies in the way data across jurisdictions is captured, coded and recorded as there is currently no standardised approach and not all jurisdictions currently require licensing of free-standing day procedure centres. In addition, any procedure that is performed in medical practitioners' rooms (as opposed to licensed facilities) will not be captured in this way, except where the type of sedation used brings them within the scope of licensing requirements.

Cosmetic (as opposed to therapeutic) procedures are not generally performed in the public hospital system and sit outside Medicare and private health insurance fund rebates (which provide possible alternative methods of data collection). Additionally, there is no available data which differentiates between initial cosmetic surgery and revision or reparative procedures. There is thus no method to ascertain the costs to both the public and private system for these procedures<sup>6</sup>.

Industry estimates provide some insight into the increasing uptake of some procedures. For example, the Cosmetic Physicians Society of Australasia indicated in 2008 that in the previous year, Australians spent an estimated \$300 million on treatments like Botox injections. In one year, that was per capita more than spent in the United States, according to comments attributed to the President of the Society. It was estimated that there had been about a 30 per cent increase over the previous couple of years and the industry was expecting probably another 10 per cent or more over the following year. Botox was the most popular procedure, followed by dermal fillers and then procedures such as laser procedures.<sup>7</sup>

In 2009, the Australasian College of Cosmetic Surgery indicated that cosmetic surgery was now a billion-dollar industry, with women spending \$130 million on breast procedures and liposuction every year.<sup>8</sup>

Cosmetic surgery “tourism” is another growing area. While it is not possible to estimate how many Australians travel overseas for cosmetic medical and surgical procedures (nor the numbers from overseas who come to Australia for such procedures) Nahai has noted the following trends in other countries<sup>9</sup>

“Travelling in search of excellence in healthcare is nothing new. Traditionally, those with the financial means would travel to Western Europe and the USA, often from

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<sup>6</sup> Honigman, Roberta. Patient Dissatisfaction with Cosmetic Surgery. Masters of Social Work, University of Melbourne, 2005 ( unpublished thesis)

<sup>7</sup> ABC News March 13, 2008, comments attributed to Dr Mary Dingley, President, The Cosmetic Physicians Society of Australasia

<sup>8</sup> Herald Sun November 6 2009, comments attributed to Australasian College of Cosmetic Surgery

<sup>9</sup> Nahai, F *Minimising risk in aesthetic surgery* Clinical Risk 2009; 15: 234-5

developing countries. However, over the last decade or two, we have seen a reversal; individuals from Western countries are now travelling to developing countries, not in search of excellence, but in search of bargain healthcare. The market in medical tourism is currently estimated to be between 20 and 40 billion US dollars annually, with a prediction that it may reach 100 billion within two years.”

He further notes that –

“Without question, some patients are operated on by well-qualified surgeons in certified and safe facilities with excellent results, for a fraction of the price they would have paid at home. Regrettably, this is not always the case. It is estimated that as many as 20% of the cosmetic tourists returning to the UK have a complication requiring attention by a specialist or even demanding hospitalisation.”

The Australasian Society of Aesthetic and Plastic Surgery in 2006 reported treating 36 people with complications arising from medical tourism on return to Australia. These were only the ones reported by Society members. The Society commented that –

“Many go unreported, are treated by other medical facilities or simply accept poor outcomes.”<sup>10</sup>

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<sup>10</sup> The Australasian Society of Aesthetic Plastic Surgery *Cosmetic Tourism 2009* (6 January 2010) Position Statement <http://www.asaps.org.au/position-statements.html>

## HOW IS IT REGULATED?

The regulatory framework within which cosmetic medical and surgical procedures are practised around Australia consists of a combination of professional (practitioner) registration, private health facilities licensing, public health measures (eg infection control), regulation of some of the devices and substances used in performing the procedures and more general consumer protection legislation, including in some jurisdictions, specific protection in relation to children.

Not all jurisdictions have all of the above measures in place, where they do have them in place they are not necessarily consistent and not all elements of the framework apply. For example, in relation to procedures performed in a medical practitioner's rooms (as opposed to a private hospital or day procedure centre), the medical practitioner is subject to professional registration and all of the measures that are applied through that mechanism. However, the medical practitioner's rooms are not captured by facilities-based licensing except in those jurisdictions where, because of the sedation used, they do come within the licensing requirements.

Two jurisdictions introduced specific regulation that restricts the carrying out of cosmetic medical and surgical procedures on children for non-medical reasons - Queensland, through its *Public Health Act 2005*, prohibits the performance of defined cosmetic procedures on children, subject to a "best interests" exception.

New South Wales, through its former Medical Board's *Cosmetic Surgery Guidelines* which supplemented its *Code of Professional Conduct Good Medical Practice* required a 'cooling off' period of 3 months followed by a further consultation during which the request was further explored, if the person was under 18 years of age. The requested surgery/procedure was not to be scheduled at the initial consultation and the person was to be encouraged to discuss the matter with their general practitioner during the cooling off period. With the introduction of national registration and accreditation of health professionals, the New South Wales Medical Board ceased to exist. The Medical Council of New South Wales has been established by the *Health Practitioner Regulation National Law (NSW)* to deal with medical practitioners' health, professional performance and conduct matters for medical practitioners whose principal place of practice is in NSW. The Council has approved in principle the *Cosmetic Surgery Guidelines* of the former Board.

All jurisdictions have independent Health Complaints Commissioners (however titled) with powers to investigate complaints about health services and practitioners.

NSW has a code of conduct that applies to unregistered health practitioners (including de-registered health practitioners) which aims to ensure they practise in a safe, ethical and competent manner. The Health Care Complaints Commissioner (HCCC) has power to investigate a complaint where it is alleged a practitioner has breached the code; if substantiated and the practitioner is considered by the HCCC to be a substantial risk to the public a prohibition order may be made to either ban their practice or put conditions on it; the HCCC may also issue a public warning about the practitioner and their services.

In addition, the Australian Health Workforce Ministerial Council agreed to a national project and consultation process on the regulation of unregistered health practitioners. It has been recognised that, while the majority of unregistered health practitioners engage in practice in a safe, competent and ethical manner, there are instances where these practitioners engage in serious misconduct that would lead to de-registration if they were subject to formal registration arrangements. A national approach would provide Australians with standards of conduct that the community expects of unregistered health practitioners and ways to manage breaches of those standards.

The consultation, led by Victoria, is to consider national standards of conduct that could be introduced as well as the mechanisms for complaints and investigations. It is not intended that this regulation should take the form of a formal registration scheme, and the current New South Wales negative licensing scheme may provide a foundation for the national approach. Consultations will occur in each State to enable all interested parties to contribute.

## **Professional registration**

### *Pre National Registration and Accreditation of Health Professionals -*

Medical Practice Acts (in some jurisdictions, omnibus health profession Acts) and the boards established under those Acts, for many years provided the mechanism by which medical practitioners were registered and protection of the public was established and maintained.

Boards registered practitioners who held various qualifications and satisfied certain other requirements (such as fit and proper person). The Acts, Regulations and codes of good practice established professional standards and defined unprofessional conduct. Disciplinary action could be taken where standards were not met. Impaired medical practitioners were monitored. Limitations could be placed on a practitioner's scope of practice.

In some (but not all) jurisdictions, in addition to a general register on which all registered medical practitioners were listed, there was also a specialist register on which medical practitioners having specialist qualifications were listed.

Where this occurred, the public was able to ascertain whether a medical practitioner had specialist qualifications in a particular field.

Similarly, nursing and midwifery practice Acts and the boards established under those Acts (in some jurisdictions, omnibus health profession Acts), for many years provided the mechanism by which nurses and midwives were registered and protection of the public was established and maintained. Boards registered practitioners who held various qualifications and satisfied certain other requirements (such as fit and proper person). Scope of practice was defined. The Acts, regulations, code of professional conduct and code of ethics established professional standards and defined unprofessional conduct. Disciplinary action could be taken where standards were not met.

#### *National Registration and Accreditation of Health Professionals -*

Following a Council of Australian Governments (COAG) decision in July 2006 to establish a single national registration and accreditation scheme for health professionals, beginning with the nine professional groups then registered in all jurisdictions (subsequently increased to ten), and a further COAG decision in March 2008 to establish the scheme by 1 July 2010 (with a further four professions joining the scheme from 1 July 2012), the professional registration landscape is in the process of undergoing considerable change.

On 3 November 2009 the *Health Practitioner Regulation National Law Act 2009*, known as the National Law, received Royal Assent in Queensland. All jurisdictions have progressively introduced legislation to adopt or apply the National Law in their jurisdiction. The Commonwealth was not required to adopt the National Law; however consequential amendments were required to Commonwealth legislation to support the implementation of the national registration and accreditation scheme.

The two registered professions within the scope of the project who are involved in cosmetic surgical and medical procedures (medical practitioners and nurses) will no longer be regulated under individual State health profession-specific registration Acts.

The National Law provides for specialist registration for medical practitioners. The new Medical Board of Australia has responsibility for making recommendations to the Australian Health Workforce Ministerial Council for approval of specialties, fields of specialty practice and specialist titles for registration purposes. Following Ministerial Council approval, the Board has published a list of specialties, fields of specialty practice and related specialist titles for the purposes of specialist

registration under the National Law. There is protection of title – medical practitioners cannot hold themselves out as being specialists unless registered as specialists in one of the recognised specialties.

The Australian Medical Council (AMC) assesses applications for recognition of fields of medical practice as medical specialties in Australia and provides advice to the Medical Board of Australia. Listing on the List of Australian Recognised Medical Specialties permits medical specialist training providers to participate in the AMC's accreditation of specialist medical education, training and professional development programs.

Schedule 4 of the *Health Insurance Regulations 1975* lists names of specialties, relevant organisations and relevant qualifications that are recognised by the Minister for Health and Ageing for the purposes of attracting Medicare rebates at the specialist level under the *Health Insurance Act 1973*. The List of Australian Recognised Medical Specialties maintained by the AMC does not relate to the Health Insurance Act. However, the recognition process as managed by the AMC can also lead to listing for the purposes of Schedule 4.

Cosmetic surgery is not currently recognised as a specialty under either Schedule 4 of the Health Insurance Regulations or on the List of Australian Medical Specialties. The Australasian College of Cosmetic Surgery has submitted an application to the AMC for Cosmetic Medical Practice to be recognised as a specialty. If the application is successful, any body wanting to be accredited as a provider of standards, training and certification in the proposed specialty would be required to apply to the Specialist Education Accreditation Committee of the AMC.

Plastic and reconstructive surgery is recognised as a medical specialty on the List of Australian Medical Specialties and also under Schedule 4 of the Health Insurance Regulations. The Royal Australasian College of Surgeons (RACS) has authorised the Australian Society of Plastic Surgeons to administer post-graduate surgical training programs for the specialty of plastic and reconstructive surgery. The training program is one of nine surgical training programs for which RACS is accredited by the AMC. Plastic and reconstructive surgeons do therapeutic cases, such as trauma, burns, deformity and cancer related surgery. They also undertake cosmetic and aesthetic procedures, such as breast augmentation and reduction, face lifts, abdominoplasty, rhinoplasty and liposuction.

The advent of national legislation, national boards and national standards provides a substantial opportunity to enhance consumer protection by providing that no matter where a practitioner practises in Australia, they will be governed by the same legislation and nationally-set standards and the way in which they represent themselves to the public will be subject to the same boundaries.

The significance of the national registration and accreditation scheme to the Working Group's deliberations and proposed recommendations is discussed in more detail later in this report.

### **Private health facilities licensing**

All jurisdictions have private health facilities licensing although it varies in the scope of its coverage. Private hospitals are licensed in all jurisdictions, most (but not all) jurisdictions license free-standing day procedure centres but medical practitioners' rooms are generally outside the scope of facilities-based licensing except where the type of sedation used brings them within the scope of the licensing requirements.

Day procedure centre licensing tends to be based around the nature of the procedures performed and typically involves consideration of the types of sedation used.

Some jurisdictions are reviewing their legislation. The Australian Commission on Safety and Quality in Health Care is undertaking a project to develop a new national model of safety and quality accreditation for health care organisations, including a set of national safety and quality health service standards to apply in the first instance to high risk areas. Part of the project involves examining the regulatory instruments for mandating the standards. This has led to the commencement of an associated project to explore opportunities for harmonisation of the coverage and definitions of private health facilities required to be licensed across Australia.

The advent of national standards and the possibility of private health facilities licensing covering the same facilities across Australia, and being extended to capture high risk procedures carried out in medical practitioners' rooms, provides an opportunity to enhance consumer protection and is discussed in more detail later in this report.

### **Medicare, accreditation, professional indemnity insurance**

There are a number of other mechanisms through which standards of medical practice are monitored.

The *Health Insurance Act 1973* and its regulations impose quality assurance requirements on providers for their services to be eligible for Medicare benefits. The requirements centre on professional training and recognition. They contain provisions which enable checks and balances to be exercised in relation to who provides what types of medical services - for example, who is recognised as a specialist for the purposes of attracting Medicare rebates at the specialist level under

Act; requirements for patients to be referred to specialists through a general practitioner; mechanisms for various forms of data collection and analysis and monitoring of overservicing.

Accreditation through external agencies is another mechanism for measuring and monitoring of standards. While most accreditation programs are voluntary and user-pays, as the Australian Commission on Safety and Quality in Health Care observed<sup>11</sup>,

"a high proportion of health services in Australia are accredited.

Maintaining their accreditation status is important for private health services such as day surgeries and private hospitals, because accreditation status is required to access funding from health insurers, Veterans' Affairs, accident compensation funders or before clinical training can be offered to tertiary students in health courses."

However, it also noted that

"there are notable gaps in accreditation of health services in Australia. A substantial and increasing number of procedures are performed in medical rooms. There is limited accreditation of services provided in medical rooms, dentistry and a range of allied health services provided in private practice."

As indicated previously, the new national model of safety and quality accreditation for health care organisations, including a set of national safety and quality health service standards, is intended to address these gaps and options for mandating the standards in relation to high risk areas are being examined.

The *Private Health Insurance Act 2007* and *Private Health Insurance (Health Insurance Business) Rules 2007* specify accreditation as one of the matters the Minister takes into account in declaring a hospital for the purposes of the legislation.

Professional indemnity insurance is a further mechanism in the regulatory framework by which both medical practitioners and the public are protected. It is a requirement of the National Law that registered health practitioners are insured (with a time-limited exemption for independent privately-practising midwives).

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<sup>11</sup> Australian Commission on Safety and Quality in Health Care *Discussion Paper: National Safety and Quality Accreditation Standards*, November 2006, page 6



## **Common Law obligations**

As *The Cosmetic Surgery Report*<sup>12</sup> observed, the doctor-patient relationship is defined in the common law in terms of the law of negligence, which imposes a duty of care on medical practitioners to care for patients.

As part of the duty of care, medical practitioners are obliged to provide such information as is necessary for the patient to give informed consent to treatment, including information on all 'material risks' of the proposed treatment. In deciding what is 'material' the medical practitioner should consider the 'nature of the matter to be disclosed, the nature of the treatment, the desire of the patient for information, the temperament and health of the patient and the general surrounding circumstances'<sup>13</sup>

"The courts regard the duty to warn as more onerous in cosmetic surgery because patients have a choice about whether to have the procedure. If there is a perceived level of inducement to have a procedure, coupled with failure to warn of risks, the doctor has a greater burden to demonstrate that the patient was properly informed. Cosmetic surgery patients may also ask more questions about risk, outcomes and the practitioner's experience." <sup>14</sup>

## **Drugs and injectables**

Therapeutic goods are regulated under the Commonwealth's *Therapeutic Goods Act 1989* and *Regulations* by the Therapeutic Goods Administration (TGA). A number of the substances used by practitioners of cosmetic medical and surgical procedures are listed in Schedule 4 (S4) of the *Standard for the Uniform Scheduling of Drugs and Poisons* - prescription only. These include substances such as -

Restylane, Perlane, Dermalive, Juvederm (hyaluronic acid)

Hylaform (hyaluronan, sodium hyaluronate)

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

Botox, Dysport (botulinum toxin)

Newfill, Nufill, Scupltra (polylactic acid)

Aquamid (polyacrylamide)

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<sup>12</sup> The Cosmetic Surgery Report op. cit. pages 15 and 16

<sup>13</sup> King CJ in *F v R* (1983) 33 SASR 189, cited with approval in *Rogers v Whittaker* (1992) 175 CLR 479 at 490

<sup>14</sup> The Cosmetic Surgery Report op. cit. page 15

which are generally administered for the purpose of temporarily removing/reducing wrinkles and lines on the face, around the eyes, forehead, lips and neck.

The advertising to consumers of Schedule 4 products is unlawful, constituting an offence under the *Therapeutic Goods Act*. However, the TGA's website suggests alternative wording that is consistent with the requirements of the Act. Medical practitioners and cosmetic/beauty therapists may legitimately continue promoting their businesses and services, by deleting the references to individual S4 items and substituting with phrases such as:

cosmetic injections

anti-wrinkle injections/treatments

wrinkle injections/treatments

injections/treatments for lips

injections/treatments for fine lines/folds/age lines

wrinkle and lip enhancement/fulfillment/augmentation

injections to enhance pouting of the lips

injections which reduce the depth of fine lines/wrinkles around the face/lips

Jurisdictional drugs and poisons legislation (however titled) reflects Uniform Scheduling and regulates the prescription, supply, possession and administration of these substances. Schedule 4 substances are prescription only - the use or supply of which should be by, or on the order of, a medical practitioner and available from a pharmacist on prescription.

### **Lasers and Intense Pulsed Light sources (IPLs)**

Lasers and Intense Pulsed Light (IPL) sources are used for a variety of cosmetic procedures (eg treatment of blood vessels, pigmented lesions, scarring, wrinkles and sun damage, resurfacing, hair removal) mostly performed in medical practitioners' rooms, day procedure centres or beauty therapists' premises. Where such procedures are performed in medical practitioners' rooms, various forms of anaesthesia may be used such as local anaesthesia and sedation.

Medical practitioners using lasers in cosmetic procedures come from a variety of backgrounds with a number of the specialist colleges providing training in use of lasers.

Class 4 lasers are the most powerful lasers and include all medical and cosmetic lasers (hair removal and treatment of skin pigmentation).

Beauty therapists may use less powerful lasers for hair removal but some use higher powered lasers (class 3B and 4).

It is difficult to determine what proportion of cosmetic procedures is undertaken by nurses. Advertising suggests some work independently and others work with medical practitioners, but under what level of supervision is not clear.

There is an Australian Standard on *Safe use of lasers in health care* (AS/NZS 4173:2004), which limits and classifies lasers used for medical purposes according to the degree of hazard. The Standard covers laser hazards, principles and procedures for laser safety, safe use, training of personnel, medical surveillance, laser safety monitoring and reporting, operator approval, quality testing, preventive maintenance and adequacy of facilities. The Standard recognises that all personnel using and handling lasers should have training appropriate to the task they perform. There is also a Standard on *Laser Safety* (AS2211).

Several jurisdictions have regulatory controls under their Radiation Protection/Safety legislation in relation to some classes of lasers. Queensland has the *Radiation Safety Act 1999 (Qld)* and *Radiation Safety Regulations 1999* which include lasers. There are also *Guidelines for the Development of a Radiation Safety and Protection Plan for Diagnostic, Therapeutic or Cosmetic practices using Laser Apparatus* which must be customised for each business and submitted to Queensland Health. In Tasmania, the *Radiation Protection Act 2005* and 2006 Regulations provide for the licensing of persons who use class 3B, class 4 lasers and Intense Pulsed Light Sources (IPL). At present, only medical practitioners are authorised via licence to use lasers. Tasmania is working towards implementing the licensing for IPLs when used for cosmetic purposes. Western Australia regulates Class 3B and class 4 lasers, regardless of the purpose of use.

The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) has a working group which is tasked with producing recommendations for nationally uniform regulation of these devices.

An opportunity exists through the work of ARPANSA for a national 'industry standard' to be set and this is discussed in more detail later in this report.

## **Fair trading**

The Commonwealth's *Trade Practices Act 1974* (TPA) promotes competition and fair trading and provides for consumer protection. The Act, which is administered by the Australian Competition and Consumer Commission (ACCC), prohibits conduct that is misleading, unfair or dishonest. This includes misrepresentation about the standard, quality, value or grade of services; conduct that is misleading or deceptive or likely to

mislead or deceive; and false representations about the sponsorship, approval, performance characteristics, accessories, uses or benefits of goods or services.

The Act also requires service providers to warrant that their services are carried out with due care and skill and are fit for the purpose for which they are supplied.

Advertising guidelines issued by former Medical Boards reflected the TPA provisions.

Jurisdictions have fair trading legislation (however titled) that mirrors the consumer protection provisions of the TPA. The TPA applies to corporations. Jurisdictional legislation applies to individuals, partnerships and other forms of professional associations, as well as corporations.

From 1 January 2011, the Australian Consumer Law will replace previous Commonwealth, State and Territory consumer protection legislation in fair trading acts and the TPA and one single law will apply across Australia, with consumer rights being the same across Australia.

The ACCC and the Health Care Complaints Commission (HCCC) of New South Wales (in consultation with similar organisations in other jurisdictions) produced the *Fair Treatment? Guide to the Trade Practices Act for the advertising or promotion of medical and health services* in 2000.<sup>15</sup> The main object of the guide is to help the health and medical sector associations, individual practitioners and others assisting in the provision of medical and health services develop strategies that will improve compliance with the requirements of the Act.<sup>16</sup>

As the ACCC comments -

"Consumers can be disadvantaged since a provider of a medical or health service knows more than the consumer about the service. This disparity in knowledge can tempt some providers into oversupplying services or advertising unrealistic expectations. ... In contrast, honest and accurate information presented in a readily understandable way can help consumers decide on services and procedures and choose between providers."

### **Advertising, marketing and promotion**

Cosmetic medical and surgical procedures are actively marketed and promoted extensively and aggressively in most areas of the media. Advertisements, 'advertorials' and stories promoting the benefits of cosmetic medical and surgical procedures appear regularly in newspapers, magazines and on television.

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<sup>15</sup> *Fair Treatment? Guide to the Trade Practices Act 1974 for the advertising or promotion of medical and health services*, Australian Competition & Consumer Commission, Commonwealth of Australia, July 2000

<sup>16</sup> *ibid*

Television programs devoted to promoting the procedures as life changing experiences for the better have become regular fixtures.

Many advertisements also offer inducements including discounts, more often than not time limited; free initial consultations; gifts or discounts if the client introduces a friend to the service. 'Before and after' photos form a common part of advertising.

Former Medical Boards around Australia had adopted general advertising provisions under their legislation (eg not false, misleading, deceptive, unreasonable expectation of beneficial treatment; no testimonials etc). Some jurisdictions (eg Victoria and New South Wales) had additional codes or guidelines specific to cosmetic procedures (eg 'before and after' patient photographs).

The new Medical Board of Australia and the Nursing and Midwifery Board of Australia have recently adopted extensive Advertising Guidelines, which, while not referring specifically to cosmetic procedures, contain provisions (eg 'before and after' patient photographs) that have particular relevance to cosmetic procedures.

Cosmetic surgical and medical procedures are sometimes offered as a prize - three jurisdictions (New South Wales, South Australia and Queensland) have provisions in their Lotteries legislation prohibiting such practices.

Practitioners, many of whom are medical practitioners, take on semi-entrepreneurial roles advertising and selling services that are not traditionally medically indicated. Methods of patient recruitment include the use of non-clinical agents or advisers who work in medical practitioners' rooms and who may receive a financial incentive related to the clients they sign up for procedures. In some instances, the client may not see the medical practitioner at the initial consultation, or indeed until the day of surgery.

Concerns about the wider health and social impacts of promotion of cosmetic medical and surgical procedures have been raised by social researchers and others over a number of years. As one submission noted in *The Cosmetic Surgery Report* put it <sup>17</sup> -

“cosmetic surgery is promoted as an anti-ageing device, which pathologises the process of natural bodily change and devalues older people in our community, especially older women....By altering normal bodies that undergo normal changes throughout the life cycle, and by removing or altering physical characteristics that impart individuality, cosmetic surgery acts as a powerful force that promotes and maintains a narrow beauty ideal. The socio-culturally defined body ideals for women and men are one of the factors involved in the creation and maintenance of body image dissatisfaction and eating disorders.”

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<sup>17</sup> The Cosmetic Surgery Report op. cit. page 56

A global survey commissioned by Dove in 2005 and quoted in an analysis of the Medical Council of New Zealand's Statement on Cosmetic Procedures<sup>18</sup> revealed that

“only 10% of women are free from concern about their body weight and shape. .... The pursuit of beauty has expanded well beyond diets and mascara to an era where a quarter of females aged 15 to 17 considers cosmetic surgery as a viable option for the future.”

A more recent survey undertaken by Girlguiding UK in 2009<sup>19</sup> of a representative sample of girls and young women across England, Wales, Scotland and Northern Ireland (not chosen specifically from within membership of Girlguiding UK), in age groups 7-11, 11-16 and 16-21 years presents a similar picture. The survey found that 50 per cent of girls aged 16-21 would consider surgery to change the way they look, with the most popular option being cosmetic surgery where a quarter of the girls were prepared to consider it. (Options were: cosmetic surgery; botox; gastric band/weight loss surgery; laser eye surgery; dental brace; other)

While it was not the role of the Working Group to debate the wider health and social impacts of promotional activity, it is within its scope to consider whether the current regulatory framework within which the promotional activity occurs is working as well as it might in protecting the interests of the consumer and whether it is acceptable for different 'boundaries' to continue to be tolerated for promotion of medical procedures that are not driven by medical need, particularly where there is significant opportunity for financial gain by those promoting them.

It was noted that the New Zealand Health and Disability Commissioner, in a submission to the New Zealand Medical Council, emphasised that advertising in this area must be realistic and not oversell the benefits of cosmetic procedures. While medical practitioners in this field operate in a commercial market, the information provided is still pre-operative information that the consumer will consider in deciding whether to undergo a particular procedure.<sup>20</sup>

In the international context, the Working Group noted that in France, aesthetic plastic surgery cannot be advertised or promoted to the public in any form, direct or indirect.<sup>21</sup>

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<sup>18</sup> Scott, Kelly *Under the knife: An analysis of the Medical Council of New Zealand's Statement on Cosmetic Procedures* (2009) 16 JLM 625, p 626 (Dove: *Beyond Stereotypes: Rebuilding the Foundation of Beauty Beliefs* (February 2006))

<sup>19</sup> Girlguiding UK, *Girls' Attitudes Survey 2009 – Health and Wellbeing* [www.girlguiding.org.uk/girlsattitudes](http://www.girlguiding.org.uk/girlsattitudes)

<sup>20</sup> Scott, Kelly op.cit. 646, 647

<sup>21</sup> Fogli, *A France sets standards for practice of aesthetic surgery* *Clinical Risk* 2009; 15: 224-6

## A NATIONAL FRAMEWORK

### Why is a national framework needed?

As *The Cosmetic Surgery Report*<sup>22</sup> found, it is difficult to assess the extent to which the regulatory framework maintains consumer safeguards in the area of cosmetic surgical and medical practice because there are few sources of information.

One potential source, albeit not providing a complete picture, is claims for compensation. In the submission of the Medical Insurance Group Australia (MIGA) to the Australian Medical Council (AMC) in response to the application to recognise cosmetic medical practice (CMP) as a medical specialty, interesting information is provided in relation to the frequency of claims<sup>23</sup>. (MIGA provides medical indemnity insurance to a range of medical practitioners.)

While it was responding to one of the AMC's recognition criteria as to whether CMP was a well defined, distinct and legitimate area of medical practice with a sustainable base in the medical profession, MIGA's submission includes the following point –

“a. MIGAS's experience mirrors the available industry experience being that the number of doctors, procedures and claims (for compensation and/or legal advice) has increased in the area of cosmetic medicine over the past 11 years eg claims frequency for doctors working in the area of cosmetics have a higher claims frequency (number of claims per 100 doctors) than the average for all doctors insured with MIGA. This frequency has increased from 30.5% for the last 11 years to 38% over the last 3 years; compared with 4.5% and 4.2% for the respective periods for all doctors.”

Experience in the United Kingdom is outlined in an article in the Medical Defence Union (MDU) Journal in 2006. Dr Stephen Green, Head of Risk Management, MDU, examined data from cosmetic surgery claims settled by the MDU in the previous 10 years.<sup>24</sup> He found that "by far the most common reason for claims arising from cosmetic surgery was dissatisfaction with the aesthetic results, perhaps reflecting a need for better pre-operative counselling to ensure the patient has realistic expectations of what surgery can achieve". Breast surgery accounted for one-third

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<sup>22</sup> The Cosmetic Surgery Report op. cit. page 16

<sup>23</sup> *Recognition of cosmetic medical practice as a Medical specialty*, MIGA letter to AMC 3 June 2009 [www.amc.org.au/](http://www.amc.org.au/)

<sup>24</sup> Green, S. *Review of independent sector cosmetic surgery claims*, MDU Journal Volume 22 Issue 2 December 2006 Claims Trends 23-24

(85) of all claims, followed by facial surgery one-third (82) of the claims (including laser treatment) and liposuction (36) 14%.

The Healthcare Commission's report to the Chief Medical Officer on the provision of cosmetic surgery in England analysed complaints to the National Care Standards Commission and Healthcare Commission over 2003/2004. 23 (out of a total of 65 acute service complaints) related to cosmetic surgery, of which 16 related to laser treatments and the most common complaint was that the outcome was not what the patient had expected.<sup>25</sup>

What is clear is that cosmetic surgery has become a multi-million dollar entrepreneurial industry. In Australia, cosmetic surgery is regarded as a 'high risk area of medicine' (Cornwall, 2000)<sup>26</sup> where rapid and ad hoc growth has opened the way for unregulated practices and questionable methods of promotion, posing ethical dilemmas for some members of the medical profession, consumers and legislators.

The cosmetic medical and surgical industry is highly mobile. Its advertising and promotion, direct and indirect, is pervasive, transcends State borders and appears across the spectrum of print and electronic media. The internet has opened up further promotional opportunities and potentially another audience and market.

Cosmetic surgery tourism raises particular safety issues for patients. As Nahai observes<sup>27</sup>

"Some patients leave home on 'package tours' not even knowing the surgeon who will operate on them, let alone details about the surgeon's qualifications or anything about where the procedure will take place. In fact, some patients leave their countries without even knowing whether they are a suitable candidate for the procedure that they seek."

The public perception of cosmetic surgery is that it is quick, easy, painless and with little or no risk, whereas most procedures are extremely complex and require 'a high degree of surgical skill and aesthetic appreciation.'<sup>28</sup>

Increasingly, cosmetic surgery is being performed in day procedure centres and medical practitioners' rooms, away from the private and public hospital system. Current regulatory provisions allow any registered medical practitioner to set up in

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<sup>25</sup> Healthcare Commission, *Provision of cosmetic surgery in England* - report for the Chief Medical Officer Sir Liam Donaldson 58

<sup>26</sup> Cornwall, A. (2004) *Facing up to it: A review of the NSW Cosmetic Surgery Inquiry*. 9<sup>th</sup> IIR Medico-legal congress, February 2000.

<sup>27</sup> Nahai, F, op. cit. 235

<sup>28</sup> Orton, C. *Regulating cosmetic surgery*. British Medical Journal(2002) 324: 1229-1230



practice and call themselves a cosmetic surgeon or physician, conveying the impression that they are specifically qualified or specialise in the area.

In other areas of medicine, the general practitioner (GP) is the "gatekeeper" for referral to surgeons. Where the cosmetic surgery industry sells procedures directly to the public, a GP referral is not required. This means that the patient's regular "family" GP is not able to offer the patient an opportunity for independent, objective discussion about the appropriateness of the procedure, from either a physical or psychological perspective, unless specifically sought by the patient. It also means that the GP is potentially uninvolved in post-procedural care, with that responsibility falling to the practitioner carrying out the cosmetic procedure. Some GPs are themselves the providers of cosmetic medical and surgical procedures.

Where jurisdictions have moved to implement specific measures in relation to the cosmetic surgery industry, it has usually been in response to local concerns about issues such as safety and quality of procedures and promotional methods. As the industry continues to expand across jurisdictions, those concerns have become more widespread.

Australia has implemented a national scheme of registration and accreditation for health professionals from 1 July 2010. It is also moving towards a national model of safety and quality accreditation for health care organisations, including a set of national safety and quality health service standards. To that extent, the die is already cast for a national approach or framework covering many of the components of the cosmetic medical and surgical industry.

It is important that national consistency is also applied to those parts of the industry that fall outside the scope of those national initiatives. Unless it is, there is the potential for an already diverse and divided industry to become more fragmented. Unregistered practitioners are a case in point. While some consistency in standards may be introduced in relation to their use of lasers and IPLs once the ARPANSA project comes to fruition, in other respects this group of practitioners remains largely able to operate independently, without a common code of conduct or a common set of core practice standards. It is acknowledged, however, that some facets of the industry have taken the initiative to establish codes and standards for themselves. Unless some parameters are set, there is the potential for the gulf between regulated and unregulated practitioners in the cosmetic medical and surgical industry to become wider, to the detriment of consumers.

The Working Group considers that a baseline of requirements within a national framework would provide consumers with some assurance of consistency in standards of conduct in the cosmetic medical and surgical industry across the country.

It noted, however, that if a jurisdiction had introduced detailed legislative measures on aspects of the matter in response to particular local circumstances, it was unrealistic to expect their relaxation – the proposed national framework should set a baseline of requirements.

The Working Group has also made a number of observations where it believes that, in the interests of consumer protection, there should be consistency in the requirements on unregistered practitioners undertaking higher risk cosmetic procedures, such as beauty therapists, with those recommended for registered practitioners. There are recommendations for further work to be undertaken to determine the most appropriate mechanism for this to be achieved.

#### **Recommendation**

- **There should be a national framework covering cosmetic medical and surgical procedures, which includes a baseline of requirements.**

#### **What should a national framework capture?**

The Working Group considered that there were five interdependent elements that formed the linchpins for a national framework – the procedures, the promotion of the procedures, the practitioner, the patient and the place. Enhancement of consumer safeguards requires all five to work together.

The Working Group identified a number of framework features that it considered should underpin a baseline of requirements for a national framework. They are described under the five elements - the procedures; the promotion of the procedures; the practitioner; the patient and the place.

The framework features are then translated into recommendations for action to achieve a national baseline of requirements and mechanisms to progress them are identified.

#### **Recommendation**

- **The national framework should be based on five interdependent elements – the procedures, the promotion of the procedures, the practitioner, the patient and the place.**

## The Procedures - definition

### *Framework Feature:*

*There should be consistency in the definition of cosmetic medical and surgical procedures*

The Working Group noted that, where regulation existed in Australia around the cosmetic surgery industry, there was variation in the way in which it was defined and therefore what was captured within the scope of the regulatory controls.

It considered that common terminology should be used so that there was a common understanding and to ensure that common elements were captured within a national framework.

The collective term "*cosmetic medical and surgical procedures*" is proposed as a more inclusive descriptor of the procedures proposed to be encompassed. That term is further defined as -

"operations and other procedures that revise or change the appearance, colour, texture, structure or position of normal bodily features with the sole intention of achieving what the patient perceives to be a more desirable appearance or boosting the patient's self-esteem."

Reconstructive surgery, being surgery performed on abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumours or disease, is not intended to be captured, nor are procedures involved in gender reassignment. Cosmetic dentistry, tattooing, body piercing and associated body modification activities are not intended to be captured.

### **Recommendation**

- **The term "cosmetic medical and surgical procedures" be the terminology used to capture cosmetic procedures within the national framework. That term is further defined as**

**"operations and other procedures that revise or change the appearance, colour, texture, structure or position of normal bodily features with the sole intention of achieving what the patient perceives to be a more desirable appearance or boosting the patient's self-esteem"**

## The Promotion of the Procedures

### *Framework Features:*

*There should be restrictions on advertising specific to cosmetic medical and surgical procedures by both registered professions and unregistered practitioners*

*Offering of cosmetic medical and surgical procedures as a prize should be prohibited*

The Working Group noted that former Medical Boards around Australia had adopted general advertising provisions under their legislation (eg not false, misleading, deceptive; not creating an unreasonable expectation of beneficial treatment; no promotion of unnecessary or inappropriate use of medical services; no use of testimonials etc). Some jurisdictions (eg Victoria and New South Wales) had additional codes, guidelines or regulations specific to advertising of cosmetic procedures (eg "before and after" patient photographs).

The national registration and accreditation scheme (the national scheme) for (ten) health professions came into force on 1 July 2010 in all States and Territories that had enacted the National Law. With the establishment of the national scheme, the autonomous State-based boards have been replaced by (ten) national boards, such as the Medical Board of Australia and the Nursing and Midwifery Board of Australia, and individual State health profession-specific registration legislation has been repealed, including codes, regulations and guidelines under it. While that has meant that advertising provisions, including the specific cosmetic surgery guidelines developed by individual jurisdictions, have disappeared, it provides a significant opportunity for them to be re-introduced and applied nationally as a standard approach. The Working Group believes that the nature of cosmetic procedures makes it highly desirable that those additional parameters be reinstated.

The Working Group noted that the ten national boards (including the Medical Board of Australia) released a standard set of Advertising Guidelines for consultation in March 2010. The guidelines were subsequently adopted by the boards and took effect on 1 July 2010.

The Advertising Guidelines apply generally to all registered medical practitioners, are extensive and appear to capture most of advertising restrictions the Working Group considers necessary in relation to cosmetic medical and surgical practice.

It remains to be seen whether the requirements relating to 'before and after' photos need to be more explicit, for example - stipulate that photographs that purport to be of the same person must in fact be of the same person; require that where

photographs depict, or claim to depict, the results of medical services, they must be accompanied by a prominent statement to the effect that the photographs show the result of the medical service performed on one person and there is no guarantee that other persons will experience the same or a similar result. It is proposed that the Medical Board of Australia monitors compliance with its Advertising Guidelines, particularly in relation to cosmetic medical and surgical practice.

The Advertising Guidelines, which sit within the scope of the legislative restrictions in the National Law, include reference to advertising of price information and use of gifts or discounts in advertising, and discourage practices, including time-limited discounts, that may mislead or encourage unnecessary use of services.

The advertising provisions in the new National Law do not *prohibit* offering gifts, discounts or other inducements to attract a person to use a health service provided by a health practitioner as long as the advertisement also states the terms and conditions of the offer. Time-limited discounts in particular can place additional pressure on a person to make a decision quickly to go ahead with a cosmetic medical or surgical procedure. The Working Group considered that such inducements, particularly time-limited discounts, were highly inappropriate in relation to cosmetic medical and surgical procedures, which are not based on medical need, and should not be permitted.

It noted that a professional body in the industry, through its own code of practice, had prohibited such practices by its members<sup>29</sup> and considers that such a prohibition should apply across the industry.

The Working Group was also mindful of the recency of the National Law and acknowledged that there needed to be a period to enable its operation in practice to be consolidated. It therefore proposes that the Medical Board of Australia monitors compliance with its Advertising Guidelines, particularly in relation to cosmetic medical and surgical practice. When the National Law is next subject to substantive amendment, consideration be given to the need to further strengthen its provisions to prohibit offering of gifts and inducements to attract people to undergo cosmetic medical and surgical procedures, and particularly to prohibit time-limited discounts.

In relation to nurses, the Working Group recognised that the numbers practising independently and offering cosmetic medical and surgical procedures is likely to be much smaller than for medical practitioners. Nevertheless, it considered that the same advertising constraints should apply to such independent practitioners, and noted that the Nursing and Midwifery Board of Australia had adopted the same Advertising Guidelines as the Medical Board of Australia to apply from 1 July 2010.

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<sup>29</sup> The Australasian College of Cosmetic Surgery *Code of Practice 2009* [www.accs.org.au](http://www.accs.org.au)

The Working Group proposes that the Nursing and Midwifery Board of Australia monitors compliance with its Advertising Guidelines, particularly in relation to nurses practising independently and offering cosmetic medical and surgical procedures.

In relation to unregistered practitioners, the Working Group considers that advertising constraints consistent with those for registered professions should apply where they are offering cosmetic medical and surgical procedures. Further work should be undertaken to determine the most appropriate mechanism for this to be achieved.

The Working Group considered that the offering of cosmetic surgery and cosmetic medical procedures as a prize should be prohibited. They are not a "commodity" to be treated lightly - they are medical interventions which carry risks and a complication and failure rate. The Working Group was aware that three jurisdictions, through their Lotteries Acts and/or Regulations, prohibited such practices and recommends that such a prohibition form part of the national framework.

#### **Recommendation**

- **The Medical Board of Australia monitor compliance with its recent Advertising Guidelines, particularly in relation to cosmetic medical and surgical practice.**
- **The Nursing and Midwifery Board of Australia monitor compliance with its recent Advertising Guidelines, particularly in relation to nurses practising independently and offering cosmetic medical and surgical procedures.**
- **Advertising constraints consistent with those for registered professions should also apply to unregistered practitioners where they are offering cosmetic medical and surgical procedures and further work should be undertaken to determine the most appropriate mechanism for this to be achieved.**
- **When the National Law is next subject to substantive amendment, consideration be given to the need to further strengthen its provisions to prohibit the offering of gifts and inducements to attract people to undergo cosmetic medical and surgical procedures, and particularly to prohibit time-limited discounts.**
- **The offering of cosmetic medical and surgical procedures as a prize be prohibited (noting that this had been achieved under Lotteries legislation in three jurisdictions).**

## The Practitioner

### *Framework Features:*

*Treatment should only be provided if the practitioner has appropriate training, expertise and experience in the procedure;*

*In relation to follow-up care, the medical practitioner should be available personally or have a formal arrangement with another suitably qualified practitioner who has full access to the patient's history and these arrangements should be made known to the patient;*

*In relation to medical practitioners, the use of the title "specialist" should be restricted to those having specialist recognition;*

*Medical practitioners should be prevented from entering into financial incentive arrangements with agents who refer patients;*

*In relation to nurses, treatment should only be provided if the nurse has appropriate training, expertise and experience in the procedure;*

*Where nurses are administering scheduled drugs or undertaking other high risk procedures in relation to cosmetic medical and surgical procedures, some as independent practitioners, this should be done in accordance with applicable laws, protocols and best practice standards;*

*Where unregistered practitioners are involved in providing cosmetic medical and surgical procedures, they should be provided in a safe and ethical manner*

As noted earlier in the report, cosmetic medical and surgical procedures, depending on the nature of the procedure, are mostly performed by medical practitioners, with nurses and beauty therapists also playing a role. Medical practitioners performing cosmetic procedures include plastic surgeons, cosmetic surgeons, cosmetic physicians, general practitioners, dermatologists, ophthalmologists (eye surgeons), otolaryngologists (ear, nose and throat specialists) and to a lesser extent, oral and maxillofacial surgeons.

Nurses also play a significant role in the industry. In addition to their traditional roles, nurses also perform some cosmetic procedures and provide patient counselling in some plastic and cosmetic surgery clinics. A large number of practitioners who administer injections in cosmetic medicine are nurses.

They also provide some laser skin treatments, dermabrasion and peels, mostly under supervision of medical practitioners but some in premises distant from a medical practitioner and some independently.

Beauty therapists are a third industry group, providing cosmetic services including removal of unwanted hair, facials and some peels. With the advent of new technology, services offered by beauty therapists have become more sophisticated and present higher risks to the public.

The practitioners thus fall into two groups - registered and unregistered.

### **Registered practitioners -**

With the implementation of the national registration and accreditation scheme, medical practitioners and nurses are no longer registered by autonomous State boards set up under State legislation. This means that, for the first time, a medical practitioner or nurse, no matter where in Australia they practise, is governed by the same legislation and subject to the same nationally-set standards.

The National Law provides for the national boards for each profession and the broad requirements for registration. Under the legislation, boards set standards and establish codes of conduct.

### **Medical Practitioners**

The Australian Medical Council (AMC), on behalf of the former Medical Boards of all States and Territories, developed a Code of Conduct - *Good Medical Practice: A Code of Conduct for Doctors in Australia*<sup>30</sup>.

The Code sets out the principles that characterise good medical practice and makes explicit the standards of ethical and professional conduct expected of medical practitioners by their professional peers and the community. Many of the policy objectives outlined above are captured by the Code and/or the National Law. The Code has been supported and welcomed by the medical profession as represented through the Australian Medical Association and by the Consumers Health Forum of Australia. The Medical Board of Australia has adopted the Code, commencing 1 July 2010, in order to provide guidance to medical practitioners registered by the Board on matters of professional practice.

The Working Group considers the advent of national registration provides a significant opportunity to gain national consistency and address some of the features of cosmetic medical and surgical practice that have characterised its development outside of 'mainstream' medicine and surgery.

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<sup>30</sup> Australian Medical Council Limited *Good Medical Practice: A Code of Conduct for Doctors in Australia*, August 2009 [www.goodmedicalpractice.org.au](http://www.goodmedicalpractice.org.au)



While noting that the Medical Board of Australia has adopted the Code *Good Medical Practice: A Code of Conduct for Doctors in Australia* and supporting that action, the Working Group believes there is a case for the Code to be supplemented by a set of guidelines specifically covering cosmetic medical and surgical practice because of the particular nature of the industry. The Working Group recommends that the Medical Board of Australia consider supplementing its Code *Good Medical Practice: A Code of Conduct for Doctors in Australia* with Supplementary Guidelines covering cosmetic medical and surgical practice. This is not to imply that some aspects of the Supplementary Guidelines do not have more general applicability across the medical profession – rather, it is to recognise that medical practitioners practising in this area are operating in a commercial market where patients seek procedures as a matter of choice, rather than medical need, and where the successful outcome of the procedure is significantly measured by whether the patient’s expectations are met. This is different from other areas of medicine, where objective indicators for treatment and outcome criteria such as morbidity and mortality rates exist, and warrants specific checks, balances and guidance.

The Working Group noted that in various countries and in some parts of Australia, specific guidelines or statements have been introduced relating to cosmetic surgery/procedures to complement or supplement generic good medical practice codes. For example, in the United Kingdom, the Independent Healthcare Advisory Services produced a document *Good Medical Practice in Cosmetic Surgery/Procedures*<sup>31</sup> to complement the General Medical Council (GMC) publication *Good Medical Practice*<sup>32</sup> with particular reference to work carried out in the field of cosmetic surgery. The document is not intended to replace the general guidance and is to be read in conjunction with *Good Medical Practice* - the GMC's website has a link to it.

In Singapore, the College of Family Physicians and Academy of Medicine Singapore in July 2008 (updated October 2008) launched *Guidelines on Aesthetic Practices for Doctors*<sup>33</sup> which have been endorsed by the Singapore Medical Council (SMC) as a standard for aesthetic practice for doctors. The Guidelines are to be read in conjunction with the SMC's *Ethical Code and Ethical Guidelines*.

An Aesthetic Practice Oversight Committee has been formed under the SMC to regulate doctors engaged in aesthetic practices in accordance with the Guidelines.

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<sup>31</sup> Independent Healthcare Advisory Services *Good Medical Practice in Cosmetic Surgery/Procedures*, May 2006

<sup>32</sup> General Medical Council *Good Medical Practice*, May 2001, London

<sup>33</sup> College of Family Physicians Singapore, Academy of Medicine Singapore, Singapore Medical Council *Guidelines on Aesthetic Practices for Doctors*, October 2008 (updated)

The Working Group acknowledged that the former New South Wales Medical Board<sup>34</sup> and the Medical Council of New Zealand<sup>35</sup> both introduced specific guidelines or statements relating to cosmetic surgery/procedures.

The Working Group draws on some of the content of both of those documents in making its suggestions as to potential content of such guidelines. Attachment 2 provides a draft of possible content of the proposed Supplementary Guidelines.

The proposed Supplementary Guidelines would be intended to be read in conjunction with the *Code Good Medical Practice: A Code of Conduct for Doctors in Australia*. The draft at Attachment 2 attempts to link the content to relevant provisions in the *Code Good Medical Practice*, as had been done with the former New South Wales Medical Board's Supplementary Guidelines. However, some of the other examples mentioned above are 'stand-alone' documents, to be read in conjunction with the generic code. The most appropriate format for presentation would be a matter for the Medical Board of Australia to determine.

Ultimately, one of the key issues for consumers is the quality, level and extent of training of the practitioner in the procedure being performed. The *Code Good Medical Practice: A Code of Conduct for Doctors in Australia* makes explicit the standards of ethical and professional conduct expected of doctors by their professional peers and the community. Medical practitioners are expected to recognise and work within the limits of their competence and scope of practice; they are expected to ensure they have adequate knowledge and skills to provide safe clinical care and to provide treatment options based on the best available information.<sup>36</sup>

The Working Group considers that the Supplementary Guidelines should emphasise to the medical practitioner that –

1. Treatment should only be provided if you have the appropriate training, expertise and experience in the particular cosmetic procedure being performed to deal with all routine aspects of care and any likely complications.
2. You are responsible for ensuring that you have the necessary training, expertise and experience to perform a particular cosmetic procedure with reasonable care and skill.

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<sup>34</sup> New South Wales Medical Board *Cosmetic Surgery Guidelines*, June 2008

<sup>35</sup> Medical Council of New Zealand *Statement on Cosmetic Procedures*, October 2007

<sup>36</sup> Australian Medical Council Limited *Good Medical Practice: A Code of Conduct for Doctors in Australia*, *op. cit.* 2.2 *Good patient care*

As noted earlier in the report, there is a range of medical practitioners involved in undertaking cosmetic medical and surgical procedures. Cosmetic medical or surgical practice is not recognised as a speciality – rather, it is an area of practice.

The Working Group was aware that The Australasian College of Cosmetic Surgery has submitted an application to the AMC for Cosmetic Medical Practice to be recognised as a speciality. It makes no comment on whether or not such recognition should occur, recognising that the application will be considered on its merits through the processes specifically established to deal with such applications.

Whether or not recognition of Cosmetic Medical Practice as a specialty occurs, the Working Group considers there is a need for guidelines or standards outlining minimum training and accreditation requirements for medical practitioners performing cosmetic procedures. The issue is not so much whether the practitioner has specialist recognition, but whether the practitioner has appropriate expertise in the procedures they are performing.

The Working Group noted a very recent report of a study by the United Kingdom National Confidential Enquiry into Patient Outcome and Death (NCEPOD) – *On the face of it – A review of the organisational structures surrounding the practice of cosmetic surgery*<sup>37</sup>. The aim of this study was to investigate variations in organisational structures surrounding the practice of cosmetic surgery in England, Scotland, Wales, Northern Ireland and the Offshore Islands. Four areas were studied –

1. Advertising, consent and patient information
2. The structure and case mix of teams providing cosmetic surgery
3. Postoperative follow-up, policies, facilities and protocols
4. Patient records and clinical audit

The study highlighted inadequacies amongst both providers and professionals working in the field of cosmetic surgery. It found that many cosmetic surgery sites were offering “a menu of procedures, some of which were only performed infrequently”.<sup>38</sup> It called, inter alia, for the issuing of national guidelines as to the training, level of knowledge and experience required for a cosmetic surgeon to achieve and maintain competence in the procedures he or she undertook.<sup>39</sup>

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<sup>37</sup> NCEPOD *On the face of it – A review of the organisational structures surrounding the practice of cosmetic surgery*, September 2010 [www.ncepod.org.uk](http://www.ncepod.org.uk)

<sup>38</sup> *ibid.* page 7

<sup>39</sup> *ibid.* page 8

It commented that the General Medical Council should give clearer guidance to doctors as to their responsibilities when caring for a cohort of patients, some of whom may be acting unwisely. “Doctors performing these procedures should have procedure-specific training and the professional regulator should insist that they adhere to a code of conduct that is responsive to the particular needs of their patients and the environment in which they work.”<sup>40</sup>

The Working Group was not aware of any recent similar studies to the NCEPOD study in Australia, but anecdotal information was that some medical practitioners with variable levels of training and experience were undertaking cosmetic procedures in Australia, sometimes infrequently.

The Working Group therefore proposes that the Medical Board of Australia, in collaboration with medical colleges and professional associations, undertake a review of the minimum training and accreditation standards for medical practitioners performing cosmetic medical and surgical procedures. The review process could be informed by the Australian Medical Council processes. Further, the review should encompass the need for processes to be in place to ensure that where medical practitioners undertake cosmetic medical and surgical procedures, they are part of a program of peer review and ongoing audit. (In this regard, the Working Group noted that the Board’s *Continuing professional development registration standard* requires medical practitioners who are not on the specialist register [or do not hold various types of limited registration] to undertake continuing professional development each year which must include practice-based reflective elements such as clinical audit, peer review or performance appraisal.)

The Working Group noted the potential for consumer confusion in relation to the use of titles, lists of qualifications and memberships, and in particular, the title “specialist”, in association with cosmetic medical and surgical procedures. It noted that the Medical Board of Australia proposed a list of specialties to the Australian Health Workforce Ministerial Council for approval under the national scheme and this was approved by Ministers and has been in operation since 1 July 2010. To some extent, the title of “specialist” will be protected.

The Working Group recommends that, in association with the review of training and accreditation standards proposed above, there should be further consideration of the use of titles, lists of qualifications and memberships so that the public is not misled into believing that someone who specialises in a particular form of treatment is in fact a “specialist” if they are not so recognised through established processes. Use of titles, qualifications and memberships should not imply that the practitioner is more skilled or has greater experience than is the case.

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<sup>40</sup> NCEPOD, op. cit. page 6

As the Code *Good Medical Practice: A Code of Conduct for Doctors in Australia* identifies, providing good patient care involves assessing the patient, taking into account the history, the patient's views, and an appropriate physical examination. The history includes relevant psychological, social and cultural aspects.

Where cosmetic medical and surgical procedures are involved, the clinical relationship between a medical practitioner performing a cosmetic procedure and a patient may be complicated by the patient's heightened expectations of the results that can be achieved and the provider's opportunities for commercial advantage.

A medical practitioner may have concerns about a patient's motivation for seeking the treatment – body dysmorphic disorder is not uncommon in patients seeking cosmetic surgery. It is estimated that up to 5-15% of cosmetic surgery patients may be suffering from the disorder – cosmetic surgery may not be appropriate for this group of patients.<sup>41</sup>

The proposed Supplementary Guidelines should therefore cover matters including -

- The first consultation should be with the operating doctor, not with an agent/patient adviser.
- Assessment should include:
  - a. An exploration of why the surgery/procedure is requested. Both external reasons (eg a perceived need to please others) and internal reasons (eg strong feelings about appearance) should be explored.
  - b. An exploration of the person's expectations of the requested surgery/procedure
- If there are indications that the person has self-esteem or mental health problems, the person should be referred to a GP or an appropriately qualified health professional (eg psychiatrist, psychologist or specialist counsellor) for review.
- A cooling-off period between the initial consult and performance of the surgery/procedure is encouraged.

The absence of the GP as the "gatekeeper" for referral to practitioners carrying out cosmetic procedures also means that the GP is potentially uninvolved in post-procedural care. Increasingly, cosmetic procedures are being performed in day procedure centres and medical practitioners' rooms, away from the private and public hospital system. The proposed Supplementary Guidelines should place responsibility on the practitioner carrying out the cosmetic procedure to ensure there are protocols in place to cover all aspects of post-operative care, including the full

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<sup>41</sup> Veale D *Body Dysmorphic Disorder*, *Postgraduate Medical Journal*, 2004: 80: 67-71

range of complications. The Guidelines should include an explicit responsibility to ensure the patient is provided with specific written information on post-operative instructions and after-care arrangements. "Post-operative" is intended to be interpreted broadly to also mean "post (non-operative) procedure" -

- There should be protocols and pathways in place to cover all aspects of post-operative care, including the full range of complications, and arrangements with specific hospitals and staff to be involved in care should the patient unexpectedly require it.
- There should be monitoring of patients receiving injectable opiates and use of narcotic medication generally.
- The operating doctor is responsible for all aspects of pre-operative, operative and post-operative care. Any delegation of care must be appropriate and arranged in advance of any procedure and these arrangements should be made known to the patient.
- Documented post-operative instructions should be provided to patients to take home after the procedure.
- On discharge, a patient must be provided with written information which tells them
  - a. How to contact the doctor if complications arise
  - b. Details of who they can contact if the doctor is not available
  - c. The usual range of post-operative symptoms
  - d. Where to go if the patient experiences unusual pain or symptoms
  - e. Appropriate instructions for medication and self care
  - f. Details of dates for follow up visits.

The Working Group considers that medical practitioners should be prevented from entering into financial inducement arrangements (eg payment of a commission) with agents who recruit patients for procedures. They should also be prevented from offering financing schemes (other than credit card facilities) to patients, either directly or through a third party, such as loans, as part of their cosmetic medical or surgical services. Such practices could constitute a conflict of interest for the medical practitioner, compromising their primary duty to the patient, and also lead to patients making decisions to go ahead with a procedure under pressure and quickly, without the desirable level of consideration. This is not to imply that such practices are acceptable in 'mainstream' medical practice, but to emphasise the more complicated

relationship between the patient and the practitioner in this area of practice where there is the potential for commercial priorities to influence patient welfare.

In relation to financial inducement arrangements, the Working Group noted that in the National Law, the definition of 'unprofessional conduct' includes offering or giving a person a benefit, consideration or reward in return for the person referring another person to a practitioner or recommending to another person that the person use a health service provided by the practitioner. It also noted that the Code *Good Medical Practice: A Code of Conduct for Doctors in Australia* contains some provisions in relation to financial and commercial dealings and also conflict of interest. It recommends that the Medical Board of Australia considers including more explicit provisions in the proposed Supplementary Guidelines to the Code to cover the above two situations.

## **Nurses**

With the introduction of national registration, the Working Group believes it is timely for the Nursing and Midwifery Board of Australia to consider the need for the development of supplementary guidelines to its code of conduct, specifically dealing with cosmetic medical and surgical procedures.

An area the Working Group believes warrants specific attention is in relation to injectable cosmetic treatments. The Working Group noted the Cosmetic Physicians Society of Australasia *Protocol for Delegated Cosmetic S4 Injections* which it understands formed the basis of a policy that was adopted by at least one former jurisdictional Nursing and Midwifery Board. It was also aware that the United Kingdom Nursing & Midwifery Council had released an advice sheet on injectable cosmetic treatments providing guidance for nurses and midwives<sup>42</sup> The Working Group recommends the matter for the national Board's attention.

## **Unregistered practitioners -**

Beauty therapists are a third industry group, providing cosmetic services including removal of unwanted hair, facials and some peels. While not registered practitioners and not traditionally regarded as 'health practitioners', with the advent of new technology, services offered by beauty therapists have become more sophisticated and present higher risks to the public. Some therapies they use are invasive and,

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<sup>42</sup> Nursing and Midwifery Council *Injectable cosmetic treatments* (updated November 2009) [www.nmc-uk.org/](http://www.nmc-uk.org/)

along with other therapies that are non-invasive, can cause physical responses requiring medical intervention.

Notable amongst these therapies are those involving lasers and IPLs. Given the variety of practitioners using lasers and IPLs for cosmetic procedures and the lack of criteria for training courses in a number of jurisdictions, there is the propensity for variable standards to be applied. For example, at present there is nothing preventing beauty therapists who use lasers or IPLs predominantly for hair removal or facial rejuvenation from treating pigmented lesions, vascularities and skin blemishes even though these may be ultimately undiagnosed and potentially dangerous.

A major concern with this expansion of treatment is that undiagnosed skin cancers are able to be treated by persons untrained in diagnosis, medical protocols or appropriate treatment of disease.

The Working Group was aware that, in conjunction with the beauty therapy industry, Service Skills Australia has been working on improvements to the Beauty Training package and developing national competency standards regarding the use of IPLs and lasers by beauty therapists. While their initiative is to be commended, the Working Group is also aware that the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) has a working group which is tasked with producing recommendations for nationally uniform regulation of these devices. It was advised that a Regulatory Impact Statement (RIS) was being developed to support its proposals and it was hoped the RIS would be released for public consultation before the end of 2010. Submissions would then be reviewed and the proposals would be finalised for presentation to Health Ministers.

An opportunity exists through the work of ARPANSA for an 'industry standard' to be set and the Working Group recommends that the work through ARPANSA be concluded as soon as possible.

As to broader regulation of unregistered practitioners, all jurisdictions have independent Health Complaints Commissioners (however titled) with powers to investigate complaints about health services and practitioners. Other mechanisms exist at the national level such as the Australian Competition and Consumer Commission (ACCC) and the Therapeutic Goods Administration. However, there are limitations on the powers of these bodies.

As mentioned earlier in this report, the Australian Health Workforce Ministerial Council agreed to a national project and consultation process on the regulation of unregistered health practitioners. It was recognised that, while the majority of unregistered health practitioners engage in practice in a safe, competent and ethical manner, there are instances where these practitioners engage in serious misconduct that would lead to de-registration if they were subject to formal registration arrangements.



A national approach would provide Australians with standards of conduct that the community expects of unregistered health practitioners and ways to manage breaches of those standards.

The consultation, led by Victoria, is to consider national standards of conduct that could be introduced as well as the mechanisms for complaints and investigations. It is not intended that this regulation should take the form of a formal registration scheme, and the current New South Wales negative licensing scheme may provide a foundation for the national approach. Consultations will occur in each State to enable all interested parties to contribute.

The Working Group understands that the scope of the project as it proceeds to consultation will be broad. This will enable its observations in relation to higher risk cosmetic medical and surgical procedures carried out by beauty therapists to be taken into consideration during the project.

The Working Group recommends that this report be made available to the project group undertaking the project on the regulation of unregistered practitioners.

## Recommendations

### Medical Practitioners -

- **The Medical Board of Australia consider supplementing the Code “*Good Medical Practice: A Code of Conduct for Doctors in Australia*” with Supplementary Guidelines specifically covering cosmetic medical and surgical practice. (Attachment 2 provides a full draft of possible content of the proposed Supplementary Guidelines.) In particular, the proposed Supplementary Guidelines should emphasise that -**
  - **Treatment should only be provided if the medical practitioner has the appropriate training, expertise and experience in the particular cosmetic procedure being performed to deal with all routine aspects of care and any likely complications;**
  - **The medical practitioner is responsible for ensuring he or she has the necessary training, expertise and experience to perform a particular cosmetic procedure with reasonable care and skill.**
- **The Medical Board of Australia, in collaboration with medical colleges and professional associations, undertake a review of the minimum training and accreditation standards for medical practitioners performing cosmetic medical and surgical procedures -**

- The review process could be informed by the Australian Medical Council processes;
  - The review should encompass the need for processes to be in place to ensure that medical practitioners undertaking cosmetic medical and surgical procedures are part of a program of peer review and ongoing audit.
- In association with the review of training and accreditation standards, the Medical Board of Australia give further consideration to the use of titles, lists of qualifications and memberships so that the public is not misled into believing that someone who specialises in a particular form of treatment is in fact a "specialist" if not so recognised through established processes. Use of titles, qualifications and memberships should not imply that the practitioner is more skilled or has greater experience than is the case.
  - The Medical Board of Australia consider including in the Supplementary Guidelines to the Code "*Good Medical Practice: A Code of Conduct for Doctors in Australia*" provisions in relation to after-care. The provisions should make explicit the responsibility of the medical practitioner carrying out the cosmetic procedure to ensure there are protocols in place to cover all aspects of post-operative (post-procedural) care, including the full range of complications. The patient should be provided with specific written information on post-operative (post-procedural) instructions and after-care arrangements.
  - The Medical Board of Australia consider including in the Supplementary Guidelines to the Code "*Good Medical Practice: A Code of Conduct for Doctors in Australia*" more explicit provisions to achieve the following:
    - Medical practitioners be prevented from entering into financial incentive arrangements with agents who recruit patients for procedures (eg payment of a commission for patients recruited).
    - Medical practitioners be prevented from offering financing schemes to patients (other than credit card facilities), either directly or through a third party, such as loans, as part of their cosmetic medical or surgical services.

## **Nurses -**

- **The Nursing and Midwifery Board of Australia consider the need for the development of supplementary guidelines to its code of professional conduct, specifically dealing with cosmetic medical and surgical procedures (including, for example, guidelines or a protocol for cosmetic Schedule 4 injections).**

## **Unregistered practitioners -**

- **Nationally uniform regulation of lasers and intense pulsed light sources (IPLs) should capture unregistered practitioners. The work of the ARPANSA working group tasked with producing such recommendations should be concluded as soon as possible.**
- **This report be made available to the project group undertaking the project on the regulation of unregistered health practitioners, to enable its observations in relation to higher risk cosmetic medical and surgical procedures carried out by beauty therapists to be taken into consideration during the project.**

## **The Patient:**

### *Framework Features:*

*There should be restrictions relating to the performance of cosmetic medical and surgical procedures on children;*

*There should be specific requirements relating to obtaining consent for the performance of cosmetic medical and surgical procedures on adults;*

*There should be reliable, accessible information available to consumers to assist them in making an informed choice about whether or not to undergo a cosmetic medical or surgical procedure;*

*The patient should recognise their responsibility to truthfully disclose their medical history, to enable the practitioner to accurately assess each patient's risk;*

*There should be accessible avenues for complaint, irrespective of whether the practitioner is a registered health professional or an unregistered practitioner.*

As *The Cosmetic Surgery Report*<sup>43</sup> observed, the doctor-patient relationship is defined in the common law in terms of the law of negligence, which imposes a duty of care on medical practitioners to care for patients.

As part of the duty of care, medical practitioners are obliged to provide such information as is necessary for the patient to give informed consent to treatment, including information on all 'material risks' of the proposed treatment.

In deciding what is 'material' the medical practitioner should consider the 'nature of the matter to be disclosed, the nature of the treatment, the desire of the patient for information, the temperament and health of the patient and the general surrounding circumstances'<sup>44</sup>

"The courts regard the duty to warn as more onerous in cosmetic surgery because patients have a choice about whether to have the procedure. If there is a perceived level of inducement to have a procedure, coupled with failure to warn of risks, the doctor has a greater burden to demonstrate that the patient was properly informed"<sup>45</sup>

The Working Group considered the issues around informed consent in relation to both adults and children. It considered them against the backdrop of increasing demand for cosmetic medical and surgical procedures and the disturbing trends in young people increasingly seeking such procedures. It noted that demand for such procedures is fuelled by lifestyle choices to enhance physical appearance and boost confidence, rather than medical need. More often than not the General Practitioner (GP) is by-passed, since a GP referral is not required, and the patient seeks the services directly from the provider. This means the level of protection provided by GP screening is absent unless specifically sought by the patient.

The Working Group noted that the Code *Good Medical Practice: A Code of Conduct for Doctors in Australia* acknowledges the importance of informed consent and availability of information. It was, however, convinced that the Code needed to be supplemented by specific provisions for obtaining consent in relation to both adults and children seeking cosmetic medical and surgical procedures.

In relation to adults, the Working Group proposes that the following features be included in the Supplementary Guidelines to the Code *Good Medical Practice: A Code of Conduct for Doctors in Australia* -

- there must be an assessment of the person's motivation for seeking treatment

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<sup>43</sup> The Cosmetic Surgery Report op. cit. pages 15 and 16

<sup>44</sup> King CJ in *F v R* (1983) 33 SASR 189, cited with approval in *Rogers v Whittaker* (1992) 175 CLR 479 at 490

<sup>45</sup> The Cosmetic Surgery Report op. cit. page 15

- there is a need to ensure the person has realistic expectations
- there should be an opportunity for a person to be referred for psychological evaluation
- informed written consent should be obtained at a pre-procedure consultation within a reasonable time period before the day of the procedure and re-confirmed on the day of the procedure
- a cooling-off period between the initial consultation and performance of the procedure should be encouraged (but not mandated)

In relation to young people under the age of 18 years, the Working Group recognised that gaining consent brings additional responsibilities for medical practitioners to ensure that the young person is appropriately assessed and that physical and emotional maturity, a stable self image and an understanding of what surgery can achieve for them can be ensured. While parental support is essential, the young person must be able to express their expectations from the surgery. This issue has been addressed in NSW and Queensland in different ways, but with the common purpose of protecting young people.

On balance, the Working Group preferred the NSW approach as a baseline requirement, namely -

In relation to persons under 18 years of age:

- if the requested surgery/procedure has no medical justification there must be a 'cooling off' period of 3 months, followed by a further consultation during which the request is further explored. The requested surgery/procedure should not be scheduled at the initial consultation.
- the person should be encouraged to discuss their desire for the surgery/procedure and any concerns with their general practitioner during the cooling off period.

In addition, the Working Group considers there should be a requirement for the person to be assessed by an appropriately qualified health professional (eg psychiatrist, psychologist or specialist counsellor.)

The Working Group proposes that these features be included in the Supplementary Guidelines to the Code *Good Medical Practice: A Code of Conduct for Doctors in Australia*.

The Working Group considers that these features should also be referred for the attention of the Nursing and Midwifery Board of Australia, for potential inclusion (as appropriate) in supplementary guidelines to its code of conduct, specifically dealing with cosmetic medical and surgical procedures, to cover those situations where nurses are practising independently.

The Working Group also considers that, as part of the national examination and consultation on options for the regulation of unregistered health practitioners, the above features (as appropriate) should be taken into consideration in relation to those services of beauty therapists which are higher risk services that can cause physical responses potentially requiring medical intervention.

The Working Group was mindful that the above special provisions are directed at outlining the service provider's role and responsibility. It was keen to ensure that the patient's role and responsibility in the consent process was not overlooked. As outlined by Nahai in his recent Clinical Risk journal article -

"First the patient must truthfully disclose their medical history, including allergies, current medications, social habits and previous operations. This enables the surgeon to accurately assess each patient's risk. Some patients have been known to hide their medical history for fear of being denied cosmetic surgery. Others "doctor shop" until they are accepted for surgery, regardless of risk."

The Working Group considers that the patient's responsibility should be clearly stated in consumer information packages.

Consumers gather information from a wide range of sources. The Working Group saw a need for broader availability of factual, easily understood information from a source that is independent of practitioners and promoters. It regarded such information as an important resource for consumers contemplating cosmetic medical or surgical procedures. Such information is not easily sourced within Australia currently, but a project in Victoria to produce such a resource, based on the well-regarded United Kingdom consumer information, is well advanced. In creating the information resource, consideration was given to - key issues when navigating for information on cosmetic procedures; questions to be asked prior to surgery/treatment; informed consent; pre-procedure checking of credentials, qualifications and premises; information about risks and possible complications; what happens when things do not turn out as planned and how to make complaints to relevant authorities. There is an opportunity for the information resource to be available nationally once it has been finalised. The Working Group recommends that the consumer information resource being produced in Victoria should be reviewed when available and considered for adoption nationally.

Cosmetic surgery "tourism" carries additional risks for the patient, but information provided by entrepreneurs can downplay the risks of the surgical procedure, including post-operative recovery.

The Working Group noted from Nahai's article<sup>46</sup> that the International Society of Aesthetic Plastic surgery (ISAPS) and the American Society of Aesthetic Plastic Surgery (ASAPS) had developed guidelines for both would-be cosmetic surgery tourists and also for the surgeons who receive and treat them.

ISAPS and ASAPS advocate that employers, insurance companies and all other entities that facilitate or incentivize either inbound or outbound plastic surgery care adhere to the guidelines and share them with their patients and customers. The guidelines are reproduced at Attachment 3.

The Working Group also noted that The Australasian Society of Aesthetic Plastic Surgery has produced a Position Statement on Cosmetic Tourism directed particularly at the patient<sup>47</sup>. The Position Statement is reproduced at Attachment 4.

The Working Group considers that the additional risks associated with cosmetic surgery "tourism" warrant the inclusion in the consumer information resource of specific information along the lines of the ISAPS/ASAPS guidelines or The Australasian Society of Aesthetic Plastic Surgery's Position Statement on Cosmetic Tourism.

As the *Australian Charter of Healthcare Rights*<sup>48</sup> observes, everyone who is seeking or receiving care in the Australian health system has certain rights regarding the nature of their care. Patients, consumers, staff and health service organisations all have a role in contributing to a safe and high quality healthcare system and achieving the best possible outcomes from the system. As the Charter highlights, it is always best to try to resolve complaints directly with the health service provider. However, a robust and accessible system for investigating and taking action in relation to complaints is an essential feature in providing public protection. It also provides one measure of how the system is operating and whether there are systemic issues that need addressing.

The Working Group was aware of the various complaints mechanisms that exist and of measures, in relation to registered practitioners, to ensure that complaints mechanisms can continue to function effectively, albeit under different arrangements with the introduction of the national registration and accreditation scheme. The Working Group recommends that the situation be monitored as the national scheme is consolidated.

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<sup>46</sup> Nahai, F op. cit. 235-236

<sup>47</sup> The Australasian Society of Aesthetic Plastic Surgery op. cit.

<sup>48</sup> Australian Commission on Safety and Quality in Health Care *Australian Charter of Healthcare Rights*  
[www.safetyandquality.gov.au](http://www.safetyandquality.gov.au)

In relation to unregistered practitioners, the Working Group considered that, as part of the national project and consultation on options for the regulation of unregistered health practitioners, particular attention be paid to ensuring that robust and accessible complaints mechanisms are available.

## **Recommendations**

- **The Medical Board of Australia consider including in the Supplementary Guidelines to the Code “*Good Medical Practice: A Code of Conduct for Doctors in Australia*” specific provisions relating to the undertaking of cosmetic medical and surgical procedures to achieve the following –**

**In relation to adults:**

- **the first consultation should be with the operating medical practitioner, not with an agent/patient adviser**
- **there must be an assessment of the person's motivation for seeking treatment**
- **there is a need to ensure the person has realistic expectations**
- **there should be an opportunity for a person to be referred for psychological evaluation**
- **informed written consent should be obtained at a pre-procedure consultation within a reasonable time period before the day of the procedure and re-confirmed on the day of the procedure**
- **a cooling-off period between the initial consultation and performance of the procedure should be encouraged (but not mandated)**

**In relation to persons under 18 years of age, the above provisions should be supplemented or replaced (where the intent is inconsistent) by the following:**

- **if the requested surgery/procedure has no medical justification there must be a 'cooling off' period of 3 months, followed by a further consultation during which the request is further explored. The requested surgery/procedure should not be scheduled at the initial consultation.**
- **the person should be encouraged to discuss their desire for the surgery/procedure and any concerns with their general practitioner during the cooling off period.**



- in addition, there should be a requirement for the person to be assessed by an appropriately qualified health professional (eg psychiatrist, psychologist or specialist counsellor.)
- The above provisions also be referred for the attention of the Nursing and Midwifery Board of Australia, for potential inclusion (as appropriate) in supplementary guidelines to its code of conduct, specifically dealing with cosmetic medical and surgical procedures, to cover those situations where nurses are practising independently.
- As part of the national examination and consultation on options for the regulation of unregistered health practitioners, the above features (as appropriate) should be taken into consideration in relation to those cosmetic procedures of beauty therapists which are higher risk and can cause physical responses potentially requiring medical intervention.
- There should be broader availability of factual, easily understood information for consumers contemplating cosmetic medical or surgical procedures from a source that is independent of practitioners and promoters. The consumer information resource being produced in Victoria be reviewed when available, and considered for adoption nationally.
- The patient's responsibility to truthfully disclose their medical history, to enable the medical practitioner to accurately assess each patient's risk, be clearly stated in consumer information packages. "Medical history" includes allergies, current medications (including complementary and alternative therapies), social habits and previous operations.
- The consumer information resource include specific information relevant to cosmetic 'tourism' along the lines of the ISAPS/ASAPS guidelines or The Australasian Society of Aesthetic Plastic Surgery's Position Statement on Cosmetic Tourism included as Attachments 3 and 4.
- Arrangements for handling complaints against registered practitioners under the new national registration scheme be monitored as the scheme is consolidated.
- As part of the national examination and consultation on options for the regulation of unregistered health practitioners, particular attention be paid to ensuring that robust and accessible complaints mechanisms are available where they are offering cosmetic medical and surgical procedures.

## The Place

### *Framework Features:*

*No matter where a medical practitioner undertakes cosmetic medical and surgical procedures, infection control and other standards should apply*

*Similar standards should apply in relation to higher risk procedures undertaken by unregistered practitioners*

The Working Group noted that all jurisdictions have private health facilities licensing although it varies in the scope of its coverage. Private hospitals are licensed in all jurisdictions, most (but not all) jurisdictions license free-standing day procedure centres, but medical practitioners' rooms are generally outside the scope of facilities-based licensing, except where the type of sedation used brings them within the scope of the licensing requirements. Day procedure centre licensing tends to be based around the nature of the procedures performed and typically involves consideration of the types of sedation used.

The Working Group was also aware that, following endorsement by the Australian Health Ministers' Conference, the Australian Commission on Safety and Quality in Health Care (ACSQHC) is undertaking a project to develop a new national model of safety and quality accreditation for health care organisations, including a set of national safety and quality health service standards to apply in the first instance to high risk services. An extensive Regulatory Impact Assessment has been part of the process. The Australian Health Ministers' Conference at its meeting in November 2010 endorsed the proposed model (to be known as the Australian Health Service Safety and Quality Accreditation Scheme) and noted that the remaining standards under development would be finalised for endorsement at the June 2011 Conference of Health Ministers.

Key features of the scheme are -

- **National Coordination within the ACSQHC –**
  - Central to the new scheme is a program of national coordination within the ACSQHC. It will develop and maintain the standards; advise Health Ministers on the scope of health services to which accreditation will apply (initially 'high risk' services - those that undertake 'invasive' procedures into a body cavity or dissecting skin while using anaesthesia or sedation); approve accrediting agencies; receive accreditation data; coordinate with regulatory authorities and report to Health Ministers annually on safety and quality.

- **The standards -**
  - The basis for developing the standards is that they represent areas where there is evidence that patients are being harmed by current practices.
  - The first five standards cover - governance for safety and quality in health service organisations; healthcare associated infection; medication safety; patient identification and procedure matching; and clinical handover.
  - Five more standards are being developed taking the total number to ten.
  - A compliance assessment framework has also been developed.
  - The first five standards were released for national consultation and piloted before being recommended for adoption as part of the final report to Ministers. The remaining five standards will follow a similar process and will be finalised for submission to Ministers in June 2011.
  
- **Scope of Accreditation –**

Accreditation against the national standards is proposed to be mandatory and to apply initially to 'high risk' services –

  - All public hospitals
  - All private hospitals
  - All day procedure centres
  - In addition, dental practices, some medical rooms where high risk activities occur such as cosmetic surgery and endoscopy, or any facility not covered above where patients are sedated and/or anaesthetised and who are subject to invasive procedures, are recommended for inclusion in the scheme (mechanisms for including this latter group in the scheme are under examination).
  
- **Accreditation and reporting -**

The proposed new model envisages that, once a health service organisation has undergone accreditation by an approved accrediting agency –

  - there will be a report to both the national coordination program within the ACSQHC and the regulatory authority
  - where the organisation needs to remedy identified deficiencies, a range of processes will be followed, but it may ultimately result in a sanction being applied, and this will be done by the relevant regulatory authority
  - regulatory authorities will be required to notify the national coordination program within the ACSQHC of action taken and outcomes
  - public reporting by the national coordination program within the ACSQHC is envisaged although the extent of reporting detail is yet to be determined.

Part of the accreditation standards project involves examining the regulatory instruments for mandating the standards. This has led to preliminary work commencing to explore opportunities for harmonisation of the coverage and definitions of private health facilities required to be licensed across Australia. The timing is opportune as some jurisdictions are reviewing, or proposing to review their legislation and others have new legislation to be brought into force once the underpinning regulations have been put into place.

The Working Group considered that the above measures would meet the policy objectives it was seeking to achieve as part of a national framework and recommended that jurisdictions use their best endeavours to ensure their legislation will allow the implementation of the proposed new model of safety and quality accreditation.

## Recommendation

- **Jurisdictions use their best endeavours to ensure their legislation will enable the implementation of the proposed new national model of safety and quality accreditation being developed by the Australian Commission on Safety and Quality in Health Care, so that cosmetic medical and surgical procedures, wherever they occur in Australia, must be in accordance with key national safety and quality health service standards, such as infection control.**
- **In relation to unregistered practitioners, the national consultation process on unregistered health practitioners give consideration to mechanisms by which appropriate standards may be applied to premises where cosmetic procedures are carried out.**

## General issues

Since the Working Group commenced the project, significant progress has been made in advancing the national initiatives. That has clarified the national context within which the project has been undertaken and has defined the mechanisms through which many of the recommendations can be progressed.

The national registration boards under the national registration and accreditation scheme for health professionals have now been established. Two of the boards – the Medical Board of Australia and the Nursing and Midwifery Board of Australia – will have jurisdiction over the two main groups of registered practitioners involved in cosmetic medical and surgical procedures – medical practitioners and nurses. Many of the recommendations are directed for the boards' attention. The cosmetic medical and surgical industry is a rapidly growing and changing industry. In that sense, the Working Group's recommendations are a "work-in-progress". It recommends that the national boards keep the situation under review.

## Recommendation

- **The Medical and Nursing and Midwifery Boards of Australia maintain a 'watching brief' on developments in the cosmetic medical and surgical industry as they relate to registered practitioners under their jurisdiction.**

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## DEVELOPMENTS SINCE NSW COSMETIC SURGERY REPORT, 1999

### SUMMARY

## AUSTRALIA

### Victoria

Reviews were carried out in relation to cosmetic surgery in 2000 and 2002. Powers of various regulatory bodies were strengthened to better address complaints concerning the practice of cosmetic surgery. Regulations for day procedure centres were strengthened so that some procedures were no longer able to be performed in unregulated clinics. The then Medical Practitioners Board released revised advertising guidelines (including use of before and after photographs).<sup>49</sup> A further regulatory review in 2008 prompted by concerns regarding safety and protection of patients included the development of consumer information proposed to be made available on the DH Better Health Channel<sup>50</sup>.

### New South Wales

In 2008, New South Wales, through its then Medical Board's *Cosmetic Surgery Guidelines* which supplemented its *Code of Professional Conduct Good Medical Practice* a 'cooling off' period of 3 months was required followed by a further consultation during which the request was further explored, if the person was under 18 years of age. The requested surgery/procedure was not to be scheduled at the initial consultation and the person was to be encouraged to discuss the matter with their general practitioner during the cooling off period.

More stringent regulations covering advertising of cosmetic surgery were also introduced (eg use of before and after photographs).<sup>51</sup> The *Private Health Facilities Act 2007* requires any surgical procedure involving sedation greater than simple sedation to be performed in a licensed facility.

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<sup>49</sup> Advertising Guidelines for Registered Medical Practitioners. Medical Practitioners Board of Victoria, 2008 [www.medicalboardvic.org.au](http://www.medicalboardvic.org.au)

<sup>50</sup> Review of the Regulation of Cosmetic Surgery, Service and Workforce Planning Branch DHS Victoria 2008

<sup>51</sup> New Cosmetic Surgery Guidelines, NSW Medical Board News June 2008 [www.nswmb.org.au](http://www.nswmb.org.au)

## **Queensland**

In 2008 following extensive community consultation, legislation was passed restricting carrying out of cosmetic medical and surgical procedures on children less than 18 years for non-medical reasons.<sup>52</sup> The *Public Health Act 2005* prohibits the performance of defined cosmetic procedures on children, subject to a "best interests" exception.

The *Private Health Facilities Act 1999* (and relevant regulations) requires medical practitioners' rooms to be licensed if they undertake procedures which as a minimum require "twilight" sedation.

## **Tasmania**

The *Health Services Establishments Act 2006* when enacted will empower the Department to regulate overnight, day procedure facilities and office-based practices.

## **NEW ZEALAND**

In 2007 following a period of consultation, the Medical Council of New Zealand, in response to concerns that the regulatory framework in that country was inadequate to protect consumers from incompetent practitioners in the 'appearance medicine' industry, developed a comprehensive *Statement on Cosmetic Procedures*, outlining standards expected of medical practitioners who performed cosmetic procedures.<sup>53</sup>

## **UNITED KINGDOM**

A Select Committee was established in Parliament in 1999 to review the need for tighter regulation of private healthcare in general, and especially cosmetic surgery. The Committee's recommendations culminated in the *Care Standards Act 2000* (enacted 1 April 2002). Any surgeon practising cosmetic surgery has to be on a specialist surgical register, following training.

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<sup>52</sup> Health Legislation (Restriction of Use of Cosmetic Surgery for Children and Another Measure) Amendment Act Queensland 2008

<sup>53</sup> Statement on Cosmetic Procedures, October 2007. Medical Council of New Zealand.  
[www.mcnz.org.nz/publications](http://www.mcnz.org.nz/publications)



(Cosmetic Surgery is not itself an independently recognised speciality and has no specialist surgical register.) Medical practitioners who were in independent cosmetic practice prior to that date were allowed to continue. The Cosmetic Surgery Inter-specialty Committee was formed by the Senate of Surgery of Great Britain and Ireland with a remit in education, training and assessment of practitioners undertaking cosmetic procedures, guidance on standards, advising on competency and development of a framework for procedure-specific accreditation.

The Healthcare Commission (which became the Care Quality Commission in April 2009) reported in 2005<sup>54</sup> that cosmetic surgery lacked a contemporary definition and that structured and dedicated training was needed, with enhanced accreditation.

In 2005, the Expert Group on the Regulation of Cosmetic Surgery also reported to the Chief Medical Officer, making recommendations on professional training, development and accountability, non-surgical cosmetic procedures and public education.<sup>55</sup>

Following these reports, an independent and authoritative British Academy of Cosmetic Practice is being formed, with the aims of promoting high quality and safety in cosmetic surgery and medicine, while defining the minimum content of a professional benchmarking portfolio based on specific criteria for qualifications, training and experience. Separate membership categories will exist for surgeons, non-surgical medical practitioners, dentists and registered adult nurses, who will voluntarily apply for entry to a list of recognized practitioners held by the Academy, having satisfied entry criteria and maintaining registration with appropriate statutory medical, dental or nursing authority. Continuing membership will be supported by appraisal and validation.<sup>56</sup>

Extensive public information, including an A-Z list of procedures and frequently asked questions, has been provided by the UK Department of Health on its website.<sup>57</sup>

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<sup>54</sup> The Healthcare Commission *Provision of Cosmetic Surgery in England* Report for the Chief Medical Officer Sir Liam Donaldson (January 2005)

<sup>55</sup> Expert Group Report on the Regulation of Cosmetic Surgery, UK Department of Health, Report to the Chief Medical Officer, January 2005

<sup>56</sup> Khoo C *Risk reduction in cosmetic surgery*, *Clinical Risk* 2009; 15 237-40

<sup>57</sup> *Considering cosmetic surgery?* [http://www.dh.gov.uk/en/Public health/CosmeticSurgery/DH\\_4123795](http://www.dh.gov.uk/en/Public%20health/CosmeticSurgery/DH_4123795)

According to the *Care Standards Act*, all independent clinics and hospitals that provide cosmetic surgery in England must be registered and inspected by the Care Quality Commission (in Wales, by the Healthcare Inspectorate of Wales and in Northern Ireland, by the Registration and Quality Improvement Authority).

## **FRANCE**

Following extensive publicity about cosmetic surgery that drew attention to the lack of traditional safeguards for patients, the French Government initiated an enquiry. This resulted in changes in 2002 and 2005 to French law. French law now defines practitioners' qualifications, range of practice and the facilities they work in. Surgical procedures, which take place in authorised facilities, can only be undertaken by surgeons who are registered specialists and deemed competent. Possession of a general medical degree, and the fact that the practitioner is "experienced" are not sufficient qualifications. The law defines the information that must be conveyed to patients about cosmetic surgery. Comprehensive information about the procedure must be imparted at the first consultation. Surgical methods, risks and potential complications together with action to correct complications must be explained.

A detailed quotation about surgical fees and services must be given to the patient at the first consultation and a mandatory waiting period of 15 days (which may not be shortened) must be allowed so that the patient does not feel pressured. The quotation must be signed by the surgeon/s and given to the patient before any part of the proposed treatment/operation is undertaken. Advertising medical and surgical cosmetic procedures is outlawed in France.<sup>58</sup>

## **SINGAPORE**

In Singapore, the College of Family Physicians and Academy of Medicine Singapore in July 2008 (updated October 2008) launched *Guidelines on Aesthetic Practices for Doctors*<sup>59</sup> which has been endorsed by the Singapore Medical Council (SMC) as a standard for aesthetic practice for doctors and an Aesthetic Practice Oversight Committee has been formed under the SMC to regulate doctors engaged in aesthetic practices in accordance with the Guidelines.

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<sup>58</sup> Fogli, A France sets standards for practice of aesthetic surgery, *Clinical Risk* 2009, 15: 224-6

<sup>59</sup> College of Family Physicians Singapore, Academy of Medicine Singapore, Singapore Medical Council *Guidelines on Aesthetic Practices for Doctors*, October 2008 (updated)

**Good Medical Practice - Code of Conduct for Doctors in Australia**  
***Draft Supplementary Guidelines for Cosmetic Medical and Surgical Procedures***

### **Purpose of these Guidelines**

These guidelines outline the additional standards expected of doctors who perform cosmetic medical and surgical procedures in Australia. They should be read in conjunction with the *Good Medical Practice: A Code of Conduct for Doctors in Australia*, and are supplementary to the standards of ethical and professional conduct set out in that Code. Relevant extracts of the Code are quoted prior to outlining the supplementary guidelines.

### **Definition of cosmetic medical and surgical procedures**

Cosmetic medical and surgical procedures are operations and other procedures that revise or change the appearance, colour, texture, structure or position of normal bodily features with the sole intention of achieving what the patient perceives to be a more desirable appearance or boosting the patient's self-esteem.

### **Providing good care**

*In clinical practice, the care of your patient is your primary concern. Providing good patient care includes –*

- *Assessing the patient, taking into account the history, the patient's views, and an appropriate physical examination. The history includes relevant psychological, social and cultural aspects.*

Supplementary guidelines in relation to cosmetic medical or surgical procedures –

In relation to adults -

1. The first consultation should be with the operating doctor, not with an agent/patient adviser.
2. Assessment should include:
  - a. An exploration of why the surgery/procedure is requested. Both external reasons (eg a perceived need to please others) and internal reasons (eg strong feelings about appearance) should be explored.

- b. An exploration of the person's expectations of the requested surgery/procedure to ensure they are realistic
3. If there are indications that the person has self-esteem or mental health problems, the person should be referred to a GP or an appropriately qualified health professional (eg psychiatrist, psychologist or specialist counsellor) for review.
4. Informed written consent should be obtained at a pre-procedure consultation within a reasonable time period before the day of the procedure and re-confirmed on the day of the procedure.
5. A cooling-off period between the initial consult and performance of the procedure is encouraged.

*Children and young people -*

*Caring for children and young people brings additional responsibilities for doctors.*

Supplementary guidelines in relation to cosmetic medical or surgical procedures –

In relation to a person under 18 years of age, the 5 provisions immediately above regarding adults should be supplemented or replaced (where the intent is inconsistent) by the following:

1. If the requested surgery/procedure has no medical justification there must be a 'cooling off' period of 3 months, followed by a further consultation during which the request is further explored. The requested surgery/procedure should not be scheduled at the initial consultation.
2. The person should be encouraged to discuss their desire for the surgery/procedure and any concerns with their general practitioner during the cooling off period.
3. The person should be assessed by an appropriately qualified health professional (eg psychiatrist, psychologist or specialist counsellor).

**Providing a suitable patient management plan**

*Good patient care includes -*

- *Formulating and implementing a suitable management plan (including arranging investigations and providing treatment and advice).*
- *Facilitating coordination and continuity of care*

- *Referring a patient to another practitioner when this is in the patient's best interests*

Supplementary guidelines in relation to cosmetic medical or surgical procedures -

1. There should be protocols and pathways in place to cover all aspects of post-operative care, including the full range of complications, and arrangements with specific hospitals and staff to be involved in care should the patient unexpectedly require it.
2. There should be monitoring of patients receiving injectable opiates and use of narcotic medication generally.
3. The operating doctor is responsible for all aspects of pre-operative, operative and post-operative care. Delegation of care must be appropriate and arranged in advance of any procedure and these arrangements should be made known to the patient.
4. Documented post-operative instructions should be provided to patients to take home after the procedure.
5. On discharge, a patient must be provided with written information which tells them
  - a. How to contact the doctor if complications arise
  - b. Details of who they can contact if the doctor is not available
  - c. The usual range of post-operative symptoms
  - d. Where to go if the patient experiences unusual pain or symptoms
  - e. Appropriate instructions for medication and self care
  - f. Details of dates for follow up visits.

## **Providing good patient care**

*Maintaining a high level of medical competence and professional conduct is essential for good patient care. Good medical practice involves -*

- *Recognising and working within the limits of your competence and scope of practice*
- *Ensuring that you have adequate knowledge and skills to provide safe clinical care*

## Supplementary guidelines in relation to cosmetic medical or surgical procedures –

1. Treatment should only be provided if you have the appropriate training, expertise and experience in the particular cosmetic procedure being performed to deal with all routine aspects of care and any likely complications.
2. You are responsible for ensuring that you have the necessary training, expertise and experience to perform a particular cosmetic procedure with reasonable care and skill.

If you do not comply with this requirement, you may be subject to a performance assessment required by the Board if there is reason to believe that your competence may be deficient.

## **Working with Patients**

*Relationships based on openness, trust and good communication will enable you to work in partnership with your patients. Patient's rights to make their own decisions must be recognised and respected.*

*Informed consent -*

*Informed consent is a person's voluntary decision about medical care that is made with knowledge and understanding of the benefits and risks involved.*

## Supplementary guidelines in relation to cosmetic medical or surgical procedures -

1. At the initial consultation, the person must be provided with written information in easily understood language about:
  - a. What the surgery/procedure involves
  - b. The range of possible outcomes of the surgery/procedure
  - c. The risks and possible complications associated with the surgery/procedure
  - d. Recovery times and specific requirements during the recovery period
  - e. Information about your qualifications and experience
  - f. Total cost
  - g. That any deposits taken, be refunded fully or partly at any point prior to when the procedure is undertaken
  - h. Other options for addressing the person's concerns
  - i. Information should be displayed at the doctor's premises advising patients that there is a complaints process available and how to access it, beginning with approaching the operating doctor.

## **Professional behaviour**

*In professional life, doctors must display a standard of behaviour that warrants the trust and respect of the community. This includes observing and practising the principles of ethical conduct. Good medical practice involves –*

- *Not offering inducements to colleagues, or entering into arrangements that could be perceived to provide inducements*
- *Avoiding financial involvement, such as loans and investment schemes, with patients*

Supplementary guidelines in relation to cosmetic medical and surgical procedures –

1. You should not provide or offer to provide financial inducements to agents for recruitment of patients (eg payment of a commission for patients recruited).
2. You should not offer financing schemes to patients (other than credit card facilities), either directly or through a third party, such as loans, as part of your cosmetic medical or surgical services.

**ISAPS/ASAPS GUIDELINES ON SURGICAL TOURISM**

1. Plastic surgery care either inbound or outbound must be voluntary.
2. A complete consultation including physical examination, alternatives to treatment, risk assessment, potential complications and an informed consent must be provided by the operating surgeon prior to actual treatment and preferably prior to travel for ultimate surgery.
3. Financial incentives for either inbound or outbound plastic surgery care should not influence or limit the diagnostic and therapeutic alternatives offered to patients or in any way restrict treatment or referral options.
4. Surgeons and/or their qualified staff should advise patients of all fees prior to travel including cost of different materials and implants as well as options for these materials.
5. Patients are strongly urged to use institutions or facilities that have been inspected and accredited by recognized international accrediting bodies such as the Joint Commission ([www.jointcommission.org](http://www.jointcommission.org)) or the American Association for Accreditation of Ambulatory Surgery Facilities Inc ([www.aaaasf.org](http://www.aaaasf.org)); Patients should ask their surgeon about the accreditation of their facilities before making any commitment. If in doubt, they should be advised to cross-check accreditation claims by consulting accrediting bodies' websites.
6. Patients should be well aware of any staff language barriers during their pre- and post-operative periods.
7. Patients are entitled to and should ask for full disclosure of treating physician as well as staff credentials including possible use of junior plastic surgery trainees prior to travel.
8. Follow-up care in the patient's home town is a critical element of any medical tourism decision. Prior to travel, local follow-up care facilities and consulting physicians must be determined and coordinated with clear discussion, understanding and acceptance of all fees.
9. In the event of a complication, clear information should be provided to the patient prior to treatment including the responsibilities of all parties, a



reasonable estimate of costs for recommended treatment of complications including ICU (ITU) care, as well as possible care by other specialists.

10. Prior to any commitment to travel for surgery, patients should be made aware of the significant variations in physician responsibilities and liability coverage for adverse events in other countries. In addition, in the event of medical errors, patients should know in advance what their recourse options are under a different country's legal system.
11. Physician licensing and procedural outcomes data as well as facility accreditation and its outcomes data should be provided to all patients both inbound and outbound, prior to departure.
12. The transfer of patient medical records to and from facilities outside the US should be consistent with HIPAA guidelines and provided by the overseas physician in the spoken language of the patient's country of origin.
13. Patients choosing to travel for their plastic surgery care should be provided with detailed information about the potential risks of combining surgical procedures with long airplane flights. Recommendations for how long the patient should remain in the country where the operation is performed should be established and confirmed in advance, and appropriate arrangements made for an extended stay.

**REFER TO FOLLOWING PAGES**



## **COSMETIC TOURISM**

Cosmetic Tourism is rapidly becoming a multi-million dollar industry. The lure of cheap cosmetic surgery and a holiday in an exotic destination thrown in for less than the price of comparable surgery at home is often too much of a temptation to resist.

The sad fact is most people spend more time anguishing and researching the purchase of their washing machine than their surgeon.

If considering Cosmetic Surgery abroad there are things you should ensure first

- 1) Your Surgeon is well trained and reputable
- 2) That the operation you are having is the right one for you
- 3) That the operation is being performed in a safe environment and any prostheses used (eg breast implants) are of the highest quality
- 4) That appropriate after-care is in place

### **YOUR SURGEON**

Ensure they are a properly trained surgeon who holds an international surgical qualification in Plastic Surgery

- i) A minimum check would be to go to an internationally recognised website such as ISAPS – the International Society of Aesthetic Plastic Surgery ([www.isaps.org](http://www.isaps.org)). If your surgeon is on this website you can at least ascertain that your surgeon has both an internationally recognised specialist qualification and that his peers in his country of practice feel he is competent. If not on this list you have to dig a bit harder – eg. you could try checking the countries medical register
- ii) Make sure you feel comfortable with your surgeon. If you were in your own country and decided you did not like your surgeon or did not entirely trust him you would simply find another. What would you do in a foreign country with a surgeon you may not have met before and may not even speak your primary language fluently – especially if you have already paid up front to have an operation and are seeing them within a day or two of your surgery

Remember you also want to know about the doctor who is anaesthetising you and keeping you asleep safely during your procedure. They also literally has your life in their hands.

### **PLANNING AN OPERATION**

This is not as easy as it seems. Eg. Many women present wanting breast enlargement when the appropriate operation is a breast lift/tightening procedure or requesting liposuction when a tummy tuck is more appropriate. An inappropriate operation can make your problems worse. A well planned operation will give you a better result and may save you money.

A fundamental problem with medical tourism is that planning and decision making is necessarily rushed. You cannot 'have second thoughts' and when surgery is planned – often without seeing the operating surgeon or seeing them just before the surgery for the first time there is no real time for reflecting on the decision made or any informed consent.

### **THE OPERATION**

Remember Cosmetic Surgery is real surgery. Complications can occur even in the best centres. Travel combined with surgery significantly increases complications especially infections and blood clots. It can also delay their treatment meaning they cause more problem than they might otherwise. Remember that while Cosmetic Surgery trips are often marketed as vacations – vacation activities should be avoided after surgery – sunbathing, drinking alcohol, swimming, jet skiing, taking extensive tours by bus or foot – can all compromise wound healing and increase infection rates and other problems.

### **MEDICAL DEVICES USED**

If you are having breast enlargement surgery you want to know the best and safest implants are used. In New Zealand and Australia quality implants themselves cost A\$2000 to A\$3500 a pair – note this is the cost of the implants themselves from the manufacturers and does not include the costs of the surgery itself.

Travel companies may also exaggerate the costs of having surgery in Australia or New Zealand. Always check that the information you have been given is accurate and not misleading.

### **AFTER-CARE**

After a cosmetic operation (except small ones) you normally stay in hospital (not a hotel) for good reason. While many things that can go wrong happen in the first 48 hours (eg. excess bleeding) there are also many things that occur a fortnight (infections) or even a couple of months (wound healing and scar problems) after surgery.

What would you do in the case of these problems? What if you need any revision surgery. What is you are unhappy with the outcome of surgery?

Revision surgery can be difficult at the best of times. As cosmetic surgery is often individualised it is more difficult to perform revision surgical when there are uncertainties over the surgical technique that has been used.

In 2006 ASAPS reported treating 36 people with complications arising from medical tourism on return to Australia. These are only the ones reported by ASAPS members. Many go unreported, are treated by other medical facilities or simply accept poor outcomes.

Revision surgery is often complex and outcomes often compromised. A revision can often be more expensive than the original surgery.

### **SUMMARY**

It is your body and your life – you only have one. Make your decisions wisely and with care

- Check out the person promoting the surgery. Are they medically trained. Do they accept any liability or provide any help if problems arise or are they simply a 'travel agent'
- ensure your surgeon is appropriately qualified
- ensure you trust your surgeon
- ensure you are being operated on in appropriate facilities and the other staff are appropriately trained. Do they speak your native language or you theirs?
- ensure you have been properly informed about your operation – that you know the alternatives, that the operation will achieve what you are wanting it to and you understand the possible complications
- check out the costs and ensure the money paid is appropriate
- make sure you know what prostheses are being used
- ensure you have an adequate aftercare plan - do you know what to do if things go wrong once you have returned home?

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