

Public Consultation Paper and Regulation Impact Statement

17 March 2015

Registered medical practitioners who provide cosmetic medical and surgical procedures

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List of abbreviations

ACCS	Australasian College of Cosmetic Surgery
ACSQHC	Australian Commission on Safety and Quality in Health Care
AHMAC	Australian Health Ministers' Advisory Council
AHPRA	Australian Health Practitioner Regulation Agency
AHWMC	Australian Health Workforce Ministerial Council
AMA	Australian Medical Association
AMC	Australian Medical Council
ASPS	Australian Society of Plastic Surgeons
CHF	Consumers Health Forum of Australia
COAG	Council of Australian Governments
CPSA	Cosmetic Physicians Society of Australasia
FDA	US Food and Drug Administration
GMC	General Medical Council (UK)
HQCC	Health Quality and Complaints Commission (Queensland)
IPL	Intense Pulsed Light
MCNSW	Medical Council of New South Wales
MCNZ	Medical Council of New Zealand
MDA	MDA National
MIGA	Medical Insurance Group Australia
National Law	Health Practitioner Regulation National Law, as in force in each state and territory
National Scheme	National Registration and Accreditation Scheme
NHMRC	National Health and Medical Research Council
NHS	National Health Service (UK)
OBPR	Office of Best Practice Regulation
RACGP	Royal Australian College of General Practitioners
RACS	Royal Australasian College of Surgeons
RIS	Regulation Impact Statement
TGA	Therapeutic Goods Administration

Introduction

This public consultation paper released by the Medical Board of Australia (the Board) seeks feedback from stakeholders on issues relating to medical practitioners who provide cosmetic medical and surgical procedures, the effectiveness of current regulation of medical practitioners providing these procedures, whether additional safeguards are needed and feasible options in relation to medical practitioners who provide cosmetic medical and surgical procedures.

This paper meets the consultation requirements of the Health Practitioner Regulation National Law, as in force in each state and territory (the National Law) and the Council of Australian Governments (COAG) requirements for a Regulation Impact Statement (RIS).

The Board is one of 14 National Boards in the National Registration and Accreditation Scheme (the National Scheme). The National Scheme is governed by the National Law.

The Board's functions include registering medical practitioners and medical students, developing registration standards, codes and guidelines for the medical profession and investigating notifications. Protection of the public is the paramount guiding principle for everything the Board does. The National Law empowers the Board to develop and approve codes and guidelines to provide clear guidance about the Board's expectations of the medical profession with regards to appropriate professional conduct and/or practice.

Any registration standards, codes and guidelines developed by the Board for the medical profession must comply with the National Law and be prepared in accordance with the Australian Health Practitioner Regulation Agency's (AHPRA) *Procedures for development of registration standards, codes and guidelines* and the COAG *Principles of best practice regulation*.

If a National Board proposes a new standard, code or guideline, the National Law requires that the Board must ensure there is wide-ranging consultation on the content of the proposal.

If a proposal from a National Board has a potentially more than minor impact on business or the community, the Office of Best Practice Regulation (OBPR) advises that impact analysis in the form of a RIS is needed. Undertaking an impact assessment ensures that the Board analyses the costs and benefits when considering options which have a regulatory impact. This RIS has been developed in consultation with the OBPR and provides a summary of the Board's assessment of the impact and cost-benefit analysis of options in relation to medical practitioners who provide cosmetic medical and surgical procedures.

This paper compares four non-regulatory and regulatory options:

- Option one – Retain the status quo of providing general guidance about the Board's expectations of medical practitioners providing these procedures via the Board's approved code of conduct
- Option two – Provide consumer education material about the provision of cosmetic medical and surgical procedures by medical practitioners
- Option three – Strengthen current guidance for medical practitioners providing cosmetic medical and surgical procedures through new, practice-specific guidelines that clearly articulate the Board's expectations of medical practitioners
- Option four – Strengthen current guidance for medical practitioners providing cosmetic medical and surgical procedures through new, practice-specific guidelines as per option three but which provide less explicit guidance to medical practitioners.

The Board is undertaking consultation to seek feedback from stakeholders to help the Board better assess the extent of the problem, the potential impacts of the proposed options, and the most appropriate response. Any response needs to be proportionate and balance the reasonable expectations that consumers may choose to access these procedures from suitably qualified, trained and competent medical practitioners who, because they are registered, have met and continue to meet standards set by the Board, and to not impose unnecessary or potentially burdensome expectations on those medical practitioners who provide cosmetic medical and surgical procedures.

Data on cosmetic medical and surgical procedures provided by medical practitioners that may help the Board, the community, medical practitioners and others assess the extent of current issues raised, as a result of the provision of these procedures by medical practitioners, are difficult to access as there is no central data collection for this type of medical practice. The Board is seeking input from stakeholders where there are gaps in the data and where the Board has been limited in the evidence it can collect on the extent and magnitude of the problem. Further data will also aid the Board to estimate the number of consumers and medical practitioners who could benefit from and/or would be impacted by the proposed options.

The Board is interested in comments from a wide range of stakeholders.

Feedback received from this public consultation will be incorporated into the final (decision) RIS that informs the decision whether to proceed with one of the proposed options.

A summary of the Board's earlier consultation on the provision of cosmetic medical and surgical procedures by medical practitioners is provided in Attachment A.

Consultation process

The Board is seeking general feedback as well as responses to questions throughout the document. A complete list of the consultation questions is provided at the end of the document.

Please provide written submissions by email, marked:
'Consultation – Registered medical practitioners who provide cosmetic medical and surgical procedures' to medboardconsultation@ahpra.gov.au by close of business on **29 May 2015**.

Submissions for publication on the Board's website should be sent in Word format or equivalent.¹

Submissions by post should be addressed to the Executive Officer, Medical, AHPRA, GPO Box 9958, Melbourne 3001.

Publication of submissions

The Board publishes submissions at its discretion.

The Board generally publishes submissions on its website to encourage discussion and inform the community and stakeholders. Please advise us if you do not want your submission published.

We will not place on our website, or make available to the public, submissions that contain offensive or defamatory comments or which are outside the scope of the subject of the consultation. Before publication, we will remove personally-identifying information from submissions, including contact details.

The views expressed in the submissions are those of the individuals or organisations who submit them and their publication does not imply any acceptance of, or agreement with, these views by the Board.

The Board accepts submissions made in confidence. These submissions will not be published on the website or elsewhere. Submissions may be confidential because they include personal experiences or other sensitive information. Any request for access to a confidential submission will be determined in accordance with the *Freedom of Information Act 1982* (Cth), which has provisions designed to protect personal information and information given in confidence. Please let us know if you do not want us to publish your submission, or want us to treat all or part of it as confidential.

¹ You are welcome to supply a PDF file of your feedback in addition to the word (or equivalent) file, however we request that you supply a text or word file. As part of an effort to meet international website accessibility guidelines, AHPRA and National Boards are striving to publish documents in accessible formats (such as word), in addition to PDFs. More information about this is available at www.ahpra.gov.au/About-AHPRA/Accessibility.aspx

Background

Definitions

Cosmetic medical and surgical procedures are surgical 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.²

Major cosmetic medical and surgical procedures ('cosmetic surgery') involve cutting beneath the skin such as; breast augmentation, breast reduction, rhinoplasty, surgical face lifts and liposuction.³

Plastic surgery includes both *cosmetic surgery* and *reconstructive surgery*. *Reconstructive surgery* is performed on parts of the body which are abnormal due to congenital defects, developmental abnormalities, injury or disease.

Reconstructive surgery differs from *cosmetic surgery* as, while it incorporates aesthetic techniques, it restores form and function as well as normality of appearance.

Other procedures are minor (non-surgical) procedures, that do not involve cutting beneath the skin, but may involve piercing the skin; for example, non-surgical cosmetic varicose vein treatment, laser skin treatments, use of CO₂ lasers to cut the skin, mole removal for purposes of appearance, laser hair removal, dermabrasion, chemical peels, injections, microsclerotherapy and hair replacement therapy.⁴

Cosmetic medical and surgical procedures provided by medical practitioners

Within the wider community, 'cosmetic' procedures are alternately viewed and promoted as medical procedures, beauty treatments and consumer products. This can lead to a vast and potentially confusing array of services and practices that can be invasive and non-invasive, lower-risk and higher-risk, and be accessed from a range of providers, including registered health practitioners.

The Board is consulting on cosmetic medical and surgical procedures provided by medical practitioners.

Cosmetic medicine and surgery provided by medical practitioners is an area of practice that is different to other areas of medical practice for a number of reasons:

- cosmetic medical and surgical procedures are entirely elective and are usually initiated and requested by the consumer
- cosmetic medical and surgical procedures are undertaken to improve appearance, not because of a diagnosed medical need
- cosmetic medical and surgical procedures are performed outside the public health system, in private hospitals, day procedure centres and medical practitioners' rooms
- consultations and cosmetic medical and surgical procedures are usually paid for directly by the consumer and can be of considerable cost.

Australia's cosmetic medicine and surgery industry continues to grow as more Australians choose to have cosmetic medical and surgical procedures provided by medical practitioners. Exact numbers of cosmetic medical and surgical procedures are not known as there is no national data collection for this area of medical practice as it is not a recognised specialty provided by a single sub-group of medical practitioners. Data from Medicare and private health insurers are not available as most procedures are not eligible for rebates.

² Definition adapted from the Medical Council of New Zealand's *Statement on Cosmetic Procedures* (2007, 2011) by the Australian Health Ministers' Advisory Council's Clinical, Technical and Ethical Principal Committee Inter-jurisdictional Cosmetic Surgery Working Group

³ New Zealand's *Statement on Cosmetic Procedures* (2007, 2011)

⁴ *ibid.*

The Australasian College of Cosmetic Surgery estimates that total annual expenditure on cosmetic procedures (including non-medical treatments) in Australia is around \$1 billion. The College estimates that Australians spend more than \$350 million on (prescription only) cosmetic injectables and approximately 8,000 breast augmentation surgeries and 30,000 liposuction procedures are performed by medical practitioners annually.⁵

Number of medical practitioners providing these procedures

Under the National Law, a specialists' register is published, making it easy to identify medical specialists from other medical practitioners. Cosmetic surgery is not a medical speciality, recognised and approved by the Australian Health Workforce Ministerial Council (AHWMC) pursuant to the National Law.

A range of medical practitioners, who have varied qualifications and training, provide cosmetic medical and surgical procedures. Medical practitioners who perform cosmetic medical and surgical procedures include (but are not limited to); plastic surgeons, general surgeons, otolaryngologists (ear, nose and throat head and neck surgeons), oral and maxillofacial surgeons, dermatologists, ophthalmologists, general practitioners and practitioners with no specialty qualifications (general registration only).

For the reasons above, the numbers of medical practitioners providing cosmetic medical and surgical procedures in Australia is not known. There are 433 medical practitioners currently registered in the specialty of plastic surgery.⁶ However, not all plastic surgeons perform cosmetic surgery and many cosmetic medical and surgical procedures are provided by medical practitioners who are not plastic surgeons.

Professional association membership provides an indication of the numbers of medical practitioners who provide cosmetic medical and surgical procedures, although membership is optional and members can belong to multiple associations (providing they meet the membership criteria). Currently, the Australian Society of Plastic Surgeons has 319 members and 96 trainees and the Australasian Society of Aesthetic Plastic Surgery has 203 members and 10 trainees. Membership of the Australian Society of Plastic Surgeons and the Australasian Society of Aesthetic Plastic Surgery is restricted to medical practitioners who hold a specialist qualification from the Royal Australasian College of Surgeons (RACS). The Australasian College of Cosmetic Surgery has approximately 150 members and the Cosmetic Physicians Society of Australasia has approximately 200 members.⁷

Current regulatory environment

Medical practitioners who provide cosmetic medical and surgical procedures are subject to a range of regulatory measures.

Medical practitioners are registered nationally under the National Scheme and must comply with the National Law and approved registration standards and are expected to follow any approved codes and guidelines issued by the Board.

⁵ Australasian College of Cosmetic Surgery, Media release, *ACCS welcomes Marie Claire Magazine's call for cosmetic medicine and surgery reforms*, 12 June 2013. Established in 1999, the Australasian College of Cosmetic Surgery is a not-for-profit, multi-disciplinary organisation including cosmetic surgeons, plastic surgeons, maxillofacial surgeons, dermatologists, ear nose and throat surgeons, ophthalmologists and other doctors who practise cosmetic medicine and surgery.

⁶ Medical Board of Australia, Medical Practitioner Registrant Data: February 2015, available at: <http://www.medicalboard.gov.au/News/Statistics.aspx>

⁷ In November 2014, the Cosmetic Physicians Society of Australasia announced the establishment of the Cosmetic Physicians College of Australasia for cosmetic medical practitioners. The Cosmetic Physicians Society of Australasia will also continue and will represent medical practitioners who perform non-invasive or minimally invasive cosmetic procedures (Cosmetic Physicians Society of Australasia, *Media Release*, November 2014).

The Board's code of conduct, *Good medical practice: A code of conduct for doctors in Australia*, describes the Board's expectations of all doctors registered to practise medicine in Australia. It sets out the principles that characterise good medical practice and makes explicit the standards of ethical and professional conduct expected of doctors by their professional peers and the community.⁸ The code of conduct is part of the current regulatory framework that applies to all registered medical practitioners; but is generic to all areas of medical practice and does not include guidance specific to a medical specialty or area of practice. The broad principles in *Good medical practice* apply to all areas of medical practice and have done so since the start of national regulation in July 2010.

If a patient is dissatisfied with the care they received from a medical practitioner, they may make a complaint to the health complaints entity in their state or territory and/or make a notification to the Board. When a notification is made, AHPRA assesses the matter and can investigate.⁹ The Board determines whether the practitioner engaged in unprofessional conduct or unsatisfactory professional performance based on the evidence gathered. As registration standards, codes and guidelines may be used as evidence of what reasonably constitutes appropriate professional conduct or practice, the Board uses these documents to help assess the practitioner's conduct and performance.

Prior to the introduction of the National Scheme, an equivalent of the National Board's code of conduct was in place in each state and territory that regulated medical practitioners. Further, the then NSW Medical Board¹⁰ had issued *Cosmetic Surgery Guidelines* which included guidance on patient assessment and the provision of written information for patients seeking a cosmetic procedure.¹¹

Each state and territory has its own drugs and poisons legislation that specifies which health practitioners are authorised to administer, obtain, possess, prescribe, sell, supply or use schedule medicines. Schedule 4 (prescription only) cosmetic injectables can only be supplied on written prescription from a medical practitioner or other authorised prescriber (who needs specific authority to do so). Note, a registered nurse can only administer schedule 4 cosmetic injectables on the order of a medical practitioner or other authorised prescriber and cannot independently obtain, possess, supply and administer schedule 4 cosmetic injectables. Unregistered persons, such as beauty therapists, cannot administer schedule 4 cosmetic injectables.

The Commonwealth's Therapeutic Goods Administration (TGA) regulates therapeutic goods under the *Therapeutic Goods Act 1989*. Devices such as lasers and intense pulsed light sources (IPLs) are only regulated by the TGA if the procedure is deemed to be for 'therapeutic purposes'.

If lasers or IPLs are used for cosmetic purposes, regulation is determined at the state or territory level and comes under a jurisdiction's radiation protection or radiation safety legislation. Only some states and territories regulate these devices.

The National Health and Medical Research Council (NHMRC) has issued *Australian Guidelines for the Prevention and Control of Infection in Healthcare* which include recommendations to prevent and control infection in healthcare facilities.¹²

⁸ Medical Board of Australia, *Good Medical Practice: A Code of Conduct for Doctors in Australia*, 2014 <http://www.medicalboard.gov.au/Codes-Guidelines-Policies/Code-of-conduct.aspx>

⁹ Further information about complaints and notifications, including how AHPRA works with health complaints entities and how the processes vary in NSW and Queensland is available at: <http://www.ahpra.gov.au/Notifications.aspx>

¹⁰ NSW is a co-regulatory jurisdiction. Medical Board of Australia policies apply to all registered medical practitioners, including NSW practitioners. When the NSW Medical Board transitioned to the Medical Council of NSW on 1 July 2010, the Medical Council approved the continued application of all previously operating NSW Medical Board policies. These policies only apply to NSW medical practitioners, or in relation to conduct or behaviour occurring in NSW. More information is available at: <http://www.mcnsw.org.au/page/419/resources/introduction-to-policies/>

¹¹ Medical Council of NSW, *Cosmetic Surgery Guidelines*, 2008, <http://www.mcnsw.org.au/page/publications-and-policies/cosmetic-surgery-guidelines>

¹² National Health and Medical Research Council, *Australian Guidelines for the Prevention and Control of Infection in Healthcare*, 2010 <http://www.nhmrc.gov.au/guidelines/publications/cd33>

Health services are accredited against the Australian Commission on Safety and Quality in Health Care's *National Safety and Quality Health Service Standards*.¹³ General practices may be accredited against the Royal Australian College of General Practitioners (RACGP) *Standards for general practices (4th edition)*.¹⁴ Accreditation for general practices is optional.

Licensing of private hospitals and day procedure centres varies across states and territories with each jurisdiction having its own legislation and regulations.

At a local level, medical practitioners are subject to the policies and procedures of the hospital or facility in which they practise.

Major reviews into cosmetic surgery in Australia

To date there have been several major reviews that have more broadly considered issues with 'cosmetic' procedures including cosmetic medical and surgical procedures provided by medical practitioners in Australia.

NSW Committee of Inquiry into Cosmetic Surgery, 1998

In 1998, in response to concerns about the promotion and the quality and safety of cosmetic surgery procedures, the NSW Minister for Health appointed a Committee of Inquiry into Cosmetic Surgery. The Committee was tasked with identifying and reviewing the adequacy and limitations of existing consumer safeguards and to review the quality and accessibility of sources of current consumer information on cosmetic procedures. The Committee reviewed the literature, held public consultations, and undertook a survey of consumer experiences.

In its report, the Committee found there was little information available on clinical standards and adverse outcomes for cosmetic procedures. It also noted the risks associated with the range of providers and the types of facilities where procedures are performed. The Committee noted that insurers and health complaint entities regard cosmetic procedures as a high risk area of practice because the complaints are primarily about clinical outcomes, and because of the unique characteristics of the industry, for example, the different nature of the doctor/patient relationship and financial arrangements.¹⁵

The Committee made recommendations to the Minister for Health for action in relation to training of medical practitioners, licensing of facilities, information for consumers, aftercare and promotion of cosmetic surgery.

AHMAC Inter-jurisdictional Cosmetic Surgery Working Group, 2010

In 2010, Australian Health Ministers, alarmed by the growth in marketing of cosmetic medical and surgical procedures and the potential impact on the community, requested an examination of the adequacy of current consumer safeguards in relation to cosmetic surgery and an assessment of the need for a national approach to regulating cosmetic surgery.

The Australian Health Ministers' Advisory Council's (AHMAC) Inter-jurisdictional Cosmetic Surgery Working Group was tasked with undertaking the review. In its report, *Cosmetic Medical and Surgical Procedures – A National Framework*, the group expressed concerns about the inconsistent nature of regulation in an area of practice with 'rapidly changing technology' and 'burgeoning activity'. The group noted that these medical and surgical procedures 'are not a commodity to be treated lightly – they are medical interventions which carry risks and a complication and failure rate'.¹⁶

¹³ Australian Commission on Safety and Quality in Health Care, *National Safety and Quality Health Service Standards*, 2012 <http://www.safetyandquality.gov.au/wp-content/uploads/2011/09/NSQHS-Standards-Sept-2012.pdf>

¹⁴ Royal Australian College of General Practitioners, *Standards for general practices*, 4th edn, 2013 <http://www.racgp.org.au/your-practice/standards/standards4thedition/>

¹⁵ Health Care Complaints Commission, *The Cosmetic Surgery Report - Report to the NSW Minister for Health*, 1999 <http://www.hccc.nsw.gov.au/Publications/Corporate-Documents>

¹⁶ Australian Health Ministers' Conference, *Cosmetic Medical and Surgical Procedures – A National Framework*, 2011, http://www0.health.nsw.gov.au/pubs/2012/cosmetic_surgery.html

The AHMAC report proposed a national framework to provide consumers with consistent standards in relation to the provision of cosmetic medical and surgical procedures across Australia.¹⁷

The report contained a number of key recommendations directed to the Medical Board about medical practitioners who perform cosmetic medical and surgical procedures.

The Medical Board was asked to respond to these recommendations as they specifically related to the Board's statutory mandate to regulate medical practitioners in the public interest, including those that provide cosmetic medical and surgical procedures. One of these recommendations was that the Board issue supplementary guidelines for medical practitioners on cosmetic medical and surgical procedures for the Board's code of conduct, *Good medical practice*. The AHMAC report suggested to the Board that the areas which the guidelines should address include; advertising, medical practitioner training, restrictions on the provision of cosmetic medical and surgical procedures for children, informed consent and health facility standards. The report included supplementary guidelines for medical practitioners that were drafted by the AHMAC Working Group.

The Board cannot issue guidelines without first consulting on the proposal with a wide range of stakeholders and assessing options and potential regulatory impacts.

The AHMAC Working Group also made recommendations to other national bodies that were within the scope of their work including that:

- the Nursing and Midwifery Board of Australia consider the need for supplementary guidelines to its code of conduct for registered nurses.¹⁸
- the Australian Radiation Protection and Nuclear Safety Agency's (ARPANSA) Radiation Health Committee undertake work to address gaps in the current regulation of lasers and IPLs which are used by both registered health practitioners and unregulated providers.¹⁹

Queensland's Health Quality and Complaints Commission, 2013

In 2013, Queensland's Health Quality and Complaints Commission (HQCC) analysed complaints received about cosmetic surgical and medical procedures provided by registered health practitioners in Queensland between 2006 and 2012. The HQCC had concerns that the risks associated with cosmetic medical and surgical procedures are underestimated by consumers. The report, *'Great expectations: A spotlight report on complaints about cosmetic surgical and medical procedures in Queensland'* found that there 'are fewer patient safeguards and less regulation in place for cosmetic procedures than for other areas of medicine' and their findings highlighted ongoing safety and quality concerns.²⁰

International approaches to cosmetic medical and surgical procedures

Other jurisdictions have also undertaken reviews of cosmetic medical and surgical procedures.

¹⁷ *ibid.*

¹⁸ The Nursing and Midwifery Board of Australia is currently considering options in relation to regulation of nurses who provide cosmetic procedures and is aware of, and has the opportunity to contribute to this public round of consultation.

¹⁹ The ARPANSA Radiation Health Committee is currently considering options for nationally consistent regulation of these devices.

²⁰ Health Quality and Complaints Commission, *Great expectations: A spotlight report on complaints about cosmetic surgical and medical procedures in Queensland*, 2013, <http://www.hqcc.qld.gov.au/News/Pages/Spotlight-on-cosmetic-procedures.aspx>

United Kingdom

The UK Department of Health has undertaken a major review of regulation of cosmetic interventions in the UK. The Review Committee on the Regulation of Cosmetic Interventions was tasked with reviewing the current arrangements for ensuring the quality and safety of cosmetic interventions. The Committee found that there was inadequate protection for consumers against many of the potential risks from cosmetic procedures.²¹ The Committee's report, *Review of the Regulation of Cosmetic Interventions - Final Report 2013* included a number of recommendations to strengthen regulation in the cosmetic surgery industry.²²

Most recently, in early 2015, the Royal College of Surgeons of England (a professional membership organisation which sets standards for surgeons) released a consultation document proposing a framework for better protection for cosmetic surgery patients. The framework was developed by the Cosmetic Surgery Interspecialty Committee and addresses recommendations in the UK review report.

The General Medical Council (GMC), who regulates medical practitioners in the UK, has also recently announced that later this year, it will produce new guidance which will set out the professional standards expected of medical practitioners offering cosmetic treatments.²³ This is in addition to the Independent Healthcare Advisory Services' *Good medical practice in cosmetic surgery* which was issued in 2013 to complement the GMC's existing code for registered medical practitioners, *Good medical practice*.²⁴

The GMC has also issued specific guidance for medical practitioners who prescribe cosmetic injectables such as 'Botox'. Medical practitioners are now required to have a face-to-face consultation with a patient before prescribing a cosmetic injectable. Remote prescribing, for example, by phone or video link, is not permitted.²⁵

New Zealand

The Medical Council of New Zealand (MCNZ) has noted the ethical, resource and regulatory issues that arise when medical practitioners provide cosmetic procedures that are undertaken where there is no 'medical condition'. The MCNZ makes its expectations clear; a medical practitioner's usual professional obligations apply regardless of the nature or setting of the practice.²⁶ The MCNZ's *Statement on cosmetic procedures* outlines the standards expected of medical practitioners who perform cosmetic procedures in New Zealand.²⁷ The statement was prompted by concern that the previous regulatory framework was inadequate in protecting consumers having cosmetic procedures provided by medical practitioners.²⁸

The statement includes expected training, skill and expertise, advertising, patient assessment and informed consent including a mandatory cooling off period for patients considering a 'category one' (major) cosmetic surgical procedure.²⁹

²¹ Department of Health, *Review of the Regulation of Cosmetic Interventions - Final Report*, UK, 2013, <https://www.gov.uk/government/publications/review-of-the-regulation-of-cosmetic-interventions>

²² *ibid.*

²³ General Medical Council, Statement, *GMC responds to RCS cosmetic surgery proposals*, 23 January 2015, <http://www.gmc-uk.org/news/26090.asp>

²⁴ Independent Healthcare Advisory Services, *Good Medical Practice in Cosmetic Surgery*, UK, 2013, http://www.independenthealthcare.org.uk/cat_view/126-cosmetic-ihas/127-cosmetic-ihas/menu-id-864

²⁵ General Medical Council, *Good practice in prescribing and managing medicines and devices*, UK, 2013, http://www.gmc-uk.org/guidance/ethical_guidance/14316.asp

²⁶ Adams J & Thorn M, 'Doctors and interventions with well people', Chapter 25 in St George IM (ed.), *Cole's medical practice in New Zealand*, 12th edn, Medical Council of New Zealand, Wellington, 2013.

²⁷ Medical Council of New Zealand, *Statement on cosmetic procedures*, NZ, 2011, <http://www.mcnz.org.nz/support-for-doctors/resources/>

²⁸ Scott K, 'Under the knife: an analysis of the Medical Council of New Zealand's Statement on Cosmetic Procedures', *Journal of Law and Medicine*, 16(4), 2009, pp 625-52

²⁹ The MCNZ's statement was revised in 2011 to add guidance for doctors who perform tumescent liposuction.

A subsequent independent analysis of the statement commended the MCNZ's actions, as the cosmetic medicine and surgery industry as it existed (without regulation of medical practitioners, specific to cosmetic procedures) 'posed serious risks (for) consumers'.³⁰

Ontario, Canada

In 2007, the Council of the College of Physicians and Surgeons of Ontario committed to a patient safety plan to improve public safety in Ontario in relation to the provision of cosmetic medical and surgical procedures. The Council expressed concerns that 'critical decisions to undergo surgery are being made in an information vacuum' as the field of cosmetic surgery rapidly expands.³¹

The Council set four objectives:³²

1. advocate for legislative change for facility inspections
2. introduce a peer assessment process to identify physicians (medical practitioners) performing high-risk cosmetic procedures without adequate training
3. review the College's *Change in scope of practice* policy, with specific attention to cosmetic medical and surgical procedures
4. develop a public information initiative to educate consumers about cosmetic medical and surgical procedures and their risks.

Singapore

In 2008, the Academy of Medicine, Singapore, the College of Family Physicians, Singapore and the Singapore Medical Council jointly implemented a framework for aesthetic practice³³ with requirements outlined in *Guidelines on aesthetic practices for doctors*.³⁴

Other countries

Other countries, including France, Denmark and Ireland, have developed guidelines aimed at assuring patient safety in response to identified risks associated with cosmetic medical and surgical procedures provided by medical practitioners.

³⁰ Scott

³¹ College of Physicians and Surgeons of Ontario, 'The Safety Imperative: Enhanced oversight for cosmetic surgery', *Dialogue*, Dec 2007, pp 7-9

³² College of Physicians and Surgeons of Ontario, *Action taken by the College to improve patient safety with respect to cosmetic procedures*, 2007, <http://www.cpso.on.ca/Policies-Publications/Positions-Initiatives/Cosmetic-Procedures-Improving-Patient-Safety>

³³ Singapore uses the term, 'aesthetic practice' which has the same definition as other jurisdictions use for 'cosmetic surgery'. It includes both non-invasive procedures (for example, IPL and chemical peels) and invasive procedures (for example, rhinoplasty and liposuction).

³⁴ Singapore Medical Council, *Guidelines on aesthetic practices for doctors*, 2008, http://www.healthprofessionals.gov.sg/content/hprof/smc/en/topnav/guidelines/guidelines_on_aesthetic_practices.html

What is the problem?

Consumers making rushed decisions to have cosmetic medical and surgical procedures provided by medical practitioners, without adequate information

Health care is characterised by encounters in which the consumer knows less about services and procedures than the provider. This information asymmetry can create a power imbalance which places the consumer at a disadvantage.

When the effect of information asymmetry on the medical market was initially explored, health care was thought of as a non-commercial activity³⁵ and patients' need for medical care was unpredictable.³⁶ Health care has since changed, and some procedures are undertaken by choice, not because of medical need. Cosmetic medical and surgical procedures are entirely elective and are usually initiated and requested by the consumer, which can amplify the information asymmetry.

Consumers usually request cosmetic medical and surgical procedures directly from the medical practitioner providing the procedure, without a referral from a general practitioner. This means that a step that usually helps consumers develop their understanding of their options and the possible risks and benefits is missing. In the NSW report, the committee noted that the absence of general practitioner referral in the cosmetic procedures market exacerbates the information asymmetry between the medical practitioner and the patient.³⁷ This direct access to the medical practitioner providing the procedure also means that the number of referrals from other medical practitioners, sometimes used as a measure of 'physician quality', is not available.³⁸

Surgical procedures are not like other products and services which are repeatedly consumed and where the consumer learns from repeated consumption. Major cosmetic surgical procedures are much less likely to be a regular, repeated purchase and therefore the consumer cannot make these decisions based on experience.³⁹

Medical practitioners who provide cosmetic procedures advertise their services directly to consumers in a competitive market. Consumers who request these procedures from medical practitioners may not have realistic expectations about the results and may have a poor appreciation of the risks of the procedure, not realising that these procedures are complex *medical and surgical* procedures. The relationship between the medical practitioner and the patient is blurred by the underlying roles of the medical practitioner as a commercial service provider (the 'seller') and the patient as a customer (the 'buyer').

Outcome data on cosmetic medical and surgical procedures provided by medical practitioners are limited and common indicators of quality in other markets, such as volume or price are unreliable – the busy medical practitioner or the high price for a procedure is not a guarantee of 'high quality' and cannot be correlated with a good surgical outcome.⁴⁰ The health consumer may know about 'price', but there will always be uncertainty about the 'quality' of the product or service.⁴¹

³⁵ Havighurst CC, 'Health Care as a (Big) Business: The Antitrust Response', *Journal of Health Politics, Policy and Law*, 26(5), 2001, pp 939-956

³⁶ Arrow KJ, 'Uncertainty and the welfare economics of medical care', *American Economic Review*, 53(5), 1963, pp 941-73

³⁷ Health Care Complaints Commission

³⁸ Haas-Wilson D, 'Arrow and the Information Market Failure in Health Care: The Changing Content and Sources of Health Care Information' *Journal of Health Politics, Policy and Law*, 26(5), 2001, pp 1031-1044

³⁹ Sloan FA, 'Arrow's Concept of the Health Care Consumer: A Forty-Year Retrospective', *Journal of Health Politics, Policy and Law*, 26(5), 2001, pp 899-912

⁴⁰ Haas-Wilson

⁴¹ Arrow

The research undertaken for the UK's review suggests that cosmetic medical and surgical procedures are 'increasingly regarded as normal' and consumers often underestimate the associated risks. It also found that some consumers may be vulnerable to marketing messages which promote easy solutions for those who are dissatisfied with their appearance. It noted that consumers contemplating cosmetic medical and surgical procedures tended to focus on the outcome of the procedure rather than the limitations and risks.⁴²

Given the information asymmetry, the sometimes unrealistic expectations of consumers, and the commercial relationship between the medical practitioner and the patient, it may be difficult for the medical practitioner to objectively determine the appropriateness of a cosmetic medical or surgical procedure and whether it is in the best interests of the patient. Therefore, there can be an increased risk of exploitation of patients.

The comprehensiveness of the initial patient assessment is variable and in some clinics is undertaken by a patient advisor or agent who is not a registered health practitioner and who has a commercial imperative to sign people up for procedures. Medical assessment of a consumer's motivation for the procedure is a critical step as there is evidence to suggest that some people seeking cosmetic procedures have a distorted body image (including conditions such as Body Dysmorphic Disorder) which may make them an unsuitable candidate for cosmetic procedures.⁴³

Information available to consumers having cosmetic medical and surgical procedures provided by medical practitioners can be of variable accuracy and quality

There is a wide range of information on the internet about cosmetic procedures, but inconsistencies and inaccuracies are common. The NSW report noted that for consumers there is a confusing array of information on procedures available through media, brochures and online sources.⁴⁴ In the AHMAC report, the working group noted that 'factual, easily understood information for consumers contemplating cosmetic medical or surgical procedures from a source that is independent of providers and promoters is not always readily available'.⁴⁵

The UK review found that consumers have difficulty assessing the quality of the information on cosmetic medical and surgical procedures and there are limited reliable data to assist patients in making assessments of the efficacy and risks of treatments.⁴⁶

In Australia, there is limited information for consumers which is comprehensive, independent and reliable and can help consumers understand what to expect when they see a medical practitioner who provides cosmetic medical and surgical procedures.

The Australian Society of Plastic Surgeons together with the New Zealand Association of Plastic Surgeons has established the Australasian Foundation for Plastic Surgery which provides patient resources.⁴⁷ However, this information is oriented to procedures provided by specialist plastic surgeons. The Australasian College of Cosmetic Surgery and the Cosmetic Physicians Society of Australasia both have information on their websites about procedures provided by medical practitioners who are members. Other sources of information include state and territory health department websites, for example, Victoria's Better Health Channel has generic information about common cosmetic procedures.⁴⁸

⁴² Department of Health

⁴³ Crerand CE, Franklin ME & Sarwer DB, 'Body Dysmorphic Disorder and Cosmetic Surgery', *Plastic and reconstructive surgery*, vol 118, no 7, 2006, pp 167-180.

⁴⁴ Health Care Complaints Commission

⁴⁵ Australian Health Ministers' Conference

⁴⁶ Department of Health

⁴⁷ Australasian Foundation for Plastic Surgery, <http://www.plasticsurgeryfoundation.org.au/patient-information/>

⁴⁸ Better Health Channel, http://www.betterhealth.vic.gov.au/bhcv2/bhcarticles.nsf/pages/ct_surgery?open&cat=Surgery_-_Cosmetic_surgery

Patients' ability to access and understand health information varies greatly. Health literacy is 'the skills, knowledge, motivation and capacity of a person to access, understand, appraise and apply information to make effective decisions about health and health care and take appropriate action.'⁴⁹ In Australia, almost 60 per cent of Australian adults have low health literacy.⁵⁰

When information is conflicting, it can be difficult for consumers to make informed decisions.⁵¹

Informed consent processes for consumers having cosmetic medical and surgical procedures provided by medical practitioners vary

Informed consent is a person's voluntary decision about medical care that is made with knowledge and understanding of the benefits and risks involved.⁵² Informed consent is a critical step that must occur before a patient decides to proceed with a procedure. The power imbalance that exists between the medical practitioner and the patient can act as a barrier to informed consent.⁵³

In the NSW report it was noted the importance of informed consent and a medical practitioner's duty to warn the patient of the risks when procedures are truly elective, such as cosmetic medical and surgical procedures.⁵⁴ The NHMRC's guidelines on providing information for patients states that 'doctors should give information about the risks of any intervention' and notes that 'discretionary' procedures, such as elective cosmetic surgery, require more information.⁵⁵

The Consumers Health Forum of Australia (CHF) notes the issues associated with informed consent for cosmetic surgery and that the elective nature of the surgical procedure 'impacts the way in which the risks and the benefits of procedures are assessed' and 'the level of risk that is considered reasonable is significantly reduced'. The CHF also notes that 'the more subjective nature of the potential benefits (of cosmetic procedures) also makes consent more difficult to assess objectively, raising the possibility of exploitation of consumers.' The CHF concludes that cosmetic surgery provided by medical practitioners is an area of medical practice where there is 'significant scope for improvement in informed consent processes.'⁵⁶

A key element of consent is ensuring that the consumer has 'time to reflect, before and after they make a decision, especially if the information is complex or (it) involves significant risks.'⁵⁷ A two stage consent process, where the patient has a 'cooling off period' after their initial consultation with the medical practitioner, encourages a period of reflection during which the patient 'has the opportunity to consider the full implications' of the proposed procedure.⁵⁸

⁴⁹ Australian Commission on Safety and Quality in Health Care. *Health literacy: Taking action to improve safety and quality*, Sydney, ACSQHC, 2014 <http://www.safetyandquality.gov.au/publications/health-literacy-taking-action-to-improve-safety-and-quality/>

⁵⁰ Australian Bureau of Statistics. *Health Literacy, Australia*, Canberra, Australian Bureau of Statistics, 2008

⁵¹ Australian Commission on Safety and Quality in Health Care. *Health literacy: Taking action to improve safety and quality*, Sydney, ACSQHC, 2014

⁵² Medical Board of Australia, *Good Medical Practice: A Code of Conduct for Doctors in Australia*, 2014

⁵³ Consumers Health Forum of Australia, *Informed Consent in Healthcare: An Issues Paper*, 2013 <https://www.chf.org.au/pdfs/chf/Informed-Consent-Issues-Paper.pdf>

⁵⁴ Health Care Complaints Commission

⁵⁵ National Health and Medical Research Council, *General Guidelines for medical practitioners on providing information to patients*, 2004 <https://www.nhmrc.gov.au/guidelines/publications/e57>

⁵⁶ Consumers Health Forum of Australia

⁵⁷ General Medical Council, *Consent: patients and doctors making decisions together*, 2008 http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp

⁵⁸ Department of Health

The Australian Society of Plastic Surgeons notes that ‘with cosmetic surgery procedures, it is particularly important that the patient is given sufficient time to think about whether the procedure is in his or her best interests.’ Its code of conduct for plastic surgeons specifies a ‘cooling off’ period of a minimum of ten days between the initial consultation between the plastic surgeon and the patient, and the cosmetic surgery procedure.⁵⁹

There is currently no consistent guidance for either consumers or medical practitioners in relation to a reasonable minimum time between when a consumer approaches a medical practitioner and when a procedure can be performed. This means that a consumer can proceed with a major, irreversible elective procedure without fully appreciating the risks, the likelihood of complications, the variable outcomes and the cost.

Complaints data support the perception that some consumers who have cosmetic medical and surgical procedures provided by a medical practitioner, do not fully appreciate the risks or the likely outcomes, suggesting that informed consent processes are inadequate or poorly done by medical practitioners providing these procedures.

Data from health complaints entities show that consumers who have cosmetic medical and surgical procedures provided by medical practitioners have disproportionately high levels of dissatisfaction, disputes about consent and complaints about adverse outcomes compared with those having other medical procedures.

Adverse events and harm following minor (non-surgical) cosmetic procedures are less common and less severe as these procedures do not require a general anaesthetic and do not include cutting beneath the skin (greatly reducing the likelihood of infection).

It should be noted that complaints data are collected differently in different jurisdictions. For example, in Western Australia, the Health and Disability Services Complaints Office cannot accept complaints about surgery or procedures undertaken purely for cosmetic purposes.⁶⁰ The Victorian Health Services Commissioner and the recently established Office of the Health Ombudsman in Queensland (which replaces the HQCC) both receive complaints about health services provided by both registered and unregistered providers.

In 2013, Queensland’s HQCC examined complaints about cosmetic surgical and medical procedures provided by registered health practitioners in Queensland. It noted a common perception by consumers that cosmetic procedures are ‘low risk’ yet will ‘transform their lives’ and yet there can be significant impact on the consumer when things go wrong.⁶¹ The HQCC analysed 245 complaints received about cosmetic surgical and medical procedures from 2006 to 2012. The HQCC found that the most frequently reported complaint in relation to cosmetic procedures related to the treatment, with complaints that the standard of the procedure was below what was expected or that the end result was significantly different to what the consumer had expected.

Complaints to the HQCC about fees also related to inadequate information – the consumer was not told about additional costs for follow up care or costs of corrective surgery.

Informed consent was also a frequent area of complaint in the Queensland cases. Information provided to consumers was insufficient and consent was inadequate. In a large proportion of cases they found the risks were ‘not appropriately disclosed’.⁶²

⁵⁹ Australian Society of Plastic Surgeons, *Code of practice*, 2011
<http://www.plasticsurgery.org.au/regulations-and-guidelines/asps-code-of-practice/>

⁶⁰ Health and Disability Services Complaints Office Western Australia, *Cosmetic treatment complaints*,
<https://www.hadscow.gov.au/complaints/cosmetic.cfm>

⁶¹ Health Quality and Complaints Commission

⁶² *ibid.*

A 2011 study of medicolegal disputes over informed consent in Australia found that plastic surgeons had disputes over consent more than twice as often as any other medical specialty or subspecialty. In 481 cases examined, cosmetic procedures were the most common procedure involved (16 per cent). The authors suggested that the elective nature of cosmetic procedures and the costs associated with the procedure may contribute to higher patient expectations and lower tolerance for poor outcomes.⁶³

In 2012, Australian researchers reviewed malpractice claims and complaints about cosmetic procedures and found the most common complaints were that the medical practitioner failed to disclose the risks of a particular complication and the potential lack of benefit was not explained. There were also complaints about the process by which consent was sought. The adverse outcomes reported included scarring and the need for reoperation.⁶⁴

In its report, the HQCC noted that the likelihood of an adverse outcome following cosmetic medical and surgical procedures is often underestimated by consumers. Yet the harm can be significant - harm reported by Queensland complainants ranged from pain, bleeding and infection through to significant scarring, nerve damage, gross deformity and severe psychological distress.⁶⁵

Other health complaints entities also report that complaints about cosmetic procedures provided by medical practitioners are most commonly in relation to dissatisfaction with the treatment received, unexpected additional costs and inadequate consent.

Data from medical indemnity insurers shows that medical practitioners who provide cosmetic medical and surgical procedures have a higher number of claims than other medical practitioners. Insurers measure claims frequency as number of claims per 100 medical practitioners. Insurance data show that medical practitioners working in cosmetic medical practice have a higher claims frequency than all other medical practitioners, and that claims frequency continues to increase.⁶⁶

Insurance companies rate areas of medical practice according to risk to determine professional indemnity insurance premiums for medical practitioners. In MDA National's (one of the larger medical indemnity insurers) 2014 risk categories, cosmetic surgery is classified as one of the highest risk categories, with only obstetrics and neurosurgery deemed a higher risk category.⁶⁷

Other factors contributing to the problem

Other factors in the provision of cosmetic medical and surgical procedures by medical practitioners contribute to the problem.

Protections specific to children only exist in some jurisdictions

An increasing occurrence in cosmetic practice is for younger people to seek cosmetic procedures. In the AHMAC report, the working group noted the 'disturbing trends in young people increasingly seeking such procedures'.⁶⁸

⁶³ Gogos AJ, Clark RB, Bismark MM, Gruen RL & Studdert, DM, 'When informed consent goes poorly: a descriptive study of medical negligence claims and patient complaints' *Medical Journal of Australia*, vol 195, 2011, pp 340–344

⁶⁴ Bismark MM, Gogos AJ, McCombe D, Clark RB, Gruen RL & Studdert DM, 'Legal disputes over informed consent for cosmetic procedures: A descriptive study of negligence claims and complaints in Australia', *Journal of Plastic, Reconstructive & Aesthetic Surgery*, vol 65, issue 11, 2012, pp 1506-1512

⁶⁵ Health Quality and Complaints Commission

⁶⁶ Medical Insurance Group Australia, *Recognition of cosmetic medical practice as a medical specialty – submission to the Australian Medical Council*, 2009, accessed at: <http://www.amc.org.au/index.php/ar/rms/assessments/290-cosmetic>

⁶⁷ MDA National, *Risk category guide for medical practitioners. Professional indemnity insurance policy*, 2014, <http://www.mdanational.com.au/media/217141/risk%20category%20guide%202014.pdf>

⁶⁸ Australian Health Ministers' Conference

The appropriateness of cosmetic medical and surgical procedures for children under the age of 18 years has been questioned (noting that this is, by definition, an invasive procedure when there is no medical need).

Research highlights the issues associated with performing major cosmetic surgery on children to improve their self-esteem and body image when their bodies are still undergoing physiological change and where there is evidence to show that 'dissatisfaction with appearance decreases with age throughout adolescence'.⁶⁹ Factors affecting whether a cosmetic medical or surgical procedure is appropriate for a person under the age of 18 include their physical maturity as well as whether they have the emotional maturity to cope with the discomfort, complications or a poor outcome.⁷⁰

The Queensland Government reviewed the research on the appropriateness of cosmetic surgery for children and found that there were both physical factors (children's bodies are still growing and developing) and emotional factors (vulnerability of young people and high rates of dissatisfaction with appearance, which lessens with age) that should be considered.⁷¹

In the United States, the Food and Drug Administration (FDA) who regulate medical devices, have restricted breast implants for augmentation by the patient's age. Saline implants are FDA approved for women 18 years or older and silicone gel filled implants are approved for women 22 years or older.⁷²

In 2013, the Cosmetic Physicians Society of Australasia called for a ban on cosmetic surgery for children, stating that 'children should not receive cosmetic medical or surgical procedures of any kind unless there are compelling medical or psychological reasons...'.⁷³ The Australian Society of Plastic Surgeons voiced concerns about reports of cosmetic procedures being used as rewards for school children stating that was 'completely inappropriate'.⁷⁴

The age of consent for medical procedures varies as it depends on the individual's competence to consent. There is legislation and common law principles that provide for those aged under 18 to give consent. The Board's code of conduct, *Good medical practice*, states that a medical practitioner should ensure that they 'consider young people's capacity for decision-making and consent'⁷⁵ – making the Board's expectations of its registrants clear for all types of medical practice.⁷⁶

In 2008, prior to the start of the National Scheme, the Queensland Government introduced amendments to its public health legislation to protect children from risks associated with undergoing higher risk and more invasive cosmetic procedures where it is not considered to be in the best interests of the child and to amend its radiation safety legislation to protect children from the potentially harmful effects of exposure to ultraviolet radiation through solarium use. No other state or territory government in Australia has taken steps to legislate to protect children from harm in this way.

⁶⁹ Zuckerman D & Abraham A, 'Teenagers and Cosmetic Surgery: Focus on Breast Augmentation and Liposuction', *Journal of Adolescent Health*, 43, 2008, pp 318–324

⁷⁰ Larson K & Gosain AK, 'Cosmetic surgery in the adolescent patient', *Plastic and reconstructive surgery*, vol 129 (1), 2012, pp135e-141e

⁷¹ Health Legislation (Restriction on Use of Cosmetic Surgery for Children and Another Measure) Amendment Bill 2008, Explanatory Notes <https://www.legislation.qld.gov.au/Bills/52PDF/2008/HealthLegAB08Exp.pdf>

⁷² US Food and Drug Administration, Breast Implants, <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/>

⁷³ Carroll L, 'Doctors seek ban on cosmetic surgery for under 18s', *Sydney Morning Herald*, 22 July 2013, <http://www.smh.com.au/lifestyle/beauty/doctors-seek-ban-on-cosmetic-surgery-for-under18s-20130721-2qcp8.html>

⁷⁴ *ibid.*

⁷⁵ Medical Board of Australia, *Good Medical Practice: A Code of Conduct for Doctors in Australia*, 2014

⁷⁶ Health Legislation (Restriction on Use of Cosmetic Surgery for Children and Another Measure) Amendment Act 2008 <https://www.legislation.qld.gov.au/Bills/52PDF/2008/HealthLegAB08Exp.pdf>

In NSW, the *Cosmetic Surgery Guidelines* (issued by the then NSW Medical Board prior to the National Scheme and since transitioned in under the Medical Council of NSW in the absence of national guidelines) specify additional requirements for medical practitioners providing cosmetic procedures for patients under the age of 18 including a three month cooling off period, but this was not legislated.⁷⁷

Due to these factors, it can be difficult to assess the extent to which specific protections for children giving informed consent or for 'cooling off' periods are needed. However, given the current provisions (in Queensland, statutory provisions) and the identification of this as an issue of concern in a number of reports, the Board is raising this as a contributing factor in the provision of cosmetic medical and surgical procedures by medical practitioners that may need to be addressed.

Post procedure care occurs outside the traditional hospital setting

Cosmetic medical and surgical procedures are not funded by Medicare and thus they occur in private facilities. Medical practitioners perform cosmetic medical and surgical procedures in many different settings including private hospitals, day procedure centres and medical practitioners' rooms.

Regulation of private facilities varies across jurisdictions. Jurisdictions differ in how they distinguish between hospitals, day procedure centres and medical clinics. Acts and regulations governing licensing of private facilities are state and territory based. National Safety and Quality Health Service Standards for accreditation of health facilities commenced in 2013, but not all jurisdictions require all private facilities to be accredited.⁷⁸ Accreditation requirements of private health funds are not applicable as cosmetic procedures are not usually covered by private health insurance. Some of the usual safeguards that protect consumers are therefore absent.

There have been two well publicised cases in Australia in which patients have died following cosmetic surgery performed by medical practitioners. In both cases, a young patient died from complications of liposuction surgery. In both cases the coronial investigations found that the post-operative care was inadequate.

In Victoria, in 2007, 26 year old Lauren James died from sepsis and other complications three days after liposuction surgery which was performed by a medical practitioner at a day procedure centre. The Coroner found that the medical practitioner 'failed in his obligation to provide adequate post-operative care' of the patient. The Coroner noted that when surgery is provided in day procedure clinics (rather than the more traditional hospital setting), clear communication and clear demarcation of responsibilities for the post-operative care of patients are critical for patient safety.⁷⁹

In South Australia, in 2008, 28 year old Lauren Edgar died as a result of multi-organ failure due to *Clostridium perfringens* myonecrosis (infection resulting in gas gangrene) five days after liposuction surgery performed by a medical practitioner. The procedure was performed in the practitioner's clinic. During the inquest it was noted that there was no formal post-operative review of the patient. In his finding (handed down in 2012), the South Australian Deputy State Coroner noted the AHMAC Working Group's review of cosmetic surgery and endorsed the recommendations in the AHMAC report to the Board about medical practitioners and the need for guidelines covering the use of titles, advertising, psychological evaluations and a cooling off period. He also made a specific recommendation about minimum standards for appropriate post-operative care following cosmetic surgery.⁸⁰

⁷⁷ Medical Council of NSW

⁷⁸ Australian Commission on Safety and Quality in Health Care, *National Safety and Quality Health Service Standards*, 2012

⁷⁹ Coroners Court of Victoria, *Finding into death with inquest – Lauren James*, 6 August 2010

⁸⁰ Coroners Court of South Australia, *Finding of inquest – Lauren Edgar*, 1 November 2012

Qualifications and training of providers varies

Medical practitioners who perform cosmetic medical and surgical procedures have widely varying levels of qualifications, training and expertise. Cosmetic surgery is not a recognised medical specialty. Rather it is a field of practice that any registered medical practitioner may practise in. There is no minimum qualification or training required to provide cosmetic procedures. Any medical practitioner with a basic medical degree can perform cosmetic medical and surgical procedures in their own clinic (although the Board's code of conduct, *Good medical practice*, states that medical practitioners must recognise and work within the limits of their competence).⁸¹

Consumers may find it difficult to distinguish between medical practitioners' qualifications. In the HQCC's report complaints about professional conduct included misrepresentation of qualifications and competence issues.⁸²

Conclusion

There is an information asymmetry between a consumer and a medical practitioner. The information that is available to consumers who seek cosmetic medical and surgical procedures provided by medical practitioners is of variable accuracy and quality. The potential repercussions of this information asymmetry are heightened as cosmetic medical and surgical procedures are elective and offered by a range of medical practitioners in a commercial market, without the traditional safeguards inherent in other types of medical practice. Consumers may find it difficult to determine which medical practitioners have the most relevant qualifications and training to perform the type of invasive procedure being sought. It is critical that the consumer who seeks a cosmetic medical or surgical procedure provided by a medical practitioner is fully informed and has time to consider all the factors before deciding to give consent.

When that consumer is under the age of 18, their ability to provide informed consent varies as it depends on the individual's capacity to understand the information and the decision they are making. The need for a comprehensive informed consent process and time to consider the decision to have elective cosmetic surgery is even more critical for patients under the age of 18.

As cosmetic medical and surgical procedures are often undertaken in private, standalone facilities, consumers are at a greater risk of poor outcomes if processes for post procedure care are not clearly outlined.

Data from health complaints entities suggest that medical practitioners who perform cosmetic medical and surgical procedures have a proportionally higher number of patient complaints than providers of other medical procedures. However, if the cosmetic medical or surgical procedure is performed by a medical practitioner without the appropriate training, or in a facility that does not have the appropriate staff or equipment, or the post-operative care is inadequate, the outcome for the consumer can be far more devastating than unmet expectations. The outcome may be a serious complication resulting in disfigurement or death.

Available data and evidence suggest that there are consumers who are making rushed decisions to have major, irreversible elective cosmetic medical and surgical procedures provided by medical practitioners, without fully understanding all the factors including what the procedure entails, the risks, the likelihood of complications, the variable outcomes and the costs.

As cosmetic medical and surgical procedures become more accepted – the so called 'normalisation' of cosmetic procedures – and the scope of cosmetic practice increases with new technology and new procedures, the numbers of consumers having cosmetic procedures provided by medical practitioners, and therefore at risk of making decisions without adequate information, is likely to increase.

It is in this context that the Board is responding to the Australian Health Ministers' request to consider options for specific guidelines that set out the Board's clear and reasonable expectations of medical practitioners who provide cosmetic medical and surgical procedures to help strengthen current safeguards for consumers.

⁸¹ Medical Board of Australia, *Good Medical Practice: A Code of Conduct for Doctors in Australia*, 2014

⁸² Health Quality and Complaints Commission

However, the Board is not consulting on a regulatory option alone. The Board is seeking feedback on the extent and nature of the problems and options identified in this paper to help protect Australian consumers from poor outcomes while not limiting consumer choice or access to cosmetic medical and surgical procedures provided by registered medical practitioners. There may be other issues relevant to the provision of cosmetic medical and surgical procedures and the Board welcomes all views.

CONSULTATION QUESTIONS

1. Do you agree with the nature and extent of the problem identified in this consultation paper, for consumers who seek cosmetic medical and surgical procedures provided by registered medical practitioners?
2. Is there other evidence to suggest that there is a problem with consumers making rushed decisions to have cosmetic medical and surgical procedures provided by registered medical practitioners without adequate information?
3. Is there other evidence that consumers cannot access reliable information or are relying on inaccurate information when making decisions about these procedures?
4. Is there evidence that inappropriate use of qualifications and titles by medical practitioners may be misleading for consumers?
5. Is there evidence that offers of finance for these procedures may act as an inducement for consumers to commit to a procedure before they have had adequate time to consider the risks?
6. Is there other evidence of disproportionate numbers of complaints or adverse events for consumers who have had these procedures?
7. Is there other evidence to identify the magnitude and significance of the problem associated with cosmetic medical and surgical procedures provided by registered medical practitioners?
8. Is there other evidence that the current regulation of medical practitioners who provide cosmetic medical and surgical procedures is not adequately protecting the public and not providing clear guidance on the Board's expectations of practitioners?

The National Law

The Medical Board is one of 14 National Boards in the National Scheme. The National Scheme is governed by the National Law.

The National Law sets out the objectives and guiding principles of the National Scheme.⁸³ The main objective of the National Scheme is to protect the public by ensuring that only health practitioners who are suitably trained and qualified to practise in a competent and ethical manner are registered. Other objectives of the National Scheme are to facilitate; workforce mobility across Australia; the provision of high-quality education and training of health practitioners; and access to services provided by health practitioners in accordance with the public interest.

The guiding principles of the National Scheme, as set out in the National Law are:

- the scheme is to operate in a transparent, accountable, efficient, effective and fair way
- fees required to be paid under the scheme are to be reasonable, having regard to the efficient and effective operation of the scheme
- restrictions on the practice of a health profession are to be imposed only if it is necessary to ensure health services are provided safely and are of an appropriate quality.

Objectives

In Australia, consumers expect, and have the right, to make their own choices about their health care, to receive safe, high quality care and to be informed about services and procedures.⁸⁴ These rights apply to all health settings, both public and private. Consumers have the right to choose to have cosmetic medical and surgical procedures without there being a medical need.

The work of the Board and AHPRA is underpinned by the National Scheme's regulatory principles.⁸⁵ Community confidence in health practitioner regulation is important and the Board's response to risk considers the need to uphold professional standards and maintain this public confidence. There is an obligation on the Board to protect the public through ensuring that only practitioners who are suitably trained and qualified to practise in a competent and ethical manner are registered. The Board sets registration standards (approved by the Ministerial Council) and issues codes and guidelines so that there are nationally consistent requirements and clear expectations of medical practitioners – no matter where they practise in Australia and to whom they provide health services (including cosmetic medical and surgical procedures).

The objective is to ensure there are appropriate protections for all consumers, including those who are vulnerable to exploitation, who seek cosmetic medical and surgical procedures provided by registered medical practitioners – whether this is by regulatory or non-regulatory means.

⁸³ Health Practitioner Regulation National Law, as in force in each state and territory, Section 3

⁸⁴ Australian Commission on Safety and Quality in Health Care, *Australian Charter of Healthcare Rights*, 2008, <http://www.safetyandquality.gov.au/wp-content/uploads/2012/01/Charter-PDF.pdf>

⁸⁵ Australian Health Practitioner Regulation Agency, *Regulatory principles for the National Scheme*, 2014, available at: <http://www.ahpra.gov.au/About-AHPRA/Regulatory-principles.aspx>

Statement of options

What options are available to the Board?

The National Law gives the Board its powers and responsibilities. The Board must balance its responsibilities to protect the public while facilitating access to services in accordance with the public interest. The Board can only act within the scope of its powers under the National Law.

COAG best practice regulation requires that all *feasible* options are considered; both regulatory and non-regulatory. The Board has considered a range of options relevant to medical practitioners who provide cosmetic medical and surgical procedures and the views of stakeholders are being sought on four feasible options.

Registration standards, codes and guidelines

Under section 38 of the National Law, the Board can develop registration standards, for example, about 'the scope of practice of health practitioners registered in the profession'. Registration standards must be approved by AHWMC (the Health Ministers of the commonwealth, state and territory governments) and set out requirements that *must* be met to obtain and retain registration in that profession.

Defining the scope of practice of medical practitioners who provide cosmetic medical and surgical procedures is difficult as cosmetic medicine and surgery is an area of medical practice where the numbers and types of procedures are continually expanding and evolving. Defining which procedures are included would not be feasible and could inhibit innovation and market growth.

Under section 39 of the National Law, the Board may also develop and approve codes and guidelines to provide guidance to the health practitioners it registers (AHWMC approval is not required). Registration standards, codes or guidelines apply to all medical practitioners in all states and territories.

An approved registration standard or a code or a guideline, is admissible in proceedings under the National Law or a law of a co-regulatory jurisdiction against a health practitioner registered by the Board as evidence of what constitutes appropriate professional conduct or practice for the health profession.⁸⁶

However, there is a difference between a registration standard that imposes requirements that practitioners must attain (and maintain) to be registered, and a code or guideline of which the prime purpose is to provide guidance to help practitioners meet a registration standard (for example, that gives options on what steps a practitioner may take to comply with a requirement), or to express the Board's clear expectations and guidance to registrants about appropriate professional conduct or practice. The Board can take into account whether a practitioner has fulfilled these expectations when assessing or investigating matters involving a registered practitioner who may have engaged in unprofessional conduct or unsatisfactory professional performance. An example is the Board's current code of conduct, *Good medical practice*.

Specialist registration

Section 13 of the National Law states that specialist recognition operates for the medical profession. The AHWMC has approved a list of specialties, fields of specialist practice and specialist titles for the medical profession.⁸⁷

Cosmetic medicine is not a recognised medical specialty and therefore the Board has no capacity to grant specialist registration to 'cosmetic surgeons'. Likewise, while there is a range of qualifications and training available, there are no minimum training requirements that must be completed by medical practitioners providing cosmetic medical and surgical procedures.

⁸⁶ National Law, Section 41

⁸⁷ Medical Board of Australia, *List of specialties, fields and related titles*, <http://www.medicalboard.gov.au/Registration-Standards.aspx>

There is currently no mechanism for the Board to restrict medical practitioners' scope of practice in relation to cosmetic procedures or to prescribe specific qualifications or training in this area of medicine. A medical practitioner does however, have a professional obligation to recognise and work within the limits of their competence.⁸⁸

The National Law protects the public by protecting certain titles for use by registered health practitioners only. That means that a person cannot use a protected title such as 'specialist medical practitioner' unless they have specialist registration. Other than restricted dental acts, prescription of optical appliances and spinal manipulation, the National Law does not restrict practice. That is, it is not an offence under the National Law for a person to perform cosmetic medicine and surgery if they do not breach any of the protection of title provisions.

Only Australian Health Ministers (AHWMC) can decide to expand the current list of approved specialties. However, that would not restrict practice in cosmetic medicine and surgery. It would only restrict the use of the agreed associated title, for example, 'cosmetic surgeon' and/or 'cosmetic physician'.

Endorsement for an area of practice

A decision to approve an area of practice endorsement for medical practitioners' registration, such as for 'cosmetic medicine' can only be made by Australian Health Ministers (AHWMC).⁸⁹ However, again, defining the boundaries of the area of practice which can be practised by a medical practitioner with endorsement would be difficult because cosmetic medicine and surgery cover a broad scope of practice and defining the procedures for inclusion would not be feasible.

Role of AHWMC

Options, such as amending the National Law to restrict practice to specified types of practitioners or endorsing an area of practice, developing a registration standard or approving a new speciality would have to be decided by AHWMC as they are not within the Board's range of powers. These options are more restrictive than codes or guidelines, with a higher regulatory impost on practitioners and potentially a greater impact on consumers.

Consumer education

While the Board does not have a mandated statutory role to educate consumers, codes and guidelines can be effective as education material for consumers because they set out the Board's expectations of medical practitioners and provide guidance in a more 'plain English' style than the statutory language of the National Law, or even the terminology used in registration standards. As a result, codes and guidelines may result in increased awareness of the risks associated with cosmetic medical and surgical procedures provided by medical practitioners. The Board may issue position statements and newsletters that can also provide community education. In this consultation paper, the Board is exploring a new non-regulatory option that would involve providing consumer education material that focuses on raising consumer awareness of some of the issues related to cosmetic medical and surgical procedures provided by medical practitioners.

⁸⁸ Medical Board of Australia, *Good Medical Practice: A Code of Conduct for Doctors in Australia*, 2014

⁸⁹ National Law, Section 15

Options identified

The Board has identified the following four options as feasible options in relation to medical practitioners who provide cosmetic medical and surgical procedures.

Option 1

Retain the status quo of providing general guidance about the Board's expectations of medical practitioners providing these procedures via the Board's approved code of conduct

Under this option no action is proposed and effectively the status quo is retained.

Guidance for medical practitioners who perform cosmetic medical and surgical procedures is provided in existing codes and guidelines of the Board. The Board could issue a statement drawing attention to existing codes and guidelines, to inform consumers and medical practitioners.

Medical practitioners (including those who provide cosmetic medical and surgical procedures) must comply with approved registration standards, and are expected to follow codes and guidelines published by the Board.

The Board's code of conduct, *Good medical practice*, outlines the standards expected of all medical practitioners. It includes guidance on providing good care, working within the health care system and with other health care professionals, professional behaviour and maintaining professional performance.

The Board's *Guidelines for advertising regulated health services* provide guidance on the advertising provisions in the National Law. They include guidance on a medical practitioner's professional obligations when advertising services and describe advertising that is not permitted such as testimonials and content that misleads consumers.

If medical practitioners are fellows of a college, additional codes of practice and protocols issued by the colleges provide guidance on acceptable practice. Some professional associations also provide their medical practitioner members with guidance.

Medical practitioners who are fellows of the Royal Australasian College of Surgeons (RACS) are required to adhere to the RACS *Code of conduct*.⁹⁰ If members do not adhere to the code, their college membership may be revoked.

The Australian Society of Plastic Surgeons has a *Code of practice* which provides specific guidance on the professional ethics and behaviour expected of plastic surgeons who are members of the Society.⁹¹ From time to time it issues policy statements on specific matters relating to cosmetic practice such as *Administration of botulinum toxin by nurses* (which outlines the responsibilities of plastic surgeons who prescribe cosmetic injectables).⁹²

The Australasian College of Cosmetic Surgery has a *Code of practice*⁹³ and a *Protocol for delegated cosmetic S4 injections*.⁹⁴

The Cosmetic Physicians Society of Australasia has policies and protocols on a range of cosmetic practice including *Protocol for delegated cosmetic S4 injections*⁹⁵ and *Advertising guidelines*⁹⁶.

⁹⁰ Royal Australasian College of Surgeons, *Code of conduct*, 2011
http://www.surgeons.org/media/346446/pos_2011_02_24_code_of_conduct_2011.pdf

⁹¹ Australian Society of Plastic Surgeons, *Code of practice*, 2011,
<http://www.plasticsurgery.org.au/regulations-and-guidelines/>

⁹² Australian Society of Plastic Surgeons, *Administration of botulinum toxin by nurses*, 2014,
<http://www.plasticsurgery.org.au/protecting-patient-safety/current-issues/who-is-qualified-to-inject-fillers-wrinkle-treatments/>

⁹³ Australasian College of Cosmetic Surgery, *Code of practice*, 2009, <http://www.accs.org.au/about/codes>

⁹⁴ Australasian College of Cosmetic Surgery, *Protocol for delegated cosmetic S4 injections*, n.d. <http://www.accs.org.au/about/codes>

⁹⁵ Cosmetic Physicians Society of Australasia, *Protocol for delegated cosmetic S4 injections*, 2013,
http://www.cosmeticphysicians.org.au/cosmetic_procedure_list.asp?pageid=3

However, not all medical practitioners are members of a professional association (or may be members of more than one association) and the primary role of a professional association is to promote and protect the interests of the members.

Medical practitioners who are not affiliated with a college or association are not subject to those codes.

This is why professional self-regulation of medical practitioners who provide cosmetic medical and surgical procedures is not a viable option to improve standards as there is not a college or professional association that represents all medical practitioners who provide cosmetic procedures. Colleges and associations only represent their members and membership is not required to practise in this area of medicine.

Option 2

Provide consumer education material about the provision of cosmetic medical and surgical procedures by medical practitioners

The second option is development of reliable and unbiased education material for consumers on cosmetic medical and surgical procedures provided by medical practitioners.

The material could cover topics such as; what to expect when having a cosmetic medical or surgical procedure provided by a medical practitioner; the likely outcomes for cosmetic medical and surgical procedures including risks and complications; and provide sample questions that consumers should consider asking their medical practitioner to become better informed about their choices, the nature of the procedure, and how much experience the practitioner has in performing the procedure, before making any decisions about whether or not to proceed.

There would be more flexibility in how this education material could be designed as it would not be bound to be presented as a code or guideline and does not need to include the more formal language that is in these evidentiary aids.

Ideally this information would be readily accessible to any consumer considering a cosmetic medical or surgical procedure.

Option 3

Strengthen current guidance for medical practitioners providing cosmetic medical and surgical procedures through new, practice-specific guidelines that clearly articulate the Board's expectations of medical practitioners

The third option is for the Board to develop and approve guidelines for medical practitioners who provide cosmetic medical and surgical procedures which explicitly outline the Board's expectations of medical practitioners engaged in this area of practice.

The guidelines would be relevant to all medical practitioners who provide cosmetic medical and surgical procedures. However, unlike the current guidance provided through the Board's code of conduct, which is generic and covers all types of medical practice, these guidelines would focus on cosmetic medical and surgical procedures, i.e., invasive procedures that are more frequently subject to complaints and adverse events as they are elective and higher risk because they involve cutting beneath the skin and require anaesthesia.

The guidelines would include specific guidance for medical practitioners who provide cosmetic medical and surgical procedures on all the key risk areas identified by the Board and those described in the AHMAC Report.

⁹⁶ Cosmetic Physicians Society of Australasia, *Advertising Guidelines*, 2010
http://www.cosmeticphysicians.org.au/cosmetic_procedure_list.asp?pageid=3

The guidelines would detail what is expected of medical practitioners who provide cosmetic medical and surgical procedures to adequately assess a patient (adults and children) including number and type of consultations, referral for independent evaluation when indicated, and cooling off periods with a specified minimum duration. Informed consent processes would be described including expected content and when consent should be obtained.

Guidance on patient management would outline who should be responsible for post-procedure care and what information should be given to patients by medical practitioners.

The guidelines would also provide specific guidance for medical practitioners on prescribing and administering of schedule 4 (prescription only) cosmetic injectables.

Other sections of the guidelines would provide guidance to medical practitioners on training, experience, qualifications and titles, as well as guidance on advertising and financial arrangements with patients.

Option 4

Strengthen current guidance for medical practitioners providing cosmetic medical and surgical procedures through new, practice-specific guidelines as per option three but which provide less explicit guidance to medical practitioners

Similar to option three, under this option the Board would develop and approve guidelines for medical practitioners who provide cosmetic medical and surgical procedures but the guidance provided, and the areas covered by the guidelines, would be less explicit.

The guidelines would include guidance for medical practitioners who provide cosmetic medical and surgical procedures on; patient assessment, consent, patient management, medical practitioners' training, experience, qualifications and titles, as well as guidance for advertising and financial arrangements with patients.

Guidelines in option four would not include guidance for medical practitioners in relation to a cooling off period, procedures for patients under 18 or guidance on prescribing and administering schedule 4 (prescription only) cosmetic injectables.

Impact analysis (costs and benefits) of options

The Board has undertaken a regulation impact assessment of the four options as the OBPR has advised that the new regulatory options being explored (options three and four) have the potential to have a more than minimal impact on practitioners, their business and potential consumers of their services.

That said, it is difficult for the Board to undertake a full economic cost-benefit analysis of options in relation to medical practitioners who provide cosmetic medical and surgical procedures as these procedures are undertaken by a range of medical practitioners, in a variety of settings, with no national data available. The costs and benefits of social economic impacts can also be challenging to quantify.

Compliance costs for medical practitioners who provide cosmetic medical and surgical procedures and price increases for consumers who seek cosmetic medical and surgical procedures provided by medical practitioners can be estimated for each of the options. However, in health care, both costs of no action (such as harm resulting in pain and suffering) and benefits of acting (such as avoided harm) are difficult to quantify and monetise. Commonly used tools such as cost of illness (COI) studies, which assess the economic burden of disease, or quality-adjusted life year (QALY) which assess quantity and quality of life following a health intervention, are not readily applicable to cosmetic procedures undertaken when there is no medical need.

The Board has therefore provided a qualitative analysis, using data where available, to assess each option.

Option 1 – Retain the status quo of providing general guidance about the Board’s expectations of medical practitioners providing these procedures via the Board’s approved code of conduct

Potential benefits for consumers, medical practitioners and the community

No change. Retaining the status quo would provide no additional tangible benefits for consumers who seek cosmetic medical and surgical procedures provided by medical practitioners than is currently provided. There would be no greater clarity for medical practitioners who provide cosmetic medical and surgical procedures about expectations of medical practitioners who provide cosmetic procedures. For medical practitioners who provide cosmetic medical and surgical procedures and consumers who elect to undergo these procedures from a medical practitioner, status quo means no change.

Retaining the status quo may be seen as appropriate and a benefit if stakeholders consider that there are no problems that need to be addressed.

Potential costs for consumers, medical practitioners and the community

No change. Retaining the status quo would mean there are no new costs passed on to consumers seeking cosmetic procedures provided by medical practitioners or any new compliance costs for medical practitioners who provide these procedures. There would be no time or other administrative impacts on these medical practitioners or consumers.

Retaining the status quo does not respond to, or address, the problems identified with the provision of cosmetic medical and surgical procedures by medical practitioners. In the longer term this may become a cost for consumers who require post procedure follow-up medical care or have poor outcomes; and to the medical profession from reduced consumer confidence in the provision of these procedures by medical practitioners.

Potential risks

Doing nothing, and relying on existing policy and legal frameworks provided by the National Scheme, through professional associations and colleges, and through statutory restrictions for children in one state, to safeguard consumers who seek cosmetic medical and surgical procedures provided by medical practitioners, may no longer be adequate to meet community expectations of ready access to quality information about these procedures (and the associated risks) so they can make informed decisions. The evidence suggests that the number of consumers accessing cosmetic medical and surgical procedures from medical practitioners is increasing, information asymmetry for consumers remains, and there are a disproportionate number of complaints about poor outcomes for cosmetic medical and surgical procedures (including a lack of information and inadequate informed consent).

The Board’s code of conduct outlines the Board’s expectations of all medical practitioners providing medical services in Australia. However, it does not address many of the unique elements of cosmetic medical and surgical practice where medical practitioners providing these procedures operate in a commercial market and procedures are entirely elective. Cosmetic surgery is without the protections that normally exist when a general practitioner acts as gatekeeper and provides independent advice for consumers seeking surgical procedures.

As medical practitioners practising in the area of cosmetic practice have varying qualifications and membership of a professional association is optional, there are no practice specific guidelines in Australia that apply to all medical practitioners providing cosmetic medical and surgical procedures. Regulations and licensing of facilities vary across jurisdictions.

With the status quo, there are inconsistencies across jurisdictions and across the medical profession sub-groups in the standards expected of medical practitioners providing cosmetic medical and surgical procedures.

There are risks if, faced with the status quo, individual jurisdictions then choose to independently address the issues identified relating to medical practitioners providing cosmetic medical and surgical procedures, by introducing state based legislation. Divergent regulation across jurisdictions that occurs in an ad hoc manner would reintroduce inconsistencies that the establishment of the National Scheme was specifically designed to reduce.

With the status quo, improvements in the quality of information and educational opportunities are lost.

As the market for cosmetic medical and surgical procedures grows, and more medical practitioners provide these procedures and more consumers seek these procedures from medical practitioners, there remains a risk that the current environment will not prevent (and at worse will lead to) more consumers being at risk of poor outcomes.

The Board seeks feedback on the option to retain the status quo.

CONSULTATION QUESTIONS

9. Does the Board's current code of conduct and the existing codes and guidelines of the professional bodies provide adequate guidance to medical practitioners providing cosmetic medical and surgical procedures?
10. How effective are existing professional codes and guidelines in addressing the problem identified by the Board?
11. Do you agree with the costs and benefits associated with retaining the status quo as identified by the Board?
12. Are there other costs and benefits associated with retaining the status quo that the Board has not identified?

Option 2 – Provide consumer education material about the provision of cosmetic medical and surgical procedures by medical practitioners

Consumers who are considering a cosmetic medical or surgical procedure provided by a medical practitioner have a reasonable expectation that they should be able to access reliable sources of information to make informed decisions about these procedures.

Potential benefits for consumers, medical practitioners and the community

Provision of consumer education material about cosmetic medical and surgical procedures provided by medical practitioners could assist consumers by enabling access to reliable, unbiased information.

As this information would be provided independently of the medical practitioner offering the procedure, the consumer could be confident that there is no commercial bias inherent in the information. The information would help the consumer understand important factors such as what the procedure entails and the range of possible outcomes.

There would be more flexibility in how this education material could be designed as the more formal language needed for Board approved evidentiary aids (codes and guidelines) would not apply. This means it could be targeted to the audience and could include; what to expect when having a cosmetic medical or surgical procedure provided by a medical practitioner; the likely outcomes for cosmetic medical and surgical procedures including risks and complications; and provide sample questions that consumers may ask their medical practitioner to become better informed about their choices, the nature of the procedure, and how much experience the practitioner has in performing the procedure.

Consumer education materials attempt to address the information asymmetry that exists where the medical practitioner knows more than the consumer. When a consumer has access to independent sources of information, the likelihood of exploitation is greatly reduced. Provision of information may reduce the number of complaints relating to patients who had a procedure particularly those that stem from a lack of awareness or understanding of the possible complications and poor outcomes that can arise from elective, invasive procedures.

There may be reciprocal benefits for medical practitioners if there are less patient complaints.

Potential costs for consumers, medical practitioners and the community

A potential cost or disadvantage of this option is the lack of clarity about who would develop consumer education material and who would fund it. As previously stated, consumer education is not a statutory function of the Board. The National Scheme is a self-funding scheme (governments do not contribute funding). The National Law requires that fees are reasonable and the fee structure must provide for the Board to perform its functions. The Board cannot increase fees for medical practitioners to fund education materials which are outside its core functions.

In other jurisdictions, consumer education information about cosmetic procedures is provided on government websites. In the UK, the National Health Service (NHS) has a 'cosmetic surgery' information page.⁹⁷ The information includes general information about cosmetic procedures. It also includes a basic description of common procedures such as breast augmentation and rhinoplasty. The GMC (who regulate UK medical practitioners) has guidelines for medical practitioners but they do not provide information specifically for consumers.

⁹⁷ National Health Service, <http://www.nhs.uk/conditions/Cosmetic-surgery/Pages/Introduction.aspx>

The MCNZ has issued a guide '*What to expect from your doctor when you have a cosmetic procedure*'. The information is general and is aimed at assisting consumers to know what to expect with cosmetic procedures. It includes similar information to the MCNZ's guidelines for medical practitioners, in a consumer oriented format. For example, categories of procedures and information about how to check the register to see whether a medical practitioner has specialist qualifications. The MCNZ's guide does not include procedure specific information such as risks and complications for each type of cosmetic procedure.⁹⁸

Provision of cosmetic medical and surgical procedures by medical practitioners is rapidly growing as demand increases but also as new techniques and technologies emerge. Consumer education material would need to be regularly reviewed and updated which would require significant resources and expertise. While the Board could work with a consumer organisation to design the material and provide input such as, what is expected of doctors, the Board does not have a statutory mandate to educate consumers nor the ability to use registrant fees to fund the development, publishing and regular updating of such publications.

If there was a body identified that could develop the consumer education material, the cost would likely be passed on to the medical practitioners and to the consumers. If materials are funded by a government funded entity, these costs are indirectly borne by the community, either directly, or indirectly by diverting funds away from other areas. When these cosmetic procedures are elective, this may be a disproportionate impact on the wider community.

Potential risks

Consumer education material, by its nature, would be generic and targeted towards educating consumers, not medical practitioners. Information about procedures and possible outcomes can include common complications, but cannot take into account the risk factors for the individual consumer.

Consumer education material is never a substitute for a comprehensive informed consent process between the medical practitioner and the patient. Even when patients have access to relevant information, 'there are limits to patients' abilities to process it and make choices independently (from their doctor)'.⁹⁹ Consumers need to be given tailored information and have the opportunity to consider it and ask questions of their medical practitioner. They should be able to feel confident that their medical practitioner is free from conflicts of interest and acting only in the patient's best interest.

Information about costs of procedures would be limited as these are elective procedures offered in a commercial market. It is difficult to provide information in generic consumer education materials on costs, as fees vary between medical practitioners and procedure costs can also vary from patient to patient according to the patient's individual requirements. When price can be a deciding factor for some consumers, medical practitioners are reluctant to publicly provide anything more specific than a price range.

It would be important to obtain input from medical practitioners and professional bodies for the drafting of the consumer education material. However, it may be difficult to reach a consensus when there are multiple membership based bodies representing different medical practitioners who provide cosmetic medical and surgical procedures. The commercial nature of cosmetic procedures where there is competition among medical practitioners for the consumer market further increases the difficulties.

⁹⁸ Medical Council of New Zealand, *What to expect from your doctor when you have a cosmetic procedure*, 2008, <https://www.mcnz.org.nz/assets/News-and-Publications/Statements/What-to-expect-from-your-doctor-when-you-have-a-cosmetic-procedure.pdf>

⁹⁹ Haas-Wilson D, 'Arrow and the Information Market Failure in Health Care: The Changing Content and Sources of Health Care Information' *Journal of Health Politics, Policy and Law*, 26(5), 2001, pp 1031-1044

Inherent in the provision of consumer education material is a presumption that consumers would actively access this information, rather than making it explicit that the medical practitioner is expected to ensure the patient has been given the information to be able to give informed consent for the procedure. Measures can be taken to improve access to information, however, if consumers have poor health literacy they may not fully comprehend all the risks or possible outcomes.

Providing consumer education materials is low impact (if the issue of design, who does it and who funds the material can be addressed) and may help address part of the problem by increasing consumer awareness, improving education and understanding about these procedures, and having accessible information that is unbiased.

However, this option is likely to only result in limited improvements to safeguards for consumers. Consumers may continue to make rushed decisions without adequate information because the onus is placed on the consumer to access the education material and take the time to comprehend and consider the benefits and risks associated with cosmetic medical and surgical procedures. Informed consent processes, particularly for the most vulnerable consumers, is unlikely to be improved under this option. For example, a patient with Body Dysmorphic Disorder is unlikely to know that they have a distorted body image and that surgery may not be the best option.

The Board seeks feedback on the option to provide consumer education material.

CONSULTATION QUESTIONS

13. Would consumer education material be effective in addressing the problem?
If so, how could it be designed to ensure it is effective and kept up to date and relevant?
14. Who do you think is best placed to design consumer education material about cosmetic medical and surgical procedures provided by medical practitioners?
15. Who should pay for the development of consumer education material?
16. Are there any other costs and benefits associated with providing consumer education material that the Board has not identified?

Option 3 – Strengthen current guidance for medical practitioners providing cosmetic medical and surgical procedures through new, practice-specific guidelines that clearly articulate the Board’s expectations of medical practitioners

Potential benefits for consumers, medical practitioners and the community

Developing guidelines specifically for medical practitioners who provide cosmetic medical and surgical procedures provides an opportunity to improve processes for medical practitioners and promote consistent, appropriate, high quality care.

Guidelines have the potential to provide many benefits for consumers. Guidelines that clearly set out the Board’s expectations of these medical practitioners, and focus on the aspects of cosmetic medical and surgical procedures that the evidence suggests pose a higher risk to consumers when good medical practice is not followed (i.e. because the procedures involve cutting beneath the skin and require general anaesthetic), may have the added benefit of better informing and educating consumers about what is reasonable to expect and hence improve safeguards for consumers who seek cosmetic medical and surgical procedures provided by medical practitioners.

The Board could promote its guidelines for medical practitioners providing cosmetic medical and surgical procedures to the broader community to help ensure that consumers have relevant, unbiased information and know that it is accepted procedure to allow time for consumers to make an informed choice about whether to have an irreversible, potentially dangerous, elective procedure.

Under this option, the guidelines would include a defined cooling off period after the patient’s initial consultation, to help ensure that consumers do not feel pressured to make a rushed, potentially inadequately informed decision to have major surgery. Guidance on the provision of written information about the procedure and the risks and possible outcomes would help ensure that the consumer is fully informed and able to make decisions based on good information. When a consumer is fully informed, the likelihood of exploitation is greatly reduced. Comprehensive informed consent processes should reduce the number of complaints relating to patients who had a procedure provided by a medical practitioner, unaware of the possible complications and poor outcomes. Clarity around financial arrangements would also help protect the consumer as they would be aware of all the costs that may be involved. This includes knowing, before consent is given, about the full cost of the procedure and the cost of revision surgery should it be required.

Guidelines can help ensure that the consumer is fully informed and has realistic expectations of the procedure and the possible outcomes. Improving these processes should reduce the likelihood of complaints such as expectations were not met or there were fees that the consumer was not told about. It is likely that improved rates of patient satisfaction would reduce the number of malpractice claims.

Explicit guidance should reduce the incidence of harm resulting from medical practitioners who have poor patient management procedures for patients who have elected to have cosmetic medical and surgical procedures. While this is an important benefit for individual consumers, putting a monetary value on avoided harm is difficult. Estimating how many consumers would benefit, the potential decrease in number of complaints or the decrease in incidence of significant harm is also difficult as data on the number of procedures performed are not available and not all complaints or adverse events are reported.

Having specific guidelines for this type of practice would complement the guidance already provided by the Board’s code of conduct, *Good medical practice*, and could help registered medical practitioners better understand and discharge their professional obligations and provide high quality care. Guidelines and the code of conduct would need to be read in conjunction. The Board has confirmed in *Good medical practice* that medical practitioners have a responsibility to work within the limits of their competence. If they do not, and concerns are raised, for example, via a notification (complaint), the Board will assess their conduct and/or performance and based on the evidence, determine whether they have engaged in unprofessional conduct or unsatisfactory professional performance.

Guidelines for medical practitioners who provide cosmetic medical and surgical procedures would help ensure consistency across different types of medical practice - regardless of their location, qualifications, college affiliation, or professional association membership.

Guidelines approved by the Board would place the onus on the medical practitioner who provides cosmetic medical and surgical procedures to follow the guidance and ensure their practice is consistent with the expectations of the Board.

In particular, under this option, medical practitioners would be expected to ensure their procedures and practice include protections for children. Additional guidance for medical practitioners providing cosmetic procedures for children would address the issues identified in research, when children seek surgery to change their appearance before their body may have finished developing. For example, a mandatory cooling off period after the initial consultation could ensure that the child has had time to more fully understand the procedure they are contemplating. A consultation with a psychologist or psychiatrist may help the child understand the need to have the emotional maturity to cope if there is a poor outcome from the surgery.

Defining good practice for the management of a patient and post procedure care following a cosmetic procedure would make the medical practitioner's responsibilities explicit and clear, and would ensure that the patient knows what to do if complications arise. This is especially relevant for cosmetic procedures as they are often performed outside a hospital setting. In the cases cited that were subject to coronial investigations, failures of post-procedure follow up by the medical practitioners resulted in death of the patients.

National consistency is a key public protection mechanism under the National Law. The benefits to consumers, practitioners, governments, employers, and others of having a nationally consistent approach to providing formal guidance that applies to all medical practitioners undertaking these procedures, mirrors the benefits identified in the RIS for the decision by governments to implement a national registration and accreditation scheme, including:

- no matter where a consumer lives, and no matter where the medical practitioner practices, the same guidance and the same expectations apply; which not only provides clarity and certainty for medical practitioners and consumers but should also preserve and potentially improve consumers' confidence that, if accessing cosmetic medical and surgical procedures from registered medical practitioners, there are clear expectations about good medical practice, and there are protections under the National Law if a practitioner does not fulfil these expectations;
- if the Board needs to take action against a medical practitioner who provides cosmetic medical and surgical procedures, the same guidelines (as an evidentiary aid) can be used along with the statutory provisions of the National Law – providing procedural fairness for the practitioner involved, and helping to provide for the protection of the public by ensuring that only practitioners who are suitably trained and qualified to practise in a competent and ethical manner are registered;
- governments and Health Ministers who have high level responsibility for the National Scheme, and any employers of medical practitioners who provide these procedures, know what the Board expects, and in turn, employers and governments know what good medical practice in cosmetic medical and surgical procedures looks like.

Implementing specific guidelines for medical practitioners who provide cosmetic medical and surgical procedures would not only respond to the request from AHMAC and Health Ministers for guidance to be implemented by the Board, but would also align Australia with the approaches taken by international medical regulators including in the UK, New Zealand, Canada and Singapore.

Potential impact on consumers

The potential impact on consumers from implementing guidelines is expected to be positive from an onus being placed on medical practitioners to better inform consumers about the nature and risks associated with these procedures and from consumers having ready access to adequate and unbiased information by being able to access guidelines so they can form their own views.¹⁰⁰ The impact is also expected to be positive from having greater confidence that there is consistency across Australia in the elements (including for informed consent) that medical practitioners are expected to follow and that these are clear and based on good medical practice so that avoidable poor outcomes are minimised.

Further, under this option there would be explicit guidance about cooling off periods and referral for independent evaluation.

The Board appreciates that people have the right to choose whether to have cosmetic procedures. In considering developing these guidelines, the Board does not expect that there would be any reduction in access to these procedures or that consumer choice would be restricted in any way. Rather, the expected impact on consumers is that they may access more consistent and appropriate standards of cosmetic medical and surgical care, in the interest of public safety.

There would be no impact on consumers' access to medically required reconstructive surgery, for example, following trauma or for a birth defect under this option. The proposed guidelines do not cover this area of medical practice – the principles of *Good medical practice* continue to apply.

Importantly, Board approved guidelines can be used by the Board when considering a notification (complaint) – currently the Board can only refer to its generic guidance about good medical practice. The Board cannot rely on guidelines issued by other bodies, such as professional associations or colleges, in disciplinary matters.

Potential costs for consumers and medical practitioners

The Board has considered possible costs of guidelines to members of the public, registered medical practitioners and governments. There may be some, largely administrative, costs passed on to consumers if the guidelines were implemented. However, when the net potential cost is placed within the context of the overall costs of cosmetic medical and surgical procedures, it is negligible, and the potential benefits through harm minimisation is also likely to outweigh any material costs.

The costs associated with proposed guidelines would only impact a small sector of business and the community, i.e. medical practitioners who provide cosmetic medical and surgical procedures and consumers who elect to have these procedures.

There may be costs associated if a consumer was, as preferred under this option, to have a consultation with the medical practitioner who will perform the procedure prior to scheduling the procedure. A medical practitioner in private practice sets their own consultation fees. Many clinics publish their fees - initial consultation fees for a consultation with the medical practitioner (not a practice nurse or patient advisor) range from no charge to \$300 or occasionally more.

There may be costs associated with implementing procedures to ensure a minimum cooling off period between the consumer giving informed consent and a major cosmetic surgical procedure were to be introduced. If informed consent, as outlined in the guidelines under this option, was to be obtained by the medical practitioner who will perform the procedure before the day of the procedure, some consumers may need a second consultation with the medical practitioner before the day of the procedure (depending when consent is given). Fee structures vary and it would be up to individual practitioners how much they charge compared with current fees.

The Board acknowledges that there would be further impact and a cost (for travel and time) for consumers in rural and regional areas who may need to travel to metropolitan areas to access these types of procedures.

¹⁰⁰ All Board guidelines are publicly available on the Medical Board's website.

It should be noted that any additional cost for consultations is low compared with the overall cost of cosmetic procedures. Prices vary, but many cosmetic surgical procedures are more than \$2,000 and several types of surgeries are over \$10,000 for a single procedure. Based on the fees quoted, an initial consultation for a consumer having major cosmetic surgery is less than a three per cent (3%) increase in the total cost incurred. Whether a fee is charged or is absorbed into the total cost of the procedure is at the discretion of the practitioner.

There would be costs associated with the guidelines under this option, if patients were referred to an independent psychologist or psychiatrist for evaluation if there are indications that the patient has significant underlying psychological problems which may make them an unsuitable candidate for the procedure. The aim of this step would be to help ensure that the consumer has thoroughly considered the procedure, their motivation for having the procedure and whether their desired outcome is realistic. It also serves a protective function as the medical practitioner has the opportunity to decline to operate if the procedure is not in the patient's best interests.

The consumer would be responsible for fees associated with the independent evaluation. Psychologists and psychiatrists in private practice set their own fees. The medical practitioner can refer directly to the psychologist or psychiatrist (the patient does not need to go to their general practitioner for a referral). The Australian Psychological Society publishes a Schedule of Recommended Fees - fees for a clinical psychological assessment range from \$125 to \$429 (cost proportional to length of appointment).¹⁰¹ Patients may be able to claim a rebate through private health insurance. The cost of a consultation with a psychiatrist varies; as an indicative cost, Medicare's scheduled fee for an initial consultation of at least 45 minutes is \$260.30.¹⁰² A Medicare rebate may apply.

Introduction of guidelines may result in some medical practitioners who provide cosmetic medical and surgical procedures incurring costs.

If the guidelines under this option were introduced, there would be some costs for medical practitioners whose practice does not currently align with the guidance proposed – but this would largely involve reviewing current procedures, identifying the gaps, and ensuring that the new guidance and expectations of the Board are followed. It is also possible that some medical practitioners may need to modify their staffing structure. For example, if a consumer's initial consultation was to be with the medical practitioner or another registered practitioner, such as a nurse, this would impact practices that employ a patient advisor who is not a registered health practitioner to undertake the first consultation. Staff member pay rates are subject to applicable national employment legislation and awards. There may be an impact on staff costs for medical practitioners if guidelines are introduced.

There may be additional costs for medical practitioners if there was guidance (as proposed under this option) about facilities, for example, appropriate staffing and equipment to manage possible complications and emergencies. Costs would vary from practitioner to practitioner as it would depend on the type and number of procedures they provide and patient risk factors as well as the type of facility, equipment and staff the practitioner currently has. It is not possible to quantify these compliance costs and the potential impact needs to be considered within the context of the harm to patients that is expected to be minimised because medical practitioners have appropriate procedures and equipment to deal with emergencies or known risks associated with cosmetic medical and surgical procedures, including reactions to the anaesthetic.

Ultimately, it would be up to the practitioner to decide whether they absorb any additional costs associated with following the proposed guidelines or decide to pass on costs to patients.

¹⁰¹ Australian Psychological Society, 2013-2014 *Schedule of recommended fees and item numbers for psychological services*, 2013, http://www.psychology.org.au/community/fees_rebates/

¹⁰² Australian Government Department of Health, *Medicare Benefits Schedule Book*, 2013

It is likely that there would be some consumers who decide during the cooling off period, not to proceed with the procedure. If the proposed guidelines are followed, there should be no cost incurred by the consumer as a deposit would not be paid until after the cooling off period. Medical practitioners should not incur costs in this instance, unless they choose to allocate theatre bookings for patients before the cooling off period has finished. However, medical practitioners' income may be impacted if significant numbers of consumers decide not to go ahead with the cosmetic procedure after their initial consultation.

Potential costs for Government and AHPRA and the National Board

Cosmetic procedures are not funded by Medicare or private health insurance. There would be no direct impact on the public purse and Government if medical practitioners decided to increase fees to cover the expected small cost of following the Board's expectations and guidance.¹⁰³

There may be a cost to Government associated with guidelines if patients who are referred to a psychiatrist are able to claim a Medicare rebate. However, just as only some medical practitioners provide cosmetic medical and surgical procedures, only some consumers seek these procedures, and it is not anticipated that there would be significant costs associated.

There would be minor administrative costs to AHPRA and the Board if guidelines were approved and implemented (for example, costs for design, publication and communication) but these would be met using existing resources at no additional costs to registrants.

Potential impact on medical practitioners

The potential impact on medical practitioners from implementing guidelines is expected to be largely positive (through having better guidance about the Board's expectation and greater clarity about what is considered to be national good practice for the provision of cosmetic medical and surgical procedures).

Professional associations' codes and protocols currently include much of the guidance proposed in option three. Most, but not all medical practitioners, are members of a professional membership organisation. Board approved guidelines would make the Board's expectations clear to all medical practitioners across Australia. This would be beneficial as guidance would not be reliant on membership based organisations (where membership is optional). The medical practitioners who would be most impacted by option three would be the (expected to be) small cohort who are not currently a member of a college or professional association that has codes or protocols. Consumers may not know if their medical practitioner is a member of a college or professional association. However, they can easily check the public register to see if a medical practitioner is registered, and know that the proposed guidance applies to all registered medical practitioners who undertake these procedures.

Cosmetic surgery professional associations have indicated their support for measures to improve safeguards for consumers, such as national guidelines for medical practitioners who provide cosmetic procedures. In July 2013, the Australian Society of Plastic Surgeons called for national guidelines to regulate popular cosmetic procedures such as cosmetic injectables, dermal fillers and laser treatments, particularly for minors.¹⁰⁴ Both the Cosmetic Physicians Society of Australasia and the Australian Society of Plastic Surgeons have voiced concerns about teenagers having cosmetic procedures, suggesting that national guidelines are needed to protect consumers.¹⁰⁵ The Australasian College of Cosmetic Surgery have also publicly supported calls for raising standards for medical practitioners who provide cosmetic medical and surgical procedures.

¹⁰³ Medicare benefits and private health rebates are payable for certain plastic and reconstructive procedures when performed for specific medical reasons, however these procedures are **not** undertaken solely for 'cosmetic' reasons and thus cosmetic guidelines would not apply.

¹⁰⁴ Australian Society of Plastic Surgeons, Media release, *Plastic surgeons call for national regulation of cosmetic procedures*, 22 July 2013

¹⁰⁵ Carroll L, 'Doctors seek ban on cosmetic surgery for under 18s', *Sydney Morning Herald*, 22 July 2013, <http://www.smh.com.au/lifestyle/beauty/doctors-seek-ban-on-cosmetic-surgery-for-under18s-20130721-2qcp8.html>

As highlighted under the potential costs for medical practitioners – for those practitioners who do not currently have an initial consultation with the consumer before the procedure, a potential impact would be in managing the time allocated for these procedures. The time allocation for the initial consultation would vary and may have some impact on the practitioner's productivity, i.e. it may reduce the number of procedures the practitioner can perform per day/week.

There may be an impact on a medical practitioner's income if guidance was introduced in relation to remote prescribing of cosmetic injectables and face-to-face consultations between the medical practitioner and the patient. The number of patients that a medical practitioner can see per day would likely be reduced.

However, as these are elective procedures that are scheduled in advance and are not time critical, there would be no adverse impact on the consumer.

Guidelines would not restrict competition. Any guidelines would apply to all registered medical practitioners who provide cosmetic medical and surgical procedures. The guidelines cannot apply to other professions that the Board does not regulate. The Board expects that all medical practitioners providing cosmetic medical and surgical procedures would provide their services consistent with any guidelines issued, just as it expects all medical practitioners to adhere to the expectations outlined in the Board's code of conduct. For those medical practitioners whose practice already aligns with proposed guidance, the impact would be cost neutral, as there would effectively be no need to review and/or change the way they practise and provide these procedures.

The National Scheme, by its very nature, provides a barrier to entry as it requires health practitioners to meet requirements and standards to gain and maintain registration which enables practitioners to use professional titles such as 'medical practitioner' while practising the profession. However, as guidelines set out expectations, rather than requirements for registration, if guidance on cosmetic medical and surgical procedures was implemented, there would be no additional barriers to entry.

Guidelines are unlikely to have any impact on innovation in the market as they would outline minimum expectations of medical practitioners when providing cosmetic medical and surgical procedures, and would not limit the use of new procedures or techniques, or expansion of services or facilities. For example, if a medical practitioner undertook training to learn a new procedure, they may offer it to patients as long as their practice continues to align with any guidance such as, undertaking a comprehensive patient assessment, obtaining informed consent from the patient, and having the appropriate equipment and processes in place for safe management of the patient.

As set out in the costings section, it is not expected that guidelines would result in prohibitive price rises for consumers as any administrative compliance costs are not expected to be significant and fees charged are at the discretion of the medical practitioner. All medical practitioners currently pay an annual fee to renew their registration. The Board and AHPRA use those fees to meet their respective regulatory responsibilities under the National Scheme which includes managing notifications. Any administrative costs associated with implementing guidelines would be met by AHPRA and the Board with no fee increase for registrants.

Guidelines, by their nature, are less restrictive than other forms of regulation, including registration standards and legislation, so the regulatory impost is expected to be less. There would be no additional impact by implementing Board-approved guidelines:

- for consumers under 18 years and medical practitioners providing these procedures who practise in Queensland, where the Public Health Act already has statutory protections for children, as these statutory requirements would remain and the Queensland government could take appropriate action against any person who breaches that law;
- for consumers and medical practitioners who practise in NSW, where the Medical Council of NSW already has guidance that is largely consistent with this option
- for those medical practitioners who are members of a college or professional association that already has guidance on aspects of cosmetic medical practice such as cooling off periods.

Potential risks

There has been recent media coverage of the apparent trend of ‘cosmetic tourism’ (where consumers travel overseas for cosmetic procedures) and significant adverse outcomes for consumers who have elected to have cosmetic surgery performed by practitioners overseas in countries where there are minimal safeguards.

Numbers of cosmetic procedures performed overseas on Australians is not known as there is no central data collection. The Australian Society of Plastic Surgeons reports that its members have performed corrective surgery on patients who have had complications arising from cosmetic surgery performed overseas.¹⁰⁶

There is a risk that there may be an unintended consequence if guidelines were introduced, whereby consumers who are reluctant to have an evaluation with a psychologist or psychiatrist could choose to travel overseas to a jurisdiction that has no to minimal regulation and where the procedure can be done quickly. However, the main driver for consumers electing to have cosmetic surgical procedures like breast augmentation and liposuction overseas, rather than in Australia, is cost. Cosmetic surgery overseas can be a fraction of the cost of surgery in Australia. The expected small additional costs for some medical practitioners who would need to review their procedures and meet the expectations of the Board if the guidelines as proposed in option three were implemented would be minor when compared with the total cost of the procedure. It is therefore not considered likely that an increase in consumers seeking procedures overseas would be a consequence of implementing guidance under this option.

Good medical practice encourages shared decision making by the medical practitioner and their patient. A potential risk of guidelines specific to the provision of cosmetic medical and surgical procedures, may be that by placing more responsibility on medical practitioners, consumers are less likely to independently manage the risks associated with these procedures.

¹⁰⁶ Australian Society of Plastic Surgeons, Media release, *Plastic surgery in a global environment – the risks of medical tourism*, April 2013

The Board seeks feedback on the option to introduce explicit guidelines for medical practitioners who provide cosmetic medical and surgical procedures that would include the Board's expectations of patient assessment, procedures for persons under the age of 18, informed consent, post-procedure patient management, prescribing and administering cosmetic injectables, facilities, and financial arrangements.

The draft content of the guidelines under this option is at Attachment B.

CONSULTATION QUESTIONS

17. The Board seeks feedback on elements for potential inclusion in guidelines:

- 17.1 Should there be a mandatory cooling off period for adults considering a cosmetic medical or surgical procedure (other than for minor procedures)?
If so, is seven days reasonable?
 - 17.2 Should there be a mandatory cooling off period for patients under the age of 18 who are considering a cosmetic medical or surgical procedure?
If so, is three months reasonable?
 - 17.3 Should medical practitioners be expected to assess patients for indications that the patient has significant underlying psychological problems which may make them an unsuitable candidate for the procedure?
 - 17.4 Should medical practitioners be expected to refer these patients to an independent psychologist or psychiatrist for evaluation?
 - 17.5 Is it reasonable to expect that registered medical practitioners refer all patients under the age of 18 to an independent psychologist or psychiatrist for evaluation before a cosmetic medical or surgical procedure is performed, regardless of whether legislation exists (as it does in Queensland via the *Public Health Act 2005*)?
 - 17.6 Should there be further restrictions for patients under the age of 18 who seek cosmetic medical and surgical procedures?
 - 17.7 Should a medical practitioner be expected to have a face-to-face consultation (in person, not by video conference or similar) with a patient before prescribing schedule 4 prescription only cosmetic injectables?
If not, why?
18. Are there other elements not included in the draft guidelines at Attachment B that could be included?
19. Do you agree with the costs and benefits associated with guidelines with explicit guidance (option 3) as identified by the Board?
20. Are there other costs and benefits associated with guidelines with explicit guidance (option 3) that the Board has not identified?
21. Would the benefits of guidelines with explicit guidance (option 3) outweigh the costs, or vice versa?

Option 4 – Strengthen current guidance for medical practitioners providing cosmetic medical and surgical procedures through new, practice-specific guidelines as per option three, but which provide less explicit guidance to medical practitioners

The key difference between the guidance that is proposed under option three and this option is that the guidance that is provided is less explicit. There would be no guidance on:

- a minimum cooling off period for consumers seeking a cosmetic medical or surgical procedure
- the provision of cosmetic medical and surgical procedures specifically for consumers under the age of 18 years
- prescribing and administering schedule 4 (prescription only) cosmetic injectables.

The guidelines under this option, would include guidance for medical practitioners who provide cosmetic medical and surgical procedures on patient assessment, consent, patient management, medical practitioners' training, experience, qualifications and titles, as well as guidance for advertising and financial arrangements with patients.

Therefore, the potential costs, benefits, impacts and risks identified at option three are also relevant to this option – but with an expected overall lesser impact across all areas.

Potential costs for consumers and medical practitioners

The overall potential impact and costs of this option should be marginally less for consumers and medical practitioners than under option three, because the guidance proposed is less explicit and would not, for example, provide guidance in relation to a 'cooling off' period or independent evaluations for consumers under 18 years – which are two key features of the guidelines at option three that may result in additional costs for medical practitioners through changed processes, costs which they may decide to pass on to consumers. Costs for medical practitioners who follow these guidelines would be marginally less under this option compared with option three.

Potential benefits for consumers and medical practitioners

Some of the improvements that may be gained through providing clear guidance to medical practitioners and better consumer awareness would also be gained under this option. However, the features that are designed to better protect the public would be lost. For example, consumers would not necessarily have the time to properly consider what the procedure involves as there is no imperative for medical practitioners to review their practice and ensure a cooling off period. Avoidable, adverse outcomes could still arise if a consumer decides to have a cosmetic medical and surgical procedure without fully appreciating its complexity or risks, or feeling as though they have been rushed into make a potentially life-changing decision.

There would be some improvements from guidance that outlines consent processes and minimum standards for post procedure care.

Potential risks

The guidelines under option four would take steps towards addressing some of the problems identified as it provides some guidance, but the risk is that without explicit guidance around cooling off periods and procedures for children, they would not be as useful to consumers, medical practitioners and the Board.

Some of the gaps that currently expose consumers to risks would still exist and therefore, these guidelines would provide only minimal safeguards for consumers.

Without explicit guidance against which to consider a medical practitioner's conduct, the Board would be limited in what action it could take to protect the public.

The Board seeks feedback on the option to introduce less explicit guidelines for medical practitioners who provide cosmetic medical and surgical procedures that would include the Board's expectations across the same range of areas as option three – except that it would not include guidance on a cooling off period (i.e. without section 2.5 in Attachment B), independent evaluations for consumers under 18 (section 3 in Attachment B) and prescribing and administering schedule 4 (prescription only) cosmetic injectables (section 7 in Attachment B).

CONSULTATION QUESTIONS

22. Do you agree with the costs and benefits associated with guidelines which are less explicit (option 4) as identified by the Board?
23. Are there other costs and benefits associated with guidelines which are less explicit (option 4) that the Board has not identified?
24. Would the benefits of guidelines which are less explicit (option 4) outweigh the costs, or vice versa?

Further feedback is sought from stakeholders on the options outlined above. Consumer scenarios are provided to illustrate potential benefits and cost estimates for consumers for each of the four options outlined (Attachment C).

CONSULTATION QUESTIONS

25. The Board seeks feedback on the cost estimates and assumptions underlying the consumer scenarios (Attachment C).
26. Are there other options that the Board has not identified?

Evaluation and conclusion

In undertaking this consultation on issues around registered medical practitioners who provide cosmetic medical and surgical procedures, the Board is not trying to restrict demand for cosmetic procedures or impose barriers for consumers seeking these procedures or the medical practitioners providing them. The Board is not suggesting that cosmetic procedures are bad and cannot result in positive outcomes for consumers.

The Board's role is to protect the public by ensuring that only medical practitioners who are suitably trained and qualified to practise in a competent and ethical manner are registered. There appears to be problems associated with the provision of cosmetic medical and surgical procedures by medical practitioners whereby, as the available evidence suggests, consumers are making rushed decisions with inadequate information, the information that is available varies in quality and accuracy, and informed consent procedures – one of the lynchpins of public protection – vary from practitioner to practitioner, and practice setting to practice setting. Questions have been raised by governments through multiple reviews, by coroners examining patient deaths, and in recent media coverage, about whether there are gaps in safety and understanding of consumers who elect to undergo invasive cosmetic medical and surgical procedures provided by medical practitioners.

It is important to ensure there are appropriate protections for consumers (particularly those that are most vulnerable) who are increasingly seeking cosmetic medical and surgical procedures provided by registered medical practitioners.

The Board seeks your views on which option could best meet the objectives of this consultation and provide the greatest net benefit to consumers.

The Board has considered four viable options and has undertaken a detailed impact analysis, using data where available, to analyse the potential costs and benefits of each option.

Option one – retaining the status quo

Not acting (option one) and retaining the status quo of providing general guidance to medical practitioners through the existing code of conduct and relying on the current environment to provide adequate information to protect the public seems inadequate in light of the information and evidence gathered to inform this consultation.

Further, if stakeholders agree there is a problem to be addressed and the status quo remains, and there was an opportunity for the Board to issue clear guidance on its expectations, the community may view this as a failure of the Board to protect the public.

The risks are significant and the outcomes potentially catastrophic if safeguards for consumers seeking cosmetic medical and surgical procedures provided by medical practitioners are inadequate.

Option two – consumer education material

Consumer education material (option two) has the potential to help consumers through the provision of user friendly, accessible, independent and reliable information to help them understand what to expect when considering a cosmetic medical and surgical procedure provided by a medical practitioner, including the risks associated with these procedures.

There remains the question of who is best placed to design and pay for consumer education material that would be effective and informative.

Access to information in isolation, combined with low levels of health literacy, is not a substitute for a comprehensive discussion between medical practitioner and patient, which takes into account the unique circumstances and individual needs of the patient before consent is given.¹⁰⁷

¹⁰⁷ Medical Board of Australia, *Good Medical Practice: A Code of Conduct for Doctors in Australia*, 2014

Further, this option (when compared with options three and four) places the onus on consumers to educate and inform themselves. There is no imperative for a medical practitioner to review their current procedures and practices and improve their consent processes, to ensure that consumers thinking about undergoing these procedures are adequately informed of all the risks.

In contrast with options three and four, provision of consumer education materials would not provide a mechanism for the Board to refer to this information as an evidentiary aid in any proceedings involving medical practitioners who may have engaged in unprofessional conduct or unsatisfactory professional performance to protect the public when a patient proceeds with a procedure without being adequately informed.

Options three and four – guidelines

The proposed guidelines would be nationally consistent and apply to all medical practitioners who provide cosmetic medical and surgical procedures. These two options have the most potential to ensure that medical practitioners are aware of the Board's expectations of them as medical professionals and the obligations medical practitioners have to their patients when providing cosmetic medical and surgical procedures.

Like option two, guidelines would be publicly available to consumers and could be a useful resource to educate and assist consumers to know what to expect from their medical practitioner. However, Board approved guidelines would place the responsibility on the medical practitioner to follow the guidelines; rather than placing the onus on the consumer to access, read and comprehend education material. The Board understands that many medical practitioners who provide cosmetic medical and surgical procedures already have practices and procedures in place that are consistent with these guidelines. However, as these guidelines would apply to all, and would be issued by the Board, they are most likely to have the highest educative value and help improve standards of medical care through preventing poor practices, when compared with options one and two.

Clearly articulating good medical practice specifically in relation to cosmetic medical and surgical procedures in Board-approved guidelines would not only be educative, and promote improved practice – it would also mean that the Board could use these guidelines as an evidentiary aid if needed, in assessing or investigating conduct or performance matters. Options three and four would best enable the Board to take action as needed to protect the public when notifications (complaints) about poor outcomes arising from cosmetic medical and surgical procedures are made to the Board.

Introducing specific guidelines for medical practitioners would bring Australia in line with the approaches taken recently in international jurisdictions, including that recently announced by the UK.

Having undertaken the required impact analysis, the Board considers that proposed guidelines would not place a major regulatory burden on medical practitioners or the public. Guidelines would not restrict competition, or create major barriers to entry, or inhibit innovation or market growth, and would still enable consumer choice.

In considering guidelines, the Board has taken into account the COAG *Principles of best practice regulation*. The Board has also considered the regulatory principles of the National Scheme which encourage a responsive, proportionate, risk based approach to protect the public.¹⁰⁸ The Board has taken care not to propose unnecessary measures that would create unjustified costs for the medical profession or the community. Guidelines would be a proportionate response to the problem identified and are the least restrictive regulatory option available to the Board that would still support it to take action to protect the public when needed.

¹⁰⁸ Australian Health Practitioner Regulation Agency, *Regulatory principles for the National Scheme*, 2014
<http://www.ahpra.gov.au/About-AHPRA/Regulatory-principles.aspx>

At this public consultation phase, the Board has assessed the relative potential costs and benefits of guidelines under options three and four:

- Option three would provide specific guidance for medical practitioners providing cosmetic medical and surgical procedures and the strongest safeguards which may result in increased costs for some consumers and costs for some medical practitioners. However, the costings explored in this consultation paper indicate that the benefits of having consistent expectations and better procedures and safeguards for consumers outweighs any modest costs. The Board considers that the possible impacts and costs are reasonable when considered in relation to the role of guidelines in promoting safe, high quality provision of cosmetic medical and surgical procedures by medical practitioners.
- Option four would provide some additional safeguards for consumers but not to the same extent as the guidelines at option three. There would be slightly less costs and slightly less impact on medical practitioners and consumers. These guidelines would provide a minimal increase to current protection of consumers, when compared with option three, and the education material at option two.

Preferred option

Based on the available data and evidence to date, and subject to the outcome of consultation with stakeholders, **option three** is the preferred option at this time.

On balance, the Board considers that while option three may have more than a minor impact, it would not have a substantive one, and would provide the greatest net benefit to the community.

For consumers this should include improved safeguards and access to better information while still enabling choice.

For medical practitioners, there would be clear, nationally consistent guidance about the Board's expectations of medical practitioners who provide cosmetic medical and surgical procedures. While some medical practitioners would need to review their procedures and practices, the guidelines are expected to have a minimal regulatory impost.

For governments, there would be nil to minimal costs and some benefits from the Board responding to the AHMAC Working Group's recommendations to provide consumers with improved safeguards and nationally consistent standards for the provision of cosmetic medical and surgical procedures by medical practitioners.

Any administrative costs associated with implementing the guidelines would be met by AHPRA and the Board with no additional impost on registrants.

CONSULTATION QUESTIONS

27. Which option do you think best addresses the problem of consumers making rushed decisions to have cosmetic procedures without adequate information?

- Option one – Retain the status quo of providing general guidance about the Board's expectations of medical practitioners providing these procedures via the Board's approved code of conduct
- Option two – Provide consumer education material about the provision of cosmetic medical and surgical procedures by medical practitioners
- Option three – Strengthen current guidance for medical practitioners providing cosmetic medical and surgical procedures through new, practice-specific guidelines that clearly articulate the Board's expectations of medical practitioners
- Option four – Strengthen current guidance for medical practitioners providing cosmetic medical and surgical procedures through new, practice-specific guidelines as per option 3 but which provide less explicit guidance to medical practitioners
- Other – please specify.

Implementation and review

The Board keeps medical practitioners and other stakeholders informed of new resources, standards, codes and guidelines through a variety of communication methods including the Board's electronic monthly newsletter which is emailed to more than 95 per cent of registered medical practitioners as well as other interested stakeholders and is published on the Board's website.

If consumer education material was to be developed (option two), the Board could help promote its availability so that consumers, registrants and other stakeholders would be aware of the new resource. The Board could publish news items on its website and in the Board's newsletter as well as requesting stakeholders to disseminate through their networks.

When implementing new guidelines, the Board is aware that registrants need time to become familiar with the guidance and time to review and if necessary, make changes to their current procedures and practices.

If, following an analysis of stakeholder feedback, guidelines (option three or four) are the preferred option, the Board would develop a plan for a staged implementation. Once finalised, the guidelines would be made public, but would not commence until an 'effective from' date approximately six weeks after they are published. An extensive communication plan through the key stakeholder groups would help ensure medical practitioners and consumers become aware of any new guidelines.

It is good practice to have scheduled reviews of Board approved documents, to ensure their continued relevance and workability. The Board would review any approved guidelines within the standard review period of three years (of their commencement), including assessment against the objectives and guiding principles in the National Law and the COAG *Principles of best practice regulation*. The Board may choose to review guidelines at an earlier point in time, if it is necessary.

Complete list of consultation questions

Problem

1. Do you agree with the nature and extent of the problem identified in this consultation paper, for consumers who seek cosmetic medical and surgical procedures provided by registered medical practitioners?
2. Is there other evidence to suggest that there is a problem with consumers making rushed decisions to have cosmetic medical and surgical procedures provided by registered medical practitioners without adequate information?
3. Is there other evidence that consumers cannot access reliable information or are relying on inaccurate information when making decisions about these procedures?
4. Is there evidence that inappropriate use of qualifications and titles by medical practitioners may be misleading for consumers?
5. Is there evidence that offers of finance for these procedures may act as an inducement for consumers to commit to a procedure before they have had adequate time to consider the risks?
6. Is there other evidence of disproportionate numbers of complaints or adverse events for consumers who have had these procedures?
7. Is there other evidence to identify the magnitude and significance of the problem associated with cosmetic medical and surgical procedures provided by registered medical practitioners?
8. Is there other evidence that the current regulation of medical practitioners who provide cosmetic medical and surgical procedures is not adequately protecting the public and not providing clear guidance on the Board's expectations of practitioners?

Option one

9. Does the Board's current code of conduct and the existing codes and guidelines of the professional bodies provide adequate guidance to medical practitioners providing cosmetic medical and surgical procedures?
10. How effective are existing professional codes and guidelines in addressing the problem identified by the Board?
11. Do you agree with the costs and benefits associated with retaining the status quo as identified by the Board?
12. Are there other costs and benefits associated with retaining the status quo that the Board has not identified?

Option two

13. Would consumer education material be effective in addressing the problem?
If so, how could it be designed to ensure it is effective and kept up to date and relevant?
14. Who do you think is best placed to design consumer education material about cosmetic medical and surgical procedures provided by medical practitioners?
15. Who should pay for the development of consumer education material?
16. Are there any other costs and benefits associated with providing consumer education material that the Board has not identified?

Option three

17. The Board seeks feedback on elements for potential inclusion in guidelines:

- 17.1 Should there be a mandatory cooling off period for adults considering a cosmetic medical or surgical procedure (other than for minor procedures)?
If so, is seven days reasonable?
 - 17.2 Should there be a mandatory cooling off period for patients under the age of 18 who are considering a cosmetic medical or surgical procedure?
If so, is three months reasonable?
 - 17.3 Should medical practitioners be expected to assess patients for indications that the patient has significant underlying psychological problems which may make them an unsuitable candidate for the procedure?
 - 17.4 Should medical practitioners be expected to refer these patients to an independent psychologist or psychiatrist for evaluation?
 - 17.5 Is it reasonable to expect that registered medical practitioners refer all patients under the age of 18 to an independent psychologist or psychiatrist for evaluation before a cosmetic medical or surgical procedure is performed, regardless of whether legislation exists (as it does in Queensland via the *Public Health Act 2005*)?
 - 17.6 Should there be further restrictions for patients under the age of 18 who seek cosmetic medical and surgical procedures?
 - 17.7 Should a medical practitioner be expected to have a face-to-face consultation (in person, not by video conference or similar) with a patient before prescribing schedule 4 prescription only cosmetic injectables?
If not, why?
18. Are there other elements not included in the draft guidelines at Attachment B that could be included?
19. Do you agree with the costs and benefits associated with guidelines with explicit guidance (option 3) as identified by the Board?
20. Are there other costs and benefits associated with guidelines with explicit guidance (option 3) that the Board has not identified?
21. Would the benefits of guidelines with explicit guidance (option 3) outweigh the costs, or vice versa?

Option four

22. Do you agree with the costs and benefits associated with guidelines which are less explicit (option 4) as identified by the Board?
23. Are there other costs and benefits associated with guidelines which are less explicit (option 4) that the Board has not identified?
24. Would the benefits of guidelines which are less explicit (option 4) outweigh the costs, or vice versa?

Consumer scenarios

25. The Board seeks feedback on the cost estimates and assumptions underlying the consumer scenarios (Attachment C).

Other options

26. Are there other options that the Board has not identified?

Preferred option

27. Which option do you think best addresses the problem of consumers making rushed decisions to have cosmetic procedures without adequate information?

- Option one – Retain the status quo of providing general guidance about the Board's expectations of medical practitioners providing these procedures via the Board's approved code of conduct
- Option two – Provide consumer education material about the provision of cosmetic medical and surgical procedures by medical practitioners
- Option three – Strengthen current guidance for medical practitioners providing cosmetic medical and surgical procedures through new, practice-specific guidelines that clearly articulate the Board's expectations of medical practitioners
- Option four – Strengthen current guidance for medical practitioners providing cosmetic medical and surgical procedures through new, practice-specific guidelines as per option 3 but which provide less explicit guidance to medical practitioners
- Other – please specify.

Attachment A - Earlier consultation

The National Law requires the Board to ensure there is wide-ranging consultation on the content of any proposed code or guideline.

The Board usually undertakes a minimum of two rounds of consultation:

1. Preliminary consultation with key stakeholders is undertaken initially. This enables the Board to test its proposals and refine them before proceeding to public consultation and seeking the views of all interested stakeholders.
2. Public consultation is the next phase of consultation. Public consultation papers are sent to stakeholders including government, the Australian Medical Association (AMA), specialist medical colleges, professional associations, complaint entities, consumer groups and the other National Boards in the National Scheme. Public consultation papers are also available on the Board's public website for download by registrants, patients and any other interested members of the public. Anyone may make a submission and the Board reviews all the feedback received. Documents are available for public consultation for a minimum of eight weeks.

The Board has already undertaken some early consultation on the provision of cosmetic and medical surgical procedures by medical practitioners to inform the Board's options. A summary of these consultations is provided below.

Public consultation on draft supplementary guidelines (2012)

The AHMAC Working Group recommended that the Board issue supplementary guidelines on cosmetic medical and surgical procedures for the Board's code of conduct, *Good medical practice*. The AHMAC report included a full draft of possible content of the supplementary guidelines. The supplementary guidelines addressed the areas of concern raised by the Working Group and provided supplementary guidance on the following areas of cosmetic practice:

- patient assessment
- informed consent
- patient management
- medical competence
- professional behaviour.

In 2012, the Board undertook public consultation on these draft supplementary guidelines. (As the Working Group had already undertaken targeted consultation on their draft document, preliminary consultation by the Board was not required.)

Sixteen submissions were received from stakeholders including government, medical colleges, medical insurers, health complaints entities and consumer groups. While there was general support for the Board to provide additional guidance in relation to areas covered in the guidelines, there was not broad agreement with all aspects of the guidelines or with the proposed approach.¹⁰⁹

The Board considered the feedback from that consultation, and decided not to proceed with the supplementary guidelines as drafted as an option but rather, to consider other options for medical practitioners who provide cosmetic medical and surgical procedures.

The feedback received informed the Board's development of other options, and the impact analysis in this RIS.

¹⁰⁹ The consultation submissions are available on the Board's website at: <http://www.medicalboard.gov.au/News/Past-Consultations/2012/Consultation-March-2012.aspx>

Preliminary consultation on draft guidelines on cosmetic medical and surgical procedures (2013)

The Board has undertaken preliminary consultation to seek feedback from key stakeholders on guidelines on cosmetic medical and surgical procedures as proposed in option three, to test this approach and identify other possible options.

Preliminary consultation provides the Board the opportunity to 'road test' its preliminary proposals and seek the views of the OBPR on the potential regulatory impact of its proposal and whether there is a need to conduct further regulatory analysis in the form of a RIS. Due to the nature of preliminary consultation, feedback is treated confidentially and the Board does not publish the submissions received unless stakeholders specifically request that their submission be published as part of the feedback after the public consultation process.

The Board does not publish the list of stakeholders who were invited to participate in the preliminary consultation. However, the Board was pleased with the number of stakeholders who elected to make a submission on the draft guidelines and the valuable feedback received which enabled the Board to refine its proposal and publicly present four options for wider consultation.

The feedback was largely positive about the proposal for guidelines to strengthen regulation and provide clear and explicit guidance to medical practitioners in this area of medical practice. The Board agreed with the need to clarify the definitions and which procedures would be within scope of the proposed guidelines. Changes were made to make the guidance on cooling off periods clearer. Elements were added to the sections on consent and financial arrangements to ensure they were comprehensive. The feedback received informed the options and the impact analysis in this consultation paper.

Attachment B – Option three – Draft guidelines

<date>

Cosmetic medical and surgical procedures

Introduction

These guidelines have been developed by the Medical Board of Australia (the Board) under section 39 of the Health Practitioner Regulation National Law as in force in each state and territory (the National Law). The guidelines aim to inform registered medical practitioners and the community about the Board's expectations of medical practitioners who perform cosmetic medical and surgical procedures in Australia. These guidelines complement *Good medical practice: A code of conduct for doctors in Australia (Good medical practice)* and provide specific guidance for medical practitioners who perform cosmetic medical and surgical procedures. They should be read in conjunction with *Good medical practice*.

Who (would) these guidelines apply to?

These guidelines apply to medical practitioners registered under the National Law who provide 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.¹

Procedures that have a medical justification and which may also lead to improvement in appearance are excluded from the definition.

Surgery or a procedure may be medically justified if it involves the restoration, correction or improvement in the shape and appearance of the body structures that are defective or damaged at birth or by injury, disease, growth or development for either functional or psychological reasons.²

The medical specialty of *plastic surgery* includes both *cosmetic surgery* and *reconstructive surgery*. These guidelines apply to plastic surgery when it is performed only for cosmetic reasons. They do not apply to reconstructive surgery.

Reconstructive surgery differs from *cosmetic surgery* as, while it incorporates aesthetic techniques, it restores form and function as well as normality of appearance.

¹ Definition adapted from the Medical Council of New Zealand's *Statement on Cosmetic Procedures* (2007, 2011) by the Australian Health Ministers' Advisory Council's Clinical, Technical and Ethical Principal Committee Inter-jurisdictional Cosmetic Surgery Working Group

² Definition from *Cosmetic Surgery Guidelines* (Medical Council NSW, 2008)

How (would) the Board use these guidelines?

Section 41 of the National Law states that an approved registration standard or a code or guideline approved by the Board is admissible in proceedings under this Law or a law of a co-regulatory jurisdiction against a practitioner by the Board as evidence of what constitutes appropriate professional conduct or practice for the profession.

These guidelines can be used to assist the Board in its role of protecting the public, by setting and maintaining standards of medical practice. If a medical practitioner's professional conduct varies significantly from this guideline, they should be prepared to explain and justify their decisions and actions. Serious or repeated failure to meet these guidelines may have consequences for a medical practitioner's registration.

Providing cosmetic medical or surgical procedures

1. Recognising potential conflicts of interest

- 1.1 Medical practitioners must recognise that conflicts of interest can arise when providing cosmetic medical and surgical procedures and must ensure that the care and wellbeing of their patient is their primary consideration.

2. Patient assessment

- 2.1 The patient's first consultation should be with the medical practitioner who will perform the procedure or another registered health practitioner who works with the medical practitioner who will perform the procedure. It is not appropriate for the first consultation to be with someone who is not a registered health practitioner, for example, a patient advisor or an agent.
- 2.2 If the first consultation is with another registered health practitioner, the patient should have a consultation with the medical practitioner who will perform the procedure, before scheduling the procedure.
- 2.3 The medical practitioner who will perform the procedure should discuss and assess the patient's reasons and motivation for requesting the procedure including external reasons (e.g. a perceived need to please others) and internal reasons (e.g. strong feelings about appearance). The patient's expectations of the procedure should be discussed to ensure they are realistic.
- 2.4 The patient should be referred to a psychologist or psychiatrist who works independently of the medical practitioner, for evaluation if there are indications that the patient has significant underlying psychological problems which may make them an unsuitable candidate for the procedure.
- 2.5 Other than for minor procedures that do not involve cutting beneath the skin³, there should be a cooling off period between the patient giving informed consent and the procedure of at least seven days. The duration of the cooling off period should take into consideration the nature of the procedure and the associated risks.
- 2.6 The medical practitioner who will perform the procedure should discuss other options for the patient, including medical procedures or treatment offered by other health practitioners and the option of not having the procedure.
- 2.7 A medical practitioner should decline to perform a cosmetic procedure, if they believe that it is not in the best interests of the patient.

3. Additional responsibilities when providing cosmetic medical and surgical procedures for patients under the age of 18

- 3.1 The Board expects that medical practitioners are familiar with relevant legislation of the jurisdiction in relation to restrictions on cosmetic surgery for patients under the age of 18.
- 3.2 The medical practitioner must assess and be satisfied by the patient's capacity to consent to the procedure.
- 3.3 The medical practitioner should, to the extent that it is practicable, have regard for the views of a parent of the patient under 18, including whether the parent supports the procedure being performed.

³ Examples of procedures that are minor (non-surgical) procedures that do not involve cutting beneath the skin, but may involve piercing the skin, include; non-surgical cosmetic varicose vein treatment, laser skin treatments, use of CO₂ lasers to cut the skin, mole removal for purposes of appearance, laser hair removal, dermabrasion, chemical peels, injections, microsclerotherapy and hair replacement therapy.

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

(Definitions adapted from the Medical Council of New Zealand's *Statement on cosmetic procedures* (2011))

- 3.4 All patients under the age of 18 must be referred to a psychologist or psychiatrist who works independently of the medical practitioner, for evaluation to identify any underlying psychological problems which may make them an unsuitable candidate for the procedure.
- 3.5 There must be a minimum three month cooling off period between the patient giving informed consent and the procedure being performed.
- 3.6 The patient should be encouraged to discuss why they want to have the procedure with their general practitioner during the cooling off period.

4. Consent

- 4.1 The medical practitioner who will perform the procedure must provide the patient with enough information for them to make an informed decision about whether to have the procedure. They should also provide written information in plain language. The information must include:
- what the procedure involves
 - the range of possible outcomes of the procedure
 - the risks and possible complications associated with the procedure
 - the possibility of the need for revision surgery or further treatment in the short term (e.g. rejection of implants) or the long term (e.g. replacement of implants after expiry date)
 - recovery times and specific requirements during the recovery period
 - the medical practitioner's qualifications and experience
 - total cost including details of deposits required and payment dates, refund of deposits, payments for follow up care and possible further costs for revision surgery or additional treatment
 - the complaints process and how to access it.
- 4.2 Informed consent must be obtained by the medical practitioner who will perform the procedure.
- 4.3 Other than for minor procedures, informed consent should be obtained in a pre-procedure consultation at least seven days before the day of the procedure and re-confirmed on the day of the procedure and documented appropriately.

5. Patient management

- 5.1 The medical practitioner who will perform the procedure is responsible for the management of the patient, including ensuring the patient receives appropriate post-procedure care.
- 5.2 If the medical practitioner who performed the procedure is not personally available to provide post-procedure care, they must have formal alternative arrangements in place. These arrangements should be made in advance where possible, and made known to the patient, other treating practitioners and the relevant facility or hospital.
- 5.3 When a patient may need sedation or analgesia for a procedure, the medical practitioner who is performing the procedure and/or administering the sedation or analgesia must ensure that there are trained staff, facilities and equipment to deal with any emergencies, including resuscitation of the patient.
- 5.4 There should be protocols in place for managing complications and emergencies that may arise during the procedure or in the immediate post-procedure phase.
- 5.5 Written instructions must be given to the patient on discharge including:
- the contact details for the medical practitioner
 - alternative contact details in case the medical practitioner is not available
 - the usual range of post-procedure symptoms
 - instructions for the patient if they experience unusual pain or symptoms
 - instructions for medication and self care
 - dates and details of follow up visits.

6. Provision of patient care by other health practitioners

- 6.1 The medical practitioner is responsible for ensuring that any other person participating in the patient's care has appropriate qualifications, training and experience, and is adequately supervised as required.
- 6.2 When a medical practitioner is assisted by another registered health practitioner or assigns an aspect of a procedure or patient care to another registered health practitioner, the medical practitioner retains overall responsibility for the patient. This does not apply when the medical practitioner has formally referred the patient to another registered health practitioner.

7. Prescribing and administering schedule 4 (prescription only) cosmetic injectables

- 7.1 Drugs and poisons (or equivalent) legislation varies across states and territories. Medical practitioners must know and comply with the requirements for possession, use, storage and disposal of 'prescription only' cosmetic injectables in their jurisdiction.
- 7.2 Medical practitioners must not prescribe schedule 4 (prescription only) cosmetic injectables unless they have had a face-to-face consultation with the patient. A face-to-face consultation is required for each course of injections. Remote prescribing (for example, by phone, email, or video conferencing) of cosmetic injectables is not appropriate.
- 7.3 If the 'prescription only' cosmetic injectable is administered by another health practitioner who is not an authorised prescriber, the prescribing medical practitioner must be contactable and able to respond if required.

8. Training and experience

- 8.1 Treatment should only be provided if the medical practitioner has the appropriate training, expertise, and experience to perform the procedure and deal with all routine aspects of care and any likely complications.
- 8.2 A medical practitioner who is changing their scope of practice to include cosmetic medical and surgical procedures is expected to undertake the necessary training before providing cosmetic medical and surgical procedures.

9. Qualifications and titles

- 9.1 A medical practitioner must not make claims about their qualifications, experience or expertise that could mislead patients by implying the practitioner is more skilled or more experienced than is the case. To do so is a breach of the National Law (sections 117 – 119).

10. Advertising and marketing

- 10.1 Advertising material, including practice and practitioner websites, must comply with the Board's *Guidelines for advertising of regulated health services*, including the Therapeutic Goods Advertising Code and the advertising requirements of section 133 of the National Law.
- 10.2 Advertising content and patient information material should not glamorise procedures, minimise the complexity of a procedure, overstate results or imply patients can achieve outcomes that are not realistic.

11. Facilities

- 11.1 The Board expects that medical practitioners are familiar with relevant legislation, regulations and standards of the jurisdiction in relation to health care facilities where the procedure will be performed.
- 11.2 Procedures should be performed in a facility that is appropriate for the level of risk involved in the procedure. Facilities should be appropriately staffed and equipped to manage possible complications and emergencies.

12. Financial arrangements

12.1 The patient must be provided with information in writing about the cost of the procedure which should include:

- total cost
- details of deposits required and payment dates
- refund of deposits
- payments for follow up care
- possible further costs for revision surgery or additional treatment
- advising the patient that most cosmetic procedures are not covered by Medicare.

12.2 No deposit should be payable until after the cooling off period.

12.3 The medical practitioner should not provide or offer to provide financial inducements (e.g. a commission) to agents for recruitment of patients.

12.4 The medical practitioner 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 the cosmetic medical or surgical services.

12.5 Medical practitioners should not offer patients additional products or services that could act as an incentive to treatment (e.g. free or discounted flights or accommodation).

12.6 Medical practitioners should ensure that they do not have a financial conflict of interest that may influence the advice that they provide to their patients.

Acknowledgements

The Board acknowledges the following organisations' codes and guidelines, which informed the development of the Board's guidelines:

- Australian Health Ministers' Advisory Council's Clinical, Technical and Ethical Principal Committee Inter-jurisdictional Cosmetic Surgery Working Group (2011) *Supplementary Guidelines for Cosmetic Medical and Surgical Procedures*
- Australian Society of Plastic Surgeons (2011) *Code of Practice*
- Medical Council of New South Wales (2008) *Cosmetic Surgery Guidelines*
- Medical Council of New Zealand (2011) *Statement on Cosmetic Procedures*

Implementation Date and Review

These guidelines will take effect on <date>.

The Board will review these guidelines at least every three years.

Attachment C – Consumer scenarios

Potential benefits and cost estimates for consumers

The following tables illustrate potential benefits and cost estimates for consumers for each of the four options outlined in this consultation paper.

A number of assumptions have been made in developing these consumer scenarios. Business models, staffing, consultation protocols, patient scheduling and costs of consultations and procedures vary – the scenarios are illustrative examples only and costs quoted are estimates.

The Board seeks feedback on the cost estimates and assumptions underlying the consumer scenarios.

Scenario 1

22 year old woman seeks cosmetic breast augmentation

Option 1 – Retain the status quo		
Timing	Consultations	Indicative cost
Day 1	Consumer attends clinic for appointment with patient advisor (who has no health qualifications).	No charge
	Consumer books in for surgery.	Consumer pays 20% non-refundable deposit
No minimum time	Consumer arrives at clinic for surgery. Consumer signs informed consent form. Surgery is performed.	\$10,000 Balance of payment (\$8000) required prior to surgery – paid using finance sourced through the clinic
		TOTAL COST \$10,000

Option 2 – Provide consumer education material		
Timing	Consultations	Indicative cost
Day 1	Consumer accesses publicly available education material	No charge
Day 2	Consumer attends clinic for appointment with patient advisor (who has no health qualifications).	No charge
	Consumer books in for surgery.	Consumer pays 20% non-refundable deposit
No minimum time	Consumer arrives at clinic for surgery. Consumer signs informed consent form. Surgery is performed.	\$10,000 Balance of payment (\$8000) required prior to surgery – paid using finance sourced through the clinic
		TOTAL COST \$10,000

Option 3 – Strengthen current guidance through new, practice specific guidelines that clearly articulate the Board’s expectations of medical practitioners

Timing	Consultations	Indicative cost
Day 1	Consumer attends clinic for appointment with medical practitioner. Medical practitioner assesses consumer and confirms she does not need to be referred for evaluation by a psychologist or psychiatrist. Consumer is given written information about the procedure. Consumer gives informed consent (or this may occur at a second consultation).	\$150
Minimum seven days cooling off period after informed consent	Consumer has minimum seven day cooling off period to consider risks and benefits of procedure.	No payment
After cooling off period	Consumer decides to go ahead with the surgery and books date of surgery and pays deposit.	Consumer pays 20% non-refundable deposit
No minimum time	Consumer arrives at clinic for surgery. Consumer reconfirms informed consent. Surgery is performed.	\$10,000 Balance of payment (\$8000) required prior to surgery
		TOTAL COST \$10,150

Option 4 – Strengthen current guidance through new, practice specific guidelines as per option three, but which provide less explicit guidance to medical practitioners

Timing	Consultations	Indicative cost
Day 1	Consumer attends clinic for appointment with medical practitioner. Medical practitioner assesses consumer. Consumer is given written information about the procedure.	\$150
	Consumer books in for surgery	Consumer pays 20% non-refundable deposit
No minimum time	Consumer arrives at clinic for surgery. Consumer signs informed consent form. Surgery is performed.	\$10,000 Balance of payment (\$8000) required prior to surgery
		TOTAL COST \$10,150

In this scenario, the safeguards for the consumer would vary considerably under each of the options.

Under option one, the consumer would have a free initial consultation but the clinic representative has no health qualifications and the consumer may be given limited information about the procedure and no information in writing that she could take home to read and consider the risks and benefits of the procedure. The consumer would pay a non-refundable deposit at the initial consultation. Consent would be sought on the day of the procedure when the consumer would have already committed to finance the procedure through a credit provider recommended by the clinic.

In option two, the consumer could access free material that provides generic information about cosmetic procedures.

Under option one and two there would be no additional costs for the consumer.

Under option three, for the consumer there would be an additional monetary cost of \$150 for the initial consultation. There would be an additional time impact associated with the initial consultation. The impact on the practitioner would be minimal as they would receive payment for the additional consultation. The consumer would receive comprehensive information to give full informed consent. She would then have at least seven days to consider the procedure and review the written information provided by the medical practitioner. There would be no financial pressure to go through with the procedure as she would not be required to pay anything until after the cooling off period. On the day of the surgery consent would be reconfirmed to ensure that the consumer is fully aware of the risks associated with the procedure.

Under option four, there would be an additional monetary cost of \$150 for the initial consultation. The additional time impact for the consumer associated with the consultation would be the same under both option three and four. The impact on the medical practitioner would be minimal as they would receive payment for the additional consultation. The consumer would be given information to help them decide whether to have the procedure however, they could book in for the surgery immediately with no cooling off period.

In option two, the consumer would have accessed generic information about the procedure prior to her first consultation which would assist her to ask specific questions in the consultation with the patient advisor. The benefits of options three and four, for both consumer and medical practitioner, would be a consumer who has been fully informed of the procedure, the risks, the potential outcomes and the fees. Option three would provide more safeguards by specifying a minimum period for the cooling off period to ensure that the consumer would have had sufficient time to consider the risks and benefits of the procedure before deciding to go ahead with the procedure. The consumer could change their mind during the cooling off period without financial pressure. Options two and four would provide minimal extra safeguards compared with the status quo. The net benefit of option three outweighs the costs.

Scenario 2

16 year old teenage boy seeks rhinoplasty (nose surgery) for aesthetic reasons (no medical need)

Option 1 – Retain the status quo		
Timing	Consultations	Indicative cost
Day 1	Consumer attends clinic and has appointment with patient advisor (who has no health qualifications).	No charge
	Consumer books in for surgery.	Consumer pays 20% non-refundable deposit
No minimum time	Consumer arrives at clinic for surgery. Consumer signs informed consent form. Surgery is performed.	\$10,000 Balance of payment (\$8000) required prior to surgery
		TOTAL COST \$10,000

Option 2 – Provide consumer education material		
Timing	Consultations	Indicative cost
Day 1 or prior	Consumer accesses publicly available education material	No charge
Day 2	Consumer attends clinic and has appointment with patient advisor (who has no health qualifications).	No charge
	Consumer books in for surgery.	Consumer pays 20% non-refundable deposit
No minimum time	Consumer arrives at clinic for surgery. Consumer signs informed consent form. Surgery is performed.	\$10,000 Balance of payment (\$8000) required prior to surgery
		TOTAL COST \$10,000

Option 3 – Strengthen current guidance through new, practice specific guidelines that clearly articulate the Board’s expectations of medical practitioners

Timing	Consultations	Indicative cost
Day 1	Consumer attends clinic for appointment with medical practitioner. Consumer is given written information about the procedure. Consumer is referred for mandatory evaluation by an independent psychologist or psychiatrist.	\$150
No minimum time	Consumer has consultation with psychologist. Psychologist assesses patient and confirms that there are no psychological problems that make them an unsuitable candidate for cosmetic surgery.	\$200 Consumer may be eligible for a rebate.
No minimum time	Consumer and parent attend clinic for appointment with medical practitioner and informed consent is given.	\$100
Minimum three months cooling off period after informed consent	Consumer has minimum three month cooling off period to consider risks and benefits of procedure.	No payment
During cooling off period	Consumer has appointment with general practitioner for another health matter and opts to discuss proposed cosmetic procedure.	\$60 (Medicare rebate available)
After cooling off period	Consumer decides to go ahead with the surgery and books in date for surgery and pays deposit.	Consumer pays 20% non-refundable deposit
No minimum time	Consumer arrives at clinic for surgery. Consumer reconfirms informed consent. Surgery is performed.	\$10,000 Balance of payment (\$8000) required prior to surgery
		TOTAL COST \$10,510 (less rebates if applicable)

Option 4 – Strengthen current guidance through new, practice specific guidelines as per option three, but which provide less explicit guidance to medical practitioners		
Timing	Consultations	Indicative cost
Day 1	Consumer attends clinic for appointment with medical practitioner. Medical practitioner assesses consumer. Consumer is given written information about the procedure.	\$150
	Consumer books in for surgery	Consumer pays 20% non-refundable deposit
No minimum time	Consumer arrives at clinic for surgery. Consumer signs informed consent. Surgery is performed.	\$10,000 Balance of payment (\$8000) required prior to surgery
		TOTAL COST \$10,150

In this scenario, the safeguards for a consumer aged under 18 vary considerably under each of the options.

Under option one, the consumer has a free initial consultation but the clinic representative has no health qualifications and the consumer is given limited information about the procedure and no information in writing that he can take home to read and consider the risks and benefits of the procedure. The consumer pays a non-refundable deposit at the initial consultation. Consent is sought on the day of the procedure when the consumer has already paid for the procedure.

In option two, the consumer can access free material that provides generic information about cosmetic procedures.

Under option one and two there would be no additional costs for the consumer.

Under option three, for the consumer there would be an additional monetary cost of \$450 comprising; \$150 for the initial consultation, \$200 for the independent evaluation and \$100 for the second consultation (assuming that the medical practitioner charges separate additional fees for each consultation rather than re-structuring their fee schedule). They may be eligible for a rebate for the consultation with a psychologist. There is also a \$60 fee for the consultation with the general practitioner, however, this is optional and in this case the patient already had that appointment for another health matter. There would be additional time impact for the consumer (and their parent) associated with the additional consultations. The impact on the medical practitioner would be minimal as they would receive payment for the additional consultations. The consumer would receive comprehensive information to give full informed consent. He would then have a minimum of three months to consider the procedure and review the written information that the medical practitioner provided. There would be no financial pressure to go through with the procedure as he would not be required to pay anything until after the cooling off period. On the day of the surgery consent would be reconfirmed to ensure that the consumer is fully aware of the risks associated with the procedure.

Under option four, there would be an additional monetary cost of \$150 for the initial consultation. The additional time impact for the consumer associated with the initial consultation would be the same under both option three and four options. The impact on the medical practitioner would be minimal as they would receive payment for the additional consultation. The consumer would be given information to help them decide whether to have the procedure however, they would not be referred for an independent evaluation and they could book in for the surgery immediately with no cooling off period.

In option two, the consumer may have accessed generic information about the procedure prior to his first consultation which could assist him to ask specific questions in the consultation with the patient advisor. The benefits of options three and four, for both consumer and medical practitioner, would be a consumer who has been fully informed of the procedure, the risks, the potential outcomes and the fees. Option three provides further safeguards by ensuring that the consumer would have had an independent evaluation. The mandatory cooling off period would ensure that they cannot make a rushed decision for major irreversible surgery without taking time to consider the risks and benefits of the procedure. The consumer could change their mind during the cooling off period without financial pressure. Options two and four provide minimal extra safeguards compared with the status quo. The net benefit of option three outweighs the costs.